

Medicaid and CHIP Payment and Access Commission (MACPAC)
1800 M Street NW, Suite 650 South
Washington, DC 20036

Via email to: comments@macpac.gov

RE: MACPAC's Work on Medicaid Rebate and Accelerated Approval Drugs

Dear MACPAC Commissioners:

The undersigned organizations represent thousands of patients and consumers facing serious and chronic health conditions. We write in response to MACPAC's proposed differential rebate models for accelerated approval drugs. Given the vulnerable populations that Medicaid serves, we believe it is paramount that MACPAC not advance its proposed recommendation to increase the rebate on these products because doing so has potential to impede access and exacerbate disparities for underserved and minority patients.

The Accelerated Approval Program was created to allow for the approval of drugs to meet an unmet medical need. Drugs that are granted accelerated approval must meet the same statutory standards for safety and efficacy as those approved through traditional pathways. Using surrogate endpoints for the FDA review has saved valuable time in the drug approval process, which has in turn provided patients the opportunity to access the drugs and begin to prevent permanent, irreversible damage. The idea that the Accelerated Approval Pathway serves as a way to access unproven treatments is not accurate. This pathway provides important access for patients, who otherwise would be forced to wait longer for life-saving treatments to come to market, if they ever do.

As patient communities, we are concerned that the proposed differential rebate models will bring unintended consequences. Increasing Medicaid rebates is likely to limit investment in research and development needed to discover new treatments, particularly drugs for which a large share of patients would be Medicaid beneficiaries. Drug manufacturers could also be potentially deterred from pursuing the accelerated approval pathway.

It was noted in conversations in MACPAC's March 2021 meeting that the increased rebate will reduce net spending for both the federal government and states, however we strongly disagree. Such speculation does not take into consideration the costs of hospitalizations when a disease is not managed with the appropriate treatment. This cost does not include costs associated with caregivers or look at quality of life and ability to contribute to society. A chronic disease not only costs the healthcare a substantial amount but more importantly managing the disease is a large financial burden to the people and families living with it. To reduce this burden on all systems

and families, treatment options and access to managed care are necessary to reduce the financial burden and enhance the quality of life for patients.

Our organizations caution against recommending a differential rebate for accelerated approval products and would be happy to act as a resource for understanding the importance of the accelerated approval process.

Sincerely,

Advocacy & Awareness for Immune Disorders Association (AAIDA)

Alliance for Aging Research

American Behcet's Disease Association (ABDA)

Caregiver Action Network

Color of Crohn's & Chronic Illness

Derma Care Access Network

Foundation for Sarcoidosis Research

HealthHIV

HIV + Hepatitis Policy Institute

IBDMoms

International Pemphigus & Pemphigoid Foundation

Lupus and Allied Diseases Association, Inc.

Lymphoma Research Foundation

Men's Health Network

MLD Foundation

National Minority Quality Forum

Relapsing Polychondritis Foundation

Sick Cells

Solve ME/CFS Initiative

Vasculitis Foundation