

Prescription for Price: Pharmacy Reform in Ohio Medicaid

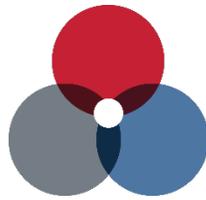
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Introduction

As an optional service in state Medicaid plans, a prescription drug benefit has become into a significant state policy concern, especially as pharmacology is an increasingly important tool to address individuals' health needs at a time of increased health care expense. Every month, Ohio Medicaid spends more than \$2 billion in services for the 1 in 4 Ohioans who receive their coverage through the program. Of that, nearly 1 out of every 5 dollars are spent on pharmacy.¹ Given this considerable expense to states, it is worthwhile to look into how state policy can impact pharmacy costs. The following brief outlines the role of the prescription drug benefit in Ohio Medicaid, highlighting some recent shifts in the policy construction of the benefit and some Medicaid considerations moving forward.

KEY TAKEAWAYS

- States have limited options in how to control costs in the Medicaid pharmacy benefit
- Ohio has implemented several reforms to simplify management of the benefit, increase transparency and enhance savings to the state and to safety-net providers
- While the elimination of the rebate cap through the American Rescue Act of 2021 will lead to significant savings for states, other options remain on how to control costs inside and outside of the Medicaid program

¹ Data retrieved from the Ohio Department of Medicaid's *Monthly Demographics and Expenditures Dashboard*. Data represents August 2020 report as a proxy for monthly spending. Accessed March 15, 2021.
<https://analytics.das.ohio.gov/t/ODMPUB/views/MedicaidDemographicandExpenditure/Home?:isGuestRedirectFromVizportal=y&:embed=y>

Role of Medicaid

The amount paid by Medicaid programs is a combination of a dispensing fee paid to the pharmacist, the amount paid to the pharmacy for drug ingredients, the rebate received from a manufacturer and the supplemental rebate negotiated by the state.² Of these elements, the state's potential policy adjustments come through the dispensing fee and supplemental rebates. The two others are a matter of pricing through market and policy conditions set by the federal government. Though generics account for most drugs dispensed in Medicaid programs, brand name drugs account for the majority of the spending.

For drug ingredients, Medicaid does not directly purchase drugs but rather pays for the drugs dispensed by pharmacists. The federal register defines this expense as the actual acquisition cost (AAC). While some states establish this through direct surveys of pharmacies, AAC often represents the Department of Health and Human Services' (HHS) determination of the actual prices pharmacy providers paid manufacturers.³ To determine this cost, the Centers for Medicare and Medicaid Services (CMS), which is a part of HHS, surveys retail pharmacies to determine the National Average Drug Acquisition Cost (NADAC). CMS establishes a price limit based on the AAC and how often the drugs are dispensed called the federal upper limit (FUL). Additionally, states can implement maximum allowable cost (MAC) provisions that, like FUL, establish the maximum amount a state will pay for a drug. Usually, states pay the lowest of the dispensing fee plus the AAC, FUL or MAC.⁴

The ability for manufacturers to set prices is a proprietary process. In this way, a manufacturer's prices have the most influence on state costs as they are an input in the AAC. As a result, most of the tools states can deploy to contain costs focus on managing the utilization of the benefit through prior authorization (PA), preferred drug lists (PDL), benefit limitations and drug utilization review (DUR).

A PDL is a list of medications that state Medicaid programs will cover without the need to request PA.⁵ Prior authorization, primarily a utilization tool for states and managed care organizations (MCOs), is a cost-containment tactic that requires a prescriber to obtain permission to prescribe medication *before* it can be dispensed to a beneficiary. Because PA can often be a time-intensive process, the PDL is intended to create an incentive for prescribers to rely on those drugs where the state can negotiate the best prices. By law, if states have a PDL, a group of pharmacists, nurses and physicians review which drugs to include on it, typically

² Medicaid's prescription Drug Benefit: Key facts. (2019, May 30). Retrieved March 15, 2021, from [https://www.kff.org/medicaid/fact-sheet/medicaids-prescription-drug-benefit-key-facts/#:~:text=Medicaid%20reimburses%20pharmacies%20for%20the,\(AAC\)%20for%20a%20drug.&text=The%20NADAC%20is%20intended%20to,or%20wholesalers%2C%20including%20some%20rebates.](https://www.kff.org/medicaid/fact-sheet/medicaids-prescription-drug-benefit-key-facts/#:~:text=Medicaid%20reimburses%20pharmacies%20for%20the,(AAC)%20for%20a%20drug.&text=The%20NADAC%20is%20intended%20to,or%20wholesalers%2C%20including%20some%20rebates.)

