U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
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States With Separate Children's Health Insurance Programs Could Have Collected an Estimated $641 Million Annually If States Were Required To Obtain Rebates Through the Medicaid Drug Rebate Program

Key Takeaways:

If the Medicaid Drug Rebate Program (MDRP) were to cover drug expenditures paid for by separate Children's Health Insurance Programs (separate CHIPs), the States could (based on 2020 calculations) have collected an estimated $641.2 million in drug rebates annually, including drug rebates totaling $125.5 million for the States and $515.7 million for the Federal Government.

Purpose of This Data Brief

Under current Federal requirements for the Medicaid Drug Rebate Program (MDRP), States must obtain drug rebates for Medicaid-covered outpatient prescription drugs that are provided through Medicaid or an expansion of its Medicaid program (Medicaid expansion). However, for separate Children's Health Insurance Program (CHIP) drugs, those Federal Medicaid drug rebate requirements do not apply.

As of the preparation of this Data Brief, 40 States operate separate CHIPs, whether in combination with Medicaid expansion or on a stand-alone basis.

We are providing this Data Brief to the Centers for Medicare & Medicaid Services (CMS) to identify the potential amount of drug rebates associated with separate CHIPs under the MDRP.

Our objective was to identify the total drug rebates that States could have collected under their separate CHIPs if States had been required to obtain those rebates through the MDRP.

BACKGROUND

Children's Health Insurance Program

Title XXI of the Social Security Act (the Act) authorizes Federal grants to States for providing child health assistance to targeted low-income children. These grants permit States to provide such coverage through either a separate CHIP, an expansion of the State Medicaid program

(Medicaid expansion CHIP), or a combination of both (Section 2101(a) of the Act). Separate CHIP is a program under which a State receives Federal funding to provide child health assistance to uninsured, low-income children and which meets the requirements of section 2103 of the Act. Medicaid expansion CHIP is a program under which a State receives Federal funding to expand Medicaid eligibility to optional, targeted categories of low-income children and which meets the requirements of section 2103 of the Act. Some States have both types of programs—that is, those States receive Federal funding to implement both a Medicaid expansion CHIP and separate CHIP.[1]

These programs are jointly financed by the Federal and State Governments. At the Federal level, CMS administers these programs. Each State operates its CHIP in accordance with a CMS-approved State plan. Within broad Federal rules, each State decides eligible groups, types and ranges of services, payment levels for benefit coverage, and administrative and operating procedures.

State agencies can either provide benefits on a fee-for-service basis or contract with managed care organizations (MCOs) to deliver covered services to individuals covered by CHIP. Both State agencies and MCOs may contract with Pharmacy Benefits Managers (PBMs) to manage or administer the prescription drug benefits on their behalf.[2]

Medicaid Drug Rebate Program

The Omnibus Budget Reconciliation Act of 1990 created the MDRP to help offset Federal and State costs for most prescription drugs dispensed to people enrolled in Medicaid.[3] For Federal financial participation (i.e., Federal matching funds) to be available for covered outpatient drugs provided under Medicaid, manufacturers must enter into rebate agreements with the Secretary of Health and Human Services (HHS) (the Secretary) and pay quarterly rebates to State Medicaid agencies.[4] These rebates decrease the cost of Medicaid prescription drugs and as a result decrease the amount of the Federal share.

Section 1927(a)(1) of the Act states: "In order for payment to be available under section 1903(a) . . . for covered outpatient drugs of a manufacturer, the manufacturer must have

[1] CHIP State Program Information. Accessed at https://www.medicaid.gov/chip/state-program-information/index.html on Jul. 3, 2023.

[2] In general, "Pharmacy Benefit Managers (PBMs) are third party companies that function as intermediaries between insurance providers and pharmaceutical manufacturers. PBMs create formularies, negotiate rebates . . . with manufacturers, process claims, create pharmacy networks, review drug utilization, and occasionally manage mail-order specialty pharmacies." National Association of Insurance Commissioners, Pharmacy Benefit Managers. Accessed at https://content.naic.org/cipr-topics/pharmacy-benefit-managers on Jul. 3, 2023.

