

# How to Strengthen the Medicaid Drug Rebate Program to Address Rising Medicaid Prescription Drug Costs

*by Edwin Park*

*Fifth in a series of briefs on the  
future of children's health  
care coverage*

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## Key Findings

- The Medicaid Drug Rebate Program is highly effective. In 2016, rebates paid by drug manufacturers lowered Medicaid prescription drug costs by more than 51.3 percent, compared to rebate savings of only 19.9 percent in Medicare Part D. To help state Medicaid programs better address rising prescription drug costs, policymakers should consider proposals that build on and strengthen the rebate program, rather than weaken it.
- Federal policymakers could consider options to strengthen the Medicaid Drug Rebate Program such as increasing the rebates to deter excessive launch prices and annual price increases, eliminating the cap on rebate amounts, and extending the rebate program to separate state CHIP programs.
- State policymakers could adopt policies already available under federal law such as expanding and maximizing the supplemental rebates that states negotiate with drug manufacturers, increasing drug pricing transparency, and enhancing the use of drug effectiveness reviews.

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## Introduction

Prescription drugs are essential for the health of tens of millions of low-income children enrolled in Medicaid. They not only are part of routine pediatric care but also provide critical treatment and maintenance for chronic conditions such as asthma and attention deficit hyperactivity disorder, illnesses like childhood cancers, serious behavioral health issues, and rarer conditions such as cystic fibrosis and spinal muscular atrophy.<sup>1</sup>

The Medicaid Drug Rebate Program (MDRP) is highly successful in significantly reducing state Medicaid prescription drug costs, while ensuring access to needed prescription drugs for low-income children, families and other beneficiaries who rely on Medicaid today. It is achieving the intent of the drug rebate program, when it was enacted in 1990, to make prescription drugs much more affordable for state Medicaid programs and low-income beneficiaries by ensuring that Medicaid gets among the



largest discounts, and thus among the lowest effective prices, available to any payer. Medicaid obtains rebates that are far larger than those in Medicare Part D and in private insurance.

Yet, while net prescription drug costs constituted only 5.4 percent of total Medicaid benefit spending in 2016 and annual Medicaid prescription drug cost growth has significantly moderated since 2014, overall prescription drug costs are expected to continue to increase at a faster rate than other health care goods and services over the next decade due in large part to continued specialty drug

cost growth, according to the Medicaid and CHIP Payment and Access Commission (MACPAC).<sup>2</sup> As a result, to better help state Medicaid programs address these rising drug costs and ensure continued access to needed prescription drugs for low-income Medicaid beneficiaries such as children and families, federal and state policymakers should take sound steps to improve and strengthen the Medicaid Drug Rebate Program, but not do anything to weaken or undermine it.

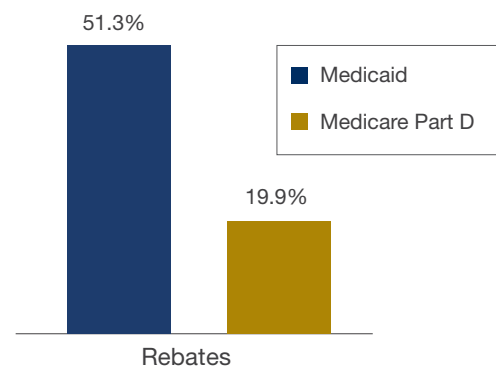
## Medicaid Drug Rebate Program Is Highly Effective

Section 1927 of the Social Security Act mandates that all drug manufacturers must provide rebates to the federal government and states under the Medicaid Drug Rebate Program as a condition of having their drugs covered by Medicaid. (They must also agree to participate in the 340B program and provide discounts to the Veterans Administration, among others.) For example, in the case of brand-name drugs, manufacturers must pay rebates equal to 23.1 percent of the Average Manufacturer Price (AMP) or the AMP minus the “best price” provided to most other purchasers, whichever is greater. (The AMP is generally the average price paid by wholesalers for drugs distributed to retail community pharmacies.) For generic drugs, rebates equal 13 percent of the AMP. Manufacturers must also pay additional rebates for both brand-name and generic drugs if their prices rise faster than general inflation.<sup>3</sup> Nearly all states also directly negotiate with manufacturers for voluntary supplemental rebates on top of these federally required rebates,<sup>4</sup> with many states negotiating together as part of a multi-state purchasing pool.<sup>5</sup> These additional rebates equal about 3 to 6 percent above the federal rebate amounts—according to one study conducted by a pharmacy benefit manager (PBM) contracting with state Medicaid programs.<sup>6</sup>

These rebates are substantial, demonstrating the effectiveness of the Medicaid Drug Rebate Program and achieving its intent when Congress enacted it in 1990 in lowering prescription drug costs for state Medicaid

programs nationwide. According to MACPAC, in federal fiscal year 2016, drug manufacturers paid \$31.2 billion in rebates to the federal government and the states, lowering Medicaid prescription drug costs by 51.3 percent.<sup>7</sup> In contrast, data from the 2018 Medicare Trustees report shows that the rebates negotiated between private insurers and drug manufacturers lowered Medicare Part D costs by only 19.9 percent in 2016 (see Figure 1).<sup>8</sup> In fiscal year 2017, manufacturers paid \$34.9 billion in rebates, lowering Medicaid prescription drug costs by 54.5 percent.<sup>9</sup>

**Figure 1: Medicaid and Medicare Part D Rebate Savings as Share of Gross Drug Spending in 2016**



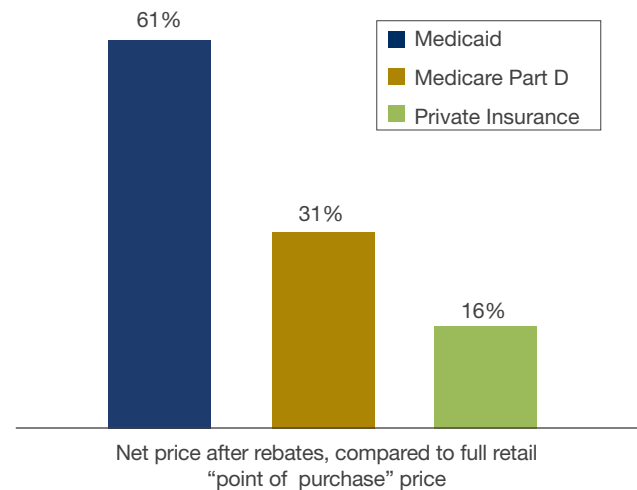
Source: MACPAC and Medicare Trustees Report