³ Definitions. 42 FR § 447.502 (2020) <https://www.law.cornell.edu/cfr/text/42/447.502>.

⁴ Medicaid Payment for Outpatient Prescription Drugs. (2018, May). Retrieved March 09, 2021, from <https://www.macpac.gov/wp-content/uploads/2015/09/Medicaid-Payment-for-Outpatient-Prescription-Drugs.pdf>

⁵ Ovsag, K., Hydere, S., & Mousa, S. A. (2008). Preferred drug lists: potential impact on healthcare economics. *Vascular health and risk management*, 4(2), 403–413. <https://doi.org/10.2147/vhrm.s926>

through creating a state pharmacy and therapeutics committee (P&T committee). Ohio's committee reflects this standard design, with membership comprised of physicians and pharmacists who represent their respective state trade associations. There are no federal requirements for P&T committees and the structure and operations vary state by state. However, the general charge of P&T committees is to ensure the safety and efficacy of the drugs included on the PDL.⁶ Because the PDL guarantees manufacturers access to a sizable market, consideration of inclusion is often economically beneficial to Medicaid programs when contemplating rebates from drug manufacturers. More analysis on rebates is in a subsequent section of this brief.

In addition to PA and the P&T committee, states have DUR. DUR is a process where the state, in conjunction with providers, looks into insurance claim data to evaluate patterns in dosage, duration, misuse and fraud as a way to enhance therapy. In Ohio, this process is prospective (where pharmacists perform in advance of dispensation), retrospective (where a committee reviews dispensed drugs) and concurrent (where the process tries to intervene if there is a potential risk posed to a patient). Recently, data has shown how members of DUR boards have been influenced by manufacturers when establishing which drugs are included onto PDLs.⁷ With that said, Ohio does have a conflict of interest disclosure policy for members of the DUR Board and the most recent data from CMS shows that only a few members of Ohio's board received any payments from drug manufacturers and that those payments were insignificant.

In addition to these controls, states can implement nominal co-payments for outpatient prescriptions. Ohio does have co-payments for most brand name drugs at \$2 per prescription refill and \$3 for every prescription or refill if the drug requires prior authorization.⁸ Typically, however, MCOs do not charge co-pays or pursue the payment.

Developments in Ohio

MCOs are the predominant state tool to implement the pharmacy benefit and play a key role to ensure costs are contained and utilization is appropriate. Previously, Ohio's MCOs were able to individually contract with a pharmacy benefit manager (PBM), like CVS Health, to assist with the process of pricing, rebates, fees, data and access. In 2018, the Auditor of the State Dave Yost released a report that the PBMs MCOs had contracted had engaged in 'spread pricing' where the PBM charged Medicaid more than what was reimbursed to pharmacies. According to the analysis, the spread pricing meant a nearly \$225 million benefit to the PBMs, including \$208

⁶ Next Steps in Improving Medicaid Prescription Drug Policy. (2019, June). Retrieved March 16, 2021, from <https://www.macpac.gov/wp-content/uploads/2019/06/Next-Steps-in-Improving-Medicaid-Prescription-Drug-Policy.pdf>

⁷ Whyte, L., Yerardi, J., & Kodjak, A. (2018, July 18). Investigation: Patients' drug options Under MEDICAID heavily influenced By drugmakers. Retrieved March 16, 2021, from <https://www.npr.org/sections/health-shots/2018/07/18/629575118/medicaid-under-the-influence-how-drugmakers-sway-medication-options-for-patients>

