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PRESCRIPTION DRUG PRICING

HEALTH POLICY BRIEF SERIES
AUGUST 2017 | 7

MEDICAID BEST PRICE

The Medicaid best price policy requires drug manufacturers to give Medicaid programs the best price among nearly all purchasers.

Medicaid "best price" was a legislated policy solution enacted over twenty-five years ago to address high drug costs and make Medicaid drug spending more manageable for states. Under this policy, a drug manufacturer must offer state Medicaid programs the best price given to any other purchaser (with a few exceptions) with a mandatory rebate of 23.1 percent off the list price. Medicaid programs must, in turn, cover all of the manufacturer's prescription drugs, with few exceptions. States, payers, and manufacturers are considering whether the Medicaid rebate and best price system is still effective policy or whether the arrangement unintentionally inhibits new ways to lower drug costs and improve access to therapies.

Background

In 1989 the Senate Special Committee on Aging issued a milestone report on prescription drug prices. The report stated, "Rising drug prices, particularly the high prices of new drugs, are driving State Medicaid program costs and projected Medicare drug benefit expenditures to unsustainable levels, causing the Congress to consider reducing benefits to the elderly and poor, and forcing State legislatures to choose between funding drug benefits or other health care needs of the elderly and poor." The committee investigation was one of several efforts that led to enactment of the Medicaid drug rebate program as part of the Omnibus Budget Reconciliation Act of 1990.

The Medicaid drug rebate program requires a drug manufacturer to enter into a national agreement with the Department of Health and Human Services whereby states get the so-called best price offered to any purchaser (there are exceptions) in exchange for Medicaid coverage of essentially all of the manufacturer's drugs. Manufacturers must also provide rebates to certain safety-net providers under the federal 340B drug pricing program and to the Department of Veterans Affairs as part of the agreement.

Program participation by drug manufacturers is essentially mandatory; companies declining to participate are excluded from all federal programs, including Medicare. Approximately 600 manufacturers have entered into rebate agreements. Medicaid beneficiaries have broad access to medications with minimal out-of-pocket expenses, and states have recouped financial returns in the form

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of rebate streams from manufacturers. The federal government shares in the Medicaid rebates as well. The weakness of the program, however, has been its failure to lower the growth rate of Medicaid drug spending over time, given that manufacturers control launch prices of new drugs and can account for rebates in the prices of new products.

> "Companies declining to participate are excluded from all federal programs."

The combination of Medicaid expansion under the Affordable Care Act (ACA) and a recent increase in new drug approvals, many of which have high launch prices, have coalesced to increase overall Medicaid prescription drug spending. Medicaid spent approximately $57 billion on prescription drugs in 2015 (the most recent year for which there are full data), compared to $42 billion in 2014.

The issue was brought to a head with the market entry of high-cost curative hepatitis C drugs in 2014. With large numbers of Medicaid recipients eligible for these medications and state requirements to cover the drugs as part of the drug rebate program, the high prices put many state budgets in crisis. Given the requirement for most states to balance budgets annually, some states had to choose between treating all eligible patients with a curative therapy or funding other fundamental state programs outside of health care.

Medicaid Best Price: What You Need To Know

Certain features of the Medicaid best price policy are critical to understanding its impact on prices in Medicaid and elsewhere.

THE REBATE FORMULA

The "best price" rebate formula applies to sole-source innovator drugs distributed to Medicaid beneficiaries. The best price must be reported to the Centers for Medicare and Medicaid Services. The statutory rebate formula takes into account three factors: (1) the Average Manufacturer Price (AMP), or list price, of the drug, which is intended to account for different discounts and price concessions for other purchasers; (2) either a minimum rebate of 23.1 percent off of AMP or the "best price" offered to any other private or public purchaser (with a few exceptions—see below) if such a purchaser receives more than the minimum discount; and (3) an adjustment if the drug price rises faster than inflation. For older drugs, the inflation component is often a significant factor in the size of the rebate.

There are different minimum rebates for certain drug categories. For example, blood clotting factors and drugs approved exclusively for pediatric populations use a minimum rebate of 17.1 percent off AMP per unit. Generic drugs have a separate rebate formula, including a minimum rebate of 13 percent and an inflation adjustment similar to the one noted above, but no "best price" component.

Each state Medicaid program tracks drugs purchased for recipients and submits quarterly invoices to manufacturers for rebates. Manufacturers must update AMP and inflation calculations and ensure that they pay the correct rebate. That builds in some lag time between actual market prices and Medicaid rebates.

EXEMPTIONS FROM BEST PRICE

There are several excluded programs that do not trigger the "best price" guarantee for Medicaid. These include federal health systems such as the Department of Veterans Affairs and the Department of Defense and also prices negotiated by private plans operating Medicare Part D plans. Such programs can receive a lower price than Medicaid for a given drug.

ACA CHANGES TO MEDICAID REBATE

The ACA made several changes to the Medicaid rebate program. The biggest impact was the change in the minimum rebate from 15.1 percent to 23.1 percent. The law also defined the AMP more broadly, leading to some adjustments in the baseline price from which rebate percentages are calculated. A new rebate was added for product-line extensions, defined in the law and by clarifying regulation. In addi-

tion, the law capped rebates at 100 percent of AMP. Unlike other statutory changes, this change reduced manufacturer rebates, as some products with significant price increases over time actually owed a rebate of more than 100 percent, because of the inflation adjustment built into the rebate formula. In other words, states were ultimately recouping more than the cost of the medicine in the form of a rebate.

