

STATE OF THE ART AND SCIENCE

Evolving Medicaid Coverage Policy and Rebates

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Abstract

Medicaid covers approximately 1 in 5 Americans and accounts for one-sixth of US health care spending. Despite having to navigate increasing and variable spending on prescription drugs, Medicaid programs must balance their annual budgets, and they rely heavily on the Medicaid Drug Rebate Program (MDRP). The MDRP requires programs to maintain an open formulary covering all of a manufacturer's drugs in exchange for being given the lowest price in the market. Recent attempts by states to close their formularies signal that the benefit of this program might be attenuated by the lack of negotiating leverage in the rest of the market, exposing Medicaid to higher prices. Regardless of whether closed formularies would succeed in constraining Medicaid prescription drug spending, this trend raises important questions about the usefulness of a system that pegs Medicaid drug spending to net prices negotiated by others in the market.

Medicaid Beneficiaries and Formularies

Medicaid programs, collectively, constitute the largest US public payer, covering 21% of the population and accounting for one-sixth of total US health care spending.^{1,2} Compared with other payers, Medicaid serves a more vulnerable population, including low-income Americans and those who are unable to work due to a disability or medical condition. Many Medicaid beneficiaries are ineligible for employer-sponsored health insurance or are unable to afford plans offered by exchanges. Medicaid also plays a critical role in addressing public health concerns, such as substance use disorders and infectious diseases, including Hepatitis C and HIV/AIDS. In 2016, Medicaid programs spent \$9.4 billion on HIV/AIDS, making it the second largest public funder for all HIV/AIDS related care.³

Although coverage of prescription drugs under Medicaid is optional, all states have opted in,⁴ and, for all states, spending on prescription drugs presents a significant and growing line item in their budgets. In 2016, Medicaid spent \$60.5 billion on prescription drugs before rebates or discounts.⁵ Although Medicaid enrollment growth is projected to slow, prescription drug spending is expected to continue placing fiscal demands on states.^{1,5,6,7} To defray some of these costs, state governments must comply with conditions of the

federal Medicaid Drug Rebate Program (MDRP), a cornerstone of which is a requirement to have an open formulary in exchange for rebate payments from manufacturers.

The alternative to an open formulary is a closed formulary, a design already adopted by other health plan types. A closed formulary allows plans to exclude drugs from coverage, increasing their ability to negotiate for discounts and rebates. The Veterans Health Administration (VHA), for example, has maintained a national formulary—which includes closed drug classes—since 1997.⁸ *Closed* in this instance means that VHA facilities are prohibited from including on their formularies any drugs excluded from the national formulary. Some exceptions aside, drugs can also be excluded from Medicare Part D formularies, a deliberate policy choice intended to give health plans leverage to negotiate for lower prices.⁹ In commercial plans of health maintenance organizations, 71% of members were subject to closed formularies in 2015,¹⁰ and some research suggests further opportunities for savings in classes of drugs that have remained open.^{11,12} An open formulary requirement is one that is unique to the Medicaid program.

Here we describe the MDRP and examine efforts by Medicaid programs to contain drug costs, including closed formularies and waivers.

Rebates and the Medicaid Drug Rebate Program

Instituted under the Omnibus Budget Reconciliation Act of 1990, the MDRP extends manufacturer rebates to Medicaid programs for drugs used by beneficiaries enrolled in fee-for-service and managed care programs. To qualify for these rebates, Medicaid programs must cover all of a manufacturer's Food and Drug Administration (FDA)-approved drugs, with few exceptions.¹³ Rebate payments are shared between the federal and state governments and amounted to approximately \$31 billion in 2016.⁷ Manufacturers' participation in the MDRP is a condition of having their products covered under Medicaid.

MDRP rebate payments are calculated based on 2 main formulas. For single-source or innovator (brand-name) drugs, the rebate is the greater of (1) a statutory discount (23.1%)¹⁴ off the average manufacturer's price (AMP), which is the average net price at which the manufacturer sells to wholesalers and pharmacies, or (2) the difference between a drug's AMP and the best price (or the lowest price) for that drug in the market. For generic drugs that come from multiple sources, the discount is 13% off the AMP.¹⁵ These discounts are provided in the form of rebate payments by the manufacturer to the Centers for Medicare and Medicaid Services (CMS). CMS also applies a Consumer Price Index penalty for drug price increases beyond the inflation-adjusted price. If price increases for a given drug exceed inflation, a penalty sum is added to the rebate payment¹⁵; this penalty sometimes results in generic drugs being more expensive than older brand-name drugs.