Other analysis has similarly found that the drug rebates manufacturers pay in Medicaid are far larger than what Medicare Part D plans receive. For example, among select brand-name drugs with the highest Part D expenditures, the Office of Inspector General at the U.S. Department of Health and Human Services (HHS) previously determined that the median “unit rebate amount” was about three times larger than under Part D in 2012 and 10 times or more for many drugs.<sup>10</sup> Altarum recently estimated that relative to the full retail or “point of purchase” price for brand-name drugs, Medicaid receives rebates of about 61 percent, while Medicare Part D plans obtain rebates of about 31 percent; private insurance plans negotiate rebates of about 16 percent. In other words, relative to the full price, the net price for brand-name drugs, after rebates, is only 39 percent in Medicaid but 69 percent in Medicare Part D and 84 percent in private insurance (see Figure 2).<sup>11</sup> In addition, preliminary results from an analysis conducted by the Congressional Budget Office finds that for the 50 top-selling, brand-name specialty drugs in Medicare Part D in 2015, the weighted average Medicaid rebate in 2015 was more than three times larger than rebates in Medicare Part D. Medicaid rebates reduced the weighted average price per specialty drug prescription (net of rebates and discounts) by nearly 56 percent, compared to nearly 18 percent in Medicare Part D (see Figure 3).<sup>12</sup>

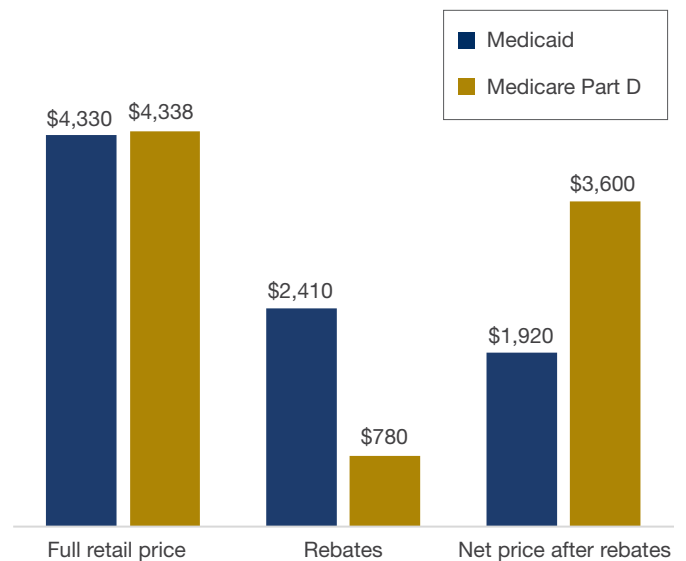
In exchange for these rebates, except for a very limited set of drug classes, state Medicaid programs cannot outright deny coverage of drugs produced by manufacturers participating in the drug rebate program. In addition, children enrolled in Medicaid receive the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit, which ensures that children can obtain any drugs their practitioners determine they need as the result of a screening and diagnosis. Medicaid also limits co-payments that may be charged on each prescription to nominal amounts, and for most children on Medicaid, co-payments and other cost-sharing are prohibited entirely. Together, these protections help ensure that low-income Medicaid beneficiaries, including children and families, have access to the prescription drugs they need.<sup>13</sup>

**Figure 2. Comparison of Rebates for Brand-Names Drugs Across Payers**



Source: Altarum

**Figure 3. Weighted Average Price for Top-Selling Brand-Name Specialty Drugs in 2015**



Source: Congressional Budget Office



More could be done, however, to ensure that these access protections are actually available to beneficiaries, including low-income children. For example, more than two-thirds of Medicaid beneficiaries received their benefits through comprehensive managed care plans in 2016 and in most states, such plans are responsible for directly providing pharmacy benefits (rather than being carved out as a separate benefit administered directly by a state Medicaid agency).<sup>14</sup> It is unclear whether Medicaid managed care plans are fully complying with the general prohibition against excluding coverage of certain prescription drugs through closed formularies, the EPSDT requirement that children are receiving all needed drugs even when they are not on plans' preferred drug list, or the requirement that they must respond to prior authorization requests within 24 hours and provide a temporary emergency drug supply.<sup>15</sup>

State Medicaid programs, however, have considerable tools to lower drug costs and manage drug utilization. For example, nearly all states use preferred drug lists and require prior authorization for certain prescription drugs, often in conjunction with supplemental rebate negotiations. (As noted above, states must respond to prior authorization requests within 24 hours and provide a 72-hour emergency supply.) They can require "step therapy" or "fail first" under which a beneficiary must first try other drugs within the same drug class. States also can require generic substitution when a generic version of a drug is available; in fiscal year 2017, the average generic utilization rate was 83 percent.<sup>16</sup> They can also deny coverage for drugs that are not used for a medically accepted indication. In addition, state Medicaid programs also must operate drug utilization review (DUR) programs, which include screening prospectively for duplication, contraindications, interactions with other drugs, incorrect dosage, and abuse and misuse. They must also retrospectively review claims and other data for overuse, inappropriate or medically unnecessary care, appropriate use of generics, and fraud and abuse. Many states also conduct provider education to ensure appropriate prescribing patterns on the part of physicians and other health professionals.<sup>17</sup>

While the Medicaid Drug Rebate Program is already highly effective, state Medicaid programs likely need additional tools and assistance from the federal government to address the two principal drug pricing problems: high launch prices and excessive annual price increases. In addition, states on their own could adopt policies that lower their Medicaid prescription drug costs using existing programmatic flexibility.

