



## VIA ELECTRONIC SUBMISSION

June 14, 2023

Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
Attention: CMS-2434-P  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Re: Comments to CMS-2434-P  
Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates under the Medicaid Drug Rebate Program

The Center for Children and Families (CCF), part of the Health Policy Institute at the McCourt School of Public Policy at Georgetown University, is an independent, nonpartisan policy and research center that conducts research, develops strategies and offers policy solutions to improve the health of America's children and families, particularly those with low- and moderate-incomes. Thank you for this opportunity to make the following comments to the Centers for Medicare & Medicaid Services (CMS) proposed rule.

*We support all provisions of the proposed rule but we especially support three aspects of the proposed rule: (1) the proposed drug pricing survey for manufacturers of certain high-cost drugs; (2) the proposed contractual requirements related to pharmacy benefit managers and Medicaid managed care plans; (3) and the proposed clarification of how manufacturers must stack applicable discounts in determining best price.* However, we also recommend that for future rulemaking, CMS should consider exercising its authority to institute drug pricing surveys of a sample of manufacturers each year to better verify the accuracy of the specific pricing information, such as Average Manufacturer Price and best price, that manufacturers must report under the Medicaid Drug Rebate Program (MDRP). This could have the effect of improving manufacturer compliance and leading to greater rebate amounts that reduce federal and state Medicaid prescription drug costs over time.

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As noted above, we support all provisions of the proposed rule, some of which involve conforming to enacted legislation related to the MDRP such as section 6 of the Medicaid

Services Investment and Accountability Act of 2019 (P.L. 116-16) and section 9816 of the American Rescue Plan Act of 2021 (P.L. 117-2). Others are highly technical revisions related to MDRP administration and compliance. Our comments focus on three provisions of the proposed rule: the proposed drug pricing survey for manufacturers of certain high-cost drugs, the proposed contractual requirements related to pharmacy benefit managers and Medicaid managed care plans, and the proposed clarification of how manufacturers must stack applicable discounts in calculating best price. We strongly believe these provisions are especially sound and should be finalized as-is.

*Proposal to Establish a Drug Price Verification Survey Process of Certain Reported Covered Outpatient Drugs (§ 447.510)*

Under longstanding authority under section 1927(b)(3)(B) of the Social Security Act, as well as the general obligation under section 1902(a)(30)(A) to ensure that Medicaid payments are consistent with efficiency, economy and quality of care, the proposed rule would amend 42 C.F.R. § 447.510 to add a new subparagraph (k) that establishes a new mandatory survey of drug manufacturers for certain high-cost covered outpatient drugs (CODs) each year. There would be a multi-step process in selecting the 3-10 high-cost drugs subject to the survey. First, CMS would identify high-cost outpatient prescription drugs based on highest drug spending per claim, highest total Medicaid drug spending, highest one-year price increase or highest launch price. Second, CMS would then exclude drugs for which a manufacturer is currently participating in CMS drug pricing programs or initiatives such as Medicare drug negotiation under the Inflation Reduction Act and the new Center for Medicare and Medicaid Innovation (CMMI) demonstration related to cell and gene therapies.<sup>1</sup> It would also exclude drugs for which at least half of states have negotiated supplemental rebates that effectively result in greater-than-average total rebates. Third, CMS would further narrow the list by considering state input regarding manufacturer efforts to work with states to lower drug prices (including negotiating subscription models and other value-based purchasing arrangements) and which of the remaining drugs have the highest costs.

The survey would require the selected manufacturers to provide certain pricing, distribution and utilization information to CMS including the Wholesale Acquisition Cost and invoice price, the average price for sales outside the United States, the actual or expected utilization of the drug, public prices for the drugs available to other federal agencies including the Department of Veterans Affairs and information related to distribution costs. Manufacturers would also have to provide other information including the characteristics of the drug; clinical efficacy; effectiveness and patient outcomes; therapeutic benefits to patients; other competing therapies and how their prices compare to the drug; and whether the drug is approved by the FDA via the accelerated approval

