Primer: The Medicaid Drug Rebate Program

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Executive Summary

- The Medicaid Drug Rebate Program, which Congress created nearly 30 years ago, requires drug manufacturers to pay a rebate for all drugs dispensed to Medicaid beneficiaries, with brand-name drugs requiring the greatest rebate and generic drugs the lowest.

- While the core of the program has remained intact since its inception, Congress has made numerous changes that have predominantly raised the rebate amount that manufacturers pay.

- The program was intended to ensure Medicaid received the best price for prescription drugs, but it has led to market distortions elsewhere in the health care sector and might be partly responsible for rising drug prices in the United States.

Origin and Rationale

While federal law does not require state Medicaid programs to cover outpatient prescription drugs—that is, prescription medication provided by a pharmacy or in a doctor's office—all states have chosen to provide such coverage. In 1990, Congress created the Medicaid Drug Rebate Program (MDRP)—often referred to as the Medicaid "best price" rule—to help ensure Medicaid received the lowest price available for all prescription drugs, from small molecule generics picked up at the pharmacy to brand-name biologics administered by a physician. The program requires drug manufacturers, as a condition of having Medicaid cover their drugs, pay a rebate for all of their outpatient prescription drugs, including biologics, taken by Medicaid beneficiaries. The amount of the required rebate is set by law such that the net price of the drug is either equal to the best price available to anyone in the private market or equal to a certain percentage of the drug's average manufacturer price (AMP)—whichever gives Medicaid the lowest price. The percentage for this rebate varies by type of drug, with brand-name drugs requiring the greatest rebate.

The MDRP has successfully ensured Medicaid pays the lowest prices (or close to it) for prescription drugs, particularly as the program has grown over time.[i] In 2016, Medicaid drug rebates totaled $31.2 billion—reducing the program's gross expenditures for outpatient prescription drugs by more than 51 percent.[ii]

Structure and Requirements

As with most health care programs, the MDRP has myriad terms and rules. The program's requirements, most notably the minimum rebate amount, have been amended over the years, most significantly by the Affordable Care Act (ACA) in 2010.

Participation Requirements

The MDRP requires drug manufacturers provide discounts for their drugs to the Veterans Administration and

for patients eligible for the 340B Drug Discount Program. Further, in order for payment to be made for any drug covered under Medicare Part B, the drug's manufacturer must be participating in the MDRP. In other words, nearly all federal health care programs require drug manufacturers to participate in multiple drug discount programs.

Average Manufacturer Price

A drug's AMP is the average price paid in the United States to a drug manufacturer by wholesalers or pharmacies purchasing directly from the manufacturer.[iii] Not deducted from the calculation of the AMP are customary prompt pay discounts or rebates and discounts provided to pharmacy benefit managers or insurers, as well as others; as a result, rebates are higher.[iv]

Best Price

The "best price" of a drug, as defined by the Medicaid statute, is "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States," inclusive of cash discounts, volume discounts, and rebates. [v] There are some exceptions, added after the program's initial launch, which include prices available to 340B entities; state-owned facilities or under a state pharmaceutical assistance program; the federal government, such as the Veterans Administration, the Department of Defense, or Medicare Part D plan sponsors; and nonprofit entities.

Rebate periods are equal to a quarter of the fiscal year, so the rebate amount may be adjusted as much as four times each year.

Brand-name Drugs

Brand-name drug manufacturers are required to pay the largest basic rebate amount (as a percentage of AMP). Congress originally set the minimum basic rebate for brand-name drugs at 12.5 percent of AMP, but this rate increased to 15.7 percent beginning in fiscal year 1993. The percentage then slowly declined until reaching 15.1 percent on January 1, 1996, where it remained until 2010. The ACA then raised the rebate amount to 23.1 percent of AMP. (There is an exception for brand-name blood clotting factor drugs and drugs approved exclusively for pediatric indications; the ACA set the minimum rebate percentage for these drugs at 17.1 percent.)

Any existing "authorized generic" must also be taken into account when determining the rebate amount for a brand-name drug.[vi] An authorized generic drug is an exact copy of a brand-name drug (having both the same active *and* inactive ingredients) but sold at a lower price and with a different name than the brand-name drug. [vii] An authorized generic may be produced by the manufacturer of the brand-name drug (or another manufacturer with whom they have a corporate relationship) or a secondary manufacturer to whom the primary manufacturer sells the drug. A manufacturer of a brand-name drug may choose to sell (or authorize the sale of) an authorized generic version to maintain market share once the market exclusivity period for its brand-name drug expires.

