



# Squeezing the balloon

**The changing Medicaid landscape  
and rising pharmaceutical costs**

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# Introduction

The growth in U.S. pharmaceutical expenditures in recent years has consistently outpaced that of total healthcare spend by several percentage points.<sup>1</sup> Although the growth in prescription drug expenditures has slowed down somewhat since 2016, many stakeholders worry that without correction, pharmaceutical spend could comprise as much as 40 percent of health plan spend in the foreseeable future.<sup>2,3</sup> A large portion of the growth in pharmaceutical spend is expected to come from specialty and high-cost developments such as gene therapies and increasingly advanced treatments for cancers, hemophilia, hepatitis, and diabetes.<sup>4</sup> With the publication of its recent Blueprint, the U.S. Department of Health and Human Services (HHS) has turned the spotlight on the rising drug prices and proposes a series of actions to stem cost growth through improved competition, a better negotiation position for purchasers, lower list prices, and lower out-of-pocket costs.<sup>5</sup>

In Medicaid, the cost of prescription is growing even faster than national rates. In the same year (2014) that national prescription spending increased by 12.2 percent, drug spend in Medicaid ballooned by double that: 24.3 percent.<sup>6</sup> With pressure on states to control healthcare cost growth only likely to increase, curtailing the continuous progression of pharmaceutical costs has become a key priority for many state administrations.

This issue brief explores a series of strategies that state Medicaid programs could consider to curb the growth in pharmaceutical spending. The strategies are a mix of changes to existing approaches and new ideas based on leading practice examples from the United States as well as globally. Where applicable, the brief draws a parallel to the approaches proposed by HHS in its “Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs,” released in May 2018.<sup>7</sup>

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<sup>1</sup> Centers for Medicare & Medicaid Services, “National Health Expenditures 2016 Highlights,” available through CMS.gov.

<sup>2</sup> Reid Rasmussen, “5 trends driving change in health care,” March 9, 2016, available through Benefitspro.com.

<sup>3</sup> The U.S. Department of Health and Human Services, “American Patients First. The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs,” May 2018.

<sup>4</sup> Kathleen Gifford, et al., “Medicaid Moving Ahead in Uncertain Times: Results from a 50-State Medicaid Budget Survey for State Fiscal Years 2017 and 2018,” October 19, 2017.

<sup>5</sup> Ibid.

<sup>6</sup> Anne B. Martin, et al., “National Health Spending In 2014: Faster Growth Driven By Coverage Expansion And Prescription Drug Spending,” *Health Affairs*, 2016;35(1),150-160.

<sup>7</sup> Department of Health and Human Services, Office of the Secretary, HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, A Notice by the Health and Human Services Department on 05/16/2018.

# Improving state negotiation positions through better insights and collaboration

One strategy that is receiving increased attention is the idea of improving state negotiating power through aggregate or bulk purchasing of pharmaceutical products. At the date of writing this brief, there are three multistate Medicaid drug pools: the National Medicaid Pooling Initiative (NMPI – vendor owned), the Top Dollar Program (TOP\$ – vendor owned), and the Sovereign States Drug Consortium (SSDC – owned by the state administrations). One potential drawback of participation in a multistate consortium is that it may limit an individual state’s ability to negotiate rebates on specific products, although many states, New York being a good example, mix and match their multistate and single-state rebate agreements for their fee-for-service recipients.<sup>8</sup>

Even in the absence of a multistate purchasing agreement, states would be well advised to improve their control over pharmaceutical spend by ramping up their ability to obtain insights through benchmarking and measuring total per member per month (PMPM) spend on pharmacy. While many states focus on either price controls or volume controls per product, it has been difficult to find examples of states that systematically review and compare key operational and financial metrics in their pharmacy spend, such as the metrics presented in Table 1. Only 16 states and territories to date have utilized the support of the Medicaid Innovation Accelerator Program<sup>9</sup> to focus on data and analytics in Medicaid. It is an option more states could consider when pursuing a more hands-on approach to obtaining systematic and data-driven insights into pharmacy spend.