Federal and state policymakers should only consider sound Medicaid policy proposals that build on, improve, and strengthen the rebate program. They should reject any policy proposals that would have the effect of weakening or undermining the program, which would result in higher federal and state Medicaid drug costs and would reduce access to needed prescription drugs among low-income beneficiaries, including millions of children and families and people with disabilities. For example, the Trump Administration has proposed a demonstration project under which states would entirely opt out of the Medicaid Drug Rebate Program, negotiate rebates on their own, and be given new authority to exclude coverage of certain prescription drugs through closed formularies. (The Administration has also encouraged states to seek similar waivers opting out of the rebate program, as well.) It is highly unlikely, however, that states could somehow negotiate better discounts with drug manufacturers than what is provided under the rebate program today. As a result, states could likely garner only a comparable or higher level of prescription drug savings, relative to current law, by imposing a closed formulary that unduly restricts access to needed high-cost drugs. Low-income Medicaid beneficiaries, especially such vulnerable populations as people with disabilities and chronic conditions, would thus be at risk of going without needed drug treatments if the medications they need are simply dropped from Medicaid formularies due to cost or overly restrictive clinical requirements.<sup>18</sup>

As MACPAC has stated, policymakers must not only consider how to rein in Medicaid drug spending but "must also consider how such efforts would affect Medicaid beneficiaries' access to therapies that extend lives and improve health and functional status."<sup>19</sup>



## Strengthening the Medicaid Drug Rebate Program at the Federal Level

To build on, improve and strengthen the existing Medicaid Drug Rebate Program at the federal level, Congress could adopt the following policies:

- **Require increases in the minimum base rebate for new brand-name drugs with excessive launch prices.**

To help state Medicaid programs address the cost of new brand-name drugs, such as specialty drugs, with very high launch prices, the minimum percentage for the Medicaid base rebate could be increased above 23.1 percent of AMP. The percentage point increase could accelerate as the launch prices exceed certain thresholds. This would not only allow states to better afford the new brand-name drugs with launch prices of tens of thousands or hundreds of thousands of dollars but also help deter manufacturers from setting such high initial prices. These rebate increases, however, should be shared between the federal government and states, unlike some of the Medicaid drug rebate increases enacted as part of the Affordable Care Act.<sup>20</sup>

- **Increase inflation-related rebates to discourage excessive price increases.**

To further deter the increasingly common tactic of manufacturers substantially hiking the price of existing drugs, the Medicaid inflation-related rebates for both brand-name and generic drugs could be further increased if annual price increases exceed certain percentage thresholds. Manufacturers could be subject to an accelerating inflation-related rebate. In other words, manufacturers would owe an inflation-related rebate that would equal the difference between the annual price increase and general inflation, plus an additional number of percentage points. The percentage point increase would be larger as the annual percentage pricing increase rises.

- **Uncap total Medicaid drug rebate amounts.**

The Affordable Care Act established a limit on total Medicaid drug rebates on both brand-name and generic drugs at 100 percent of AMP. That, however, undermines the effectiveness of Medicaid's inflation-related rebates in discouraging manufacturers from

instituting excessive annual price increases. When Congress enacted the 100 percent of AMP limit, it did not anticipate the very large year-to-year price increases for both brand-name and generic drugs that have occurred in recent years. For example, assume a new brand-name drug has an initial AMP of \$1,000 but its manufacturer doubles the price each year. By the fourth year, state Medicaid programs would no longer be fully shielded from annual price increases because of the 100 percent of AMP limit (assuming the base rebate amount is equal to the minimum rebate percentage of 23.1 percent of AMP and general inflation of 2.4 percent). Without the 100 percent of AMP limit, the manufacturer would otherwise owe a total of \$8,774 in rebates per unit in that fourth year, with inflation-related rebates constituting 80 percent of that amount. But because of the 100 percent of AMP limit, the manufacturer would only owe \$8,000.

Eliminating the 100 percent of AMP cap would thus ensure that state Medicaid programs receive rebates equal to the full amount of such percentage price increases in excess of general inflation. That would have the benefit of helping state Medicaid programs better address excessive annual drug price increases while also seriously deterring manufacturers from instituting such increases.

- **Include all pharmacy benefit manager (PBM) rebates in calculation of best price.**

Some rebates negotiated by PBMs in the private insurance market are excluded from the best price calculation in the Medicaid Drug Rebate Program. (Rebates that are passed on to the retail or provider level are included in best price.<sup>21</sup>) The Centers for Medicare and Medicaid Services (CMS) should reconsider this exclusion and amend the best price regulations to include all PBM rebates in the determination of best price on a statutory basis. Alternatively, Congress could simply require best price to include all PBM rebates. Because private insurers in both the employer-based and individual markets increasingly rely on PBMs to negotiate rebates and discounts on their behalf, it is appropriate that such





rebates be included in best price. That would have the effect of increasing base Medicaid rebates for certain drugs and thus lowering overall federal and state Medicaid prescription drug costs.

- **Conduct periodic audits on drug manufacturers to ensure better rebate compliance.**

Currently, the Centers of Medicare and Medicaid Services has no systematic review process to ensure the accuracy of the information reported by manufacturers under the Medicaid Drug Rebate Program (AMP, best price, classification of drugs as brand-name or generic, etc.). CMS could establish a new mandatory process under which it would conduct periodic audits of manufacturers participating in the drug rebate program. Each manufacturer would be subject to an audit on a rolling basis (i.e. once every three or five years). The audits would verify the accuracy of the pricing information submitted as well as of the methods, assumptions and underlying data manufacturers used. Manufacturers could be required to repay any additional rebate obligations resulting from these audits. To ensure that CMS has the resources and additional staffing and infrastructure to conduct these audits, Congress would also need a significant amount of annual, mandatory, and dedicated funding for the audits. This would ensure better compliance with the requirements of the drug rebate program and that manufacturers are fully paying the rebates they owe to state Medicaid programs.

- **Give states full access to Medicaid pricing data on a confidential basis.**

AMP and best price information reported by manufacturers are confidential and not shared by CMS with the states. Even MACPAC lacks access to specific unit rebate amounts in conducting analysis of the drug rebate program.<sup>22</sup> This means, for example, that states do not know how the supplemental rebates they negotiate with manufacturers compare to federally required rebates. They also cannot help enforce manufacturer compliance with the Medicaid Drug Rebate Program by checking any pricing information they may obtain (such as from pharmacies, wholesalers and pharmacy benefit managers licensed

by the state, as discussed below) with the information submitted to CMS. Sharing confidentially such pricing information with states would better ensure manufacturer compliance with the rebate program as well as help states negotiate larger supplemental rebates, among other purposes.