Determining the AMP and best price for brand-name drugs with an existing authorized generic requires understanding the manufacturer of the authorized generic and its relationship to the primary manufacturer. The price of an authorized generic must be included in the AMP of the brand-name drug if the brand-name drug

manufacturer (or a manufacturer with whom it has a corporate relationship) produces the generic and sells it to a wholesaler or directly to a pharmacy.[viii] If the drug is sold to a secondary manufacturer acting as a wholesaler, then the transfer price paid by the secondary manufacturer to the primary manufacturer would be included in the calculation of the AMP.[ix] In these instances, the AMP is referred to as a blended AMP.[x] Further, the best price for these drugs would be the lowest price paid for either the brand-name drug or the authorized generic drug.[xi] If, however, an authorized generic is produced by a secondary manufacturer with whom the primary manufacturer has no corporate relationship, the price of the authorized generic would not be included in calculating the brand-name drug's AMP or best price; the generic AMP would be calculated separately and the rebate would be payable by the secondary manufacturer.

To the extent that the price of an authorized generic is included in the AMP of the brand-name drug and that price is lower than the price of the brand-name drug, its inclusion will have the effect of lowering the AMP, which in turn reduces the amount of the rebate.

Generic Drugs

Unlike brand-name drugs, prices for generic drugs do not typically vary substantially from one payer to the next. Thus, generic drugs are not subject to a best price provision and instead face a fixed rebate amount. Originally set at 10 percent of the AMP, the rate was increased to 11 percent in 1994, and the ACA increased it to 13 percent in 2010.

Inflationary Rebate Penalty

Both brand-name and generic drugs are also subject to an inflationary rebate penalty in addition to the basic rebate. The inflationary rebate serves to discourage drug manufacturers from raising the price of their drugs at a rate greater than inflation. If they do, drug manufacturers must pay an additional rebate equal to the amount by which the price increase exceeds the rate of inflation, measured by the Consumer Price Index for All Urban Consumers (CPI-U). The inflationary rebate originally applied only to brand-name drugs, but the Bipartisan Budget Act of 2015 extended the requirement to generic drugs beginning on January 1, 2017.

The ACA also established an alternative inflationary rebate formula, later amended by the Bipartisan Budget Act of 2018, for products that are new formulations of brand-name drugs known as line extensions. The alternative formula is to be used if it would produce a greater rebate amount than would otherwise be calculated for the line extension drug. The alternative formula requires applying the highest additional inflationary rebate amount of any dosage form of the original brand name drug to the AMP of the line extension drug.[xii] This alternative formula intends to ensure drug manufacturers cannot limit their rebate liability by selling slightly modified versions of their brand-name drugs. Such line extensions are technically new products in the eyes of the FDA, and so the baseline period for determining their inflationary rebate amount is set when the new formula is introduced to the market, rather than when the original product was introduced.[xiii] If the MDRP did not account for this shift, the drug's price inflation rate would effectively be reset to zero.

Maximum Rebate Amount

For the first year of the program, the basic rebate was capped at 25 percent of AMP; in 1992, the cap was raised to 50 percent of AMP. The ACA again raised the cap to 100 percent of the AMP beginning in 2010, but applied this cap to the total rebate—that is, the sum of the basic rebate and the inflationary rebate amounts.

Prior to the ACA, the Medicaid Dug Rebate Program only applied to beneficiaries covered by Medicaid fee-for-service, not those in Medicaid managed care plans. Managed care plans have become increasingly popular over the past two decades, however, with enrollment among beneficiaries increasing from 23 million in 2002 (58 percent) to 65 million (81 percent) in 2016.[xiv] Thus, as enrollment in managed care increased, the reach of the rebate program decreased. In 2010, 39 million (71.5 percent) Medicaid beneficiaries were enrolled in a managed care plan.[xv] The authors of the ACA decided to extend the program to Medicaid managed care organizations (MCOs) so that the program would once again reach all Medicaid beneficiaries.[xvi] As a result, drug manufacturers now provide rebates for their drugs to nearly a quarter of the U.S. population through this one program alone.[xvii]

Who Gets the Rebates?

The amount of the rebates collected are (mostly) shared between states and the federal government based on states' federal medical assistance percentage (FMAP)—the ratio that determines how much of a state's Medicaid funding that the federal government covers.

