Georgetown University
McCourt School of Public Policy
CENTER FOR CHILDREN
AND FAMILIES

VIA ELECTRONIC SUBMISSION

May 28, 2024

The Honorable Ron Wyden, Chair
The Honorable Mike Crapo, Ranking Member
U.S. Senate Committee on Finance

Re: Comments to the Discussion Draft of the "Drug Shortage Prevention and Mitigation Act"

Dear Senator Wyden and Senator Crapo:

The Center for Children and Families (CCF), part of 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 discussion draft bill language for the "Drug Shortage Prevention and Mitigation Act."

We appreciate your strong commitment to address the ongoing problem of generic drug shortages, especially with cancer patients continuing to face severe shortages of widely used generic chemotherapy drugs. We also appreciate all of the intensive work you and the Committee have conducted on this important issue to date, including holding a hearing on this issue last December, issuing a white paper with potential policy options in January of this year, and now releasing discussion draft bill language on May 3rd.

Our comments focus solely on the Medicaid provisions in Section 3 of the discussion draft. Unfortunately, we believe that these Medicaid provisions raise serious concerns. In particular, the Medicaid provisions would permanently and fully exempt most generic drugs from the inflation-related rebates under the Medicaid Drug Rebate Program irrespective of whether the drugs are in shortage or at risk of being in shortage. Only single source drugs that have an annual cost over $100 would, in general, remain subject to the inflation-related rebates. As a result, this exemption would constitute a broad rollback of the Medicaid inflation-related rebates for generic drugs. In turn, the exemption would leave state Medicaid programs at risk of facing higher prescription drug costs resulting from price spikes for most generic drugs even as it would likely have little effect in ameliorating generic drug shortages. We instead recommend the Medicaid provisions be

revised substantially to make any exemption from the Medicaid generic inflation-related rebates far more targeted, temporary and limited.

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In 2015, Congress enacted the Bipartisan Budget Act (P.L. 114-74). Among its health provisions, the law extended inflation-related rebates under the Medicaid Drug Rebate Program (MDRP) — which have applied to brand-name drugs since the MDRP's inception — to generic drugs starting on January 1, 2017, in order to discourage manufacturers of generic drugs from instituting excessive price increases and to produce Medicaid savings for both the federal government and the states. When the Medicaid inflation-related rebates for generic drugs were enacted, the Congressional Budget Office (CBO) estimated that the provision would reduce federal Medicaid spending by $1 billion over ten years and by $156 million in the tenth year.[1] But according to researchers at Brigham and Women's Hospital and Harvard University, Medicaid inflation-related rebates for generic drugs reduced federal and state Medicaid generic prescription drug costs by between 2 and 12 percent or $516 million to $6.5 billion in just the first four years (2017-2020) they were in effect.[2] As a result, extending the Medicaid inflation-related rebates under the MDRP to generic drugs have been very effective in lowering Medicaid prescription drug costs.

Inflation-Related Rebate Exemption Is Not Targeted, Constitutes Broad Rollback for Most Generic Drugs

Under Section 3 of the discussion draft, starting on January 1, 2027, any generic drug that is not single source — for example, the brand-name drug including any authorized generic is not being marketed and there is no other therapeutically equivalent drug — would be fully exempt from the Medicaid inflation-related rebate on a permanent basis, even if they are not in shortage or at any risk of being in shortage. Yet according to researchers from Brigham and Women's Hospital and Harvard University, nearly 70 percent of generic drugs in 2017 had at least two manufacturers and nearly half had three or more manufacturers.[3] Moreover, under Section 3, additional single source generic drugs would also be made exempt if their annual cost does not exceed $100 (annually adjusted for inflation), if they are first entrants during a 180-day exclusivity period or if they are a first biosimilar. As a result, under the discussion draft, the large majority of generic drugs would no longer be subject to the Medicaid inflation-related rebates.

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[1] Congressional Budget Office, Cost Estimate of "H.R. 1314, Bipartisan Budget Act of 2015," October 28, 2015, https://www.cbo.gov/publication/50938.

[2] The researchers estimated a range of savings due to data limitation issues. Benjamin Rome, Aayan Patel and Aaron Kesselheim, "Inflationary Rebates for Generic Drugs Sold Through Medicaid Saved Billions During 2017-2020," *Health Affairs*, June 2023, https://www.healthaffairs.org/doi/10.1377/hlthaff.2022.01029.

[3] Aayan Patel, Aaron Kesselheim and Benjamin Rome, "Frequency of Generic Drug Price Spikes and Impact on Medicaid Spending," *Health Affairs*, May 2021, https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.02020.

State Medicaid Programs Placed at Substantial Risk of Price Spikes for Generic Drugs

Exempting most generic drugs from the Medicaid inflation-related rebate would reduce the total rebates paid by manufacturers and raise net Medicaid prescription drug costs. The discussion draft would increase the basic rebate for generic rebates from the current 13 percent of the Average Manufacturer Price to a higher but unspecified percentage point amount, which is intended to "keep the Medicaid program whole for any lost rebates…" according to the bill summary.[4] Presumably, the percentage point increase in the basic rebate would be set to equal the amount estimated by CBO to produce federal savings that roughly offset the increased federal spending resulting from a very broad exemption from the inflation-related rebate.

