MILLIMAN WHITE PAPER

Inflation Reduction Act

What health plans and Part D sponsors need to know to be prepared

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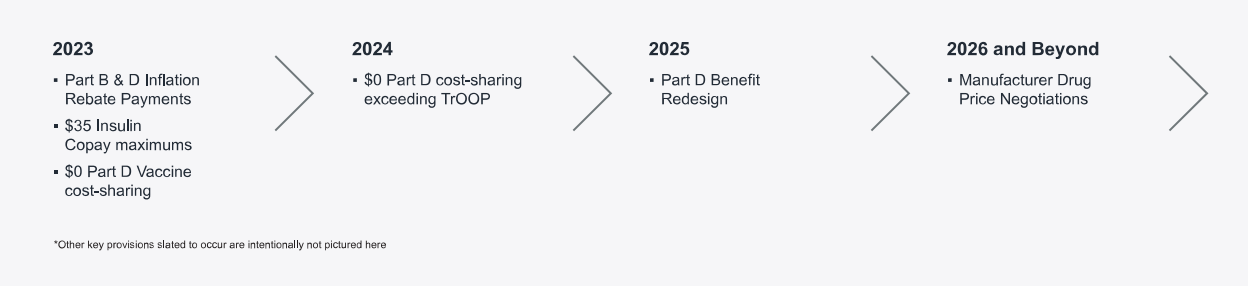
Background

The Inflation Reduction Act of 2022 (IRA) was signed into law on August 16, 2022, and will mandate major changes in healthcare over the next few years. Immediate impacts will be felt in 2023 with additional regulatory guidance phasing in over the next several years. We discuss these provisions in the sections below.

FIGURE 1: INFLATION REDUCTION ACT TIMELINE OF EVENTS



2023 IMPACTS

- **Part B & D inflation rebate payments:** For drugs not selected for price negotiations, drug manufacturers must pay inflation rebates to the federal government for any drug prices that increase faster than the Consumer Price Index for All Urban Consumers (CPI-U).
- **$35 insulin copay maximum:** Insulin cost sharing for Medicare beneficiaries is capped at $35 for both Part B and D covered insulin drugs.
- **$0 Part D vaccine cost sharing:** No cost sharing can be administered for Part D vaccines.

2024 IMPACTS

- **$0 Part D member cost sharing exceeding TrOOP:** The true out-of-pocket (TrOOP) level is defined as the maximum amount of cost a member accumulates before entering the catastrophic benefit phase. In 2024, beneficiaries that surpass the TrOOP level are not at liability for any additional cost.

2025 IMPACTS

- **Part D benefit redesign:** The implementation of a new Part D benefit redesign that includes a $2,000 maximum out-of-pocket (MOOP) and the removal of the Coverage Gap Discount Program (CGDP) will be implemented in 2025.

2026 AND BEYOND IMPACTS

- **Manufacturer drug price negotiations:** Beginning in 2026 with 10 drugs, the government will negotiate drug prices directly with drug manufacturers through a methodology that dictates a “maximum negotiated price.”

While the bill is specifically focused on Medicare, there is potential for these changes to impact all types of healthcare coverage, including the commercial health insurance market.

This paper primarily focuses on considerations for health plans and their Medicare-eligible population, while also highlighting potential spillover into other sources of healthcare coverage. For additional detail, you can also refer to the Milliman Brief "Weathering the Reform Storm."[1]

