April 7, 2021

Melanie Bella
Chair
Medicaid and CHIP Payment and Access Commission
1800 M Street NW, Suite 650 South
Washington, DC 20036

Dear Chairperson Bella,

On behalf of the nation's Medicaid Directors, NAMD is writing to support a recommendation from MACPAC to enhance mandatory rebates to states and the federal government under the Medicaid Drug Rebate Program (MDRP) for drugs approved by the Food and Drug Administration (FDA) under accelerated approval pathways. Increased rebates will ensure states are able to afford coverage of these expensive therapies while actual clinical outcomes continue to be assessed and provide incentives for manufacturers to expeditiously complete post-marketing clinical trials for these drugs.

NAMD is a bipartisan, nonprofit association representing the Medicaid Directors leading programs across the 50 states, the District of Columbia, and the five U.S. territories. The Medicaid program is a critical component of the health care system, providing access to services and supports for millions of Americans, many of whom are the most vulnerable populations in the country. These include pregnant women and children, individuals living with physical, intellectual, or developmental disabilities, and individuals in need of substance use disorder treatment.

The steadily increasing cost of prescription drugs is a significant issue for the sustainability of the Medicaid program. Medicaid is unique among payers in its statutory obligation to cover any FDA-approved therapy, in exchange for mandatory rebates under the MDRP. While this system has been effective for most therapies, the introduction of genetic therapies, curative therapies, and therapies approved under accelerated approval pathways – all of which are typically introduced at very high price points – are straining state budgets even with mandatory rebates. Further, such products rarely have competition, which means states have little ability to negotiate supplemental rebates to better manage costs. NAMD has long sought additional flexibility to manage these issues to ensure that the clinical transformation these products represent are mirrored by innovations in financing and coverage approaches.[1]

[1] July 2020 comments on VBP rule: https://namdstg.wpengine.com/wp-content/uploads/2022/02/NAMD-Submits-Comments-on-Pharmacy-Value-Based-Purchasing-Rule_pdf.pdf
February 2019 comments on draft PAVE Act: https://namdstg.wpengine.com/wp-content/uploads/2022/02/NAMD-Comments-on-Draft-PAVE-Act_pdf.pdf
March 2016 comments to Senate Finance Committee on drug value: https://namdstg.wpengine.com/wp-content/uploads/2022/02/NAMD-Provides-Thoughts-on-High-Cost-Drugs-to-Senate-Finance_pdf.pdf
April 2015 comments on draft 21st Century Cures Act: https://namdstg.wpengine.com/wp-content/uploads/2022/02/NAMD-Highlights-Impact-of-21st-Century-Cures-on-Medicaid_pdf.pdf
October 2014 requests to Congress on prescription drug coverage flexibility: https://namdstg.wpengine.com/wp-content/uploads/2022/02/NAMD-Urges-Congress-to-Address-Break-Through-Drugs_pdf.pdf

The expedited approval pathway, under which the FDA approves a therapy based on surrogate endpoints rather than specific clinical outcomes, is an area of particular concern for Medicaid. Because of the MDRP's requirements, states must cover these products even as their clinical benefit remains undetermined during the post-marketing trial period. The absence of this data makes setting appropriate prior authorization criteria for these therapies difficult. In some cases, such as Makena, the clinical benefit fails to be determined after years of state coverage and millions of dollars in state and federal expenditures.[2]

For these reasons, NAMD sees utility in increasing the MDRP's mandatory and inflationary rebates for products brought to market under the accelerated approval pathway. Increased rebates, particularly if they are applied during the post-market clinical trial period, will encourage manufacturers to expeditiously complete this important work and generate real-world clinical data. States and the federal government would be further fiscally safeguarded against products that ultimately prove to not be clinically effective.

Lastly, implementing an increased rebate structure is administratively straightforward and preferable to focusing solely on value-based purchasing (VBP) arrangements to contain costs for these products. While NAMD does not oppose VBP for pharmaceutical products in principle and notes that several states have such arrangements in place today, an exclusive reliance on VBP for accelerated approval products cannot be the singular approach offered to states. In addition to being administratively demanding, fundamental questions remain on how to structure VBP arrangements to effectively measure the value of a given drug. Those questions must often be resolved on a per-manufacturer or per-product basis, ultimately inhibiting the overall utility of VBP. There is also no guarantee that VBP arrangements will successfully contain costs for states. While such questions are sorted through, payment and coverage will likely default to the current, unsustainable status quo.

NAMD encourages the Commission to recommend Congressional adoption of increased mandatory and inflationary rebates for accelerated approval pathway products. This would be helpful step in supporting the long-term sustainability of the Medicaid pharmacy benefit.

Sincerely,

Matt Salo
Executive Director, NAMD

[2] https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/makena-hydroxyprogesterone-caproate-injection-information