Weekly Checkup

Not-so GENEROUS Medicaid Drug Policy

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Last week, the Centers for Medicare & Medicaid Services (CMS) announced the GENErating cost Reductions fOr U.S. Medicaid (GENEROUS) Model pilot program, designed to implement most-favored-nation (MFN) pricing for outpatient drugs reimbursed by Medicaid. Beginning in January 2026, the voluntary program invites pharmaceutical manufacturers to negotiate standardized coverage criteria for each of their products with Medicaid. In return for uniform coverage across all participating Medicaid programs, manufacturers must provide rebates that "guarantee" each state pays a net price comparable to the second-lowest net price offered in peer nations. **While intended to address rising drug costs, the program's pricing formula could discourage manufacturers from offering certain drugs.** The GENEROUS model marks the latest federal initiative to control prescription drug prices and a potentially damaging shift in the already troublesome evolution of the Medicaid Drug Rebate Program (MDRP).

For more than 30 years, manufacturer rebates under MDRP – often referred to as the Medicaid "best price" rule – have been a defining feature of the Medicaid pharmacy benefit. **The original purpose of manufacturer rebates was to offer prescription drugs to low-income beneficiaries with little to no cost-sharing, while also helping states and the federal government manage rising Medicaid expenditures.** Under MDRP, manufacturers are required to pay a rebate equal to a certain percentage of the product's average manufacturer price (AMP) or the best price available in the commercial market for every drug dispensed to Medicaid beneficiaries. This statutory payment, known as the Unit Rebate Amount (URA), includes an inflationary adjustment that discourages manufacturers from increasing the drugs' AMP faster than inflation. The URA is calculated differently based on how the drug is classified, with "single source" or "innovator" drugs having a higher rebate percentage. In addition to mandatory rebates, all 50 states also negotiate supplemental rebates that are used to place drugs on each state's preferred drug list.

From fiscal years 2016–2023, combined manufacturer rebates under MDRP are estimated to have reduced Medicaid spending on covered outpatient drugs (CODs) by more than 50 percent of the gross costs each year (see table below). While these savings are substantial, MDRP is not without its flaws. **Notably, the Medicaid best price rule ultimately led manufacturers to stop offering charitably discounted or free drugs to uninsured patients**. Instead of removing "gifted" drugs from the best price definition, Congress created the 340B Discount Drug Pricing Program, which has since greatly increased COD spending and undermined the purpose of MDRP. Moreover, many of the drugs listed in MDRP have rebate requirements greater than 100 percent of the AMP. Unsurprisingly, some manufacturers stopped offering higher-priced products to avoid paying rebates that exceeded the drugs' prices. Further, audits of MDRP reveal that state Medicaid agencies often lack the administrative infrastructure required to fulfill the statutory rebates. The addition of a new rebate model will only further complicate an already complicated system.

Estimated Medicaid Spending on CODs From FY 2015–2024

Fiscal Year	Gross Medicaid COD Spending	Total Manufacturer COD Rebates	Net Medicaid COD Spending
2015	$53.5 billion	$24.0 billion	$29.5 billion
2016	60.9	31.2	29.7
2017	64.7	34.9	29.8
2018	62.4	36.2	26.2
2019	68.5	37.1	31.4
2020	72.7	39.2	33.5
2021	81.5	42.5	39.0
2022	92.4	49.0	43.4
2023	104.8	53.7	51.1
2024	119.4	59.4	60

Source: KFF, CMS, CMS-64 Financial Management Reports (FY 2015–2023)

The GENEROUS Model builds on the existing framework of MDRP by establishing a voluntary supplemental rebate agreement (SRA) between participating state Medicaid agencies and pharmaceutical manufacturers. This supplemental rebate –

applied on top of the statutory URA – is calculated by leveraging international pricing data from all G-7 countries (excluding the United States), as well as Denmark and Switzerland. Using this data provided by manufacturers, CMS determines the MFN price – that is, the second-lowest net price offered in any of the selected countries – for each nine-digit drug code. This figure is also referred to as a guaranteed net unit price (GNUP). The sum of GNUP and basic rebate value would be subtracted from the wholesale acquisition cost (WAC) of each COD, which would result in supplemental rebates used by state Medicaid agencies to effectuate MFN prices.

The calculation uses this formula: ***Supplemental Rebate = WAC – (GNUP + URA)***

Many economists have warned of the consequences of importing foreign prices in Medicaid, suggesting that it "can lead to a reduction in patient access to certain drugs, less investment in the research and development of new drugs, and cost-shifting that raises the prices of other therapeutics." Even ignoring these criticisms of MFN price-setting, participating in the GENEROUS Model would be a poor business decision. Let's consider two examples to demonstrate this. The first example listed below indicates that **the model's supplemental rebate for a COD sold to wholesalers at $100 would increase the total rebate percentage by almost 23 percent, not including inflationary rebates or other non-mandatory supplemental rebates**.

Example 1:

The WAC of a drug in the United States is $100

The AWP is $120

The MFN price (after financial concessions) is $50

URA (excluding inflationary rebate) = 0.231 x $120 = $27.72

Supplemental rebate = $100 – (50+27.72) = $22.73

Notably, the GENEROUS Model SRA is designed to be a replacement for existing supplemental rebates already negotiated between states and manufacturers. While a standardized SRA could be an attractive option for manufacturers looking to reduce administrative burdens, it is unclear how these new rebates would compare to payments already in place and if this new approach would undermine preferred drug lists. More troubling, if the lowest net price of a drug offered in other nations is within a certain range of the WAC, manufacturers would be paying state Medicaid agencies a negative supplemental rebate (see example 2). **The GENEROUS Model could mean some**

manufacturers would effectively have to pay Medicaid to sell their drugs to beneficiaries. While such a scenario would likely not occur in practical terms, the mere possibility illustrates the issue with this model. Even if manufacturers ignored this clearly flawed incentive structure, the companies would have to raise prices to offset financial losses, causing a spillover effect in other markets.

Example 2:

The WAC of a drug in the U.S. is $100

The AWP is $120

The MFN price (after financial concessions) is $80

URA (excluding inflationary rebate) = $27.72

Supplemental Rebate = $100 – (80+27.72) = $-7.72

The GENEROUS Model – like other plans to implement MFN pricing – is a flawed approach to managing prescription drug costs. As many have suggested, these price controls will likely reduce patient access to treatments and hinder innovation in the pharmaceutical sector. Given these potentially harmful outcomes, it is unwise to double down on MFN strategies in the Medicaid program, which many vulnerable patients rely on for dependable access to prescription drugs.