

# Innovations in State Medicaid Programs to Control Prescription Drug Costs

Medicaid serves nearly one in five Americans, including many with chronic conditions, and purchases about 10% of total prescription medications dispensed in the U.S.[\[1\]](#) From 2013 to 2016, Medicaid's nationwide drug spending increased almost 50%, from \$22.4 billion to \$33.4 billion.[\[2\]](#) Medicaid programs consume an increasing percentage of state budgets and threaten to overtake funding for other programs like education and infrastructure.[\[3\]](#) In 2018, the National Association of State Budget Officers (NASBO) estimated that Medicaid accounted for nearly 30% of total state spending and is the fastest growing component of state budgets.[\[4\]](#) As a result of increasing Medicaid expenditures – especially on prescription drugs – many states have attempted to reduce spending on Medicaid prescription drug coverage through the use of four key strategies: closed formularies, global budgets, outcome- or value-based purchasing, and administering pharmaceutical coverage directly through direct purchasing or removing pharmacy benefit managers (PBMs) from managed care plans.

## 1. *Closed Formularies*

Existing law requires Medicaid programs to cover most drugs approved by the FDA, including multiple drugs in each drug category. To help Medicaid pay for drugs it must cover, federal law requires manufacturers to give rebates to state Medicaid programs ensuring that the program gets the “best price”.[\[5\]](#) States can negotiate additional, supplemental rebates with

manufacturers. When negotiating with manufacturers, states may also use a preferred drug list (PDL), which would require physicians to obtain prior authorization before using any drug not included on the list.

In 2017, Massachusetts requested a waiver from the Centers for Medicare and Medicaid Services (CMS) to use a closed formulary, noting that drug spending in MassHealth, the state Medicaid program, had grown at a compound annual growth rate of 13% since 2010 and was threatening to “crowd out important spending on health care and other critical programs.”[\[6\]](#) Massachusetts requested to use a restrictive formulary that includes at least one drug in each category, but could exclude some drugs typically covered by Medicaid. The power to completely exclude drugs from the formulary, and not just remove them from a PDL, would give the state additional bargaining power with manufacturers, because the state could threaten to exclude the drug in exchange for more significant discounts.

In June 2018, however, CMS denied Massachusetts’ waiver, saying that the state could not continue to collect federally-mandated rebates while excluding some drugs from coverage.[\[7\]](#) CMS noted that if Massachusetts directly negotiated with drug manufacturers and agreed to forgo all manufacturer rebates available under the federal Medicaid Drug Rebate Program, “[t]he State could... exclude specific drugs from coverage based on cost-effectiveness or other approved criteria.” [\[8\]](#) As a result of CMS’s determination, other states have not applied to use closed formularies.

Nevertheless, closed formularies have the potential to save money for Medicaid programs. An analysis of the drug expenditures of MassHealth, Massachusetts’ Medicaid program, during fiscal year 2016 found that 20% of the program’s expenditures were for drugs that CVS or ExpressScripts excluded

from their formularies.[\[9\]](#) Limiting coverage for these drugs not only directly reduces MassHealth's spending for less cost-effective drugs, but also increases the agency's ability to negotiate prices for covered drugs. Given closed formularies' potential for substantial cost savings, states should continue to explore ways to work with CMS to use such programs in Medicaid, including considering forgoing the mandated "best price" rebates. States that agree to forgo Medicaid-mandated rebates should also consider negotiating directly with manufacturers as a coalition to increase bargaining power and reduce administrative burden.

## **2. *Global Budgets***

Instead of using a closed formulary, New York increased its negotiating power with prescription drug manufacturers by enacting a global budget for prescription drugs as part of its 2018 Health and Mental Hygiene budget.[\[10\]](#) The budget limits the annual increase in prescription drug spending by the state's Medicaid program to the rate of medical inflation.[\[11\]](#) If New York's Department of Health (DoH) projects Medicaid spending will exceed the limit, the state Commissioner of Health must identify specific drugs for review by the Drug Utilization Review (DUR) Board. The Commissioner and DUR board then consider the drug's "affordability and value" and negotiate supplemental rebates from manufacturers of drugs that are "priced disproportionately to ...[their] therapeutic benefits."[\[12\]](#)

In 2018, the projected expenditures exceeded the cap and state officials requested additional manufacturer rebates for thirty drugs.[\[13\]](#) For the thirty drugs identified, Vertex Pharmaceuticals was the only company that refused to provide the requested discounts for Orkambi, a drug to treat cystic fibrosis with a list price of \$273,000 per year.[\[14\]](#) Vertex has played

hardball with this drug and also refused to offer discounts to Great Britain after the National Institute for Health and Care Excellence (NICE) recommended that Orkambi not be covered by the National Health Service at the price Vertex demanded.[\[15\]](#) Most state Medicaid programs would have no ability to negotiate with Vertex, but New York's use of global budgets for drugs increases the bargaining power of the state Medicaid program by subjecting "unaffordable" drugs to additional prior authorization review. For drugs that have therapeutic substitutions, requiring patients to get preapproval for the drug will likely significantly reduce the use of the costly drug. It remains unclear, however, whether the threat of requiring prior authorization gives the state *enough* negotiating power for a drug with few therapeutic substitutes like Orkambi. Nonetheless, New York's global budget for drugs with its threat of preapproval restrictions and public shaming of drug manufacturers caused the vast majority of manufacturers to give additional discounts to New York for drugs the state determined were "excessively priced".