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<sup>1</sup> U.S. Department of Health and Human Services, "HHS Secretary Responds to the President's Executive Order on Drug Prices," February 14, 2023, <https://www.hhs.gov/about/news/2023/02/14/hhs-secretary-responds-to-the-presidents-executive-order-on-drug-prices.html> and Edwin Park, "Medicaid Drug Rebate Program News and Notes," *Say Ahhh! Blog*, Georgetown University Center for Children and Families, March 21, 2023, <https://ccf.georgetown.edu/2023/03/21/medicaid-drug-rebate-program-news-and-notes/>.

pathway. The selected manufacturers would also have to provide any other information requested by CMS that is needed to verify prices and charges reported under the MDRP such as Average Manufacturer Price and best price. CMS would share information collected in the survey with state Medicaid programs. It could also publicly post non-proprietary information and require manufacturers to participate in a public forum. Manufacturers that refuse to comply with the survey would be subject to civil monetary penalties.

*We strongly support the new survey requirement in § 447.510(k).* The benefit of such a survey would be to help state Medicaid programs better understand manufacturer pricing, which in turn could increase states' leverage in negotiating larger supplemental rebates for a limited number of high-cost drugs. Larger rebates would lower net Medicaid prescription drug costs related to these drugs for both the federal government and for states. Moreover, in the preamble, CMS notes that the pricing information collected by the survey could be especially useful for high-cost drugs that are dispensed through specialty pharmacies — for which prices and distribution costs are particularly opaque — rather than dispensed through traditional retail pharmacies.

Importantly, CMS also emphasizes that this new survey, while likely to have modest benefits due to its limited scope, is a far better approach than other proposals that would allow states to restrict or entirely eliminate Medicaid coverage of high-cost prescription drugs. The preamble affirms Medicaid's open formulary protection under section 1927 of the Social Security Act — which requires coverage of nearly all FDA-approved drugs — and states that the survey “is not intended to limit or deny access to any of the CODs included on the survey list, assess cost effectiveness of such drugs, or supplant findings from the applicable FDA approval process.” CMS also states that “neither the selection of CODs subject to the survey, nor the information collected in response to a survey under this proposal, would impact coverage of a COD consistent with section 1927 of the Act, or supplant any of the Federal requirements under section 1927 of the Act and the implementing regulations....” This is in sharp contrast to some recent, flawed proposals from states that would address the high cost of some drugs by restricting Medicaid coverage. For example, Tennessee previously sought a provision waiving Medicaid's open formulary protection and instead imposing a closed formulary for its Medicaid program to lower its prescription drug costs, a proposal which it eventually dropped. Under Tennessee's proposal, the Medicaid program would have had to cover only one drug per class and high cost could have been the sole factor for exclusion from the formulary.<sup>2</sup> And Oregon initially proposed, though later dropped, a flawed proposal to exclude coverage of certain “accelerated approval” drugs.<sup>3</sup>

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<sup>2</sup> Edwin Park, “Federal Government Accepting Public Comments on Tennessee Medicaid Block Grant Waiver Proposal Restricting Access to Prescription Drugs,” *Say Ahhh! Blog*, Georgetown University Center for Children and Families, August 19, 2021, <https://ccf.georgetown.edu/2021/08/19/federal-government-accepting-public-comments-on-tennessee-medicaid-block-grant-waiver-restricting-access-to-prescription-drugs/>.

<sup>3</sup> Edwin Park, “Oregon Seeks to Limit Medicaid Coverage of Accelerated-Approval Drugs,” *To the Point Blog*, The Commonwealth Fund, April 5, 2022, <https://www.commonwealthfund.org/blog/2022/oregon-seeks-limit-medicaid-coverage-accelerated-approval-drugs>.

However, now that CMS has proposed to finally exercise its longstanding but unused statutory survey authority for a limited number of high-cost drugs, it should also consider for future rulemaking exercising this authority under section 1927(b)(3)(B), and under its general obligation under section 1902(a)(30)(A) of the Act to ensure that Medicaid payments are consistent with efficiency, economy and quality of care, to institute a more comprehensive survey of a sample of manufacturers subject to the MDRP to better ensure compliance with MDRP requirements and ensure that manufacturers are fully paying the rebates they owe to state Medicaid programs. Currently, CMS has no systematic audit or survey process to ensure the accuracy of the pricing information reported by manufacturers under the MDRP such as Average Manufacturer Price (AMP) and best price.<sup>4</sup>

CMS could require a sample of manufacturers each year be subject to a mandatory survey in order to collect detailed pricing information documenting how the manufacturers calculated AMP and best price. This would help verify that their reported prices were accurate. Such a proactive survey approach would be more effective and more timely than how compliance with the requirements of the MDRP is effectively enforced today, through whistleblower lawsuits and Office of Inspector General (OIG) audits of individual manufacturers or individual drugs. By leading to more accurate pricing information reported by manufacturers, MDRP rebates would likely increase and therefore reduce net Medicaid prescription drug costs for the federal government and states.