MDRP rebate amounts vary by drug depending on the negotiating power of Medicare Part D and commercial health plans, which determines whether the best price of a brand-name drug falls above or below the statutory minimum discount of 23.1% for Medicaid. Brand-name drugs with many competitors often require significant net price concessions to pharmacy benefit managers and health plans in order to gain favorable coverage; these concessions benefit Medicaid when drugs' net prices fall well below the 23.1% statutory minimum discount for brand-name drugs. However, payers are often unable to negotiate lower net prices for those brand-name drugs with few therapeutic alternatives, strong consumer demand, or coverage requirements that shield them from utilization management or access restrictions. In these cases, Medicaid plans are more likely to obtain the 23.1% rebate level.^{6,16} The barrier to negotiation is particularly common for brand-name specialty drugs, which, in 2017, accounted for \$9.8 of \$12 billion in US net spending growth on new brand-name drugs.¹⁷ Brand-name [drugs used to treat cancers](#), hepatitis C, HIV/AIDS, and multiple sclerosis were major drivers of this spending. Drugs for hepatitis C and HIV/AIDS constitute a disproportionately large share of Medicaid prescription drug spending,¹⁸ and their increased budget impact has amplified the need to protect vulnerable patients while also forcing difficult trade-off decisions for Medicaid programs.

Cost Containment

The MDRP requires states to cover all of a manufacturer's FDA-approved drugs, with a few exceptions, regardless of their cost or performance relative to other options, and this is a vulnerability for Medicaid programs. Currently, states' primary means of persuading manufacturers to offer greater net price concessions is their preferred drug list (PDL).⁶ PDLs include drugs for which manufacturers offer supplemental rebates beyond those offered by the MDRP and are primarily enforced through utilization management tools that seek to control prescription drug use by patients. Utilization management could require beneficiaries to gain prior authorization, comply with step edits, and navigate refill limits.¹⁹ These kinds of requirements are not without their drawbacks: one study found that between 47% and 79% of Medicaid beneficiaries were subject to these [cost-containment](#) utilization management tools and that 22% have experienced compromised access to needed medications.⁴ Introduction of high-cost treatments for hepatitis C, for example, compelled Medicaid programs struggling to protect their budgets to draw on these tools. More than half of states have instituted prior authorization requirements conditioned on patients' liver fibrosis scores, although some of these requirements have not survived challenges in federal courts.²⁰

Pressure to contain rising drug spending, particularly for drugs in classes that have been protected from competition and net price erosion, has prompted states to seek new approaches to administering Medicaid drug benefits. For example, some states participate in purchasing collectives, which help them negotiate net price concessions from manufacturers.²¹ Some also rely on managed care programs to negotiate with

manufacturers and administer their prescription drug benefit by including in their capitation amounts for prescription and outpatient drugs.²² New York has implemented a spending cap that allows the state's Medicaid program to negotiate for additional rebates for specific drugs if overall drug spending exceeds a pre-determined growth target.²³ This spending cap was first enforced when determining coverage for a cystic fibrosis drug, lumacaftor/ivacaftor. In 2018, New York negotiated with this drug's manufacturer an annual price of \$83 000, down from the \$250 000 per year list price.^{24,25}

More ambitious efforts by state Medicaid programs to contain drug costs, such as [closed formularies](#), stand at odds with open formulary provisions of the MDRP and require a federal waiver to implement.