- **Bar manufacturer gaming using “authorized generics” to lower rebate amounts**

As MACPAC has noted, manufacturers that make their own generic version of their drugs (known as “authorized generics”) can artificially lower the Medicaid rebates they pay. Drug companies sometime sell the authorized generic version of their brand-name drug to another manufacturer so that it can be distributed. But if that second company has a corporate relationship with the brand-name drug company (for example, they have the same parent company), the brand-name company may intentionally charge a much lower “transfer” price than it would otherwise charge another manufacturer or wholesalers. This would have the effect of lowering the Medicaid rebates the manufacturer pays for its brand-name drug because the formula used to determine rebate amounts takes into account the price of authorized generics. In other words, manufacturers can game the rebate program through this approach and reduce the rebates they otherwise would owe to state Medicaid programs. MACPAC thus recommends eliminating these types of authorized generic transactions from the calculation of rebates.<sup>23</sup>

- **Give HHS better enforcement tools to prevent manufacturers from misclassifying drugs to lower their rebate amounts.**

Some manufacturers have inappropriately and inaccurately classified some of their brand-name drugs as generics in order to reduce how much they pay in rebates. The minimum rebate for generic drugs is 13 percent of Average Manufacturer Price (AMP), while the minimum rebate for brand-name drugs is 23.1 percent of AMP. Moreover, generic drugs are not subject to the “best price” requirement like brand-name drugs are. According to MACPAC, to address the problem of misclassification, the secretary should be given the explicit authority to impose civil monetary



penalties on manufacturers for misclassification and to directly change the classification of a drug.<sup>24</sup> That's because it is unclear whether the secretary currently has the authority to impose these intermediate-level sanctions. The secretary can always end Medicaid coverage of all of a manufacturer's drugs but CMS has never used this termination authority to sanction misclassification. (Such a provision was included in a bipartisan bill (H.R. 7217) passed overwhelmingly by the House of Representatives in December 2018 but the full bill was not considered by the Senate before the end of the Congressional session.)

- **Extend Medicaid rebates to separate state CHIP programs.**

Unlike for CHIP-funded Medicaid coverage, the Medicaid Drug Rebate Program does not apply to separate state CHIP programs. It is very likely that managed care plans contracting with separate state

CHIP programs are obtaining considerably smaller rebates than what is now required under Medicaid, as was the case prior to the Affordable Care Act extending the rebate program to Medicaid managed care. (The Congressional Budget Office previously estimated that extending the Medicaid Drug Rebate Program to Medicaid managed care would have produced savings, without the ACA's increase in the minimum rebate, because the rebates negotiated by Medicaid managed care plans were considerably less than those under the rebate program.) Extending the Medicaid Drug Rebate Program to separate state CHIP programs would thus help lower CHIP prescription drug costs.<sup>25</sup> That would provide some financial assistance to states facing a scheduled transition from the currently enhanced federal CHIP matching rate to the regular CHIP matching rate starting in 2020.

## Addressing Rising Medicaid Prescription Drug Costs at the State Level

States can also take advantage of their existing flexibility under federal law to better address prescription drug cost growth on their own. For example, states could:

- **Expand their supplemental rebates.**

Four states—Hawaii, New Jersey, New Mexico and South Dakota—do not currently negotiate supplemental rebates with drug manufacturers.<sup>26</sup> Those states could establish a supplemental rebate program to generate additional prescription drug savings. In addition, in the large majority of states, these supplemental rebates do not apply to Medicaid managed care, even though the large majority of Medicaid beneficiaries receive their pharmacy benefits through managed care and such rebates could end up being significantly larger than the rebates that managed care plans are negotiating on their own. For example, as discussed below, Medicaid managed care plans often have their own preferred drug lists, which differ not only from fee-for-service but also from those of other plans. This likely dilutes their overall

negotiating leverage. While the federally required base rebate and inflation-related rebate apply to Medicaid managed care, only 19 states currently extend some of their supplemental rebates to Medicaid managed care, and in one of those states (Minnesota), it applies only to drugs treating Hepatitis C.<sup>27</sup> States also may currently leave out certain drugs, drug classes or physician-administered drugs from their supplemental rebate negotiations and should evaluate whether they could obtain additional savings if they started negotiating supplemental rebates for more drugs and a larger number of drug classes. Finally, as researchers at the Pew Charitable Trust note, Medicaid supplemental rebates are generally fixed amounts added to the base Medicaid rebate but do not include an inflation-related component. States could seek supplemental rebates on top of the federal Medicaid inflation-related rebate for drugs with large annual price increases, especially in the case of drugs that would otherwise be subject to the 100 percent of AMP cap (assuming it remains in place).<sup>28</sup>



- **Maximize supplemental rebates negotiated by Medicaid managed care plans and enhance plan oversight.**

If states continue to rely on Medicaid managed care plans to negotiate supplemental rebates on behalf of their enrollees, states could ensure that preferred drug lists are uniform across plans and aligned with the preferred drug list used in fee-for-service Medicaid. That could have the effect of maximizing negotiating leverage and supplemental rebate amounts for prescription drugs covered by both managed care plans in the state and in fee-for-service. According to the Kaiser Family Foundation, in state fiscal year 2018, only 14 states required uniform preferred drug lists for at least one drug class in managed care contracts, with three additional states planning to institute such a list in 2019.<sup>29</sup> More states could apply the uniform preferred drug list and extend it to more drug classes. In addition, states should periodically audit Medicaid managed care plans and their contracted PBMs to ensure that states are effectively receiving the full benefit of any supplemental rebates (and other cost savings) in the form of lower net pharmacy costs and thus reduced monthly capitation rates.<sup>30</sup>

- **Review multi-state purchasing arrangements.**

Many states participate in multi-state purchasing pools to increase their leverage in negotiating supplemental rebates. Twenty-eight states and the District of Columbia participate in one of the three pools—the National Medicaid Pooling Initiative, Top Dollar Program or the Sovereign States Drug Consortium—under which states contract with an administrative entity to negotiate supplemental rebates on their behalf.<sup>31</sup> States could regularly review the performance of these administrative entities to ensure that states are maximizing their supplemental rebates. For example, coupled with drug pricing transparency efforts, as discussed below, states could better assess how the rebate amounts these entities negotiate compare to what PBMs are obtaining for commercial insurers. In addition, states could consider increasing the leverage provided under these arrangements by aligning their preferred drug lists to a much greater extent with those of other states participating in the same purchasing pool as well as with other non-Medicaid state programs, such as corrections and state employee health plans.