⁸ Pharmacy Benefits. Retrieved March 16, 2021, from <https://medicaid.ohio.gov/FOR-OHIOANS/Already-Covered/Medicaid-Copays>

million from generic drugs. An additional \$20 million in spread was retained by an additional pharmacy benefit administrator controlled by one of the MCOs, bringing the total captured spread to approximately \$245 million in just one year of the managed care pharmacy program. CVS Health, then the PBM contractor for most plans in Ohio, responded to the report by stating they were able to negotiate more than \$145 million in savings while also passing along the entirety of their applicable drug manufacturer rebates back to the Medicaid MCOs.⁹

As an answer to this issue, the Ohio General Assembly required the Ohio Department of Medicaid to pursue a single PBM (SPBM) structure. With this, the state would have a consolidated PBM, which would still have a managed care contract, but a different type of contract as we have documented in previous research.¹⁰ The design of this shift includes a SPBM to manage the benefit and an operational support vendor (OSV). Now, the SPBM will be responsible for most of the services provided, including the management of Ohio's unified PDL and rebate processing under their financial management responsibilities. The OSV, on the other hand, will manage pharmacy reimbursement and oversee the operations of the PBM. In totality, the design is intended to increase the transparency of drug acquisition and benefits management while also saving the state resources by consolidating the administrative expense from five separate contracts into two aligned but separate MCO products.¹¹ Additionally, Ohio created a Prescription Drug Transparency and Affordability Council through the budget in the 133rd General Assembly. This council must provide recommendations to the General Assembly, Governor Mike DeWine, and the Joint Medicaid Oversight Committee on "Ohio's best path forward for issues such as prescription drug price transparency, affordable payment models, and health care efficiency."

Outside of the direct purview of the state, there is a federal program which helps certain providers obtain discounts on outpatient drugs (other than vaccines) called the 340B Drug Pricing Program (340B). For background, states may not claim a Medicaid rebate for a drug that was purchased under 340B. As such, before describing how 340B operates, it may be helpful to understand how rebates in general work.

Rebates ensure that Medicaid receives a consistent "lowest and best" price established by the manufacturer. In exchange for rebates, a state must cover a manufacturer's drugs, which has the functional effect of making all Food and Drug Administration approved medications available in the state's pharmacy list (also known as a formulary). To calculate the rebate, the federal government first calculates the unit rebate amount (URA) for the drug, then the state

⁹ Meltzer, R. (2018, August 16). Ohio cracks down on PBM contracts after audit shows egregious spread pricing in Medicaid. Retrieved March 16, 2021, from <https://www.fiercehealthcare.com/regulatory/ohio-takes-action-after-finding-pbms-engaged-egregious-spread-pricing-medicaid>

¹⁰ Anthes, L. (2020, October 09). Moving from payers to Populations: A review of Ohio's Medicaid managed Care bid. Retrieved March 16, 2021, from <https://www.communitysolutions.com/research/moving-payers-populations-review-ohios-medicaid-managed-care-bid/>

¹¹ Candisky, C. (2020, November 06). Ohio Medicaid requesting bids for Pharmacy administrator to help clean up the PBM mess. Retrieved March 16, 2021, from <https://www.dispatch.com/story/news/2020/11/06/medicaid-stepping-up-oversight-pharmacy-benefit-program-saving-taxpayers-money-due-pbm-abuses/6181248002/>

multiplies that by the number of units dispensed during the rebate period and submits it to the manufacturer for payment. The rebate has two components: a basic rebate amount and an inflationary component.

For brand name drugs, the basic amount is 23.1 percent of the average manufacturer price (AMP) or AMP minus “best price,” which is the lowest price available to any wholesaler, retailer or other paying entity. For generic drugs, this amount is 13 percent and there is no “best price” comparison.¹² The total potential rebate is capped at 100 percent of the AMP. Interestingly, both amounts were increased from 15.1 and 11 percent, respectively, as a part of the Affordable Care Act (ACA) and the ACA also enabled states to collect rebates through managed care – a practice previously only possible in a fee-for-service environment.

