State Medicaid Programs are a Tool to Address Rising Drug Costs

Rising prescription drug prices concern nearly all Americans, with 80% reporting that drug prices are "unreasonable". The problem of rising drug expenditures is particularly acute for state Medicaid programs, which provide health coverage for low-income and disabled Americans. 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] Furthermore, Medicaid's nationwide drug spending increased almost 50% between 2013 and 2016 (from $22.4 billion to $33.4 billion).[2] In a survey of Medicaid programs, 36 states reported increased cost containment efforts for prescription drugs for 2018. In response to escalating drug expenditures, two states —Massachusetts and New York— are testing novel ways to provide cost-effective medications to their Medicaid beneficiaries. This post details the specifics on those two programs and finds that if either program successfully controls prescription drug spending, many states will likely follow their examples.

Current Medicaid Prescription Drug Coverage

Although technically optional, all states provide coverage for prescription drugs through their Medicaid program.[3] In order to receive coverage for a prescription drug, manufacturers must enter into a Medicaid National Drug Rebate Agreement with the Centers for Medicaid and Medicare Services (CMS). This agreement requires manufacturers to give the state rebates when the state purchases a drug to ensure that Medicaid receives the "best price."[4] In exchange, Medicaid must cover essentially any FDA-approved drugs covered by the agreement, including multiple drugs in each drug category. States can negotiate additional, supplemental rebates with manufacturers, but the requirement to cover nearly all prescription medications means that Medicaid can't employ closed formularies to control costs the way that private insurers can.

Private insurers typically use pharmacy benefit managers (PBMs) to negotiate deep discounts to drug prices in exchange for preferred placement on a formulary. When a drug has preferred placement over other drugs in the therapeutic category, it will be used by more patients, so PBMs have significant leverage when using closed formularies in a negotiation. Federal law allows Medicaid programs to create a Preferred Drug List (PDL), which are drugs that do not require preapproval for coverage and typically include cheaper drugs or those for which the state negotiated supplemental rebates, but they are not allowed to use a closed formulary. States must provide access to all prescription drugs for which the manufacturer entered into a rebate agreement with CMS, although they are allowed to use preapproval requirements and limit coverage to medically accepted indications.[5] With the legal requirement to cover almost all prescription drugs, the Medicaid program has very little leverage to negotiate better prices.

Massachusetts Waiver Application to Use a Drug Formulary in Medicaid

In September 2017, Massachusetts, a leader in state health reform efforts, attempted to change this limitation and submitted a Section 1115 Waiver to CMS requesting permission to use a closed formulary in its Medicaid program. In the waiver application, Massachusetts noted that drug spending in MassHealth, the state Medicaid program, increased 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] According to the application, MassHealth will ensure that at least one drug option exists in each therapeutic class and maintain a process by which patients can apply for a medical exception for specific clinical needs. In addition, MassHealth asked to exclude "drugs with limited or inadequate evidence of clinical efficacy" from the formulary.

Following Massachusetts' lead, Arizona submitted a letter to CMS in December 2017, signaling its intention to submit a Section 1115 waiver that also requests a closed formulary. Arizona would model its formulary requirements after those allowed in Medicare Part D plans, i.e., at least two drugs per drug category or class, unless (1) only one drug is available for a particular drug category or class, or (2)

only two drugs are available in a category or class but one drug is clinically superior to the other.

Legal experts question whether CMS has the legal authority to waive the drug coverage mandate without also waiving the rebate mandate, and others expect CMS to reject Massachusetts' waiver application. According to news reports, U.S. Health and Human Services Secretary Alex Azar believes allowing a waiver that permits a closed formulary would allow drug manufacturers to successfully sue the United States, and that approving the Massachusetts waiver would open the floodgates to all states that wish to follow similar cost containment programs. Nonetheless, Massachusetts' waiver application demonstrates the state's willingness to try novel ways to control prescription costs without jeopardizing access to necessary prescriptions for some of the neediest patients.

New York's Global Medicaid Budget

While states await the outcome of Massachusetts' application, New York took a different approach to control prescription drug spending. Beginning in 2011, New York instituted a cap on total Medicaid spending, and in January 2017, budget bill S2007B made New York the first state in the nation to adopt an annual cap on Medicaid *prescription drug* spending.[7] The cap ties Medicaid's total spending on prescription drugs to the rate of medical inflation.[8] If New York's Department of Health (DoH) projects Medicaid spending will exceed the limit, the state Commissioner of Health will 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 then negotiate supplemental rebates from manufacturers of drugs that are "priced disproportionately to …[their] therapeutic benefits."[9]

The first test of the new process occurred in April 2018. In a unanimous vote, the state DUR authorized the DoH to negotiate with Vertex Pharmaceuticals about supplemental rebates for Orkambi, a cystic fibrosis drug, which has an annual price tag of $272,000.[10] Because of the statutory requirement that Medicaid receive at least 23.1% in rebate, New York's Medicaid program pays less than a total of

$209,000 a year for this drug.[11] After a cost-effectiveness review, including input from the independent Institute for Clinical and Economic Review (ICER),[12] the DUR Board recommended that Medicaid pay less than $57 per unit, or the equivalent of $83,200 per year.[13] Whether the state is able to demand these additional rebates from Vertex for Orkambi is particularly significant. Specifically, because Orkambi is the only drug in its class, with no therapeutic equivalents, it must be included on any Medicaid formulary.

