Medicaid Drug Pricing: Overview and Proposed Changes

Introduction

Driven by concerns over rising prescription drug costs, Congress established the Medicaid Drug Rebate Program (MDRP) in 1991. Under the MDRP, a drug manufacturer's products may not receive Medicaid coverage unless the company agrees to provide substantial discounts on covered drugs for Medicaid programs and other federal health programs. On top of federally mandated discounts under the MDRP, states typically negotiate with manufacturers for additional, supplemental rebates on drugs purchased for Medicaid beneficiaries. Together, these rebates have considerably reduced the financial burden on states. Yet, despite the MDRP's success, many states continue to struggle to ensure affordable access to prescription drugs via Medicaid while remaining within budgetary constraints. This is, in part, attributable to the high introductory prices seen in recent years, particularly among specialty drugs.

In light of these challenges, advocates and policymakers have pushed for changes at the federal and state level intended to alleviate the burden of high drug costs within Medicaid. At the federal level, these options include updating the MDRP's rebate formula to better account for rising costs; improving transparency, monitoring, and enforcement of the program; and giving states more flexibility to take actions that could reduce costs. States' options, on the other hand, include expanding the scope and amount of supplemental rebates states negotiate with manufacturers; improving transparency and review procedures to help ensure appropriate usage of drugs and secure optimal rebate amounts; and considering alternative models for the payment and delivery of prescription drugs in Medicaid.

OVERVIEW OF MEDICAID DRUG PRICING

Medicaid is a federal-state partnership program that provides health care coverage and certain support services for eligible individuals with low incomes. While Medicaid offers some latitude to states in deciding which benefits to include, all states currently elect to provide coverage for outpatient prescription drugs.[1] The principal mechanism for controlling drug costs within Medicaid is the Medicaid Drug Rebate Program (MDRP), established by Congress in 1991.[2] Under the MDRP, a drug manufacturer's products may not receive Medicaid coverage unless the company enters into a national rebate agreement with the U.S. Department of Health and Human Services (HHS). This agreement must stipulate, among other things, that the manufacturer will provide substantial rebates on the use of its drugs by Medicaid. In return, state Medicaid programs must generally agree to cover all of a manufacturer's drugs. The MDRP's rebate requirements apply to most drugs, including over-the-counter products that are covered by Medicaid. But some drugs, such as those administered during office visits or patient stays in health care facilities, are exempt.

The size of a drug's MDRP-mandated rebate will generally depend on whether it is a brand-name or generic drug. For brand-name drugs (i.e., drugs marketed under a brand name by a company that has the exclusive right to produce and sell them), the MDRP

dictates that the rebate amount must be the greater of two alternatives: (a) 23.1 percent of the drug's average manufacturer price (AMP), or (b) the difference between the drug's AMP and its "best price"—the lowest price at which the drug (including any authorized generic version) is sold on the market. By contrast, generic drugs (i.e., drugs that are identical to their brand-name equivalents but sold by another company, often at a lower price, after any patents or exclusivities on the brand-name drug have ended) receive a flat rebate of 13 percent of the drug's AMP. This typically results in a smaller rebate for generics. On top of these fundamental rebate formulas, the MDRP applies an inflationary rebate penalty to both brand-name and generic drugs, which caps year-to-year increases in a drug's price to the rate of inflation. Combined, the total MDRP rebate amount on an individual drug must not exceed 100 percent of its AMP—a change made under the Affordable Care Act (ACA).[3] This overall cap effectively limits the financial liability of manufacturers under the MDRP.

Most states augment the MDRP rebates they receive with additional, "supplemental" rebates that states negotiate with manufacturers. In exchange for these supplemental rebates, state Medicaid programs agree to place a manufacturer's drugs on a preferred drug list (PDL), which essentially grants the product a dominant status in the market by removing certain utilization restrictions that would otherwise apply. Though some states individually negotiate supplemental rebates with manufacturers, others do so via multi-state purchasing pools.[4]

These efforts have, to a significant degree, shielded Medicaid from the burden of high prescription drug costs. Currently, state Medicaid programs pay among the lowest effective prices available to any payer. For example, rebates to Medicaid programs totaled $34.9 billion in fiscal year 2017, representing cost savings of 54.5 percent.[5] Moreover, consistent with Congressional intent, the MDRP has generally achieved this success without compromising beneficiaries' access to the drugs they need.