Expected Medicare changes from the IRA

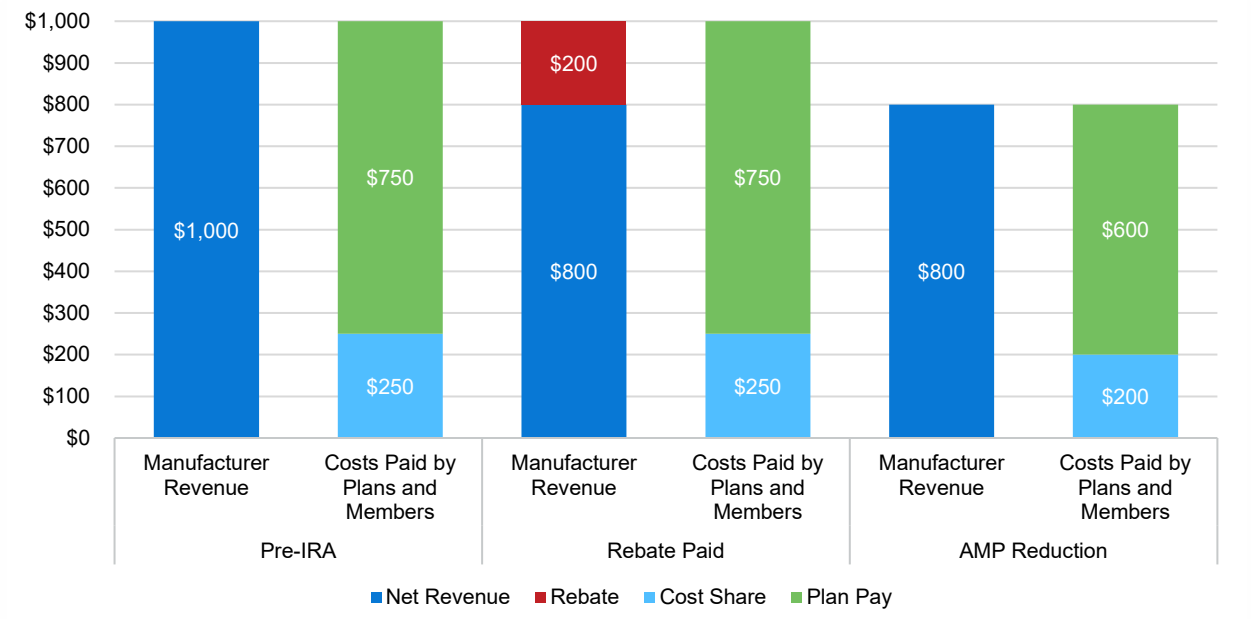
2023: INFLATION REBATES

Beginning in 2023, the Centers for Medicare and Medicaid Services (CMS) will require drug manufacturers to pay an inflation rebate to the government if drug prices (measured by average manufacturer price, or AMP) increase faster than the CPI-U, compared to their 2021 costs. These inflation rebate payments would be made from manufacturers to the federal government for all single-source and biologic drugs (starting in 2026, drugs selected for price negotiation will be exempt from inflation rebates).

Manufacturers affected by this provision could respond in a few different ways. Two potential responses include (1) directly reducing drug prices and/or AMP, or (2) paying the inflation rebate to the government. Figure 2 considers three illustrative scenarios for a Part D drug that is applied to a non-low-income member currently positioned in the initial coverage phase, where the member pays 25% and the plan pays 75%.

- **Pre-IRA:** In the first scenario, which is prior to the impact of the IRA, the drug costs $1,000.
- **Rebate paid:** In the second scenario, the manufacturer would pay a $200 rebate.
- **AMP reduction:** In the last scenario, the manufacturer reduces the drug price to $800.

FIGURE 2: INFLATION REBATE IMPACT



[1] Cline, M., Karcher, J., Klaisner, J.K., & Klein, M. (August 2022). Weathering the Reform Storm: The Inflation Reduction Act's Changes to Medicare and Other Healthcare Markets. Milliman Brief. Retrieved December 4, 2022, from https://www.milliman.com/en/insight/weathering-the-reform-storm.

From a plan and member perspective, a direct reduction in cost occurs if the AMP is reduced compared to what the manufacturer would pay as a rebate to the government.[2] At the same time, there may be a deterioration of rebate contracts relative to the pre-IRA scenario, as many rebate contracts currently have an inflation protection component, and manufacturers may be resistant to "double-pay" rebates to both the government and plans.

The manufacturer perspective tells a different story. Focusing only on the Medicare market, the net cost impact is relatively straightforward: in the above example, whether the manufacturer pays the rebate or reduces AMP, it would see a $200 reduction in net revenue. Therefore, manufacturers have little or no direct incentive to prefer reducing their prices instead of paying the rebate in the Medicare market alone.

However, a reduction in AMP would affect other lines of business, so a manufacturer that reduces its prices in the Medicare market to avoid paying inflation rebates could also see reductions in revenue in the commercial market. Additionally, the timing of cash flows further favors paying the rebate from the manufacturer perspective, as they receive payment in full first, and then pay the inflation rebate to the government later.