The inflationary component is added when the AMP exceeds the increase of the Consumer Price Index for All Urban Consumers (CPI-U) and, in recent years, represents an increasing share of total rebate amounts.¹³ States can also negotiate “supplemental” rebates with manufacturers by negotiating, either on their own or with other states, in a pool (as is the case with Ohio), to receive an additional rebate sum to be placed on the PDL. In 2019, Ohio collected nearly \$134 million in total rebates.¹⁴ In a 2015 report from the federal Office of the Inspector General (OIG), it was found that if the inflationary component was extended to generics, state Medicaid programs would have realized an additional \$1.4 billion in additional rebates for the top 200 drugs.¹⁵ According to this report, the reason for this increase is that generic prices have been steadily increasing. The OIG recommended CMS seek additional authority to extend the rebate structure to generics to influence the price.

As stated before, if a 340B provider purchases a drug, the state cannot claim a rebate. Before Ohio’s SPBM, 340B providers identified issues with how MCOs leveraged contracts with PBMs to negotiate all or part of the 340B savings to the providers’ out-of-pharmacy reimbursement. In response, the 133rd General Assembly of Ohio passed Senate Bill 263. This legislation prohibits MCOs from negotiating these savings by establishing a reimbursement rate based on national drug acquisition costs. SB 263 also allows for a negotiated fee between the distributor and the covered entity.¹⁶

¹² Reynolds, I. (2018, June 28). Use of state Medicaid inflation rebates could discourage drug price increases. Retrieved March 17, 2021, from <https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2018/06/use-of-state-medicaid-inflation-rebates-could-discourage-drug-price-increases>

¹³ Medicaid Payment for Outpatient Prescription Drugs. (2018, May). Retrieved March 16, 2021, from <https://www.macpac.gov/wp-content/uploads/2019/06/Next-Steps-in-Improving-Medicaid-Prescription-Drug-Policy.pdf>

¹⁴ Data access through the Ohio Department of Medicaid’s “Pharmacy Dashboard”: <https://analytics.das.ohio.gov/t/ODMPUB/views/PBMRxDashboard/Overview?%3AisGuestRedirectFromVizportal=y&%3Aembed=y>

¹⁵ Average manufacturer prices increased faster than inflation for many generic drugs. (2015, December 16). Retrieved March 17, 2021, from <https://oig.hhs.gov/oas/reports/region6/61500030.asp>

¹⁶ Ohio Senate Bill 263. Legislative Analysis and Language available: <https://www.legislature.ohio.gov/legislation/legislation-documents?id=GA133-SB-263>

Finally, in 2019, the Medicaid and CHIP Payment and Access Commission (MACPAC) recommended the elimination of the rebate cap. Incidentally, as a part of the American Rescue Plan Act of 2021, starting in 2024, the cap will be eliminated. According to Congressional Budget Office (CBO) estimates, lifting the rebate cap would reduce federal Medicaid spending by \$15.9 billion and state Medicaid spending by \$7.6 billion over the next 10 years (2021-2030).¹⁷ With Ohio's total Medicaid spending representing 4 percent of the national spending on the program, if this ratio was equally applied to the potential benefit of the cap removal, Ohio could stand to gain more than \$304 million over the same time period.¹⁸ In this way, the elimination of the cap acts as a disincentive for manufacturers to raise their prices beyond the AMP and will likely have a deflationary impact on price. If not for the benefit of lower prices, the state would then realize greater savings and lower costs to maintain and augment the program.

Policy options

As COVID-19 has demonstrated, pharmaceutical innovation is a cornerstone of modern medical achievement. However, the typical refrain from manufacturers is that any effort to restrain price or encourage the promotion of generics will impede this type of innovation because the costs for research and development (R&D) are so high. Hence, the argument is these organizations can only recoup the value of their investment through patent protections and a deregulated price environment. However, the evidence does not support this claim as taxpayers often finance much of this research, including \$230 billion over the last decade. Furthermore, pharmaceutical companies are generally more profitable, as measured by net income, compared to similar, publicly traded companies and consistently establish prices in the U.S. far beyond the cost of their global R&D expenses.^{19,20}

At the end of 2020, the state's Prescription Drug Transparency and Affordability Advisory Council released six recommendations for the state to consider, per its legislative mandate.²¹