CONTINUED CHALLENGES IN MEDICAID DRUG SPENDING

Despite the success of the MDRP, recent trends in Medicaid drug spending have drawn the concern of policymakers and stakeholders. Though drugs currently constitute only a small proportion of the Medicaid's overall spending, the past few years have seen the cost of drugs rise considerably compared to other aspects of the Medicaid program. For instance, in 2015, drug spending in Medicaid before rebates increased by 21 percent, followed by an additional 11 percent uptick in 2016.[6] Experts attribute the growth of Medicaid drug spending to a number of factors, including the introduction of new, high-cost specialty drugs (such as Sovaldi, Gilead's hepatitis C drug) alongside higher rates of service utilization by Medicaid beneficiaries which, in turn, are due to the ACA expansion of Medicaid coverage in many states.[7] This upward trend is predicted to continue through the next decade, with some suggesting that overall Medicaid drug spending growth will reach more than 24 percent per year.[8]

On top of the financial burden on the federal government, these increases are of particular concern to states, which are faced with addressing the rapid rise of Medicaid costs within their state budgets. Similarly, Medicaid managed care plans, which receive a fixed amount of money to care for each patient, may face hardships coping with the increased utilization of high-cost drugs. These circumstances have given rise to discussions about how to improve upon Medicaid's existing cost-containment strategies. Some proposed solutions are summarized below.

PROPOSED FEDERAL OPTIONS FOR ADDRESSING THE HIGH COST OF DRUGS IN MEDICAID

Updating The Rebate Formula to Reduce Costs and Deter Excessive Pricing

Many observers believe that, under the current regime, manufacturers are able to avoid providing adequate rebates on some drugs. For this reason, policymakers and stakeholders have pushed for various changes that would better ensure adequate rebates and discourage unhelpful manufacturer practices. For example:

- Congress could raise the current ceiling on a drug's total rebate amount, established by the ACA, to a level above the currently capped 100 percent of AMP. Lifting the statutory cap on rebate amounts could help to address excessive annual drug price increases by manufacturers—a trend in recent years that has permitted companies to avoid providing full rebates.[9] The statutory cap could either be removed for the total rebate amount (including base rebates and inflationary penalties), or simply the inflationary component which may not be as concerning to private payers.

- Congress could eliminate the rule that the AMP of brand-name drugs and their authorized generic versions be "blended" in calculating drug rebates. Currently, manufacturers are able to exploit the blending requirement by selling authorized generics

at a low price to a secondary company (*e.g.*, a subsidiary) which, in turn, sells the product to Medicaid. Because of the blending rule, this practice reduces the rebate amount that is owed by the primary manufacturer on the authorized generic's brand-name counterpart.[10]

- Since drug spending in Medicaid is disproportionately attributable to specialty drugs with high launch prices, it has been recommended that these drugs be treated differently when determining rebates. For instance, Congress could raise base rebates for high-cost specialty drugs to an amount greater than the current 23.1 percent of AMP.[11] Moreover, where manufacturers have increased a drug's price at a rate above inflation, rebate amounts could be calibrated to keep up with artificial and excessive year-to-year price increases.

- Congress or the CMS could consider including rebates negotiated between pharmacy benefit managers (PBMs) and insurers in the calculation of a drug's rebate amount. Currently, these prices are excluded from the determination of MDRP's best price requirement, which results in a lower base rebate and higher costs to Medicaid programs.[12]

Improving Transparency, Auditing, and Enforcement in Medicaid

Existing mechanisms to monitor and enforce manufacturers' compliance with MDRP have been criticized as inadequate. This has led to calls for increased scrutiny of drugmakers and better enforcement tools for both states and CMS. For example:

- CMS could improve its monitoring efforts by instituting routine audits of MDRP-participating drug manufacturers. Currently, the federal government's power to verify information and data submitted by drug manufacturers is limited. As a result, errors and misrepresentations regarding drug prices by manufacturers may go unaddressed. Among other things, improved CMS monitoring activities would help to ensure that manufacturers provide sufficient rebates on drugs. In order to do so, however, Congress would likely have to provide additional resources to CMS.[13]

- CMS could provide states with drug pricing information reported by manufacturers, which is currently held confidentially. This would permit states to share monitoring and enforcement responsibilities with the federal government, as well as assist states in effectively negotiating supplemental rebates with manufacturers.[14]

- Congress could direct CMS to require retail community pharmacies to report data on their actual costs of acquiring covered drugs as a component of CMS's existing National Average Drug Acquisition Cost (NADAC) survey. Though CMS has regularly requested this information since the survey's inception in 2012, pharmacies' participation in the NADAC is currently voluntary. Since CMS encourages Medicaid programs to base their reimbursement methodologies on the NADAC in order to satisfy Medicaid's requirement that reimbursement to pharmacies must not exceed the actual acquisition cost (AAC) of a covered drug,[15] legislators have argued that making survey responses mandatory will increase the quality of information available for use by states and ensure they avoid excessive payment.[16]