And finally, if the CPI-U is unknown in advance, manufacturers may prefer to be more conservative in their pricing, as there is no recovery mechanism should they set prices to match inflation and instead undershoot the CPI-U trend. This consideration may be especially important given the recent uptick in inflation values; the longer high inflation persists, the more pressure manufacturers may face to not only avoid slowing down their price increases, but to potentially increase their drug prices further to keep up with inflation.

The divergent incentives between manufacturers and plans and unknown responses of different stakeholders may create a volatile pricing environment for drugs that would otherwise be subject to inflation rebates. It will be critical for plans to consider the impacts of this changing environment on their Part D bids for 2024 and beyond.

2023: COST-SHARING LIMITS

In addition to the inflation rebates, the IRA also implements two cost-sharing provisions in 2023. Cost sharing for insulin is now limited to $35 per month for all beneficiaries, and vaccines covered by Medicare Part D are now set at zero cost sharing. For 2023, these values will be funded by the government via retrospective subsidies to plans. CMS released additional guidance on this topic in a September 26 memo; plans should carefully review this guidance in advance of 2023.[3]

2024: REMOVAL OF COST SHARING ABOVE TROOP

In the current defined standard Part D benefit, members are subject to 5% cost sharing above the TrOOP maximum, which is $7,400 in 2023. Effective in 2024, beneficiary cost sharing above this threshold will be eliminated, with plans paying for the difference, increasing plan liability from 15% to 20% above TrOOP.

For plans with a disproportionate share of high-cost members, this could have a significant impact on 2024 bids. It will be important for plans to consider the shape of their cost curves when developing their 2024 bids, analyzing their base period data including the gross drug cost above Part D out-of-pocket threshold (GDCA) as well as anticipated trends, new drug launches, brand-name patent expirations, formulary changes, and contracting changes.

[2] For Part B drugs, the member cost sharing is reduced proportionally when the manufacturer pays a rebate.

[3] CMS (2022). HPMS Memos for WK 5 September 26-30. Retrieved December 4, 2022, from https://www.cms.gov/httpseditcmsgovresearch-statistics-data-and-systemscomputer-data-and-systemshpmshpms-memos-archive/hpms-memos-wk-5-september-26-30.

2024: PREMIUM STABILIZATION

Starting in 2024, the government will cap the national average member premium (NAMP) at no more than 6% more than the prior year's value. The government will then increase the direct subsidy value to fund the excess of this cap on NAMP values.

This change could have a substantial effect on Part D premiums in 2024, given generally high national inflation values potentially contributing to increased drug spend. Also, the IRA has created multiple new policies that could reshape the cost curve, such as the requirement to have point-of-sale drug costs reflect pharmacy direct and indirect remuneration (DIR) amounts, or the removal of cost sharing above TrOOP, as discussed above.

When premium stabilization applies, increasing the direct subsidy paid to plans, plans could improve benefits or reduce member premiums. Note, however, that a given plan's premium can still increase by more than 6%. This would occur if a plan's bid increases by more than the national average; such increases could be due to overall trend, changes in formulary, the IRA's changes to CGDP and reinsurance, or other factors. It is also possible that plans see premium decreases for plan populations with lower-cost drug utilizers, if the direct subsidy increases due to premium stabilization provisions more than make up for plan liability increases.

NEW PART D BENEFIT DESIGN IN 2025

While we have discussed the anticipated impacts of the 2023 and 2024 provisions, some of the largest impacts of the IRA on Part D will be felt in 2025 and beyond. Beginning in 2025, the government will substantially change the overall benefit design of the Part D program, incorporating a maximum out-of-pocket (MOOP) amount for beneficiaries (distinct from the cutoff of member cost sharing above TrOOP that happens in 2024). Furthermore, in 2026, the government will begin negotiating drug prices with manufacturers for certain brand-name drugs.