¹⁷ Park, E., Alker, J., & Brooks, T. (2021, February 26). CBO estimates Confirm Lifting Medicaid Drug Rebate Cap results in significant federal and State Savings. Retrieved March 17, 2021, from <https://ccf.georgetown.edu/2021/02/21/cbo-estimates-confirm-lifting-medicaid-drug-rebate-cap-results-in-significant-federal-and-state-savings/>

¹⁸ Total medicaid spending. (2020, October 29). Retrieved March 19, 2021, from <https://www.kff.org/medicaid/state-indicator/total-medicaid-spending/?currentTimeframe=0&selectedRows=%7B%22wrapups%22%3A%7B%22united-states%22%3A%7B%7D%7D%2C%22states%22%3A%7B%22ohio%22%3A%7B%7D%7D%7D&sortModel=%7B%22colld%22%3A%22Location%22%2C%22sort%22%3A%22asc%22%7D>

¹⁹ Ledley, F. D., MD. (2020, March 03). Profitability of large pharmaceutical companies vs other large public companies. Retrieved March 17, 2021, from <https://jamanetwork.com/journals/jama/fullarticle/2762308>

²⁰ Yu, N. L. (2017, March 07). R&d costs for pharmaceutical companies do not explain elevated us drug prices: Health affairs blog. Retrieved March 17, 2021, from <https://www.healthaffairs.org/doi/10.1377/hblog20170307.059036/full/>

²¹ Prescription Drug Transparency and Affordability Council. (2020, December). Retrieved March 16, 2021, from <https://das.ohio.gov/Portals/0/DASDivisions/AdministrativeSupport/Prescription%20Drug%20Transparency%20and%20Affordability%20Advisory%20Council%20report.pdf?ver=EyidzVM2t6Liy7LGym8DWg%3d%3d>

This group is comprised of 13 members including five state health and human service agency directors, and representation from a diversity of interests representing organized labor, business and local government. Included in these recommendations were:

- 1) Consider a single prescription drug purchasing plan for public employers across the state;
- 2) Further research how a reverse-auction process may be implemented in Ohio;
- 3) Consider establishing a single formulary across state entities;
- 4) Find additional ways to benefit the consumer;
- 5) Consider health equity when developing prescription drug policies; and
- 6) Require clarity and accountability in PBM contract terms.

As the state's biennial budget continues to be deliberated, the report and the findings provided to the General Assembly create an opportunity to deliberate those recommendations. Still, as this Council continues to meet quarterly, it should track the progress on those recommendations in the budget process and consider other policy opportunities.

The National Academy for State Health Policy (NASHP) has identified two pieces of model legislation that seek to address costs in pharmaceuticals across the board. The first legislation, which five states have introduced, uses international reference rates to achieve significant savings.²² The second, which has been introduced in three states, fines manufacturers with price increases that are unsupported by clinical evidence.²³ With research showing unsubstantiated price increases led to a net spending increase of \$5.1 billion between 2017 to 2018, this second policy option has the potential to shield consumers and employers from rapid price increases.²⁴

Regarding Medicaid, specifically, the state and federal governments should collaborate to enact better policies to protect taxpayers. First, Congress could act on MACPAC's other 2019 recommendation to allow states to exclude or otherwise restrict coverage for a drug after it has been approved. As the law currently mandates coverage upon entering the market, this would give states more flexibility to plan and coordinate resources to achieve the best possible price.

Second, the state should consider seeking regulatory flexibility to either close the state's formulary and, in extreme cases, leverage the government's ability to use patent law. The latter of these options would require excessively-priced drugs to be "reasonably compensated" or enable the legal importation of international generics, something the State of Louisiana proposed in 2017 for the excessive increases in the price they were paying for Hepatitis C

²² An Act to Reduce Prescription Drug Costs Using International Pricing. (2021, January 11). Retrieved March 17, 2021, from <https://www.nashp.org/an-act-to-reduce-prescription-drug-costs-using-international-pricing/>