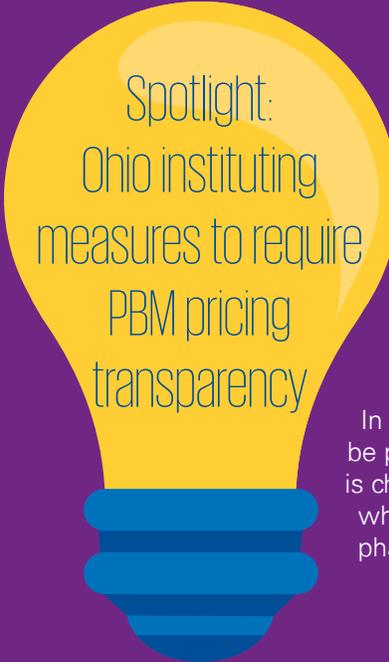
**Table 1:** Pharmacy Benchmarks – example metrics

Operational Metrics:	Financial Metrics:
Headcount of resources dedicated to Pharmacy	Cost per script
Scripts per member per year	Cost PMPM
Aggregate mix of generic/specialty scripts	Cost as a percentage of total health benefits
Frequency of review of members with high utilization of pharmacy scripts	

<sup>8</sup> National Conference of State Legislators, Pharmaceutical Bulk Purchasing: Multistate and Inter-agency Plans. Published online June 1, 2018.

<sup>9</sup> Medicaid.gov Web site: Innovations Accelerator Program, Data Analytics support. <https://www.medicaid.gov/state-resource-center/innovation-accelerator-program/iap-functional-areas/data-analytics/index.html>

Over half of the states (26) have delegated the management of their Medicaid program to managed care organizations (MCOs). With the risk of managing total costs, including pharmacy, in the hands of the MCO, there is a lesser tendency for the state to need to get involved directly negotiating and managing pharmacy costs. However, seven of the managed care states are still administering pharmacy benefits themselves—although the potential cost-saving effect of the pharmacy carve-out is disputed—with Kentucky and Ohio being the latest to add themselves to the list of states seeking to take back the management of Medicaid drug benefits into their own hands.<sup>10</sup>



Spotlight:  
Ohio instituting  
measures to require  
PBM pricing  
transparency

Starting January 1, 2019, Ohio Medicaid will require that Managed Care plans only engage in contracts with pharmacy benefit managers (PBMs) that adhere to prescribed and transparent pass-through pricing models. PBMs will only be allowed to charge Medicaid exactly what it pays the pharmacy for the prescription drug and a dispensing fee, along with an administrative fee.

In addition, any rebates and discounts must be passed back to the state. Currently, what is charged by the PBM may be different than what it pays the pharmacy and what the pharmacy charges clients.

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<sup>10</sup> Kentucky Senate Bill 5, AN ACT relating to pharmacy benefits in the Medicaid program. (Passed) April 13, 2018—signed by Governor (Acts, Ch. 157). Copy can be downloaded from: <https://legiscan.com/KY/text/SB5/id/1773425/Kentucky-2018-SB5-Draft.pdf>

# Tackling rebates and prices

Strategies that address the cost per individual drug type of category remain among the most popular approaches for states looking to curb pharmacy spending. Rebates are one of the most common leveraged price management tools, with 47 states and the District of Columbia entering into single and/or multistate supplemental rebate agreements as of March 2018.<sup>11</sup> Almost as popular as rebates is the use of reference pricing, currently in use by 45 states.

In fiscal year 2016, Medicaid programs spent \$61 billion on prescription drugs, although significant rebates from drug manufacturers lowered net spending to \$30 billion.<sup>12</sup> States looking to get more out of their rebate strategies may consider adjusting their rebate formula to determine Average Manufacturer or Best Price determinations as suggested in the HHS Blueprint. Alternatively, states may consider increasing the involvement of their Drug Utilization Reviews (DUR) in the rebate process. All states are, by law, required to implement a DUR. However, the extent to which states leverage their DUR approaches to help generate savings differs across the country. In New York, a Drug Utilization Review Board (DURB) helps the state evaluate and negotiate additional rebates from manufacturers where cost growth in certain drugs threatens the annual global spending cap.<sup>13</sup>