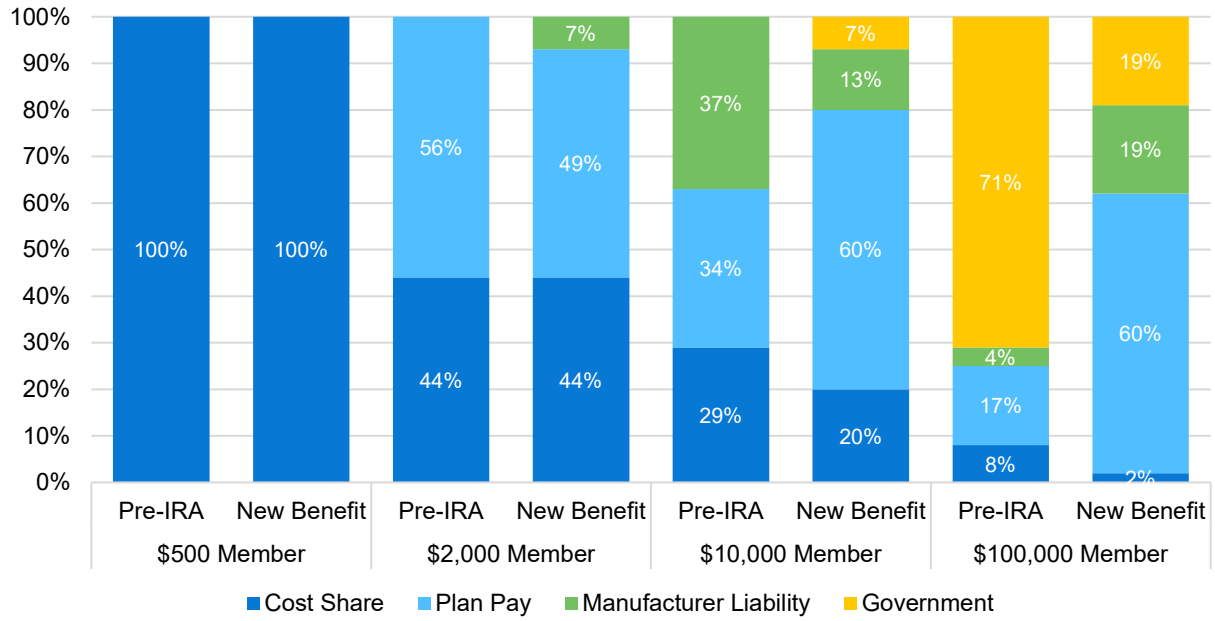
The new benefit design redistributes the cost liability by stakeholder, adding new manufacturer liability at lower points in the cost curve, while extending it indefinitely, along with reducing the federal reinsurance amounts for high-cost members.[4] It also eliminates the coverage gap phase, and meaningfully changes the definition of the catastrophic phase; previously, it was based on a $7,400 TrOOP amount (combined member and manufacturer spend), but now it is set at a $2,000 MOOP value (member spend only), which has the effect of members reaching the catastrophic phase sooner.

We consider the impacts of these changes from multiple perspectives. In Figure 3, we show the impact of the changes on four illustrative non-low-income (NLI) members who each take a single brand-name drug (incurring $500, $2,000, $10,000, and $100,000 of allowed drug charges, respectively):[5] We presume for the sake of illustration that the 2023 defined standard values—$505 deductible, $4,660 initial coverage limit (ICL), $7,400 TrOOP—would otherwise be in place, while in actuality those amounts would trend forward to 2025.

[4] See Appendix B of https://www.milliman.com/en/insight/weathering-the-reform-storm for an example of this.

[5] For low-income members, there is a different distribution of which stakeholders are responsible for which costs, under both pre-IRA and post-IRA benefit designs.

FIGURE 3: IMPACT OF NEW BENEFITS, BY GROSS DRUG COST



For each of these members, we consider both the pre-IRA benefit design and the new benefit design starting in 2025.

As shown in Figure 3, the impact to particular stakeholders will vary substantially based on the size of the gross drug cost as described below:

Individual members: NLI members will see their cost sharing capped at $2,000, the new MOOP value. Under the pre-IRA structure, member costs could increase indefinitely, with 5% coinsurance above the TrOOP. This is highlighted most clearly by the member with $100,000 in drug costs, whose out-of-pocket costs are reduced over $5,000 under the IRA design.

Additionally, both low-income (LI) and non-low-income members will also be allowed to spread out cost sharing over monthly installments.