*Drug Cost Transparency in Medicaid Managed Care Contracts (§ 438.3)*

Like in Medicare and in private insurance, “spread pricing” is a serious problem in Medicaid managed care. Many Medicaid managed care plans contract with pharmacy benefit managers (PBMs) to administer the pharmacy benefit for their enrollees. But as states have discovered in recent years, some PBMs have been charging Medicaid managed care plans for pharmacy claims costs well in excess of the actual costs of reimbursing pharmacies for drugs dispensed to beneficiaries, net of any supplemental rebates the PBMs obtain from drug manufacturers. The PBMs retain the difference, known as the “spread,” as profit. That, in turn, can artificially inflate the capitation payments that states must pay managed care plans, resulting in higher overall federal and state Medicaid costs. However, according to the preamble to the proposed CMS rule, only about one-fifth of states have enacted legislation prohibiting spread pricing in Medicaid managed care.

In 2019, CMS issued a Center for Medicaid & CHIP Services (CMCS) Information Bulletin (known as a “CIB”) on May 15, 2019 which was intended to modestly reduce the inappropriate use of spread pricing in managed care.<sup>5</sup> That CIB required that any drug

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<sup>4</sup> Edwin Park, “How to Strengthen the Medicaid Drug Rebate Program to Address Rising Medicaid Prescription Drug Costs,” Georgetown University Center for Children and Families, January 9, 2019, <https://ccf.georgetown.edu/2019/01/09/how-to-strengthen-the-medicaid-drug-rebate-program-to-address-rising-medicaid-prescription-drug-costs/>.

<sup>5</sup> Centers for Medicare & Medicaid Services, “Center for Medicaid & CHIP Services Informational Bulletin: Medical Loss Ratio (MLR) Requirements Related to Third-Party Vendors,” May 15, 2019,

rebates received and accrued (whether by the plan itself or by a contracted PBM) must be deducted from incurred pharmacy claims for purposes of Medical Loss Ratio (MLR) calculations. (The MLR is the share of plan payments that goes to enrollees' claim costs, rather than for administrative costs and profit.) The CIB stated that PBMs must report to managed care plans all revenue and expenditure information necessary for the plans to calculate its MLR, including accurate reporting of amounts paid to pharmacies minus any rebates. The CIB better ensured that managed care plans' MLR calculations reflect their net pharmacy costs even if the prescription drug benefit is administered by a contracted PBM. By leveraging the MLR requirement to promote greater transparency in this manner, the CIB made it somewhat less likely that PBMs use spread pricing and thereby inflate federal and state Medicaid managed care costs.

The proposed rule appropriately builds on the 2019 CIB by amending 42 C.F.R. § 438.3 to add a new subparagraph (s)(8) requiring Medicaid managed care plans to structure any contract with subcontractors (i.e., PBMs) for the delivery or administration of the covered outpatient drug benefit so that the subcontractors separately report out incurred claims (including reimbursement for the cost of the prescription drug itself, payments for other patient services and dispensing fees to pharmacies and other providers) and other administrative costs, fees and expenses of the subcontractor. Essentially, by making PBMs break out their costs, state Medicaid programs would have a better sense of whether spread pricing is occurring. It would also result in more accurate calculation of plan MLRs, which could lower capitation rates to actuarially sound levels. Of course, a far more effective approach would be a uniform prohibition of spread pricing in Medicaid managed care. Congress is currently considering numerous bills related to PBM practices and could include a prohibition of spread pricing in Medicaid managed care as part of those efforts. Nevertheless, the proposed rule takes another positive, albeit modest, step towards reining in spread pricing and thereby reducing federal and state Medicaid managed care costs over time. *As a result, we strongly support the proposed revisions to § 438.3 adding a new subparagraph (s)(8).*