Understandably, as this negotiation is the first under New York's new budget cap, Vertex is unyielding in negotiations. In an interview with STAT, Vertex spokesperson said that "[o]ur cystic fibrosis medicines are the first and only medicines to treat the underlying cause of this devastating disease and … the price of our medicines reflect the significant value they bring to patients. This law was never intended to apply to medicines like Orkambi, and we do not believe an additional rebate is warranted."[14] If Vertex and the DoH do not reach an agreement regarding supplemental rebates, the DoH can demand internal information from Vertex to better understand how the company set the price for the drug. The DoH must keep the information confidential, but if, after reviewing the material, they believe the cost of the drug exceeds the benefits, the state can implement additional measures to limit use of the drug, including subjecting the drug to preapproval processes and allowing Medicaid managed care programs to not cover the drug.[15]

New York's cap on spending in Medicaid represents one of the first times purchasers have power to negotiate with a manufacturer with monopoly power for a drug without therapeutic substitutes. When a manufacturer has monopoly pricing power, traditional methods for increasing competition are often ineffective and purchasers have little ability to negotiate better prices with them.[16] For example, under the Massachusetts' waiver approach, even if approved, the state would have little negotiating power with the manufacturer. New York's budget cap gives the state some bargaining leverage to negotiate with manufacturers that set exorbitantly high prices for drugs without therapeutic substitutions.

States are Trying a Multitude of Solutions for Rising Drug Costs

In the past two legislative sessions, forty-eight states have introduced legislation to rein in the cost of prescription drugs.[17] States that adopted new laws, however, including Nevada, California, and Maryland, faced significant legal challenges from industry groups. In particular, the 4th Circuit Court of Appeals recently found, in a 2-1 decision, that Maryland's law is unconstitutional because it violates the dormant commerce clause.[18] While it remains unclear whether states will be successful at enacting legislation to control drug prices, any state seeking solutions to escalating drug expenditures should expect a long and expensive legal fight with industry.

In the midst of this legal quagmire, Massachusetts and New York suggested novel solutions to rising drug prices. Both states modified (or asked for permission to modify) their Medicaid program to more effectively negotiate with drug manufacturers. These programs only apply to Medicaid beneficiaries, but they reflect a larger desire to provide access to lifesaving medications at prices that reflect their value. If Massachusetts and New York successfully reduce prescription drug spending in Medicaid, other states will undoubtedly follow their example. While legislative solutions may provide a more comprehensive approach to controlling drug prices as they apply to all state residents, states can use their Medicaid programs to reduce the amount of state tax revenue spent on prescription medications and take a first step toward reining in the cost of essential drugs.

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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] Medicaid.gov. **Prescription Drugs.** https://www.medicaid.gov/medicaid/prescription-drugs/index.html. Accessed

May 7, 2018.

[4] "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.

[5] Young K and Garfield R. **Snapshots of Recent State Initiatives in Medicaid Prescription Drug Cost Control**. Kaiser Family Foundation. February 21, 2018. Available from: https://www.kff.org/medicaid/issue-brief/snapshots-of-recent-state-initiatives-in-medicaid-prescription-drug-cost-control/.

[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] Silverman E. **New York panel votes to lower the cost of a pricey Vertex drug for cystic fibrosis**. STAT. April 26, 2018. Available from: https://www.statnews.com/pharmalot/2018/04/26/new-york-vertex-cystic-fibrosis-price/?utm_source=STAT+Newsletters&utm_campaign=a6fa3382f2-Pharmalot&utm_medium=email&utm_term=0_8cab1d7961-a6fa3382f2-150326049.

[8] 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.

[9] New York Public Health Law § 280.4.

[10] Niedzwiadek N and Goldberg D. **State board recommends supplemental rebate for cystic fibrosis drug**. Politico. April 26, 2018. Available from: https://www.politico.com/states/new-york/albany/story/2018/04/26/state-board-recommends-supplemental-rebate-for-cystic-fibrosis-drug-387847.

[11] Since states are allowed to negotiate for prices better than Medicaid's federally mandated price, the actual amount that New York's Medicaid program pays for the drug is unknown.

[12] Institute for Clinical and Economic Review (ICER). **Cystic Fibrosis.** https://icer-review.org/topic/cystic-fibrosis/. Draft scoping document available from: https://icer-review.org/material/cf-draft-scope/.

[13] Silverman 2018.

[14] Silverman 2018.

[15] Helgerson JA. **Medicaid Drug Cap Webinar**. New York State Department of Health, Office of Health Insurance Programs. August 31, 2017. Available from: http://freepdfhosting.com/d4debb5eed.pdf.

[16] Scott Morton F and Boller LT. **Enabling Competition in Pharmaceutical Markets**. https://www.brookings.edu/wp-content/uploads/2017/05/wp30_scottmorton_competitioninpharma1.pdf.

[17] National Academy for State Health Policy (NASHP). **State Legislative Action on Pharmaceutical Prices**. Updated May 1, 2018. https://nashp.org/state-legislative-action-on-pharmaceutical-prices/.

[18] Ass'n for Accessible Medicines v. Frosh, 887 F.3d 664 (4th Cir. 2018). Available from: http://www.ca4.uscourts.gov/Opinions/172166.P.pdf.