[3] CMS, *Medicaid Drug Rebate Program*. Accessed at https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html on Jul. 3, 2023.

[4] Sections 1927(a)(1) and (b)(1) of the Act.

entered into and have in effect a rebate agreement. . . ." Section 1903(a) of the Act provides for Federal financial participation (Federal share) in State expenditures for these drugs.

Additionally, State agencies can negotiate their own supplemental drug rebate agreements with drug manufacturers, either directly or through their contractors, for drugs dispensed to people enrolled in Medicaid or separate CHIP.

Federal Requirements for Drug Rebates in the Children's Health Insurance Program

States that provide CHIP coverage through Medicaid expansion CHIPs must also generally comply with Medicaid requirements, including obtaining rebates to help offset the cost of outpatient prescription drugs (the Act § 1902(a)(54) and 42 CFR § 457.70(c)).

However, States that operate separate CHIPs are not required to comply with section 1927 of the Act, and thus, the Medicaid drug rebates under the MDRP are not available for the outpatient prescription drug expenditures made under separate CHIPs.[5] A State does have the ability to negotiate rebate agreements with manufacturers in order to obtain rebates for drugs administered through its separate CHIP. For example, one State that receives supplemental rebates said that it "relies on the PBM for drug rebate negotiations with drug manufacturers. The program [separate CHIP] does not have enough 'negotiating' power to negotiate rebates on its own due to small membership and total drug expenditures." Furthermore, CMS officials emphasized to us during this audit that under current statutory provisions, States that operate separate CHIPs may find it challenging to negotiate contracts with drug manufacturers because doing so could impact the rebate amounts received through the MDRP (see footnote 10 later in this Data Brief).

Proposed Changes to the Medicaid Drug Rebate Program and the Separate Children's Health Insurance Program

Our efforts to calculate of amount of drug rebates associated with States' separate CHIPs are separate and independent from ongoing discussions involving the relationship between separate CHIPs and the MDRP. For context, though, it is relevant to note that other stakeholders have also focused on this relationship. For instance, in calendar year 2020 the Fair Drug Prices for Kids Act was introduced in both Houses of Congress. If passed, the Fair Drug Prices for Kids Act would have amended the Act to give States the option to extend the Medicaid drug rebate program to their separate CHIPs. The Senate referred this bill, S. 4448 116th Cong. (2020), to the Committee on Finance on August 5, 2020. The House referred this bill, H.R. 8546, 116th Cong. (2020), to the Committee on Energy and Commerce on October 6, 2020. The Fair Drug Prices for Kids Act was re-introduced to the Senate as S. 2531 on July 29,

[5] If a rebate were required in accordance with section 1927 of the Act, States that operate separate CHIPs would be required to comply with section 1927 requirements, which would include pricing and drug coverage requirements.

2021, and the House re-introduced this bill as H.R. 5576 to the Subcommittee on Health on October 13, 2021. As of preparation of this Data Brief, none of these bills has passed into law.[6]

Separate from this legislative activity, we sought to estimate the amount of rebates that would have been obtained if all 40 States that operated separate CHIPs had invoiced for rebates for outpatient prescription drugs provided through those programs. As a related matter to our objective, we also sought to identify any differences between these States with respect to the policies that their separate CHIPs have in place to invoice manufacturers for rebates.

Data Used To Develop This Data Brief

Our primary sources of data for this Data Brief were the State agencies' responses to a survey we sent to them—in particular, their data on the outpatient prescription drug costs, as reported to us by State agencies, for people enrolled in the separate CHIPs operated by 40 States.[7] Each survey asked: (1) whether that State had a separate CHIP in place; (2) if so, the total outpatient prescription drug costs for individuals receiving benefits under that State's separate CHIP; and (3) whether that State collected rebates for drugs purchased under its separate CHIP. We used the State agencies' responses to the survey to estimate the total rebates that States could have collected if the MDRP's rebate requirements were to be extended to all States that operated separate CHIPs. We did not verify in what capacity the rebates were received, nor did we examine rebate agreements with manufacturers.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

The Appendix describes our audit scope and methodology.