Health plans: Health plans will see a reduction of net costs for mid-level drug cost patients for applicable (mostly brand-name) drugs, as the plan liability level in the initial coverage phase drops from 75% to 65%. For non-applicable (mostly generic) drugs, plan costs will remain at 75% below the MOOP.

However, the new standard coverage phase will now include a substantial portion of the former coverage gap phase. Here, plan liability for applicable drugs will increase to 65% (previously it had been 5% for NLI and 0% for LI members). Moreover, plans will see a large increase in costs above the MOOP, as they are now liable for 60% of costs, whereas in 2023 they were only liable for 15% of costs for all drugs past TrOOP.

We expect these changes to increase plans' overall costs in aggregate. While in isolation we might expect them to result in increases to premiums, there will be other moving parts including changes to risk scores in the prescription drug hierarchical condition categories (RxHCC) model, changes in direct subsidy amounts, and changes to low-income premium subsidy amounts (for plans targeting LIS beneficiaries).

However, individual health plans may see material and volatile impacts. In particular, plans serving more higher-cost members will see substantial increases in costs, and plans serving lower-cost members may see smaller increases in costs. We also expect a change to the CMS RxHCC risk score model will be necessary to compensate plans for these changes in risk.

When developing pricing for bids in 2025 and beyond, it will be particularly important for plans to fully consider the expected cost distribution across their target populations and how the new benefit structure will add to or reduce costs on a per member basis.

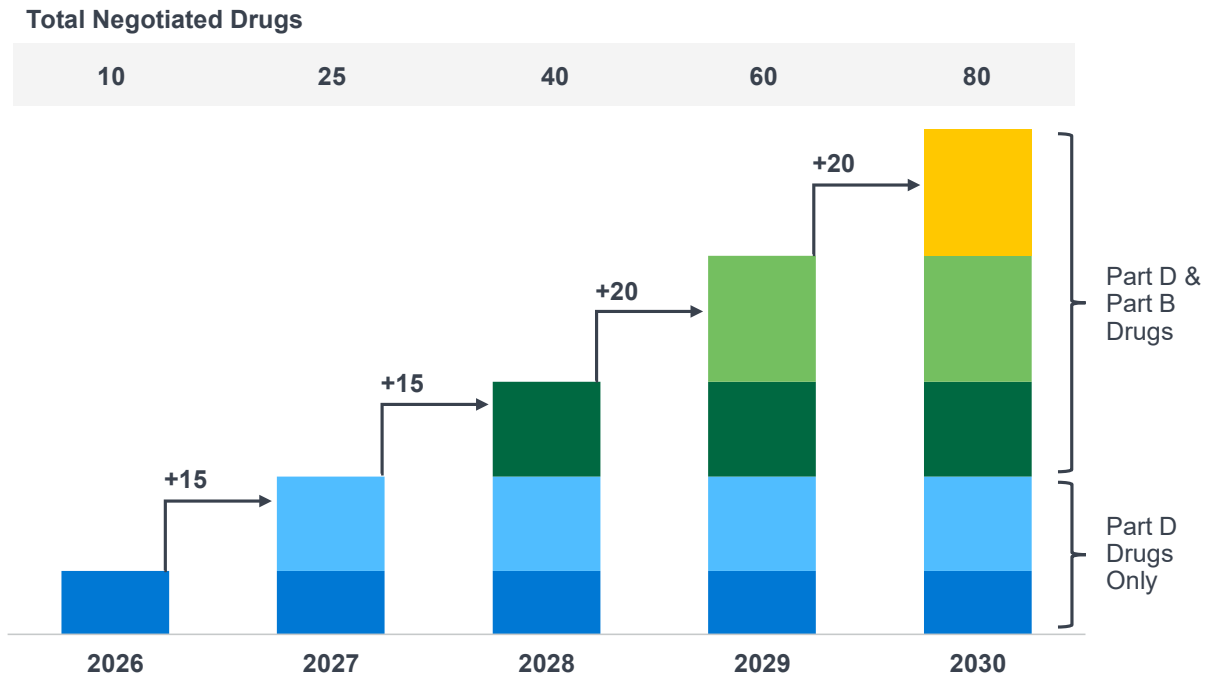
Manufacturers: The shape of manufacturer liability has substantially shifted. Previously, it was 70% for applicable drugs in the coverage gap and 0% in all other phases, but under the IRA it will be 10% between the deductible and the MOOP and 20% above MOOP for all applicable drugs. In the example in Figure 3 above (for an NLI member), manufacturers would see increased costs for the $2,000 and $100,000 gross cost members, but reduced costs for the $10,000 member. For an LI member, the impact is even greater, as manufacturers now pay liability on all members, versus only NLI members today. We also note that drugs negotiated by the government are not subject to the new manufacturer discount program payments, but manufacturers are likely to see reduced margins on these drugs due to negotiation.

