

April 22, 2024

Via electronic submission:

Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services,  
Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244-1850  
Attn: CMS-2434-F

**Re: Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program [CMS-2434-F]**

Dear Administrator Brooks-LaSure:

The National Hispanic Medical Association and the group of undersigned organizations write to express our concern over a proposed revision to the Medicaid Drug Rebate Program. The proposal (CMS-2434-F) is intended to reduce Medicaid spending on prescription drugs. In practice, however, we have grave concerns about its effects on equity and access to medicine, particularly for communities of color. The revision would slow the development of new treatments and make it much more difficult for providers to give Medicaid beneficiaries the care they deserve.

As advocates representing the marginalized groups that comprise a disproportionate share of the Medicaid population, we fear that the new rule would have a particularly devastating impact on underserved communities -- exacerbating health disparities already pervasive throughout the country.

In the United States today, Black, Hispanic, and Native people are worse off than White people across most measures of health and healthcare access, according to the Kaiser Family Foundation.<sup>1</sup> For example, Native and Black people have a shorter life expectancy at birth than White people, and Native, Hispanic, and Black people saw larger declines in life expectancy during the pandemic.<sup>2</sup> Black infants are more than two times as likely to die as White infants, and Black and Native women have the highest rates of mortality related to pregnancy.<sup>3</sup>

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<sup>1</sup> <https://www.kff.org/racial-equity-and-health-policy/report/key-data-on-health-and-health-care-by-race-and-ethnicity/>

<sup>2</sup> <https://www.kff.org/racial-equity-and-health-policy/report/key-data-on-health-and-health-care-by-race-and-ethnicity/>

<sup>3</sup> <https://www.kff.org/racial-equity-and-health-policy/report/key-data-on-health-and-health-care-by-race-and-ethnicity/>

At the same time, minority groups have had lower access to flu vaccines, mental health services, and health insurance than the White population in recent years.<sup>4</sup> And due to persistent income disparities, people of color are more likely to enroll in Medicaid.<sup>56</sup>

For underserved patients with chronic and life-threatening illnesses, improved health often hinges on the development of cutting-edge drugs. But medicines for diabetes and liver disease don't emerge from a vacuum. On average, it costs a staggering \$2.6 billion for biotech companies to bring a single new therapy to market, accounting for failed drug candidates.<sup>7 8</sup>

The proposed rule would make this process economically untenable by redefining the "best price" that Medicaid pays for drugs. For more than three decades, Medicaid has received a sizable manufacturer rebate for name-brand drugs, based generally on the lowest or "best" price offered to any other purchaser in the supply chain -- such as an insurer or purchasing organization that acquires drugs for hospitals.<sup>9</sup> However, the new rule would calculate a medicine's best price by *aggregating* the rebates and discounts that a manufacturer provides to different purchasers of a single drug.

In theory, "stacking" these rebates to derive a "best price" might seem like an easy way to shore up Medicaid budgets. However, these stacked rebates would make it extremely difficult for biopharmaceutical companies to recoup the enormous upfront expenses required to create new drugs. In some cases, the total of rebates would add up to *more* than the average price of a medicine.<sup>10</sup>

That would give drug developers no choice but to consider slashing investment in new treatments -- or forgo participating in Medicaid altogether. Fewer life-saving drugs would reach patients, and underprivileged groups would suffer worse health outcomes in the long term. This is especially troubling for us and the communities we represent.

For historically disadvantaged and underserved communities, new treatments can be a great equalizer. Breakthroughs have the potential to benefit all patients without regard to their demographic profile or where they fall on the spectrum of income or educational attainment.

We have many hurdles yet to overcome in ensuring that new medications equitably reach patients in communities of color. Once patients do have access, though, the treatments themselves don't discriminate. The more there are, the better. Yet we're concerned that this Medicaid proposal could drastically curtail research into new ones.

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<sup>4</sup> <https://www.kff.org/racial-equity-and-health-policy/report/key-data-on-health-and-health-care-by-race-and-ethnicity/>

<sup>5</sup> <https://www.census.gov/newsroom/facts-for-features/2023/hispanic-heritage-month.html#:~:text=63.7%20million,19.1%25%20of%20the%20total%20population.>

<sup>6</sup> <https://www.kff.org/medicaid/state-indicator/nonelderly-medicare-rate-by-raceethnicity/?currentTimeframe=0&sortModel=%7B%22collId%22:%22Location%22,%22sort%22:%22asc%22%7D>

<sup>7</sup> <https://sitn.hms.harvard.edu/flash/2020/modern-drug-discovery-why-is-the-drug-development-pipeline-full-of-expensive-failures/#:~:text=%242.6%20billion%20is%20the%20estimated,the%202019%20GDP%20of%20Nebraska!>

<sup>8</sup> <https://www.nature.com/articles/nrd.2016.136>

<sup>9</sup> <https://www.americanactionforum.org/research/primer-the-medicare-drug-rebate-program/>

<sup>10</sup> <https://avalere.com/insights/cms-best-price-discount-stacking-proposal-may-trigger-amp-cap>

The proposed rule also contains other concerning provisions, such as a "price verification survey" measure that would allow CMS to extract additional manufacturer rebates if it does not think a drug's price is justified.

Yet Medicaid would only include a drug's direct research-and-development expenses in its calculation. The proposal neglects to consider the massive investments in candidate drugs that never win approval -- about nine out of 10 that enter clinical trials.<sup>11</sup> Any successful drug's final price has to account for the cost of failures built into the development process.

The Medicaid Drug Rebate Program has enabled millions of underserved patients to access groundbreaking therapies -- while preserving incentives for ongoing research into novel drugs. The suggested rule would upend this balance and ultimately harm the very people it intends to help. For the sake of those vulnerable patients, we implore you to rescind this proposal.

Sincerely,

National Hispanic Medical Association  
African American Male Wellness Agency  
ALLvanza  
Asian & Pacific Islander American Health Forum  
Black Women's Health Imperative  
BLKHLTH  
Carrie's TOUCH  
Center for Medicine in the Public Interest  
Color of Gastrointestinal Illnesses (COGI)  
Financial Services Innovation Coalition (FSIC)  
GLMA: Health Professionals Advancing LGBTQ+ Equality  
Health Education Advocacy and Learning, Inc.  
Hispanic Business Alliance  
Institute for Gene Therapies  
Lupus and Allied Diseases Association, Inc.  
MANA, A National Latina Organization  
National Alliance for Caregiving  
National Association of Hispanic Nurses  
National Black Nurses Association  
National Caucus and Center on Black Aging, Inc. (NCBA)  
National Hispanic Council on Aging  
National Medical Association  
National Minority Quality Forum  
Northeast Ohio Black Health Coalition  
No One Left Alone  
Ohio Federation for Health Equity and Social Justice  
Ohio Grandparent Kinship Coalition

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<sup>11</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9293739/>

Partnership to Fight Chronic Disease  
Southern Christian Leadership Global Policy Initiative (SCLGPI)  
The Balm In Gilead, Inc.  
Tigerlily Foundation  
TOUCH, The Black Breast Cancer Alliance

CC: Office of Management and Budget