In addition to rebate strategies, states may focus on reference pricing strategies by capping drug prices at a Maximum Allowable Cost (MAC) based on substitutes and limiting prices of multiple-sourced drugs in addition to the Federal Upper Limit.<sup>14</sup> There exists strong evidence of the success of MAC in reducing pharmaceutical spending

without altering health outcomes in Medicaid programs.<sup>15</sup> States have the option to change the formulas employed in reference pricing approaches. These include:

- 1** Employing more aggressive MAC pricing formulas, including “least of” factors such as National Average Drug Acquisition Cost and Usual and Customary pricing. This includes reviewing when a dispensing fee (typically \$10 or more) per filled prescription will be applied based on pricing type, a mechanism already structured into Wyoming’s Drug Reimbursement plan—a tactic that, according to research, could save other states as much as 20 percent on their own spending on generic drugs.<sup>16,17</sup>
- 2** Easing the restrictions on classifications of substitutes means more savings can be achieved by deploying less restrictive classification definitions, although the methods and the parties who determine therapeutic equivalence remain a topic of debate among industry and policy-maker stakeholders. Applications of this philosophy may support the use of indication based-pricing, which is discussed later in the brief.

A third pricing strategy for states to consider is to enter into longer-term price agreements with manufacturers. The HHS Blueprint discusses the potential for long-term financing models to help states with managing the costs of new high-cost drugs unexpectedly hitting the market by spreading payments over multiple years.

<sup>11</sup> Centers for Medicare & Medicaid Services, “Medicaid Pharmacy Supplemental Rebate Agreements (SRA), as of March 2018” (2018),

<sup>12</sup> Medicaid and CHIP Payment and Access Commission, “Medicaid Gross Spending and Rebates for Drugs by Delivery System, FY 2016 (millions)” (2017).

<sup>13</sup> The PEW Charitable Trust, “New York’s Medicaid Drug Cap: A look at the state’s new effort to manage pharmaceutical spending,” April 2, 2018. Published on PEW Web site: <http://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2018/04/new-yorks-medicaid-drug-cap#5-endnotes>

<sup>14</sup> Multiple-sourced drugs are drugs for which there is at least one drug product that is rated as therapeutically equivalent, is pharmaceutically equivalent and bioequivalent, as determined by the FDA.

<sup>15</sup> Joy Li-Yueh Lee, et al., “A Systematic Review of Reference Pricing: Implications for US Prescription Drug Spending,” *The American Journal of Managed Care*, 2012, 18(11) e429-e437.

<sup>16</sup> Daniel Levinson, “Medicaid Drug Pricing in State Maximum Allowable Cost Programs,” August 2013, available through [Oig.hhs.gov](http://Oig.hhs.gov).

<sup>17</sup> Medicaid.gov, Medicaid Covered Outpatient Prescription Drug Reimbursement Information by State, Quarter ending March 2018.

# Managing volumes and utilization controls

On the other side of the coin to price controls are controls over the volume or type of pharmaceutical products that are paid for out of state budgets. At present, nearly all states employ the use of preferred drug lists (PDL) in their fee-for-service programs as a tool to drive utilization towards drugs on the PDL (as opposed to the higher priced, nonpreferred drugs) and increase negotiating leverage against drug manufacturers for lower prices and higher rebates. For Medicaid Managed Care, only 15 states at present require that the MCOs adhere to a uniform PDL with at least four other states looking to introduce similar requirements in 2018.<sup>18</sup>

More stringent than the use of PDLs is the installment of closed formularies that limit the access to certain drugs altogether. The Veterans Health Administration (VHA) implemented a national closed formulary in 1997 and was able to effectively shift prescribing behavior toward the selected drugs on the closed formulary, achieve sizable price reductions from manufacturers, and a decrease in average price per pill of 25 percent.<sup>19</sup> Common concerns with closed formularies include limiting patients' access to necessary medicines with potential increases to inpatient care utilization.<sup>20</sup> MassHealth's proposed 1115 waiver request to set up a closed formulary was recently denied by Centers for Medicare & Medicaid Services (CMS), making this an avenue that will likely be difficult to pursue for other states thinking of a similar approach.<sup>21</sup>

Also in the category of volume controls are drug caps and the enforcement of prescription guidelines. While very effective at achieving cost savings, care must be taken in a drug cap approach to not overly restrict patient access to necessary treatments and to make sure short term cost gains are not achieved at the expense of longer-term care outcomes. States have various criteria for consideration to implement a drug cap such as:

-  Total dollar amount per member
-  Number of prescriptions per member
-  Number of drug claims per member
-  Days supply per member per drug class

In the wake of the opioid crisis, states are increasingly turning to forms of prescription and utilization management to control the amount of opioid-related harms. In a recent Kaiser Family Foundation survey held in 2017, all states but Hawaii reported having some form of opioid management strategy in place in their fee-for-service programs. Nearly three-quarters of states (37) reported the intent to implement at least one volume-tackling action on opioids in 2018 and 11 states have or will require that Medicaid MCOs adopt Centers for Disease Control and Prevention opioid prescribing guidelines. Examples include applying day-limits, or maximum morphine equivalent limits to opioid prescriptions, and automated clinical criteria claim system edits.<sup>22</sup>

<sup>18</sup> Kaiser Family Foundation, "States Reporting Managed Care Pharmacy Uniform Preferred Drug List (PDL) Requirements," October 19, 2017, available through [kff.org](http://kff.org).

<sup>19</sup> Haiden Huskamp, Arnold Epstein, and David Blumenthal, "The Impact Of A National Prescription Drug Formulary On Prices, Market Share, And Spending: Lessons For Medicare?," *Health Affairs*, 2003;22(3), 149–158.

<sup>20</sup> Patrick Ross, "Could a Medicaid closed formulary work?," October 13, 2017, available through [Healthcareinamerica.us](http://Healthcareinamerica.us).

<sup>21</sup> Insights Article, "CMS Rejects Massachusetts' Medicaid Closed Formulary Proposal," July 3, 2018.

<sup>22</sup> Gifford, et al., "Medicaid Moving Ahead in Uncertain Times: Results from a 50-State Medicaid Budget Survey for State Fiscal Years 2017 and 2018"

# New value-based approaches

With pressures to decrease the cost growth of brand-name drugs, the pharmaceutical industry has started to respond by offering outcome-based or other forms of performance-based contracts in which either the price or the rebate levels are tied to specific outcomes, results, or degree of clinical effectiveness. While many states are currently already working on forms of cost-sharing such as kick payments and drug carve-outs, these forms of risk-sharing are not necessarily tied to the actual outcomes or “value” of care provided.<sup>23</sup> In the commercial market space and abroad, several examples exist of performance (or value) based agreements in pharmacy for states to consider and draw from (see Table 2). Although the prospects for performance-based contracting are promising, it is not suitable for every type of treatment. Before deciding whether to apply this payment method, there are two essential preconditions for a drug or therapy:<sup>24</sup>

- 1 Measurable outcomes:** Measurable outcomes for the population being treated by a drug or therapy must exist, and these outcome measures should have at least a significant correlation with the drug product use.
- 2 No generic alternatives available:** If there are generic versions of the product already on the market—or soon to be available—the product is competing with other products on costs only rather than outcomes, reducing the relevance of the concept of value or performance.

In order to secure value-based contracts within Medicaid, access to the right data and the ability to track, measure, and compare the necessary outcome measurements is key.

<sup>23</sup> Ibid.

<sup>24</sup> Van den Heuvel, R., et al. “Value-based pricing in pharmaceuticals – hype or hope?,” KPMG, October 24, 2016.



**Table 2:** Examples of performance-based agreements used by the pharmaceutical industry in the United States and abroad

Product	Targeted disease state	Country	Description of performance-based arrangement
Repatha (Amgen) and Praluent (Sanofi/Regeneron)	Hyper-cholesterolemia	United States	In mid 2017, Amgen signed a money-back guarantee with the Harvard Pilgrim health plan: if a patient on Repatha has a heart attack or stroke, the drug maker will provide a full refund. <sup>25</sup> Earlier, in 2016, Cigna inked agreements with both Amgen and Sanofi/Regeneron for increased discounts if the drugs fail to achieve LDL cholesterol reductions equal to those achieved in clinical trials. <sup>26</sup>
Enbrel (Amgen)	Rheumatoid arthritis	United States	In early 2017, Amgen and Harvard Pilgrim Healthcare entered into an agreement in which payment for Enbrel is linked to performance on a number of measures including patient compliance. <sup>27</sup>
Valsartan (Novartis)	Lowering BP	Denmark	In 2004, Novartis started the first “No cure, no pay” initiative in Europe. It came with a money back guarantee if Valsartan was not effective. <sup>28</sup>
Pazopanib (GSK)	Advanced Kidney Cancer	United Kingdom	In 2010, GSK offered a rebate if Pazopanib performed inferior to other drugs in a head-to-head trial. <sup>29</sup>