Government: Government reinsurance will now apply sooner during a member's total annual spend than under the pre-IRA system. However, the percentage liability is substantially lower, as instead of 80% of costs above TrOOP, it will now be 20% of costs above the MOOP (for applicable drugs) or 40% (for non-applicable drugs). In addition, low-income cost-sharing subsidies (LICS) should decrease due to no member cost sharing above the MOOP and the elimination of the coverage gap (where LICS covered 100% pre-IRA). We also expect that certain revenue-related items (direct subsidy, low-income premium subsidies) will increase due to the increase in plan sponsor costs, as noted above.

DRUG NEGOTIATION IN 2026 AND BEYOND

Under the current (pre-IRA) structure, Medicare pays for Part B drugs based on a set formula of 106% of the average sales price (ASP) and at rates negotiated by plan sponsors for Part D drugs. Starting in 2026, the IRA provisions will instead allow the government to negotiate prices for a certain number of single-source Part D brand-name drugs and biologics, and starting in 2028 the IRA will allow the government to negotiate both Part D and Part B drugs. We illustrate the maximum number of negotiated drugs in Figure 4.

FIGURE 4: MAXIMUM NUMBER OF NEGOTIATED DRUGS BY YEAR, 2026-2030



Other key provisions for negotiated drugs include:

- The only eligible drugs for price negotiation are the 50 highest-cost Part B or 50 highest-cost Part D drugs, with carve-outs for biotech drugs with small market shares
- Drugs with generic or biosimilar equivalents cannot be negotiated, and already negotiated drugs will be removed should a generic or biosimilar equivalent launch
- The manufacturer discount program is waived for all selected Part D drugs; such drugs will be treated as non-applicable instead
- Part D drugs selected for negotiation must be covered on all Part D plan formularies
- The statute defines the detailed calculations supporting the maximum negotiated price[6]

The direct impact of this policy would be to reduce drug costs, primarily for higher overall spend drugs, which will directly affect members taking brand-name or specialty medications more than members taking fewer or primarily generic prescriptions. Member impacts could be felt both in terms of cost sharing and in terms of premium reductions.

There may also be material second-order impacts of this change. We discuss these potential impacts in later sections of this paper.

Additional considerations for health plans

As discussed above, plan sponsor costs could change materially due to the changes in risk from the IRA. The competitive nature of the Medicare Advantage (MA) and Prescription Drug Plan (PDP) programs will place pressure on plans to find creative ways to mitigate some of the impacts of the provisions above. What can plans do to offset some of these cost headwinds? In this section, we discuss key considerations that health plans may consider when competing in this market.

FORMULARY DESIGN CONSIDERATIONS

The choice of which drugs to cover on a plan's formulary, and on which tier to position those drugs, has become a vital component of the competitive environment for Medicare Part D. Additionally, a dynamic relationship exists between the formulary a plan selects, gross cost by drug tier, and the negotiated manufacturer rebates. As IRA regulatory guidance begins to unfold, Part D sponsors should look to utilize some of the available tools for managing costs, one of those being formulary design development.

WILL PRESCRIPTION DRUG FORMULARIES GET NARROWER OR BROADER?

A Part D sponsor seeking to reduce its plan liability in the future might consider narrowing the number of covered drugs on a plan's formulary. Limiting the number of covered drugs or developing new or innovative utilization management (UM) programs could reduce plan liability and help shift current members to preferred products or lower-cost alternatives. However, there are limitations to formulary construction, and CMS conducts formulary reviews as part of the Part D bid submission process. Additionally, limiting drug coverage could trigger dissatisfaction by members and negatively affect drug plan ratings and overall member approval, a key component of Medicare star ratings. Plans will need to consider the potential loss of manufacturer rebates for products excluded from a formulary, and what utilization will remain on these products to evaluate the potential net cost impact of a narrow formulary.