- **Increase drug pricing transparency.**

As noted above, states do not have access to the AMP or best price data reported by drug manufacturers for purposes of the Medicaid Drug Rebate Program. As a result, without a change in federal law, states cannot determine how their supplemental rebates compare to the underlying base rebate (or how they compare to those obtained by other states and payers). States, however, might be able to calculate proxies for AMP and best price through other means. For example, states could use their licensing authority to require that drug pricing information, including rebates in private insurance, be reported by PBMs and manufacturers, as the National Academy of State Health Policy recommends,<sup>32</sup> and by other parts of the drug supply chain including wholesalers, group purchasing organizations and pharmacies. According to the Pew Charitable Trusts, states could also try to negotiate for such pricing and rebate information from manufacturers, on a confidential basis, as part of preferred drug list decisions, although that may initially result in smaller supplemental rebate amounts in exchange.<sup>33</sup> Such pricing information would be invaluable to states in determining whether they are maximizing their supplemental rebate amounts and assessing the performance of the purchasing pools in which they participate.

- **Expand use of drug effectiveness reviews.**

Some states contract with research entities to evaluate the clinical effectiveness and safety of drugs, including comparisons to competing drugs. For example, the Center for Evidence-based Policy within the Oregon Health and Science University provides certain state Medicaid programs with clinical evidence and prescription drug policy reports.<sup>34</sup> Drug effectiveness reviews can better inform state Medicaid program decision making for their preferred drug lists by ensuring the lists are established in clinically sound ways. They can also enhance leverage when negotiating supplemental rebates with drug manufacturers. For example, the state of New York is using clinical effectiveness reviews as part of its recent effort to obtain larger supplemental rebates for certain high-cost drugs.<sup>35</sup> Oklahoma is also experimenting with so-called value-based purchasing contracts,





under which the state is negotiating preferred drug list placement and supplemental rebate amounts based on actual drug effectiveness, clinical outcomes, and costs. Supplemental rebate amounts would automatically increase if a drug does not satisfy benchmarks such as reduced hospitalizations, overall net costs and higher drug adherence.<sup>36</sup> Michigan recently received approval for a similar approach. Only a handful of manufacturers, however, have agreed to negotiate under these approaches to date. States not already using clinical effectiveness reviews could start obtaining them, and other states could expand their use to more drugs and drug classes. The clinical effectiveness data could also be used to support ongoing provider education efforts to improve prescribing patterns, avoid unnecessary care, and prevent poorer health outcomes.

- **Assess drug utilization review (DUR) programs**

As noted, all states are required to operate prospective and retrospective drug utilization review (DUR) programs that screen for duplication, contraindications, interactions with other drugs, incorrect dosage and abuse and misuse. These programs also review claims and other data for overuse, inappropriate or medically unnecessary care, appropriate use of generics and fraud and abuse. (Federal opioids legislation enacted earlier this year also included provisions clarifying that Medicaid managed care contracts include a requirement that they operate DUR programs that fully comply with all federal requirements and mandating that states and managed care plans include safety edits for opioid refills, an automated claims system for concurrent use of opioids, antipsychotics and benzodiazepines, and monitoring of antipsychotic medication use among children as part of their DUR programs.<sup>37</sup>) As a result, this detailed DUR data can help state Medicaid programs identify ongoing efficacy, fraud and abuse, and patient safety issues related to certain drugs. Such findings could also be used in both setting preferred drug lists and in supplemental rebate negotiations. States should assess whether they are taking full advantage of this useful data.

In addition, states could also perform detailed assessments of their DUR programs to determine whether overall improvements could be made. For example, according to a CMS survey of states for fiscal year 2017, most states do not have the capacity to incorporate physician-administered drugs in their DUR programs. And while Medicaid managed care plans operate their own DUR programs that must meet general federal requirements, only four states in 2017 required plans to use the same prospective and retrospective DUR criteria as in fee-for-service. Moreover, only 14 of the responding states required Medicaid managed care plans to monitor or report on their separate drug utilization reviews. (A 2016 Medicaid managed care final regulation newly required all Medicaid managed care plan contracts to include a requirement for plans to submit a detailed description of their DUR activities to state Medicaid programs, but it did not require managed care plans to share their underlying DUR data with states.<sup>38</sup>) States could periodically assess whether managed care plans are operating DUR programs in full compliance with federal requirements as the final 2016 regulation requires, determine whether they are at least as effective as for fee-for-service, and require managed care plans to report their detailed DUR data to states. According to the 2017 CMS survey, DUR activities can reduce pharmacy costs by 20 percent, on average, based on state program evaluations.<sup>39</sup> More robust and expansive DUR programs hold the promise of helping lower prescription drug costs for state Medicaid programs by potentially facilitating higher supplemental rebates and changes in overall prescribing and dispensing patterns.





## Conclusion

The Medicaid Drug Rebate Program is highly successful in significantly reducing state Medicaid prescription drug costs. Building on and strengthening the rebate program at both the federal and state levels, as recommended above, could produce additional savings and help state Medicaid programs better address rising prescription drug costs driven by new high-cost specialty drugs and substantial annual price increases for existing drugs. Any efforts to weaken or undermine the effective rebate program, however, should be rejected, as they would not only likely increase state Medicaid drug costs but also seriously threaten access to needed medications for millions of vulnerable low-income children, families, and other Medicaid beneficiaries.