### **3. *Outcome- or Value-based Purchasing***

A third strategy used by state Medicaid programs to control drug costs is value-based or outcome-based purchasing, which links the price of a drug to its effectiveness. In the simplest example of value-based purchasing, a manufacturer may set a price for a drug and then offer rebates if the drug fails to have the intended benefit. Novartis priced Kymriah, a gene therapy treatment for relapsed acute lymphoblastic leukemia, at \$475,000 for a single treatment, and offered a "money-back guarantee" if the drug didn't work.[\[16\]](#) In another example of outcomes-based contracting, Spark Therapeutics offered rebates for its drug Luxturna, a one-time gene therapy treatment for

retinal dystrophy which costs more than \$850,000, if a patient failed to meet clinical outcomes after treatment.[\[17\]](#) The question remains, however, whether these outcome-based purchasing programs save money. Patients and insurers may be willing to pay a higher price for a drug with a guarantee of success, so pharmaceutical manufacturers may be able to raise the initial price of a drug in outcome-based purchasing.

Manufacturers and payers, however, argue that the Medicaid “[best-price rule](#)” inhibits the use of value-based contracts.[\[18\]](#) As noted above, federal statutes require the Medicaid program to get “the lowest price available from the manufacturer during the rebate period”[\[19\]](#) with some exceptions including prices paid by the U.S. Department of Veterans Affairs (VA). The statutes, however, are silent on exactly how the “best-price” is calculated. Legal scholars suggest that to achieve value-based purchasing under the best-price requirement, CMS could write regulations that provide a weighted average of the price that a manufacturer receives through an outcome-based pricing arrangement.[\[20\]](#) Without clarification from CMS or Congress on how the Medicaid best-price is calculated, value-based purchasing in commercial plans may remain limited to high cost drugs that have limited use among Medicaid beneficiaries.[\[21\]](#)

Nonetheless, in 2018, some states began using value-based purchasing in their Medicaid programs. In June 2018, CMS approved a waiver application from Oklahoma to pursue voluntary agreements that would include supplemental rebates based on the effectiveness of the drug.[\[22\]](#) In the announcement of the approval, CMS noted that as a supplemental rebate agreement (SRA), Oklahoma’s value-based program was exempt from Medicaid’s “best-price” rule.[\[23\]](#) A few months later, Michigan became the second state to get approval from CMS,[\[24\]](#) and on February 25, 2019, CMS approved Colorado’s waiver, making it the third state with permission to negotiate voluntary value-based contracts

with drug manufacturers.

While the contracts and supplemental rebates negotiated by the states remain confidential, news reports described a contract between Oklahoma's Medicaid program and Alkermes, the manufacturer of Aristada, a drug to treat schizophrenia. The contract includes terms for rebate increases every month that a patient refills a prescription, so that the price decreases over time.[\[25\]](#) Outcome-based purchasing contracts allow insurers, including Medicaid programs, to ensure that they only pay for drugs that work. Furthermore, value-based purchasing works as a way for insurers to minimize their financial risk when covering a drug for a wider patient population than was included in a clinical trial, thereby allowing a wider patient population access to the drug.

Yet whether these contracts save money by only paying for effective drugs or have the opposite effect of allowing manufacturers to increase prices remains to be seen. Nevertheless, value-based contracts appear to be an important step toward getting better value for money spent on healthcare. States should continue to work with CMS both to test value-based payments within the Medicaid program and to ensure that federal rules allow private insurers to use value-based contracts without infringing on regulations regarding Medicaid best-price calculations.

#### ***4. Regulation or Removal of PBMs from Medicaid***

Finally, in order to control drug costs in their Medicaid programs, some states restrict how PBMs charge for prescriptions or even remove private PBMs from their Medicaid programs by creating a state agency to act as a PBM.