[6] The Build Back Better Act (H.R. 5376), which passed in the House in November 2021, included a provision that would have required manufacturers to pay rebates for drugs provided under separate CHIPs. A different version of this bill became the Inflation Reduction Act, P.L. No. 117-169 (Aug. 16, 2022), which did not include a rebate requirement for separate CHIPs.

[7] We sent surveys to all 50 State agencies and received responses from 49 of them. One State, Wisconsin, elected not to respond. We excluded the District of Columbia from data collection for this Data Brief. We did not verify the information that the State agencies provided in their responses to our survey.

RESULTS OF ANALYSIS

If Federal law were to require States to obtain rebates under the MDRP for separate CHIP drugs, the 40 States that operated separate CHIPs could, according to our estimates (see the Appendix), have invoiced, collected, and directly received $641.2 million from the drug manufacturers for calendar year 2020. These estimated rebates totaled $125.5 million for the States and $515.7 million for the Federal Government.[8]

STATES ARE NOT REQUIRED TO OBTAIN REBATES FOR DRUGS PAID FOR BY THE SEPARATE CHILDREN'S HEALTH INSURANCE PROGRAM

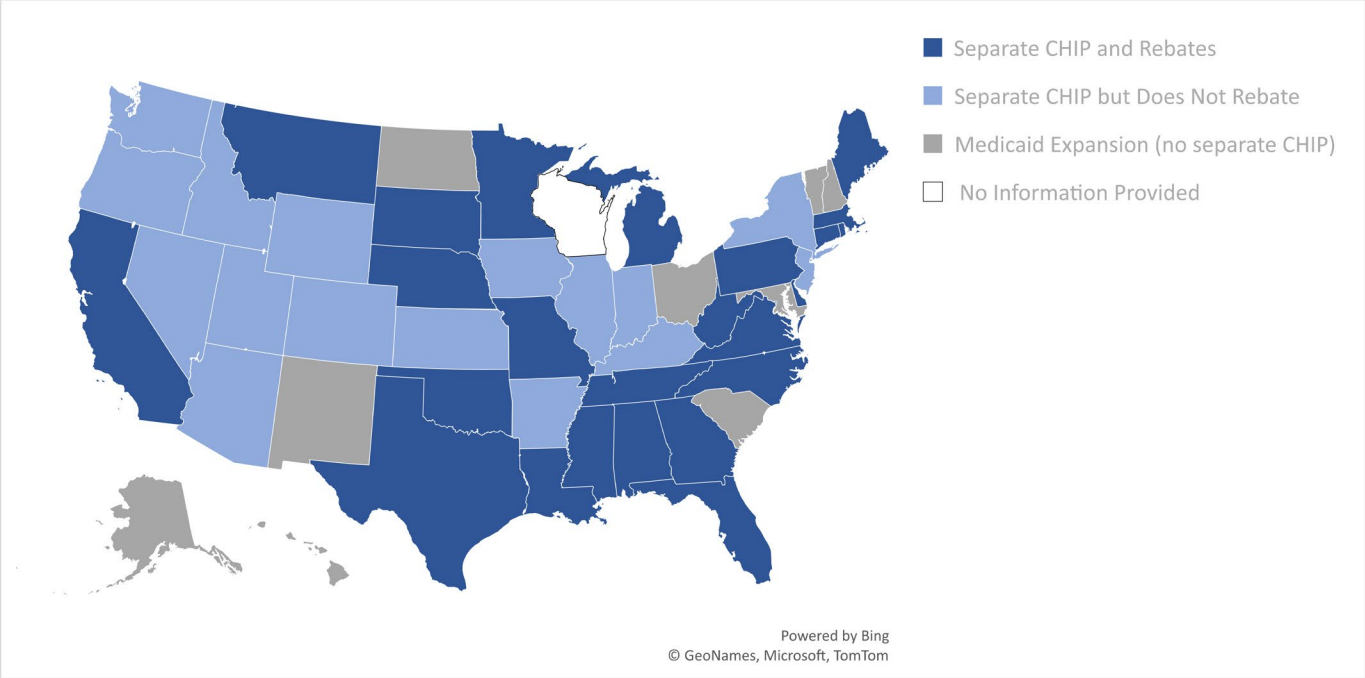
Under current Federal requirements, States must obtain drug rebates for Medicaid-covered outpatient prescription drugs that are provided through Medicaid expansion CHIP or the Medicaid expansion portion if the State chooses a combination of Medicaid expansion and separate CHIP.[9] However, for separate CHIP drugs, those Federal Medicaid drug rebate requirements do not at present apply.