#### *Proposal to Account for Stacking When Determining Best Price (§ 447.505)*

The best price requirement is a critical component of the MDRP that substantially lowers federal and state Medicaid spending on brand-name drugs. The intent of the best price provision is to ensure that Medicaid obtains discounts at least as large as those available to most purchasers in the commercial sector. The Congressional Budget Office (CBO) has found that Medicaid obtains the lowest prices, net of rebates and discounts, among other

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<https://ccf.georgetown.edu/2019/05/22/trump-administration-leverages-medical-loss-ratio-requirements-to-help-address-problem-of-drug-spread-pricing-in-medicaid-managed-care/> and Edwin Park, "Trump Administration Leverages Medical Loss Ratio Requirements to Help Address Problem of Drug 'Spread Pricing' in Medicaid Managed Care," *Say Ahhh! Blog*, Georgetown University Center for Children and Families, May 22, 2019, <https://ccf.georgetown.edu/2019/05/22/trump-administration-leverages-medical-loss-ratio-requirements-to-help-address-problem-of-drug-spread-pricing-in-medicaid-managed-care/>.

federal programs and agencies including the Department of Veterans Affairs,<sup>6</sup> with the CBO analysis showing that the best price requirement is an essential contributor to the MDRP's success in lowering federal and state Medicaid prescription drug costs.<sup>7</sup> In February 2016, CMS finalized its Medicaid Covered Outpatient Drug rule.<sup>8</sup> In the preamble to the final rule, in responding to public comments, CMS appropriately clarified that in the case of a manufacturer providing multiple price concessions to two or more entities for the same drug transaction, all discounts related to that transaction which adjust the price available from the manufacturer should be considered when determining best price. CMS, however, did not revise 42 C.F.R. § 447.505 to incorporate this clarification related to "stacking" of price concessions. As the preamble to the proposed rule notes, a manufacturer successfully argued via litigation that there was thus not a clear federal requirement that manufacturers "stack" their price concessions in calculating best price.

We agree with CMS' conclusion that best price "must include (or 'stack') all the discounts and rebates associated with the final price, even if the entity did not buy the drug directly from the manufacturer. By stacking, best price reflects the lowest realized price at which the manufacturer made that drug unit available." We also agree that if manufacturers "are required to take rebates into account for multiple entities when calculating AMP, and for logical reasons, best price should do so as well, since including them in AMP and not accounting for them in best price could result in AMP being lower than best price." Stacking price concessions is wholly consistent with the definition of best price under section 1927(c)(1)(C) of the Social Security Act which refers to the "lowest price available from the manufacturer" to any applicable entity.

To ensure that all manufacturers subject to the MDRP "stack" their price concessions for purposes of best price moving forward, the proposed rule would revise 42 C.F.R. § 447.505 by adding a new subclause (d)(3) specifically requiring that manufacturers must adjust best price if cumulative discounts, rebates or other arrangements subsequently adjust the price available from the manufacturer and that such cumulative discounts, rebates or other arrangements must be stacked to determine a final price realized by the manufacturer, including discounts, rebates and other arrangements provided to different best price eligible entities. The proposed rule would therefore better ensure that manufacturers are complying with the best price requirement, which would increase basic rebates under the MDRP and thereby lower net federal and state Medicaid prescription drug costs over time. *We strongly support these revisions related to stacking price concessions for purposes of best price.*

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<sup>6</sup> Congressional Budget Office, "A Comparison of Brand-Name Drugs Among Selected Federal Programs," February 18, 2021, <https://www.cbo.gov/publication/56978>.

<sup>7</sup> Edwin Park, "New CBO Study Compares Net Prices for Brand-Name Drugs Among Federal Programs, Finds Medicaid Gets Largest Discounts," *Say Ahhh! Blog*, Georgetown University Center for Children and Families, February 22, 2021, <https://ccf.georgetown.edu/2021/02/22/new-cbo-study-compares-net-prices-for-brand-name-drugs-among-federal-programs-finds-medicaid-gets-largest-discounts/>.

<sup>8</sup> 81 Fed. Reg. 5170 (February 1, 2016).

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Thank you again for the opportunity to make the above comments to the proposed rule. Please contact me at [Edwin.Park@georgetown.edu](mailto:Edwin.Park@georgetown.edu) if you have any questions or if we can be of further assistance.

Respectfully submitted,

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