In the last few years, a few states have begun regulating PBM pricing practices in Medicaid managed care programs. Specifically, some states now prohibit PBMs from using spread pricing[\[26\]](#) in any Medicaid contract. In 2018, a Louisiana bill prohibiting spread pricing, defined in the law as “any amount charged or claimed by a pharmacy benefit manager to a managed care organization that is in excess of the amount paid to the pharmacy that filled the prescription,”[\[27\]](#) unanimously passed both houses and was signed by the state’s governor. The law limits the fees a PBM can charge to a transaction fee set by the Louisiana Department of Health. Similarly, in August 2018, the Ohio Department of Medicaid announced that it would no longer allow PBMs to use spread pricing in contracts. A report released in June 2018 found that the two PBMs that serve the state’s Medicaid Managed Care plans charged the program over \$223 million in excess of the amounts paid to pharmacies for filling the prescriptions (an 8.8% spread).[\[28\]](#) In response, Ohio announced that starting in 2019, PBMs can only charge Medicaid the cost they pay to the pharmacy plus an administrative fee (estimated to be between \$0.95 and \$1.90) per prescription.[\[29\]](#)

More drastically, two states – West Virginia and Kentucky – ended contracts with private PBMs and designated a state agency to act as PBM for all Medicaid beneficiaries in the state. In 2017, West Virginia carved pharmacy benefits from its Medicaid Managed Care plans and designated the Bureau for Medical Services’ Office of Pharmacy Services (OPS) to act as the PBM for all state Medicaid recipients. Based on savings from the first six months of the new program, West Virginia estimates that it will save \$70 million annually through reduced administrative costs and increased compliance with the Preferred Drug List.[\[30\]](#) Following West Virginia’s example, Kentucky passed a law in 2018 that requires the Department for Medicaid Services to directly administer all outpatient pharmacy

benefits.[\[31\]](#) The law requires PBMs to disclose all contracts and fees and allows the state Department for Medicaid Services to create, approve, and “change at any time for any reason, reimbursement rates between a [PBM] and a contracted pharmacy.”[\[32\]](#) The law passed unanimously in both houses and was signed by the governor, demonstrating the desire for more transparency and control over how Medicaid money is spent on drugs.

Using a slightly different approach, Vermont considered bypassing PBMs and purchasing pharmaceuticals directly from a wholesaler. In May 2018, the Vermont governor signed a law[\[33\]](#) creating a working group to “investigate and analyze prescription drug pricing throughout the prescription drug supply chain in order to identify opportunities for savings for Vermont consumers and other payers and for increasing prescription drug price transparency at all levels of the supply chain.” In November 2018, the group recommended that the Department of Vermont Health Access, the state’s Medicaid program, explore a contract with a single drug wholesaler to supply drugs to Medicaid-enrolled pharmacies for the Vermont Medicaid program. The working group “believes that both savings and transparency can be achieved through channel simplification.”[\[34\]](#) The group, however, did not receive any responses to a request for information from wholesalers. As a result, whether Vermont can realistically implement a direct purchasing arrangement remains unknown. Vermont’s experience shows that even when a state has the political will and resources to implement new strategies to control costs, it is still subject to retaliation by the industry.

The variety of methods states have used to address rising drug costs in their Medicaid programs reflect the diversity in the

residents, ideology, and political will among states. More importantly, the variation in approach also reflects an urgency to address rising costs that strain state budgets. As a result, state Medicaid agencies are taking an active role in testing new ways to address rising drug costs, which may provide greater transparency to lawmakers and the public. This approach allows other insurers to use such experience and information to design their own mechanisms to achieve cost-savings in pharmaceutical coverage.

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[1] CMS.gov. **NHE Fact Sheet**. 2016. Available from: <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html>.

[2] Dworkowitz A. **Efforts to Cut Drug Prices in Medicaid**. Manatt Phelps and Phillips LLP. February 27, 2018. Available from: <https://www.lexology.com/library/detail.aspx?g=9f8fef25-d178-40f6-9c0b-9ee511c018e9>.

[3] [https://www.urban.org/research/publication/governing-tight-budgets/view/full\\_report](https://www.urban.org/research/publication/governing-tight-budgets/view/full_report).

[4] [https://higherlogicdownload.s3.amazonaws.com/NASB0/9d2d2db1-c943-4f1b-b750-0fca152d64c2/UploadedImages/Issue%20Briefs%20/2018\\_State\\_Expenditure\\_Report\\_Summary.pdf](https://higherlogicdownload.s3.amazonaws.com/NASB0/9d2d2db1-c943-4f1b-b750-0fca152d64c2/UploadedImages/Issue%20Briefs%20/2018_State_Expenditure_Report_Summary.pdf).

[5] “Best price” is defined in 42 U.S.C. § 1396r-8(c)(1)(C) to be the “lowest price available from the manufacturer ... to any

wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States”, with a few specific exclusions including the Veterans Affairs and the Indian Health Service.

[6] Commonwealth of Massachusetts Executive Office of Health and Human Services, Office of Medicaid. **MassHealth Section 1115 Demonstration Amendment Request**. September 8, 2017. Available from: <http://www.mass.gov/eohhs/docs/masshealth/masshealth-section-1115-demonstration-amendment-request-09-2017.pdf>.

