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Mckenzie Taylor
University of Massachusetts Medical School

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Better negotiations between payers and manufacturers in an effort to reduce drug prices

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Mckenzie Taylor, PharmD
Managed Care Pharmacy Resident, Clinical Pharmacy Services



Of the four strategies identified in the blueprint, *American Patients First: The Trump Administration Blueprint to Low Drug Prices and Reduce Out-of-Pocket Costs*, better negotiations have seen a modest amount of activity at both the federal and state level. This summary focuses on the actions occurring in the public space; however, activity is happening within commercial and private sectors as well.

In August 2018, three months after the release of the blueprint, the Centers for Medicare & Medicaid Services (CMS) announced Medicare Advantage and Part D plans would be permitted to additional utilization management strategies than traditionally allowed. The new guidance allows Medicare Advantage plans the option to apply step therapy for Part B drugs, which includes those that are physician-administered.¹ Step therapy is an approach that uses less expensive options first before ‘stepping up’ to more costly alternatives. Medicare Advantage plans that apply step therapy will be able to negotiate prices for Part B drugs, while ensuring their enrollees receive the most preferred drug therapy first before progressing to other therapies. In addition, Medicare Advantage plans will have the option to cross-manage across Part B and Part D drugs.¹ That means that a Medicare Advantage plan may require a beneficiary to use a Part D drug before permitting access to a Part B therapy, or vice versa, ultimately increasing competition.

Three weeks following the Medicare Advantage step therapy announcement, CMS detailed measures for Part D plans to allow indication-based formularies.² Currently CMS requires that a Part D plan must cover all U.S. Food & Drug Administration (FDA)-approved indications for any drug on the formulary. The indication-based formulary design allows plans to limit a drug’s coverage to certain FDA-approved indications, while including alternative therapeutics for the drug’s non-covered indications. This change will begin in 2020 and beneficiaries can utilize online tools to see how indication-based formularies vary among plans before selecting a plan for that year.^{2,3} The new formulary design expands on the current utilization management strategies that include step therapy and prior authorization requirements. It is expected to be an improvement compared to the current approach of employing preferred agents as it will allow beneficiaries to have access to more drugs at lower negotiated prices. Our pharmacy team utilizes similar formulary management tools, which give clients leverage to negotiate with manufacturers.

In comparison to the actions taken by CMS since the blueprint was released, novel proposals to improve negotiation ability have been discussed at the state level for some time. Historically, Medicaid pharmacy benefits must include all FDA-approved drugs so long as the manufacturer is entered into a federal rebate agreement. Individual states can apply prior authorizations and enter into supplemental rebates in order to create ‘preferred’ status within particular pharmacologic classes.

Oklahoma and New York are examples of two states that have implemented innovative solutions to target rising drug prices. Both states acted by positioning their Medicaid pharmacy program to be able to more effectively negotiate with drug manufacturers through value-based pricing and spend capping strategies. These efforts reflect a shift seen across the payer landscape to provide access to new medications at prices that reflect their value.

In June 2018, Oklahoma submitted a state plan amendment (SPA) to CMS. The SPA outlined their proposal for supplemental rebate agreements in the form of value-based purchasing arrangements.⁴ CMS approved this proposal as an important example of innovative actions by states can to lower costs. Still in the implementation stage, Oklahoma’s proposal allows the state to work directly with pharmaceutical companies for extra rebates based on predetermined health outcomes within specific patient populations.^{4,5}

New York implemented a different approach to control drug costs by placing an annual cap on Medicaid prescription spend.⁶ Under this approach, if New York's Department of Health projects Medicaid spending will exceed the prespecified annual limit, the state Commissioner of Health can identify specific high cost drugs for review by the Drug Utilization Review Board. The Department of Health can negotiate supplemental rebates with manufacturers for these specific drugs. If the state and the manufacturer can't agree on a rebate amount, and the state determines the cost of the drug exceeds the benefits, the state can place additional measures to limit the use of that drug.^{6,7}

Since New York implemented this annual cap strategy in August 2017, it has identified 30 drugs that have contributed to exceeding the spending cap. All but one of these drugs has resulted in successful negotiations with the respective drug company.^{6,7} New York's cap on spending represents the first time a state Medicaid program, or any purchaser for that matter, could negotiate with high profile manufacturers for a drug without therapeutic alternatives.