Based on the HHS Blueprint, the new Administration places high hopes on the ability of value-based payment (VBP) reforms to help cut drug costs while maintaining access and standards of care. In June 2018, CMS approved Oklahoma’s state plan amendment to use its supplemental rebate agreements with manufacturers to engage in VBP.<sup>30</sup> With details of the arrangement yet to be released, it is unclear what Oklahoma’s VBP approach entails and whether it emulates what is described in the Blueprint

as “indication-based payment” or whether it employs a different approach. Indication-based payment would look to move towards paying different prices for the same drug based on its efficacy for different indications.

While it is not clear exactly what type of VBP CMS is most likely to approve, it is clear that the Administration is supportive of new value-based approaches to pharmacy reimbursement and is willing to assist state experiments in this space.

<sup>25</sup> Eric Sagonowsky, “Amgen puts Repatha outcomes data to work in refund deal with Harvard Pilgrim,” *FiercePharma*, May 3, 2017.

<sup>26</sup> Tracy Staton, “Cigna inks results-based deals on pricey Amgen, Sanofi PCSK9 meds,” *FiercePharma*, May 11, 2016.

<sup>27</sup> Eric Palmer, “Amgen strikes Enbrel ‘outcomes’ contract with Harvard Pilgrim,” *FiercePharma*, February 22, 2017.

<sup>28</sup> C. Møldrup, “No cure, no pay,” *BMJ: British Medical Journal*, 2005;330(7502), 1262–1264.

<sup>29</sup> Reuters Staff, “GSK offers UK rebate if Pfizer cancer drug better,” December 23, 2010, available through Reuters.com.

<sup>30</sup> Health and Human Services, Letter to Becky Pasternik-Ikard. June 27, 2018.



Spotlight:  
Payment for results  
and risk-based  
pharmacy  
contracts  
in Italy

The Italian health system is a largely public system that is composed of several agencies including the Agenzia Italiana del Farmaco (AIFA)—the Italian pharmacy agency. Starting in 2006, the AIFA commenced administering a series of performance-based risk-sharing arrangements in an effort to curb growing pharmaceutical costs as part of the national health budget. Between 2006 and 2010, several products were subjected either to “pay by results” agreements or other forms of “risk-sharing.”

In the “pay by results” agreements, the manufacturer does not receive any reimbursement in the cases where patients do not respond to treatment.<sup>31</sup> For example, Pirfenidone (a product manufactured by InterMune under the brand name Esbriet), used to treat idiopathic pulmonary fibrosis, is only paid for if less than 10 percent decline is measured in forced vital capacity six months after treatment initiation.<sup>32</sup>

In “risk-sharing” arrangements, the height of the reimbursement is scaled according to the measured clinical effectiveness rather than a “no cure, no pay” approach. Depending on the effectiveness, the levels of risk experienced by manufacturers may be similar to “pay by results” approaches. For example, with Panitumumab (active ingredient in therapies used to treat metastatic colorectal cancer), the manufacturer is required to payback 50 percent of the cost for nonresponders (evaluation after two months of treatment).

Between 2006 and 2012, the financial impact of the “pay by results” agreements varied heavily by product, ranging between 0.03% reimbursement of total costs by the manufacturer for nonresponders to almost 70 percent of total costs reimbursed.

<sup>31</sup> Livio Garattini and Gianluigi Casadei, “Risk sharing agreements: What lessons from Italy?,” *International Journal of Technology Assessment in Health Care*, 2011;27(2) 169–172.

<sup>32</sup> Navarria, et al., “Do the Current Performance-Based Schemes in Italy Really Work? “Success Fee”: A Novel Measure or Cost Containment of Drug Expenditure,” *Value in Health*, 2015;18(1), 131–136.

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