[7] <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ma/MassHealth/ma-masshealth-demo-amndmnt-appvl-jun-2018.pdf>

[8] <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ma/MassHealth/ma-masshealth-demo-amndmnt-appvl-jun-2018.pdf> p. 2.

[9] Ibid.

[10] New York Senate Bill 2007B, <http://legislation.nysenate.gov/pdf/bills/2017/S2007B>.

[11] For 2018, net prescription drug spending cannot exceed the 10-year rolling average of medical inflation (3.2 percent) plus 5 percentage points (totaling 8.2 percent at the time of the bill’s enactment), minus an additional \$55 million. For 2019, prescription drug spending cannot exceed the 10-year rolling average of medical inflation plus 4 percentage points, minus \$85 million.

See <http://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2018/04/new-yorks-medicaid-drug-cap>.

[\[12\]](#) New York Public Health Law § 280.4.

[\[13\]](#)

<https://www.nytimes.com/2018/06/24/health/drug-prices-orkambi-new-york.html>

[\[14\]](#)

[https://icer-review.org/wp-content/uploads/2018/06/MWCEPAC\\_RAAG\\_060718.pdf](https://icer-review.org/wp-content/uploads/2018/06/MWCEPAC_RAAG_060718.pdf)

[\[15\]](#)

<https://www.parliament.uk/documents/commons-committees/Health/Correspondence/2017-19/Letters-relating-to-availability-of-Orakambi-on-NHS-7-11-18.pdf>

[\[16\]](#)

<https://khn.org/news/cascade-of-costs-could-push-new-gene-therapy-above-1-million-per-patient/>

[\[17\]](#)

<https://healthpayerintelligence.com/news/outcomes-based-contracts-offer-payers-new-pharmaceutical-options>

[\[18\]](#) PhRMA. 2016. “Promoting Value-Driven Health Care.” March. [phrma-docs.phrma](#)

[.org/sites/default/files/pdf/proactive-policy-value-driven.pdf](#)

[\[19\]](#) 42 U.S.C. § 1396r-8(c)(1)(C)

[\[20\]](#) Sachs, Bagley and Lakdawalla

<https://pdfs.semanticscholar.org/1f0e/6e6598fc0548da6b8eef90c8c3455c3f3b38.pdf> The scholars note that CMS regulations (42 C.F.R. 477.506(e)(2)) require the best-price to be calculated on a “unit basis”

[\[21\]](#) While value-based purchasing can be used for any drug, it

is only likely to be worth the administrative hassle of negotiating effectiveness thresholds and money-back mechanisms for high-cost drugs. Furthermore, it is likely to be limited to drugs that are not widely used in Medicaid programs so that companies do not risk large financial losses if their programs are found to violate the “best-price” rule.

[\[22\]](#)

<https://www.cms.gov/newsroom/press-releases/cms-approves-state-proposal-advance-specific-medicaid-value-based-arrangements-drug-makers>

and

<https://www.medicaid.gov/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/OK/OK-18-08.pdf>

[\[23\]](#) Ibid. SRAs are exempt from the Medicaid best price requirement under 42 CFR 447.505(c)(7).

[\[24\]](#)

<https://www.medicaid.gov/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/MI/MI-18-0009.pdf>

[\[25\]](#)

<https://www.forbes.com/sites/joshuacohen/2018/09/04/medicaid-to-introduce-value-based-drug-pricing/#719defeb3234>

[\[26\]](#) Spread pricing is a common practice in which the PBM charges an insurer more for a drug than they pay to a pharmacy to fill a prescription. For a more detailed discussion, see <https://www.bloomberg.com/graphics/2018-drug-spread-pricing/> and <https://www.drugchannels.net/2016/01/solving-mystery-of-employer-pbm-rebate.html>.

[\[27\]](#) SB 130 Act 483 at §1648 (3).

[\[28\]](#)

<https://www.healthtransformation.ohio.gov/Portals/0/Press%20Rele>

ases/PBM%20HDS%20Final%20Report%20Executive%20Summary.pdf?ver=2018-06-21-114617-170

[\[29\]](#)

<https://www.ajmc.com/newsroom/ohio-tells-medicaid-pbms-that-2019-will-be-a-time-for-transparent-contracts>

[\[30\]](#)

<http://wvahc.org/wp-content/uploads/Options-for-Controlling-Prescription-Drug-Spending-at-the-State-Level-6-9-2018.pdf>

[\[31\]](#) SB 5 (Act # 157) <https://legiscan.com/KY/bill/SB5/2018>

[\[32\]](#) Id at KRS 205.647 (6)(b)

[\[33\]](#) Act 193

[\[34\]](#)

<https://legislature.vermont.gov/assets/Legislative-Reports/Sec.11a-Act-193-Prescription-Drug-Cost-Savings-and-Price-Transparency.pdf>