[6] This maximum is discussed in further detail in "Weathering the Reform Storm," op cit.

WILL MORE PLAN SPONSORS CONSIDER IMPLEMENTING CUSTOM FORMULARIES WITH PBMS?

Typical formulary design options take the form of either standard formularies (template-based standardized drug lists) or custom formularies. Custom formularies allow plan sponsors to control drug coverage, tiering strategy, and UM strategy. Some Medicare Advantage and Prescription Drug (MAPD) plans put a large emphasis on developing care coordination strategies specific to their populations. Custom formularies may be an avenue to strengthen that strategy. Note that most effective custom formularies come with significant financial and operational investments. Often, plan sponsors and their pharmacy benefit managers (PBMs) have teams of staff managing and maintaining the formulary, making decisions on drug inclusions and exclusions, and managing UM protocols and other pharmacy benefit management strategies. Plans pursuing this route may gravitate to PBM partners willing to provide visibility into the rebate impacts of various formulary decisions.

HOW WILL THE INTERPLAY BETWEEN DISCOUNTS AND REBATES AFFECT FORMULARY CONTRACTING?

As the intricacies of the IRA provisions begin to phase in, impacted stakeholders will look to adjust their business models to adapt. This is likely to begin with drug manufacturers. Manufacturers negatively affected by Part D benefit design changes or those with drugs chosen for price negotiation may look to adjust their rebate strategy with PBMs. We could see PBMs pass through some of this financial burden to plans in the form of lower rebate guarantees or higher administrative fees. Plans are likely to feel the adaptations from manufacturers and PBMs cascade through the system directly into their contracting arrangements (whether through changes to discounts and dispensing fees or via reduced rebates).

Impact on Part D premium setting

PLAN DESIGN CHANGES

Plan sponsors that see higher premiums due to the IRA may seek ways to reduce these increases. Offering leaner benefits for enhanced plans (higher copays, coinsurance, or deductibles) could help mitigate financial impacts to the plan. This may be especially likely for plans in competitive markets that continue to target $0 total member premium as part of their strategic business plan. The changes in Part D premium costs could also affect the amount of MA rebates that plans have to invest in Part C cost-sharing enhancements and other supplemental benefits for plans electing to hold their premiums flat.

Conversely, there may be certain situations where plans are positively impacted by the regulations, due to the mix of members and the effectiveness of their cost or utilization management programs. For these plan sponsors, we could see opportunities to leverage strategic advantages through benefit design in the highly competitive Part D market.

THE IMPORTANCE OF POPULATION HEALTH MANAGEMENT IN MAPD

Part C and D sponsors that find success in Medicare typically concentrate resources on population health management. This could include intricate analytics that inform behavior patterns for many chronic conditions, such as diabetes, heart disease, and chronic obstructive pulmonary disease (COPD). Other strategies include disease management, designed to coordinate care for defined patient populations, as well as utilizing outreach programs to ensure medication adherence and that a member's overall health is being managed effectively. As drug price negotiations and Part D benefit redesigns continue to phase in, plan sponsors will be looking to optimize their business overall.

Population health management will be essential moving forward. Part D sponsors that are impacted by the IRA regulatory changes may consider operational changes to their business in order to help maintain and control population health. Some noteworthy considerations may include a stronger financial focus on drug cost management, a strengthening of a plan's medication therapy management (MTM) programs, and the continued importance of step therapy and prior authorization in a care management system. In particular, Part D sponsors may need to revise step therapy or prior authorization protocols for drugs that are selected for price negotiations. In addition, plans with strong population health management programs for chronic conditions can design formulary and benefit offerings to pair with their programs to attract that type of member to their plans.

INCREASES TO MEDICATION ADHERENCE RESULTING FROM LOWER OUT-OF-POCKET COST

With the introduction of a $2,000 MOOP threshold for all members, plans may see increased medication adherence for their members. As the financial burden of costly medication shifts from the member to other stakeholders, member behavior may change. For example, a member utilizing a high-cost drug may pay 5% of the cost in perpetuity in the catastrophic phase under the current benefit design and may not fill as many medications due to the large cost burden.

