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The Other Medicaid Drug Rebate News: Oklahoma's State Plan Amendment Approved

OKLAHOMA'S REQUEST TO IMPLEMENT VALUE-BASED DRUG REBATES APPROVED

On June 27, 2018, the Centers for Medicare & Medicaid Services (CMS) approved a state plan amendment (SPA) authorizing Oklahoma's Medicaid program to enter into value-based purchasing arrangements with drug manufacturers. The new SPA permits the state to negotiate supplemental drug rebates based on performance and outcome benchmarks as part of a value-based contract, which the state of Oklahoma and drug manufacturers may enter into voluntarily. The new rebate program is in addition to the federal rebate program and the state's supplemental rebate program, both of which are based on a drug's utilization versus performance.

Oklahoma's Medicaid program will implement any value-based contract based on the model agreement entitled "Value-Based Supplemental Rebate Agreement," proposed to CMS on March 29, 2018 and authorized retroactively for use as of January 1, 2018.[1]

CONTEXT

U.S. Department of Health and Human Services (HHS) Secretary Alex Azar, whose priorities include lowering drug costs and advancing value-based payments, commented that the SPA "is an important example of how states can innovate to bring down drug costs."[2] The Trump administration's support for value-based purchasing of drugs is also reflected in the administration's blueprint for lowering drug prices and reducing out-of-pocket costs, "American Patients First."

CMS's approval of Oklahoma's SPA was announced on the same day that the agency denied Massachusetts' proposal to use a formulary to exclude certain drugs from its Medicaid program. But the denial was not a complete rejection of the proposal. In CMS's response to Massachusetts, the agency noted that they were responding to "a number of additional flexibilities on which CMS continues to work with the state and that CMS is not approving *at this time*" (emphasis added); further, that "CMS supports the State's goal of lowering drug costs and will continue to provide technical assistance on options to test innovative drug coverage mechanisms."

The chart below provides a comparison of the two proposals and CMS's rationale concerning each.

[1] https://www.medicaid.gov/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/OK/OK-18-08.pdf
[2] https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2018-Press-releases-items/2018-06-27.html

Comparison of Drug Pricing Proposals: Oklahoma vs Massachusetts			
	Oklahoma	Massachusetts	CMS Actions on Drug Pricing
Proposal	Authorizes the state to pursue select drug supplemental rebates using performance- and outcomes-based benchmarks, in addition to the current Medicaid drug rebate program.	Authorizes the state to implement a commercial-style closed formulary. The formulary would ensure at least one medication per therapeutic class is available,[3] but enable the state to exclude drugs with limited treatment value from Medicaid.	• CMS approved Oklahoma's proposed State Plan Amendment (SPA) for outcomes-based supplemental rebates. • CMS denied Massachusetts' 1115 Waiver proposal for a drug formulary under the demonstration.
Type of Model	Voluntary	Restrictive	• Oklahoma's SPA allows the state to voluntarily enter into supplemental rebate agreements with manufactures. • Massachusetts proposed a model that would have restricted overall access to certain drugs.
Impact on Medicaid Drug Rebate Program	Retains core elements of Section 1927 of the Social Security Act (SSA) [4,5,6]	Waived key portions of Section 1927 of the SSA	• Massachusetts submitted a request for a waiver of 1902(a)(54) to the extent that is incorporates certain rules in section 1927. CMS noted that by only waiving certain sections of 1927, the waiver would have enabled the state to continue to collect manufacturer rebates under Section 1927, while excluding certain drugs from coverage. Because this proposal waived only a select provision within Section 1927 and did not address the current arrangement that rebates guarantee access, the proposal was rejected. CMS noted that waiving "guaranteed access" would require the state to waive the entire federal drug rebate program, which would also have required the state to renegotiate all its drug rebates.
Selection Process for Drugs	Those drugs for which outcomes can be determined relatively quickly, and for which the state and manufacturers can reach agreement on a supplemental rebate.	Those drugs that meet the clinical needs of the vast majority of members and are cost effective based on the state's own review process.	• Oklahoma has the discretion to determine which drugs will meet its criteria for a value-based purchasing approach (likely a very limited number of outpatient drugs). • Massachusetts sought to implement its own rigorous review process, in partnership with the University of Massachusetts Medical School, to determine coverage of new drugs and exclude drugs with limited or inadequate clinical efficacy from its primary formulary.
CMS's Perspective	Approved	Denied; but CMS indicated it would work with the state to refine its approach.	• CMS noted that it would be willing to move ahead with a demonstration program for Massachusetts if the state would consider dropping the optional state plan drug coverage under section 1902(a)(54) of the SSA so that those receiving coverage under section 1902(a)(54) could obtain coverage of outpatient drugs under the expenditure authority in section 1115(a)(2).

[3] https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ma/ma-masshealth-pa3.pdf
[4] Section 1927 of the SSA speaks to the requirement for the manufacturer of covered outpatient drugs to have entered into a rebate agreement with the State. It governs the Medicaid Drug Rebate program and requires any formulary developed by a state to include all drugs that have entered into a rebate agreement, only allowing exclusion of a drug if there is no "significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment".
[5] Social Security Act § 1927(d)(4)(B)
[6] Social Security Act § 1927(d)(4)(C).

IMPLICATIONS

At a minimum, CMS's actions on Oklahoma's SPA and Massachusetts' waiver are messages for pharmaceutical manufacturers—there is federal and state interest in infusing value-based payment approaches into Medicaid pharmacy programs. Analyzing how CMS viewed these two proposals provides insight into the direction the administration wishes to pursue for innovating drug pricing approaches. Oklahoma's approach appears most consistent with CMS's stated priorities to advance the transition to value and support state flexibility through voluntary approaches. However, in a strictly voluntary program there is the question of what leverage a state might have to incentivize a manufacturer to join in an agreement with the state on supplemental drug rebates. Outcomes-based contracting for pharmaceuticals has its own hurdles, including increased data/performance tracking, choosing products with defined clinical outcomes that can be tracked in a discrete period of time, etc. These hurdles face greater challenges as states prioritize maximizing cost reductions and manufacturers attempt at maximizing market penetration.

The Massachusetts proposal was oriented around providing the state more leverage to negotiate favorable rebate agreements with manufacturers by restricting access to certain drugs. For each therapeutic class, the state could have offered manufacturers an essentially guaranteed volume in exchange for a larger rebate. Massachusetts also sought to implement its own rigorous review process to determine coverage of new drugs that had been approved through the Food and Drug Administration's accelerated approval pathway. Interestingly, Massachusetts' proposal was denied but not completely rejected. CMS indicated that it would be willing to move forward with a demonstration if the state would consider moving its Medicaid coverage of outpatient drugs from the current optional State Plan program under Section 1902(a)(54) to a new expenditure authority of the 1115(a)(2) demonstration. However, under this scenario the state would have to forgo all rebates under the federal Medicaid Drug Rebate program and negotiate directly with drug manufacturers, which would be a significant financial risk and administrative burden. CMS's statement that they look forward to continuing to work with Massachusetts to refine its approach will likely be interpreted as a further signal to drug manufacturers that the agency will seek additional ways to support state efforts to better manage their drug costs.

CMS's actions on Oklahoma's SPA and Massachusetts' waiver are likely to encourage other states to adopt innovative approaches to their pharmacy benefits and encourage manufacturers to engage in voluntary value-based payment arrangements to avoid more restrictive models in the future. The success of these initiatives will be important for HHS to hold off critics who seek more direct pressure on manufacturers.