One notable exception to the above rule is referred to as the "federal offset" of the enhanced rebate amounts imposed by the ACA. Essentially, the value of the rebates "attributable" to the changes in the ACA—that is, those rebates beyond what would have been required prior to the law's passage—must be paid entirely to the federal government.[xviii] In other words, the federal government keeps the entirety of the difference between the rebate amount that is now required under the ACA and the amount that would have been paid absent the ACA's changes. For brand-name drugs, because the ACA increased the minimum rebate amount from 15.1 percent to 23.1 percent, the federal government is entitled to up to 8 percent of the AMP in addition to the share it receives based on a state's FMAP. Whether the federal government receives the full 8 percent offset depends on the difference between the AMP and best price, since the best price was determinative of the rebate amount prior to the ACA's changes. The following chart shows examples of the different offset amounts that would be payable to the federal government for brand-name drugs based on the difference between AMP and best price:

	AMP ($)	Best Price ($)	AMP-BP (%)	Pre-ACA Minimum Rebate: Greater of 15.1% or AMP-BP (%)	ACA Minimum Rebate: Greater of 23.1% or AMP-BP (%)	Offset Amount [(ACA Min Rebate) – (Pre-ACA Min Rebate)]
AMP-BP ? 15.1%	100	90	10	15.1%	23.1%	23.1% – 15.1% = 8%
15.1%<AMP-BP<23.1%	100	80	20	20%	23.1%	23.1% – 20% = 3.1%
AMP-BP ? 23.1%	100	70	30	30%	30.0%	30% – 30% = 0

For generic drugs, the ACA increased the minimum rebate amount from 11 percent to 13 percent. Since best price is not considered in the calculation of a generic drug's rebate, the federal government will always receive the additional 2 percent rebate.

Supplemental Rebates

All but four states have also been able to negotiate supplemental rebates above and beyond the mandatory minimum rebates required by the MDRP.[xix] These supplemental rebates are typically provided in exchange for preferential treatment on a state's preferred drug list. Such a preference typically guarantees increased market share for the preferred drug. Managed care plans may also negotiate with manufacturers for supplemental rebates.

Oversight and Compliance

The federal government has limited authority to enforce compliance with the Medicaid Drug Rebate Program. Manufacturers are responsible for reporting all necessary pricing, sales, and product information to the Centers for Medicare & Medicaid Services (CMS). If information provided is not accurate or not provided in a timely fashion, manufacturers may face civil monetary penalties.[xx] If manufacturers violate the terms of the agreement, they may also be terminated from the program.[xxi] The government is unlikely to use this penalty, however, since doing so would result in beneficiaries (including Medicare Part B beneficiaries) losing access to all drugs produced by that manufacturer. Regarding potential misclassifications of a drug (whether listed as a brand-name drug or a generic), CMS currently has no authority to require correct classification or to penalize manufacturers who fail to do so.[xxii]

Results and Consequences

As the program has grown and evolved, flaws and unintended consequences have emerged. As discussed, various amendments over the years have addressed some of those needs, but other issues persist. As explained here, the program may even be worsening the problem it was created to mitigate—rising drug prices.

For instance, in defining "best price," Congress included no exception for drugs donated by manufacturers free of charge. As a result, manufacturers' charitable donations became virtually non-existent after 1990, as such "sales" would have set a drug's best price at zero and would have then required all sales of that drug to Medicaid beneficiaries to be provided for free. After realizing the problem, Congress created the 340B Drug Discount Program in 1992 and, as previously mentioned, made a limited number of exclusions from the calculation of a drug's best price, including sales to 340B entities, state-owned facilities, and public or nonprofit entities.[xxiii] Unfortunately, the creation of the 340B program brought with it other unintended consequences that have had broad and severe repercussions on the health care market, as discussed here.

The requirement that the price of authorized generics be blended with the AMP of brand-name drugs is another provision which seems to have unintentionally created a loophole. According to the Medicaid and CHIP Payment Advisory Commission (MACPAC), Congress did not intend for the provision to allow sales of an authorized generic to lower a drug's AMP and thus reduce its mandatory rebate. MACPAC notes that the allowance is the result of two changes included in separate pieces of legislation five years apart: The Deficit Reduction Act of 2005 required the blending of the AMP of the brand-name drug with an authorized generic, while the ACA added a definition of wholesaler to include a manufacturer engaged in wholesale distribution. MACPAC recommends that Congress disallow this practice that enables reduced rebates.[xxiv]

The lack of authority to enforce correct classification of products has also recently proven to be a significant problem with the program as 2016 congressional hearings revealed.[xxv] An investigation by the Department of Health and Human Services (HHS) Office of the Inspector General found that the misclassification of products has resulted in more than $1.3 billion in lost rebates between 2012 and 2016.[xxvi] The Right Rebate Act, introduced in the 115th Congress, would resolve this issue by providing the Secretary of HHS greater authority

and ability to monitor drug manufacturers, to correct any misclassifications, to collect any underpayment amounts that should have been paid, and to impose civil monetary penalties if a manufacturer knowingly misclassifies a drug.[xxvii] Senators Grassley and Wyden (S. 3702) and Representatives Schrader and Welch (H.R. 7223) introduced this legislation late in 2018, but the legislation failed to pass before the end of the year; it was re-introduced by Senator Grassley on January 24, 2019.