This, however, would still leave state Medicaid programs at risk for significant price increases instituted by manufacturers for individual generic drugs, especially if those price increases are more widespread, frequent or larger than what CBO assumes. Notably, the researchers at Brigham and Women's Hospital and Harvard University found that one in five generic drugs experienced a price spike from at least one manufacturer between 2014-2017, with nearly half of generic injectable drugs experiencing a price spike over the period. (A price spike was defined as price increases of 100 percent or more over the previous year or 50 percent or more over the previous quarter.) They conclude that because of the generic inflation-related rebates, state Medicaid programs are now protected from these price spikes; "generic drug spikes now have little or no impact on state Medicaid spending…."[5] Section 3 of the discussion draft would considerably undercut that fiscal protection for Medicaid programs (and roll back the disincentives for manufacturers to sharply raise prices over time, irrespective of whether such generic drugs are in shortage or at risk of being in shortage).

Exemption Would Likely Have Little Effect in Ameliorating Generic Drug Shortages

While generic drug manufacturers blame the Medicaid inflation-related rebates as a major contributor to drug shortages,[6] it is important to recognize that generic drug shortages have been a persistent, serious problem well before the Medicaid inflation-related rebates first took effect in 2017. Notably, the Food and Drug Administration (FDA), the Government Accountability Office (GAO) and the Office of the Assistant Secretary for Planning and Evaluation (ASPE) at the Department of Health and Human Services have all

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[4] U.S. Senate Finance Committee, "Section-by-Section: Senate Finance Committee Prescription Drug Shortage Discussion Draft," May 3, 2024, https://www.finance.senate.gov/imo/media/doc/050124_sfc_drug_shortages_discussion_draft_section_by_section.pdf.

[5] Patel, Kesselheim and Rome, "Frequency of Generic Drug Price Spikes and Impact on Medicaid Spending," *op cit*.

[6] Association for Accessible Medicines, "Drug Shortages, Causes and Solutions," June 2023, https://accessiblemeds.org/sites/default/files/2023-06/AAM_White_Paper_on_Drug_Shortages-06-22-2023.pdf.

examined the causes of generic drug shortages in recent years.[7] Like GAO and ASPE, in its 2019 report entitled "Drug Shortages: Root Causes and Potential Solutions," FDA cites quality problems among manufacturers, intense price competition, the lack of purchaser incentives for good manufacturing practices and the complexity of the supply chain as the major contributors to ongoing drug shortages. While the FDA acknowledged the generic drug manufacturer arguments that the Medicaid inflation-related rebates "could erode the incentive for the manufacturer to continue marketing the drug and increase the likelihood of drug shortages," FDA also noted that the "argument that the CPI-U rebate will make it difficult for manufacturers to recoup rising input costs may be weak…. There is little evidence that manufacturing input costs are rising faster than the CPI-U, and they are likely to be captured in the rising costs of consumer goods that the CPI-U measures."[8] Finally, nothing in Section 3 of the discussion draft ties its broad and permanent exemption from the Medicaid inflation-related rebates for most generic drugs to any manufacturer actions or commitments that could actually reduce the risk of shortages such as improvements in compliance with good manufacturing practices and in supply chain management and benchmark increases in production capacity with clear timelines.

A More Targeted, Temporary and Limited Exemption for Generic Drugs in Shortage or at Risk of Shortage

We therefore recommend substantially revising Section 3 so that it would instead only provide limited new authority for the Secretary of Health and Human Services to temporarily reduce the Medicaid inflation-related rebate in the case of certain critical high-need generic drugs in shortage, suffering from a severe supply chain disruption or determined to likely be in shortage without a reduction of the inflation-related rebate, with the Secretary determining what drugs in shortage are critical and high need. Similar to how the new Medicare inflation-related rebate is being implemented, reductions in Medicaid rebate amounts should vary based on factors such as the length of time a drug is on the FDA's shortage list and any reduction should be limited to only a portion of the inflation-related rebate, not a full exemption.[9] Reductions should also vary based on the severity of the shortage and any reductions should be available only for a short duration. That would help reduce the risk of gaming by manufacturers to enter or remain in shortage and limit the negative impact on net Medicaid prescription costs. In addition, severe supply chain disruptions that qualify for a reduction should be limited to those due to

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[7] U.S. Food and Drug Administration, "Drug Shortages: Root Causes and Potential Solutions," October 2019, https://www.fda.gov/drugs/drug-shortages/report-drug-shortages-root-causes-and-potential-solutions; U.S. Government Accountability Office, "Drug Shortages: Certain Factors Are Strongly Associated with this Persistent Public Health Challenge," July 7, 2016, https://www.gao.gov/products/gao-16-595; and Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, "ASPE Report to Congress: Impact of Drug Shortages on Consumer Costs," May 22, 2023, https://aspe.hhs.gov/reports/drug-shortages-impacts-consumer-costs.

[8] U.S. Food and Drug Administration, "Drug Shortages: Root Causes and Potential Solutions," *op cit*.

[9] Centers for Medicare and Medicaid Services, "Fact Sheet: Medicare Prescription Drug Inflation Rebate Program Revised Guidance," December 14, 2023, https://www.cms.gov/files/document/fact-sheet-medicare-prescription-drug-inflation-rebate-revised-guidance.pdf.

factors outside a manufacturer's control rather than issues like failure to comply with good manufacturing practices.

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Thank you again for the opportunity to make the above comments to the discussion draft. Please contact me at Edwin.Park@georgetown.edu if you have any questions or if we can be of further assistance.

Respectfully submitted,

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