Forty of the 50 State agencies told us that they operated separate CHIPs. Of the 40 State agencies that had separate CHIPs in place at some point during our audit period, 24 of them stated that rebates had been obtained for these separate CHIP drugs. The other 16 State agencies reported that they did not obtain drug rebates. The figure on the following page shows the States that operated separate CHIPs and the States that invoiced for rebates associated with separate CHIP drugs.

[8] We calculated this amount by multiplying the separate CHIP drugs' expenditures (as reported to us by the State agencies) by the estimated drug rebate percentage. See the Appendix for further details regarding the methodology.

[9] Sections 1927(a)(1) and (b)(1) of the Act.

Figure: States With Separate State Children's Health Insurance Programs That Did and Did Not Invoice for Rebates



Had Federal law required States to obtain rebates under the MDRP for separate CHIP drugs, the 40 States that operate separate CHIPs could, according to our estimates (see the Appendix), have invoiced, collected, and directly received $641.2 million from the drug manufacturers for calendar year 2020, which would have resulted in estimated drug rebates totaling $125.5 million for the States and $515.7 million for the Federal Government.

SOME MANAGED CARE ORGANIZATIONS ARE INVOICING FOR DRUGS FUNDED THROUGH SEPARATE CHILDREN'S HEALTH INSURANCE PROGRAMS

A number of the State agencies that operate separate CHIPs responded to our survey with statements that either acknowledged or suggested that these State agencies: (1) were aware that MCOs in their States were invoicing for rebates and (2) believed in some cases that the MCOs were retaining the rebates.

Some of the State agencies responded that their States' MCOs do collect drug rebates for the separate CHIP drugs, but because there is not a requirement for these rebates to be collected and subsequently reported, the MCOs are retaining the rebates. For example, one State agency responded to our survey by stating: "the separate CHIP program . . . is administered through managed care organizations so rebates would not necessarily be passed to the [State agency] but rather to the health plans directly providing services to enrollees." Another State agency said that it believed that these drug rebates are factored in during annual capitation rate

review, which may result in lowered capitated payment rates that the State agency would pay for each of the separate CHIP enrollees. Neither of these two State agencies provided additional information that would permit us to identify whether the rebates were: (1) being retained in their entirety by the MCOs or (2) being factored in when determining the capitated payment rates.

Another State agency said, "if the MCOs have negotiated any manufacturers rebates, they would keep them. I cannot speak as to whether this occurs as we do not monitor the MCOs processes for CHIP rebates." Another State agency said, "Yes, the MCO keeps the rebates because [the State agency] does not have a drug rebate program for CHIP."

When State agencies that operate separate CHIPs do not directly receive the rebate amounts, the Medicaid program may not realize the decreases in costs of prescription drugs toward which the MDRP aims.