Empowering and Providing Additional Flexibility to States

Within existing parameters, states are constrained in their ability to take certain steps to relieve the high burden of Medicaid drug spending. Advocates have proposed a number of options that the federal government could adopt to expand states' latitude to further achieve drug-related savings within their Medicaid programs. For example:

- CMS could issue guidance on and approve waivers from states requesting the removal of certain high-cost prescription drugs from Medicaid coverage. This is likely to enhance states' bargaining power when negotiating with manufacturers.[17] Efforts to exclude particular drugs from coverage, however, would have to be carefully tailored to avoid impeding access to medically necessary drugs for Medicaid beneficiaries.

- Unlike state Medicaid programs receiving Children's Health Insurance Program (CHIP) support, separate state CHIP programs currently are not eligible to receive rebates through the MDRP. Congress could take action to apply the MDRP to separate CHIP programs in order to ensure the availability of larger rebates on drugs purchased in connection with such programs.[18]

- Congress could authorize CMS to partner with state Medicaid programs in a Federal-State purchasing pool for the purpose of negotiating supplemental rebates for high-cost drugs. If implemented, this proposal could save nearly $6 billion over ten years.[19]

- CMS could grant states the opportunity to lead demonstration projects in order to pilot innovative payment and delivery models for prescription drugs

in Medicaid without forfeiting their participation in the MDRP. This may include, for instance, importing drugs from other countries, such as Canada, where drug prices are lower.[20]

PROPOSED STATE OPTIONS FOR ADDRESSING THE HIGH COST OF DRUGS IN MEDICAID WITHIN EXISTING CONSTRAINTS

Increasing The Scope and Amount of Supplemental Rebates

Some states do not currently negotiate supplemental rebates, while others do not extend their supplemental rebate agreements to all drugs or drug classes provided within their Medicaid programs. Thus, commentators have suggested ways that states could increase the scope and amount of the supplemental rebates they negotiate with manufacturers in order to achieve greater cost-savings. For example:

- States that have not negotiated supplemental rebates could do so. Other states could seek to apply supplemental rebates to drugs accessed by managed care beneficiaries, extend rebate negotiations to a larger group of drugs, or add an inflation-related component to supplemental rebates, if they have not already exhausted these options.[21]
- States could ensure that managed care plans are in the best position to negotiate supplemental rebates by, for example, establishing uniformity in preferred drug lists (PDLs) across fee-for-service and managed care programs.[22]
- States that have entered into multi-state purchasing pools could periodically assess whether their negotiated rebates are optimal.[23]

Enhancing Transparency and Review Procedures

States have tools at their disposal to obtain information and data about drug pricing, and to strengthen review of the effectiveness and utilization of drugs. Leveraging these tools correctly, according to analysts, could help states control Medicaid drug spending. For example:

- States could consider instituting reviews of the clinical effectiveness of drugs. On top of their utility for formulating PDLs, using and expanding the use of drug effectiveness reviews could contribute to states' bargaining power when negotiating supplemental rebates with manufacturers.[24]
- States could explore evaluating and strengthening drug utilization review (DUR) programs, which collect information to help ensure the appropriate use of drugs provided under Medicaid. Data obtained through DUR programs could inform efforts to bring down costs, such as the formation of PDLs and when negotiating with manufacturers.[25]
- States could take steps to require that drug pricing information be made public by entities subject to the state's licensing authority, including manufacturers, PBMs, wholesalers, and pharmacies.[26] Alternatively, states could negotiate for this information as a part of their broader supplemental rebate discussions with manufacturers.[27] Access to this information would improve states' ability to achieve optimal rebate amounts.

Testing and Implement Alternative Payment and Delivery Models

States could consider testing and implementing alternative ways to purchase, pay for, and deliver prescription drugs to Medicaid beneficiaries. For example:

- In order to improve their leverage when negotiating rebates with manufacturers, states could explore implementing a bulk purchasing arrangement across state programs.[28]
- States could pursue value-based purchasing of drugs, or, for certain high-cost medications, they could use a subscription approach to purchasing where a fixed price is paid a manufacturer in return for a specified volume of product.[29]

ENDNOTES

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2 *See* 42 U.S.C. § 1396r–8.

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