A $2,000 MOOP will help alleviate that burden and could incentivize members to maintain adherence when the Part D benefit redesign begins in 2025. Additionally, the mechanism that allows members to spread the $2,000 MOOP over the course of the year could improve the predictability and stability of beneficiary payments, further strengthening patient health and adherence. We also note that improved adherence could have positive effects on medical claims experience.

We also note that there could be other impacts on adherence from the IRA; for instance, should plans elect to tighten formularies to manage net costs, there could be negative impacts on adherence.

Commercial market spillover impacts

While the IRA is focused on Medicare, the implications could have an impact on commercial health plans as well.

CROSS-SUBSIDIZATION OF COST INTO THE COMMERCIAL BLOCK OF BUSINESS

The IRA seeks to reduce the cost of prescription drugs under Medicare Part B and Part D by allowing CMS to negotiate drug costs with manufacturers. However, reduced costs for Medicare beneficiaries could potentially result in increased costs for employer-sponsored plans due to cost shifting. Lower payments for drugs purchased through Medicare could result in higher costs for non-Medicare plans in future years with Medicare drug price negotiations beginning in 2026, if manufacturers elect to increase prices or lower rebates for their commercial business to make up for lost revenue. In addition, inflation rebate penalty payments apply to Medicare utilization only (though a similar mechanism exists today in Medicaid), and manufacturers may attempt to make up lost revenue by increasing prices in aggregate and paying the rebate in Medicare. At the same time, competitive pressures between manufacturers could help mitigate some of this risk for plan sponsors. Health plans will need to consider these financial impacts for all lines of business to estimate costs and price products appropriately in the upcoming years.

DRUG PRICING SPILLOVER

If manufacturers lower prices on certain drugs or increase prices by less than they otherwise would have, commercial drug payments would be affected. This could impact both medical and retail pharmacy drug payments, depending on how agreements are structured. With Part B drugs available for inflation rebates in 2023 and price negotiations beginning in 2028, there is potential to have an indirect impact on medical drug pricing in the commercial market, to the extent health plans base reimbursement on a factor of a Medicare-based reference price or if drug manufacturers change their pricing habits to avoid the IRA's inflation rebate payments.

BIOSIMILAR REIMBURSEMENT CHANGES

With the October 1, 2022, implementation of the 8% add-on above the average sales price (ASP) for biosimilar drugs for Part B Medicare reimbursement (the typical add-on is 6%), commercial health plans may seek to incorporate a similar reimbursement structure in their own provider negotiations. With this approach, plans could experience an uptick in biosimilar utilization, shifting costs from more expensive brand-name drugs to clinically equivalent biosimilar products. This enhancement could also entice more drug pricing competition for biosimilars and has potential to create savings in the healthcare system as a whole.

LEVERAGING FORMULARY AND REBATE NEGOTIATIONS

With CMS negotiating drug prices directly with drug manufacturers and posting the negotiated prices publicly, commercial health plan PBMs may attempt to leverage this information for their own negotiations with manufacturers in the commercial market.

CREDITABLE COVERAGE IMPLICATIONS

Commercial health plans whose policies include prescription drug coverage are required to notify policyholders who are eligible for Medicare when their policy does not meet or exceeds the coverage offered by a Medicare Part D prescription drug plan. Because the IRA will impact Medicare Part D benefit plans, formularies, and drug prices, this could create changes with how commercial health plans will determine whether creditable coverage requirements are met; however, the government will need to specify how to adjust creditable coverage testing for the new Part D benefit designs.

Conclusion

The Inflation Reduction Act aims to lower prescription drug costs for many Americans through investments in drug pricing reform and cost realignment. A deep and accurate understanding of the law's provisions and the effects on health plans will be essential as these provisions begin to take effect as early as 2023. Both stakeholders of the Medicare Advantage and Part D landscape as well as stakeholders in other healthcare markets will need to consider each provision and the impact it may have on their business. Commercial health plan implications are likely to occur and will continue to emerge over time, with more information and transparency unfolding as the provisions of the IRA continue to take effect.

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