²³ An Act to Protect Consumers from Unsupported Price Increases on Prescription Drugs (2020, July 28). Retrieved March 17, 2021, from <https://www.nashp.org/an-act-to-protect-name-of-state-consumers-from-unsupported-price-increases-on-prescription-drugs/>

²⁴ DeArment, A. (2019, October 09). Drug price increases without supporting evidence raised spending BY \$5.1B, ICER says. Retrieved March 17, 2021, from <https://medcitynews.com/2019/10/drug-price-increases-without-supporting-evidence-raised-spending-by-5-1b-icer-says/>

drugs.²⁵ Regarding a closed formulary, several states have pursued this option through an 1115 demonstration waiver, but only Tennessee has been able to achieve approval from CMS in the context of a different waiver.²⁶ While some have critiqued closed formularies as a way to restrict access to benefits, a waiver, by design, is temporary. What's more, any pursuit of a closed formulary should have strong guardrails against the potential for policymakers to subjectively eliminate coverage of certain classes of medications or eliminate coverage for certain medications that they deem too expensive. As such, there should be strong expectations of review regarding access through the Council, the P&T committee and DUR Board.²⁷

In the end, a cost-efficient Medicaid program relies on the continued pursuit of policies which seek to control prices in a largely unregulated pricing marketplace. While Ohio has enacted a number of reforms to increase transparency, reduce redundancy and ensure the effective and efficient use of drugs, there still remains the fundamental challenge of a system defined by the absence of price controls or economic logic. While the former may not be of interest to policymakers, officials on the state and federal levels can do more to incentivize a more balanced marketplace that benefits everyone.

Glossary of terms

AAC: Actual acquisition cost. Defined as a state Medicaid agency's determination of the pharmacy providers' actual prices paid to acquire drug products marketed or sold by specific manufacturers.

PDL: Preferred drug list. A list of medications that Medicaid will cover the cost for without the need to request a prior authorization

DUR: Drug utilization review. Defined as an authorized, structured, ongoing review of prescribing, dispensing and use of medication. DUR encompasses a drug review against predetermined criteria that results in changes to drug therapy when these criteria are not met.

FUL: Federal upper limit that caps the federal financial contribution toward state expenditures for certain multiple source drugs.

²⁵ Neuman, T., & Cubanski, J. (2019, October 17). What's the latest on medicare drug price negotiations? Appendix. Retrieved March 17, 2021, from <https://www.kff.org/report-section/whats-the-latest-on-medicare-drug-price-negotiations-appendix/>

²⁶ Cohen, J. (2021, March 03). Tennessee's Medicaid waiver for a Closed Drug Formulary could be a trendsetter. Retrieved March 17, 2021, from <https://www.forbes.com/sites/joshuacohen/2021/03/03/tennessees-medicaid-waiver-for-a-closed-drug-formulary-could-be-a-trendsetter/?sh=28f56e5a5f5b>

²⁷ Coursolle, A., & Turner, W. (2019, March 19). Closed formularies in Medicaid are no solution for lowering drug costs. Retrieved March 17, 2021, from <https://healthlaw.org/closed-formularies-in-medicaid-are-no-solution-for-lowering-drug-costs/>

PA: Prior Authorization. A decision by your health insurer or plan that a health care service, treatment plan, prescription drug or durable medical equipment is medically necessary. Sometimes called prior authorization, prior approval or precertification. Your health insurance or plan may require pre-authorization for certain services before you receive them, except in an emergency. Pre-authorization isn't a promise your health insurance or plan will cover the cost.

(S)PBM: (Single) Pharmacy benefit manager. Pharmacy benefit management companies serve as the middlemen between insurance companies, pharmacies and manufacturers, securing lower drug costs for insurers and insurance companies. PBMs do this through negotiating with pharmacies and drug manufacturers for discounts on drug prices, and pass discounts along to insurance companies, up-charging the drugs or retaining portions of rebates for profit.

URA: Unit rebate amount. The rebate amount calculated by CMS that a drug manufacturer must pay under the Medicaid Drug Rebate Program. The rebate amount is calculated on a unit basis for each drug at the National Drug Code level.

MAC: Maximum allowable cost. Payment limit on certain multiple source drugs and select other drugs set by state Medicaid agencies.



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