CONCLUSION

If the requirements of the MDRP were to be extended to cover drug expenditures paid for by separate CHIPs, the States that operate separate CHIPs could (based on 2020 calculations) invoice for and receive an estimated $641.2 million in drug rebates annually, including $125.5 million for the States and $515.7 million for the Federal Government. In the meanwhile, these data point to the opportunity for CMS to work with State agencies to encourage them to create a drug rebate program that allows them to collect rebates for their separate CHIP drug expenditures.[10]

We issued a draft of this data brief to CMS on July 7, 2023. On July 18, 2023, CMS furnished technical comments, which we addressed as appropriate.

[10] State agencies may currently face challenges negotiating with manufacturers for separate CHIP drug rebates. Specifically, manufacturers may be reluctant to offer higher rebates for separate CHIP drugs because, under the provisions of section 1927(c)(1)(C) of the Act, doing so could potentially establish a lower best price that could result in an increase of the amounts paid as Medicaid drug rebates.

APPENDIX: AUDIT SCOPE AND METHODOLOGY

To estimate the rebates associated with outpatient prescription drug costs for States that operated separate CHIPs, we sent a survey to each of the 50 State agencies (footnote 7). Each survey asked: (1) whether that State had a separate CHIP in place; (2) if so, the total outpatient prescription drug costs for individuals receiving benefits under that State's separate CHIP; and (3) whether that State collected rebates for drugs purchased under its separate CHIP. We used the State agencies' responses to the survey to estimate the financial impact—that is, the total rebates that States could have collected—if the MDRP's rebate requirements were to be extended to all States that operated separate CHIPs. We did not verify in what capacity the rebates were received or examine rebate agreements with manufacturers.

In their responses to our survey, State agencies reported the outpatient prescription drug costs for individuals receiving benefits under their separate CHIPs. We did not verify the information that the State agencies provided in their responses to our survey. Using those reported costs, we calculated the amount of drug rebates that each State could have received if the MDRP's rebate requirements were to be extended to that State's CHIP. We multiplied the amount of outpatient prescription drug costs for individuals receiving benefits under a State's separate CHIP by the estimated drug rebates that we calculated.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

CALCULATION OF DRUG REBATE PERCENTAGE

To calculate the drug rebate percentage, we obtained the MACStats Medicaid and CHIP Data Book (MACStats Data Book) dated December 2021.[11] Published by the Medicaid and CHIP Payment and Access Commission (MACPAC), the MACStats Data Book is a compilation of Medicaid and CHIP data.[12] According to this source, the total Medicaid gross drug spending for fiscal year (FY) 2020 was $71.8 billion and the total amount of drug rebates was $39.2 billion. Using the reported Medicaid drug rebate utilization data in the MACStats Data Book, we divided the total drug rebates ($39.2 billion) by the total Medicaid drug gross spending ($71.8 billion) for FY 2020; the result was an estimated drug rebate percentage of 54.6 percent.

[11] *MACStats: Medicaid and CHIP Data Book* dated December 2021. Accessed at https://www.macpac.gov/wp-content/uploads/2021/12/MACStats-Medicaid-and-CHIP-Data-Book-December-2021.pdf on Jul. 3, 2023.

[12] MACPAC is a nonpartisan legislative branch agency that provides policy and data analysis and makes recommendations to Congress, the Secretary, and the States on a wide array of issues affecting Medicaid and CHIP. See About MACPAC : MACPAC (accessed on Jul. 3, 2023). The U.S. Comptroller General appoints MACPAC's 17 commissioners, who come from diverse regions across the United States and bring broad expertise and a wide range of perspectives on Medicaid and CHIP.

CALCULATION OF REBATES THAT COULD HAVE BEEN COLLECTED FROM DRUG MANUFACTURERS

In their responses to our surveys, State agencies reported totals of $1.2 billion in outpatient prescription drug costs for individuals receiving benefits under States' separate CHIPs.[13] Using the 54.6-percent drug rebate percentage that we calculated (as discussed just above), we multiplied the $1.2 billion by that percentage to estimate the total drug rebates that States could have collected under their separate CHIPs if those rebates had been required as part of the MDRP.

[13] According to the completed surveys, the total separate CHIP gross spending for drugs totaled $1,174,283,786 for calendar year 2020.