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The Georgetown University Center for Children and Families (CCF) is an independent, nonpartisan policy and research center founded in 2005 with a mission to expand and improve high-quality, affordable health coverage for America's children and families. CCF is based in the McCourt School of Public Policy's Health Policy Institute.

## About this Series

*This issue brief is fifth in a series of papers from Georgetown University Center for Children and Families on the future of children's health coverage. Other briefs in the series include:*

[The Future of Children's Coverage: Children in the Marketplace](#). *Focuses on ways to improve marketplace coverage and the associated financial assistance for children.*

[Fulfilling the Promise of Children's Dental Coverage](#). *Focuses on pediatric dental coverage and ways to improve children's oral health.*

[How Medicaid and CHIP Shield Children from the Rising Costs of Prescription Drugs](#). *Focuses on how Medicaid and CHIP protect most children from the rising costs of prescription drugs.*

[Promoting Young Children's Healthy Development in Medicaid and the Children's Health Insurance Program \(CHIP\)](#). *This paper examines ways for state and federal policymakers to use Medicaid and CHIP to more effectively put young children on the best path for success in school and in life.*



## Endnotes

<sup>1</sup> Jack Hoadley and Joan Alker, “How Medicaid and CHIP Shield Children from the Rising Costs of Prescription Drugs” (Washington: Georgetown University Center for Children and Families, July 2017), available at <https://ccf.georgetown.edu/wp-content/uploads/2017/07/Prescription-drugs-v3-link-fix.pdf>.

<sup>2</sup> Medicaid and CHIP Payment and Access Commission, “Chapter 1: Improving Operations of the Medicaid Drug Rebate Program, June 2018 Report to Congress” (Washington: Medicaid and CHIP Payment and Access Commission, June 2018), available at <https://www.macpac.gov/wp-content/uploads/2018/06/Improving-Operations-of-the-Medicaid-Drug-Rebate-Program.pdf>. According to the Office of the Actuary at the Centers for Medicare and Medicaid Services, Medicaid retail prescription drug costs increased by 3.1 percent in 2017, as compared to 5.0 percent in 2016, 11.6 percent in 2015 and 23.9 percent in 2014. The rapid increases in 2014 and 2015 were driven largely by the market entry of new drugs treating Hepatitis C. See Office of the Actuary at the Centers for Medicare and Medicaid Services, “Table 16: Retail Prescription Drug Expenditures” (Washington: Office of the Actuary at the Centers for Medicare and Medicaid Services, December 2018), available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html>.

<sup>3</sup> Medicaid and CHIP Payment and Access Commission, “Chapter 1: Improving Operations of the Medicaid Drug Rebate Program, June 2018 Report to Congress,” op cit.

<sup>4</sup> Centers for Medicare and Medicaid Services, “Medicaid Pharmacy Supplemental Rebate Agreements (SRA)” (Washington: Centers for Medicare and Medicaid Services, September 2018), available at <https://www.medicare.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/xxxsupplemental-rebates-chart-current-qtr.pdf>. According to the Office of Inspector General at the Department of Health and Human Services, supplemental rebates in most states are structured to ensure a guaranteed, fixed price net of rebates. In other words, the supplemental rebate would equal the amount needed to result in a net price, after subtracting any federally required rebates. Office of Inspector General, U.S. Department of Health and Human Services, “States’ Collections of Offset and Supplemental Medicaid Rebates” (Washington: Office of Inspector General, U.S. Department of Health and Human Services December 2014), available at <https://oig.hhs.gov/oei/reports/oei-03-12-00520.pdf>.

<sup>5</sup> National Conference of State Legislatures, “Pharmaceutical Bulk Purchasing: Multi-State and Inter-Agency Plans” (Washington: National Conference of State Legislatures, June 1, 2018), available at June 1, 2018, <http://www.ncsl.org/research/health/bulk-purchasing-of-prescription-drugs.aspx> and Medicaid and CHIP Payment Access Commission, “Medicaid Payment for Outpatient Prescription Drugs” (Washington: Medicaid and CHIP Payment Access Commission, May 2018), available at <https://www.macpac.gov/wp-content/uploads/2015/09/Medicaid-Payment-for-Outpatient-Prescription-Drugs.pdf>.

<sup>6</sup> Douglas Brown, “State Levers for Managing Medicaid Prescription Drug Utilization and Costs” (Washington: Magellan Health, December 2017), available at <https://www.macpac.gov/wp-content/uploads/2017/12/State-Strategies-for-Managing-Prescription-Drug-Spending.pdf>.

<sup>7</sup> Medicaid and CHIP Payment and Access Commission, “MACStats: Exhibit 28 Medicaid Gross Spending and Rebates for Drugs by Delivery System, FY 2016” (Washington: Medicaid and CHIP Payment and Access Commission, December 2017), available at <https://www.macpac.gov/publication/medicaid-gross-spending-and-rebates-for-drugs-by-delivery-system/>.

<sup>8</sup> See Table IV.B8, “2018 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds” (Washington: The Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, June 2018) available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf>

<sup>9</sup> Medicaid and CHIP Payment and Access Commission, “MACStats: Exhibit 28 Medicaid Gross Spending and Rebates for Drugs by Delivery System, FY 2017,” op cit.

<sup>10</sup> Office of Inspector General, U.S. Department of Health and Human Services, “Medicaid Rebates for Brand-Name Drugs Exceeded Part D Rebates by a Substantial Margin” (Washington: Office of Inspector General, U.S. Department of Health and Human Services, April 2015), available at <https://oig.hhs.gov/oei/reports/oei-03-13-00650.pdf>.

<sup>11</sup> Charles Roehring, “The Impact of Prescription Drug Rebates on Health Plans and Consumers” (Washington: Altarum, April 2018), available at <https://altarum.org/publications/the-impact-of-prescription-drug-rebates-on-health-plans-and-consumers>.

<sup>12</sup> Anna Anderson-Cook, Jared Maeda and Lyle Nelson, “Prices for and Spending on Specialty Drugs in Medicare Part D and Medicaid” (Washington: Congressional Budget Office, June 11, 2018), available at <https://www.cbo.gov/system/files/115th-congress-2017-2018/presentation/53929presentation.pdf>.

<sup>13</sup> Hoadley and Alker, op cit.