REBATES AS A REVENUE STREAM FOR STATES

The time lag built into the program tends to encourage states to treat rebates as a stand-alone income line in the budget, instead of looking at total Medicaid drug spending. The amount is significant: In fiscal year 2014, Medicaid programs spent $42 billion on prescription drugs and collected about $20 billion in rebates.

THE "BEST PRICE" FLOOR

One ripple effect of guaranteeing the best price for Medicaid is that it weakens the leverage of private commercial payers and pharmacy benefit managers (PBMs) in negotiations with manufacturers, in effect setting a floor under prices. Private payers argue that they would be able to negotiate even lower prices for patients if manufacturers were not obliged to offer the same price to all fifty state Medicaid programs. Best price is also confidential by law, so manufacturers could use that argument to deny a discount below the 23.1 percent minimum, even if they did in fact provide better pricing to other customers (although misreporting best price or otherwise violating the rules for calculating Medicaid rebates can be prosecuted as a violation of the False Claims Act).

The Future Of Medicaid Rebates And Best Price

Several important issues will play into the future impact of rebates and best price on Medicaid drug spending.

IMPACT ON OUTCOMES-BASED PURCHASING

Policy experts, lawmakers, drug developers, and payers are generally united in their desire to explore the potential of outcomes-based drug purchasing models (also called "value-based" purchasing models). Under such models, the payer and manufacturer agree upon assumptions about a drug's expected improvement in outcomes for the population. If the drug fails to perform as expected, the manufacturer must pay a rebate to the purchaser. However, according to a July 2016 policy notice from CMS, manufacturers' concerns over compliance with best price provisions have made some wary of entering into those agreements, which might ultimately lower the best price. In that memo, CMS says that value-based purchasing contract questions, as they relate to the best price requirement, should be taken case by case and that manufacturers should seek guidance from the agency when seeking to enter into these agreements. One interpretation of the policy notice is that manufacturers are encouraged to experiment with outcomes- or value-based models in Medicaid first, as opposed to attempting to employ the agreements in the private sector.

AN OPT-OUT FOR STATES

Some state program administrators and Medicaid managed care organizations have explored the potential benefits of a state opt-out from the Medicaid rebate program. The driving factor is the requirement that essentially all outpatient drugs from a given manufacturer must be covered by the state in exchange for the best price guarantee and rebates. For some states, the financial risk of covering all drugs, including new high-cost therapies, is not worth the benefit of the rebate. Eliminating that requirement and moving to more aggressive formulary management tools could give Medicaid programs more latitude for responding to high-price new therapies entering the market.

OTHER OPTIONS FOR STATE SAVINGS

Instead of significantly altering the best price paradigm, policy makers could dial up the minimum rebate further. The sole-source brand rebate was originally phased in from 12.5 percent in 1990, to 15.1 percent in 1995, to its current 23.1 percent. There is, in principle, no reason the minimum rebate could not be adjusted higher again.

Alternatively, policy makers could align the rebate program with potential caps on Medicaid spending, in

the context of either federal reforms to the program or states' initiatives to contain their share of costs. Some states have considered instituting a cap on Medicaid drug spending. New York, for example, recently passed legislation (Senate Bill S2007B) that sets a target cap on drug spending growth at 5 percent above inflation. If the target growth rate is exceeded, the breach triggers reviews by a drug utilization review board "for a recommendation as to whether a target supplemental Medicaid rebate should be paid by the manufacturer."

Key Terms

- **Best price:** According to statute, "The term 'best price' means, with respect to a single-source drug or innovator multiple-source drug of a manufacturer (including the lowest price available to any entity for any such drug of a manufacturer that is sold under a new drug application approved under section 505(c) of the Federal, Food, Drug, and Cosmetic Act), 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."
- **Outcomes-based or value-based drug purchasing:** Linking the purchase price of a medicine to a given clinical outcome or measure. If the drug fails to deliver on efficacy or safety metrics demonstrated in trials or other forms of real-world evidence, the manufacturer pays a rebate or other concession to the purchaser.
- **Average Manufacturer Price:** The AMP provides the baseline to determine Medicaid's federal upper limit on prices paid to pharmacies for generics. In addition, the new AMP calculation may also serve as the baseline for calculations states use to reimburse Medicaid drugs more broadly. Therefore, the rule impacts which drugs are new or exempted from a higher rebate, the calculation of prices, and the rebate amount. The January 2016 Medicaid Covered Outpatient Drug final rule revised the long-standing definition of AMP to "now mean the average price paid to the manufacturer for the drug in the United States by wholesalers for drug distribution to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer."

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Health Policy Briefs are produced under a partnership of *Health Affairs* with the generous support of the Commonwealth Fund and Memorial Sloan Kettering Cancer Center. Text highlighted in blue is hyperlinked to outside sources in the online version of this brief.

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Cite as: "Health Policy Brief: Medicaid Best Price," *Health Affairs*, August 10, 2017. DOI: 10.1377/hpb2017.8