IRA creates new opportunities and challenges for Medicaid

On August 16, 2022, President Biden signed into law the Inflation Reduction Act (IRA), a comprehensive legislative package that includes provisions related to tax reform, clean energy, and health care.

Medicare focus, but Medicaid components

The health care components of the law are aimed primarily at the Medicare program. One of the law's signature provisions — the authority for the federal government to directly negotiate prices for select Medicare covered drugs — represents a paradigm shift for Medicare and the drug marketplace overall.

Despite the Medicare focus of the law, there are provisions that will affect the Medicaid program, both directly and indirectly. Medicaid programs should be prepared for:

- Mandated coverage for adult vaccines in Medicaid and CHIP
- Potential increased volatility in Medicaid federal drug rebates as drug costs shift in the marketplace
- New Medicare Part B formulas for physician administered drug payment that incent biosimilar utilization
- Possibility for decreased Medicare Part D clawback over time

The Inflation Reduction Act and subsequent supporting guidance and regulations usher in a new era in the prescription drug market. State Medicaid programs will need to be agile to ensure continued drug purchasing efficiency in this changing marketplace.

Improved vaccine access

Medicaid and CHIP Programs required to cover adult vaccinations

Effective October 1, 2023, state Medicaid and CHIP programs are required to cover, without cost sharing, adult vaccines recommended by the Centers for Disease Control's Advisory Committee on Immunization Practices. An additional 1% Medicaid federal match for both the vaccine ingredient and administration costs is available for two years.

Big changes are coming to the prescription drug marketplace

Potential additional volatility in the Medicaid drug rebate program

Medicare Inflation Rebates: Under the IRA, manufacturers of brand name Part B drugs and all Part D drugs that cost over $100 per month will be required to pay a rebate if the price of the drug increases faster than inflation. Manufacturers that do not pay the rebate would be subject to a civil monetary penalty. The first rebates for Part B drugs could be invoiced as early as July 2023. The first rebates for Part D drugs would be due July 1, 2024.

Medicare Drug Price Negotiation Program: The Department of Health and Human Services has been prohibited from negotiating drug prices for Medicare Part D since the program's inception in 2006. Beginning in 2026, the Medicare program will negotiate maximum fair prices for selected drugs. The program will start with 10 drugs in 2026 and will ramp up to 20 drugs per year in 2029 and beyond. In the event the negotiated price is lower than the 340B ceiling price, manufacturers would be required to make the price available to the 340B covered entities.

Manufacturers that do not participate in the negotiation process will be subject to an excise tax on total sales of the drug that starts at 65% and goes up to 95% over time.

Some drugs will be exempt from negotiation; drugs only indicated for one orphan condition, drugs that have been on the market for less than seven years (eleven years for biologics), and drugs made by small biotech firms will be exempt. Negotiations can also be delayed for drugs likely to face biosimilar competition within two years.

Impact to the Medicaid Drug Program: Drugs covered by the Medicaid program are already subject to an inflationary penalty. Inflation was low during much of the 1990s through 2010s, yet many drug manufacturers continued to significantly increase prices each year. As a result, the inflationary penalties contribute significantly to the discounts available to state Medicaid programs.

The addition of negotiated discounts and inflationary penalties to the Medicare program may create change in manufacturer pricing tactics that could spill over to state Medicaid programs.

- With more of the pharmaceutical market subject to negotiated discounts and inflationary penalties, manufacturers may be less willing to offer significant discounts in the private market or through supplemental rebates, which could increase the net price for Medicaid
- It is possible that drug manufacturers will elect to reduce the list prices of select drugs to reduce inflation penalties, which would paradoxically increase the net price for the Medicaid program
- Manufacturers may introduce new products at even higher list prices knowing that they will be limited in the ability to increase the price over time
- Depending on the success of the Medicare negotiation program, there may be instances where 340B prices are lower than Medicaid prices for select drugs. Depending on the drug and the individual state, it might make sense to encourage more 340B utilization of select drugs or select providers

Given the uncertainty of how the new Medicare negotiated discounts and inflationary penalties will affect drug prices overall, Mercer Government recommends that states enter into guaranteed net unit price contracts with drug manufacturers to the extent possible to protect against rising net prices.

Potential for savings on the Medicare Part D clawback

If the IRA is successful in slowing the growth of drug spend, states could benefit from reduced clawback payments

Before Medicare Part D was created in 2005, State Medicaid programs were responsible for the prescription drug costs of dual-eligible enrollees. When Medicare Part D took over the responsibility for the drug benefit, state Medicaid programs were required to make payments, known as the clawback, to help cover the cost of the Part D benefits.

The clawback payments for each state are calculated based on a formula, and the IRA does not change the formula in any way. However, one of the factors in the formula is the trended forward annual per capita Part D drug expenditures. If the drug pricing reform provisions of the IRA are ultimately successful in slowing the growth of Medicare Part D drug spend over time, states could benefit from slower growth, or in theory even a decrease in the per capita clawback amount.

Medicare Part B updates payment methodology for biosimilars

Medicaid programs that follow ASP methodology may want to evaluate the changes to see if they fit with state strategy

The IRA includes a temporary five year provision that increases the add-on payment for biosimilars from six percent of the reference product average sales price to eight percent. This change is meant to further incent adoption of biosimilars by providing the opportunity for more margin by administering providers.

Increased adoption of biosimilars does not always benefit state Medicaid programs. Many brand biologics have been on the market for a long time and are subject to large Medicaid rebates. In many cases, the net cost of the biosimilar is significantly more than the associated brand product. States that employ the Medicare fee schedule should review their payment policy for physician-administered drugs and consider adjustments if needed to align with state policy.

Further delay of the rebate safe harbor rule

The IRA further delays implementation of the Trump administration's rebate rule until 2032

The 2020 rebate safe harbor rule was intended to dramatically transform the system of drug rebates in Medicare Part D from back end rebates collected by PBMs to point-of-sale price concessions that would benefit patients through lower cost sharing.

Medicare plan sponsors raised concerns about increased premiums as a result of the rule. Implementation was delayed multiple times — most recently by the Biden administration in response to litigation. The IRA further delays implementation until at least 2032.

> IRA ushers in a new era in prescription drug pricing. States must be prepared to respond to increased volatility in Medicaid rebate values

Please contact Sara Drake at sara.drake@mercer.com or your team's pharmacy consultant with any questions or comments related to the Medicaid drug provisions of the IRA.

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