<sup>14</sup> Medicaid and CHIP Payment and Access Commission, “Exhibit 29: Percentage of Medicaid Enrollees in Managed Care by State, July 1, 2016” (Washington: Medicaid and CHIP Payment and Access Commission, December 2018), available at <https://www.macpac.gov/publication/percentage-of-medicare-enrollees-in-managed-care-by-state/> and Medicaid and CHIP Payment and Access Commission, “Exhibit 26: Medicaid Gross Spending for Drugs by Delivery System and Brand or Generic Status” (Washington: Medicaid and CHIP Payment and Access Commission December 2018), available at <https://www.macpac.gov/publication/medicaid-gross-spending-for-drugs-by-delivery-system-and-brand-or-generic-status/>.

<sup>15</sup> Federal Medicaid managed care rules finalized in 2016 explicitly required all plans to comply with federal requirements under section 1927 of the Social Security Act starting in 2017. See Michael Kalber and Ian Spatz, “CMS Clarifies Medicaid Managed Care Prescription Drug Access” (Washington: Manatt Health, June 13, 2016), available at <https://www.manatt.com/Insights/Newsletters/Medicaid-Update/CMS-Clarifies-Medicaid-Managed-Care-Prescription-D> and Julia Paradise and MaryBeth Musumeci, “CMS’ Final Rule on Medicaid Managed Care: A Summary of Major Provisions” (Washington: Kaiser Family Foundation, June 9, 2016), available at <http://files.kff.org/attachment/CMSs-Final-Rule-on-Medicaid-Managed-Care>. A proposed rule issued



in November 2018 amending the 2016 final Medicaid managed care rule would not modify this requirement.

<sup>16</sup> Centers for Medicare and Medicaid Services, “Medicaid Drug Utilization Review State Comparison/Summary Report FFY 2017 Annual Report” (Washington: Centers for Medicare and Medicaid Services, October 2018), available at <https://www.medicaid.gov/medicaid/prescription-drugs/downloads/drug-utilization-review/2017-dur-summary-report.pdf>. See also Medicaid and CHIP Payment and Access Commission, “MACStats: Exhibit 28 Medicaid Gross Spending and Rebates for Drugs by Delivery System, FY 2017,” op cit.

<sup>17</sup> As permitted under federal law, some states also set arbitrary, numerical limits on the number of prescription drugs that will be covered in any given month, even for people with multiple chronic conditions who require many prescription drugs. This can severely restrict access to needed drugs. Children, however, are not subject to these limits under EPSDT requirements.

<sup>18</sup> See, for example, Edwin Park, “Trump Administration Medicaid Drug Rebate Proposal Raises Serious Concerns for Beneficiaries, Unlikely to Reduce Costs” (Washington: Georgetown University Center for Children and Families, April 2, 2018), available at <https://ccf.georgetown.edu/2018/04/02/trump-administration-medicaid-drug-rebate-proposal-raises-serious-concerns-for-beneficiaries-unlikely-to-reduce-costs/> and Edwin Park, “Trump Administration Encourages States to Seek Waivers to Opt Out of Medicaid Drug Rebate Program” (Washington: Georgetown University Center for Children and Families, July 16, 2018), available at <https://ccf.georgetown.edu/2018/07/16/trump-administration-encourages-states-to-seek-waivers-to-opt-out-of-medicaid-drug-rebate-program/>.

<sup>19</sup> Medicaid and CHIP Payment and Access Commission, “Chapter 1: Improving Operations of the Medicaid Drug Rebate Program, June 2018 Report to Congress,” op cit.

<sup>20</sup> Among other provisions, starting in 2010, the Affordable Care Act increased the minimum base rebate for brand-name drugs (from 15.1 percent of AMP to 23.1 percent of AMP) and generic drugs (from 11 percent to 13 percent) and changed the treatment of new drug formulations. Any increased drug rebates resulting from these changes (above the rebate amounts determined under prior law) effectively accrue only to the federal government, rather than to both the federal government and states.

<sup>21</sup> See 42 C.F.R. § 447.505(c)(17).

<sup>22</sup> Medicaid and CHIP Payment and Access Commission, Transcript: Public Meeting, September 15, 2017, <https://www.macpac.gov/wp-content/uploads/2016/10/September-2017-MACPAC-meeting-transcript.pdf>.

<sup>23</sup> Medicaid and CHIP Payment and Access Commission, “Chapter 1: Improving Operations of the Medicaid Drug Rebate Program, June 2018 Report to Congress,” op cit. See also Edwin Park, “MACPAC Report Recommends Sound Improvements to Medicaid Drug Rebate Program,” Say Ahhh! Blog, Georgetown University Center for Children and Families, June 19, 2018, <https://ccf.georgetown.edu/2018/06/19/macpac-report-recommends-sound-improvements-to-medicaid-drug-rebate-program/>.

<sup>24</sup> Medicaid and CHIP Payment and Access Commission, “Chapter 1: Improving Operations of the Medicaid Drug Rebate Program, June 2018 Report to Congress,” op cit. See also Edwin Park, “MACPAC Report Recommends Sound Improvements to Medicaid Drug Rebate Program,” op cit.

<sup>25</sup> Hoadley and Alker, op cit.

<sup>26</sup> Centers for Medicare and Medicaid Services, “Medicaid Pharmacy Supplemental Rebate Agreements (SRA),” op cit.

<sup>27</sup> The states are Arizona, California, Delaware, Florida, Illinois, Iowa, Kansas, Kentucky, Massachusetts, Minnesota, Nebraska, New Hampshire, New York, North Dakota, Oregon, Texas, Virginia, Washington and West Virginia. Centers for Medicare and Medicaid Services, “Medicaid Pharmacy Supplemental Rebate Agreements (SRA),” op cit.

<sup>28</sup> Pew Charitable Trusts, “[Use of State Medicaid Inflation Related Rebates Could Discourage Drug Price Increases](#)” (Washington: Pew Charitable Trusts, June 2018), available at [https://www.pewtrusts.org/-/media/assets/2018/06/implementingstatemedicaidinflationrebatescoulddiscouragedrugpriceincreases\\_factsheet.pdf](https://www.pewtrusts.org/-/media/assets/2018/06/implementingstatemedicaidinflationrebatescoulddiscouragedrugpriceincreases_factsheet.pdf).