Finally, policymakers point to the cap on total rebates as a flaw of the program. Some have claimed that by limiting the total rebate that must be paid, drug manufacturers are able to increase the cost of their drug with limited repercussions beyond providing product at no cost to Medicaid. Removing this cap, however, would result in drug manufacturers having to pay—rather than be paid—for the use of their drugs in Medicaid. As explained here, this could worsen, rather than mitigate, the problem it is intended to fix by creating incentives for higher launch prices and less negotiation (to increase best price) in other markets.

Conclusion

Congress created the Medicaid Drug Rebate Program to reduce Medicaid's expenditures on prescription drugs. The program has successfully provided Medicaid with the lowest net prices for prescription drugs of almost any payer in the nation. The program unfortunately also has several flaws that distort the broader market, as Medicaid's cost reductions are often transformed into cost increases in other sectors of the health care market. In 2016, Medicaid rebates totaled $31.2 billion, reducing the program's prescription drug bill by more than half. Such high rebate amounts, while seemingly good federal and state fiscal policy, have a significant impact on the prescription drug market as a whole.

[i] https://oig.hhs.gov/oei/reports/oei-03-13-00650.pdf

[ii] https://www.macpac.gov/wp-content/uploads/2018/06/Improving-Operations-of-the-Medicaid-Drug-Rebate-Program.pdf

[iii] Section 1927(k)(1) of the Social Security Act

[iv] Section 1927(k)(1)(B) of the Social Security Act

[v] https://www.ssa.gov/OP_Home/ssact/title19/1927.htm

[vi] Section 1927(k)(1)(C) of the Social Security Act

[vii] https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/abbr

[viii] Answer 27 of the FAQs published by CMS on July 6, 2016: https://www.medicaid.gov/federal-policy-guidance/downloads/faq070616.pdf

[ix] Answer 28 of the FAQs published by CMS on July 6, 2016: https://www.medicaid.gov/federal-policy-guidance/downloads/faq070616.pdf

[x] https://www.macpac.gov/wp-content/uploads/2018/06/Improving-Operations-of-the-Medicaid-Drug-Rebate-Program.pdf

[xi] Answer 27 of the FAQs published by CMS on July 6, 2016: https://www.medicaid.gov/federal-policy-guidance/downloads/faq070616.pdf

[xii] https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/unit-rebate-calculation/s-or-i-line-extension-drugs/index.html

[xiii] https://www.macpac.gov/wp-content/uploads/2017/12/Potential-Recommendations-on-Medicaid-Outpatient-Drug-Rebates.pdf

[xiv] https://www.medicaid.gov/medicaid/managed-care/downloads/enrollment/2016-medicaid-managed-care-enrollment-report.pdf

[xv] https://www.medicaid.gov/medicaid-chip-program-information/by-topics/data-and-systems/downloads/2011-medicaid-mc-enrollment-report.pdf

[xvi] https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html

[xvii] https://www.americanactionforum.org/insight/understanding-the-policies-that-influence-the-cost-of-drugs/#ixzz5bsJuHW1b

[xviii] https://www.medicaid.gov/Federal-Policy-Guidance/downloads/SMD10019.pdf

[xix] https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/xxxsupplemental-rebates-chart-current-qtr.pdf

[xx] Section 1927(b)(3)(C) of the Social Security Act

[xxi] Section 1927(b)(4)(B) of the Social Security Act

[xxii] https://oig.hhs.gov/oei/reports/oei-03-17-00100.pdf

[xxiii] https://www.hrsa.gov/opa/program-requirements/public-law-102-585.html

[xxiv] https://www.macpac.gov/wp-content/uploads/2018/06/Improving-Operations-of-the-Medicaid-Drug-Rebate-Program.pdf

[xxv] https://www.c-span.org/video/?415549-1/mylan-inc-ceo-heather-bresch-testifies-epipen-price-increases

[xxvi] https://oig.hhs.gov/oei/reports/oei-03-17-00100.pdf

[xxvii] https://www.congress.gov/bill/115th-congress/senate-bill/3702/text