Waivers and Closed Formularies

A closed formulary would allow a Medicaid program to decline to cover certain drugs, increasing its negotiating leverage and containing costs. In effect, programs could wield the threat of exclusion to gain greater net price concessions from manufacturers. Closed formularies have been adopted by Express Scripts (ESI) and CVS,²⁶ which administer drug benefits of commercial health insurance and Medicare Part D plans. These companies' formularies are substantially more restrictive than current Medicaid plans' drug benefits; in the 2016 fiscal year, 20% of drugs covered in Massachusetts's Medicaid plans were not covered either by CVS or ESI formularies or by both.²⁷

Closed Medicaid formularies are not unprecedented. Before the start of the MDRP, 19 of 47 state Medicaid programs then in operation adopted a restricted (closed) formulary design with drugs selected by state agencies on the basis of cost or efficacy.²⁸ Excluded drugs included growth hormones such as somatrem, isotretinoin, and a selection of branded nonsteroidal anti-inflammatory drugs.²⁹ A review of studies from this era found that these states' Medicaid plans incurred modest savings from these restrictions.²⁸ However, past experience is unlikely to be informative, as federal pricing and reimbursement policies have changed substantially since this period.

Medicaid programs' attempts at exclusionary approaches to formulary design have met with mixed enthusiasm at the federal level. Massachusetts, a state with a history of pioneering health care policy choices (one example being the establishment of the Massachusetts Health Connector, on which the Affordable Care Act health insurance exchange was modeled), applied for a Section 1115 waiver (a request to waive the MDRP requirement to have an open formulary) from CMS and proposed to close its Medicaid formulary, restricting coverage such that at least one drug in every therapeutic class would be covered.³⁰ CMS rejected the waiver request, reaffirming in its official announcement that, unless Massachusetts chose to forgo MDRP rebates altogether, all drugs produced by manufacturers participating in the MDRP must be covered by Medicaid. Despite this rejection, the President's budget request for fiscal year 2019

called for up to 5 states to pursue demonstration projects that address high costs of prescription drugs via closed Medicaid formularies.³¹

Leverage and Vulnerable Patients' Drug Needs

Manufacturers often rely on high list prices to give them headroom to offer discounts and rebates to Medicare Part D and commercial plans in exchange for their formulary preference. The MDRP leaves Medicaid programs reliant on rebates that depend heavily on decisions and actions taken by commercial and Medicare Part D health plans, which determine whether net prices of brand-name drugs fall below the minimum 23.1% discount guaranteed to Medicaid. The MDRP thus established a way to ensure that Medicaid programs had access to the same, or better, net prices negotiated by these other entities. Although the statutory rebate has protected Medicaid programs from the growing differences between list and net prices in some drug classes, the program is less effective at addressing expenditures on drugs with minimal rebates, such as those used to treat cancers and HIV/AIDS. As spending among drugs with lower rebates continues to grow, MDRP payments might no longer suffice to subsidize their use.

Medicaid programs' ambition to experiment with closed formularies arose after the rest of the market had already begun to incorporate this mechanism. Although it seems likely that this approach has afforded health plans more negotiating power to obtain net price concessions in competitive classes of drugs, which would be passed through to Medicaid, whether and to what extent it has improved their ability to lower costs for drugs with minimal rebates, for which there is high demand and coverage protections, is unclear. The uncertain success of closed formularies raises a question about whether Medicaid could improve on that performance. There are no safeguards in place to ensure that these same tools do not increase Medicaid spending. For example, it is possible that using more aggressive management strategies, such as closed formularies, reduces access to some drugs and amplifies financial burden on patients with commercial, health exchange, or Part D plans that rely on closed formularies, increasing the likelihood that they will become eligible for Medicaid.

Conclusion

The design of the MDRP program has left Medicaid programs exposed to the consequences of access and pricing decisions by others in the market, including other payers, pharmacy benefit managers, and manufacturers. While this approach leverages the negotiating power of other payers in competitive classes of drugs, it fails to benefit Medicaid programs when commercial negotiating leverage falls short. In the near term, economic benefits to states with closed Medicaid formularies would likely depend on whether increases in list prices for drugs with lower rebates exceeds reductions in net prices for those drugs that do offer substantial concessions to commercial and Medicare Part D plans.

Regardless of whether or how they are implemented, closed formularies signal a deeper market challenge for brand-name drugs and reflect evolving demands on policies that aim to protect Medicaid by leveraging other payers. In addition to concerns about access restrictions for the most vulnerable patient populations, debate over closed formularies raises broader questions about the usefulness of commercially negotiated rebates as a strategy for controlling costs and the effects on Medicaid of escalating payer restrictions in other parts of the market. Policymakers might find benefit in revisiting the assumptions underlying the program and in exploring other options to secure a more predictable and constrained pattern in Medicaid prescription drug spending.

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