<sup>29</sup> In 2018, the states with a uniform preferred drug list for at least one drug class included: Arizona, Delaware, Florida, Iowa, Kansas, Massachusetts, Minnesota, Mississippi, North Dakota, Nebraska, Oregon, Texas, Virginia and Washington. The states adding a uniform preferred drug list in 2019 include Louisiana, Ohio and Utah. Kathleen Gifford et al., “States Focus on Quality and Outcomes Amid Waiver Changes: Results from a 50-State Medicaid Budget Survey for State Fiscal Years 2018 and 2019” (Washington: Kaiser Family Foundation, October 25, 2018), available at <http://files.kff.org/attachment/Report-States-Focus-on-Quality-and-Outcomes-Amid-Waiver-Changes-Results-from-a-50-State-Medicaid-Budget-Survey-for-State-Fiscal-Years-2018-and-2019>.

<sup>30</sup> In Ohio, for example, PBMs for Medicaid managed care plans were found to have been using “spread” pricing — under which their prescription drug claim costs were reimbursed by managed care plans, and in turn the state Medicaid program, at levels well in excess of the PBMs’ actual net costs in reimbursing pharmacies for drugs dispensed to beneficiaries—in order to maximize profits. That effectively inflated Medicaid costs for drugs provided to managed care enrollees. See Auditor of State of Ohio, “Ohio Medicaid Managed Care Pharmacy Services Auditor of State Report” (Toledo: Auditor of State of Ohio, August 16, 2018), available at [https://ohioauditor.gov/auditsearch/Reports/2018/Medicaid\\_Pharmacy\\_Services\\_2018\\_Franklin.pdf](https://ohioauditor.gov/auditsearch/Reports/2018/Medicaid_Pharmacy_Services_2018_Franklin.pdf). See also Pennsylvania Auditor General, “Bringing Transparency and Accountability to Drug Pricing” (Harrisburg: Pennsylvania Auditor General, December 11, 2018), available at [https://www.paauditor.gov/Media/Default/Reports/RPT\\_PBM\\_FINAL.pdf](https://www.paauditor.gov/Media/Default/Reports/RPT_PBM_FINAL.pdf).

<sup>31</sup> The National Medicaid Pooling Initiative contracts with Magellan Health/Provider Synergies and includes the following states: Alaska, the District of Columbia, Kentucky, Michigan, Minnesota, Montana, New Hampshire, New York, North Carolina, Rhode Island and South Carolina. The Top Dollar Program also contracts with Magellan Health/





Provider Synergies and includes Connecticut, Idaho, Louisiana, Maryland, Nebraska and Wisconsin. The Sovereign States Drug Consortium contracts with Change Healthcare and includes Delaware, Iowa, Maine, Mississippi, North Dakota, Ohio, Oklahoma, Oregon, Utah, Vermont, West Virginia and Wyoming. National Conference of State Legislatures, “Pharmaceutical Bulk Purchasing: Multi-State and Inter-Agency Plans,” op cit.

<sup>32</sup> See, for example, National Academy for State Health Policy, “Pharmacy Benefit Manager Model Legislation” (Washington: National Academy for State Health Policy, August 2018), available at [https://nashp.org/wp-content/uploads/2018/08/PBM-Model-Act-FINAL-8\\_9\\_2018.pdf](https://nashp.org/wp-content/uploads/2018/08/PBM-Model-Act-FINAL-8_9_2018.pdf) and National Academy for State Health Policy, “Transparency Model Legislation” (Washington: National Academy for State Health Policy, March 2017), available at <https://nashp.org/wp-content/uploads/2017/03/Transparency-Model-Legislation1.pdf>.

<sup>33</sup> Pew Charitable Trusts, “Better Data Could Help Medicaid Programs Cut Drug Spending” (Washington: Pew Charitable Trusts, July 9, 2018), available at <https://www.pewtrusts.org/en/research-and-analysis/factsheets/2018/07/better-data-could-help-medicaid-programs-cut-drug-spending>.

<sup>34</sup> For a list of states partnering with the Center for Evidence-based Policy, see “The Drug Effectiveness Review Project” (Portland, OR: Center for Evidence-based Policy), available at <https://centerforevidencebasedpolicy.org/our-approach/derp/> and “The Medicaid Evidence-based Decisions Project” (Portland, OR: Center for Evidence-based Policy), available at <https://centerforevidencebasedpolicy.org/our-approach/med/>.

<sup>35</sup> Pew Charitable Trusts, “New York’s Medicaid Drug Cap” (Washington: Pew Charitable Trusts, April 2, 2018), available at <https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2018/04/new-yorks-medicaid-drug-cap>.

<sup>36</sup> Jennifer Reck, “Oklahoma Signs the Nation’s First State Medicaid Value-Based Contracts for Rx Drugs” (Washington: National Academy for State Health Policy, September 25, 2018), available at <https://nashp.org/oklahoma-signs-first-medicaid-value-based-contracts-for-rx-drugs/>.

<sup>37</sup> See MaryBeth Musumeci and Jennifer Tolbert, “Federal Legislation to Address the Opioid Crisis: Medicaid Provisions in the SUPPORT Act” (Washington: Kaiser Family Foundation, October 5, 2018), available at <http://files.kff.org/attachment/Issue-Brief-Federal-Legislation-to-Address-the-Opioid-Crisis-Medicaid-Provisions-in-the-SUPPORT-Act>.

<sup>38</sup> See 42 C.F.R. §438.3(s)(5).

<sup>39</sup> Centers for Medicare and Medicaid Services, “Medicaid Drug Utilization Review State Comparison/Summary Report FFY 2017 Annual Report,” op cit.

Georgetown University Center for  
Children and Families  
McCourt School of Public Policy  
Box 571444  
3300 Whitehaven Street, NW, Suite 5000  
Washington, DC 20057-1485  
Phone: (202) 687-0880  
Email: [childhealth@georgetown.edu](mailto:childhealth@georgetown.edu)



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