In September 2017, Massachusetts submitted a waiver to CMS requesting permission to use a closed formulary for its Medicaid program.^{7,8} In the waiver, MassHealth ensured that at least one drug option would be covered in each therapeutic class and stated that beneficiaries could still access non-formulary drugs for specific clinical needs. Despite their attempts, CMS turned down the waiver proposal. Shortly after Massachusetts submitted its waiver, Arizona sent a letter to CMS requesting a similar closed formulary model. In contrast to the Massachusetts proposal, Arizona stated that at least two drugs per category or class would be covered.⁷ The status of this request is pending.

While no single action can tackle this issue alone, the cumulative actions taken by CMS and state Medicaid programs are a first important step in the larger agenda to provide patients with more medication choices while lowering overall drug spend.

In December, lower list prices will be the focus of our latest blog on actions being taken to reduce drug prices.

¹Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage [press release on the internet]. Baltimore (MD): Department of Health and Human Services; 2018 Aug 7 [cited 2018 Sept 7]. Available from: https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf

²Indication-Based Formulary Design Beginning in Contract Year (CY) 2020 [press release on the internet]. Baltimore (MD): Department of Health and Human Services; 2018 Aug 28 [cited 2018 Sept 7]. Available from: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/Downloads/HPMS-Memos/Weekly/SysHPMS-Memo-2018-Aug-29th.pdf>

³CMS loosens restrictions on part D drug formularies to allow indication-based coverage [press release on the internet]. Newton (MA): Questex LLC. 2018 Aug 28 [cited 2018 Sept 7].

Available from: https://www.fiercehealthcare.com/regulatory/cms-overhauls-restrictions-around-part-d-drug-formularies?mkt_tok=eyJpIjoiTURoaFlXSmtOV0pqT1RJNCIsInQiOiJCbmlpTjZHMzd1ckNrOVVmZko2WDZWk3pTMWtJQXhGZ3lmN01OaXB4VUdNNk11dFlpOSSt6d0ZLN040RjdDWHJVUGxUM1dkM201QUJQTIU2dmIXaDBwZEErU2puU1ZOZHFKSzRwM3VDN2xnZ2hjRkNkdXRvdXZHREI5TlwwNkhcL1JOIn0%3D&mrkid=71814580

⁴CMS Approves State Proposal to Advance Specific Medicaid Value-Based Arrangements with Drug Makers [press release from the internet]. Baltimore (MD): The Centers for Medicare and Medicaid Services; 2018 June 27 [cited 2018 Sept 13]. Available from:

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

⁵Feds Send Mixed Responses on States' Efforts to Control Medicaid Drug Costs [press release on the internet]. Portland (ME): National Academy for State Health Policy; 2018 July 10 [cited 2018 Sept 7]. Available from: <https://nashp.org/feds-send-mixed-responses-on-states-efforts-to-control-medicaid-drug-costs/>

⁶New York's Medicaid Drug Cap [press release on the internet]. Philadelphia (PA): Pew Charitable Trusts; 2018 Apr 2 [cited 2018 Sept 7]. Available from:

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

⁷State Medicaid Programs are a Tool to Address Rising Drug Costs [press release on the internet]. San Francisco (CA): The Source on Healthcare Price and Competition; 2018 May 8. [cited 2018 Sept 7]. Available from: <http://sourceonhealthcare.org/state-medicaid-programs-are-a-tool-to-addr...>

⁸Value-Based Purchasing for Prescription Drugs Takes a Leap Forward in State Medicaid [press release on the internet]. Pharm Exec; 2018 June 29 [cited 2018 Sept 7]. Available from: <http://www.pharmexec.com/value-based-purchasing-prescription-drugs-takes-leap-forward-state-medicaid>