October 3, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services

Re: Addressing Copay Accumulator Adjustment Policies in the 2024 Notice of Benefit and Payment Parameters

Dear Administrator Brooks-LaSure,

The All Copays Count Coalition (ACCC), on behalf of the 73 undersigned organizations, urges CMS to ensure patients receive the full benefit of copay assistance by repealing 42 CFR §156.130(h) and clarifying that insurers must count any assistance paid by or on behalf of a patient toward their annual deductible and out-of-pocket limit. We appreciate the Biden-Harris Administration's commitment to increasing access to health care but have been disappointed that CMS has not put a halt to health plan and pharmacy benefit manager (PBM) use of copay accumulator adjustment policies (CAAPs) and other policies that prevent copay assistance from supporting patients in need. These policies allow health plans and PBMs to profit from assistance intended to help patients by not counting it towards the enrollee's annual deductible and out-of-pocket limit. They disproportionately target the most financially vulnerable patients with serious and chronic health conditions and undermine pre-existing condition protections provided by the Affordable Care Act (ACA). The ACCC strongly urges CMS to address these policies in the 2024 Notice of Benefit and Payment Parameters (NBPP) and we respectfully request an opportunity to meet with you to discuss this concerning issue.

The ACCC represents the interests of patients with chronic and serious health conditions who rely on copay assistance to make medically necessary drug treatments affordable. For patients with serious, chronic health conditions, including life-threatening illnesses, ongoing and continuous access to medication is essential. However, these patients often face multiple barriers to the therapies they need to treat their conditions, such as administrative hurdles like prior authorization and step therapy that limit access to specialty medications. And once approved, patients often face skyrocketing deductibles and steep cost-sharing requirements. For millions of insured Americans living with complex chronic conditions, the only way to afford their specialty or brand medications, which often do not have generic alternatives, is by using copay assistance.

We strongly agree with CMS's position that "manufacturer-sponsored patient assistance programs can be helpful to patients in obtaining necessary medications." Yet with CAAPs in place, plans benefit instead of the patient. With 83% of commercial market enrollees now in plans that have an accumulator adjustment policy, vulnerable patients are left unable to benefit from assistance needed to access their medications. The use of CAAPs increased exponentially following CMS' adoption of CFR §156.130(h), which exempted manufacturer copay assistance from the ACA's limits on cost-sharing, in direct conflict with the ACA's statutory definition (Section 1302(c)(3)), which says: "*Cost sharing* means any expenditure required by *or* ***on behalf of*** an enrollee with respect to essential health benefits…."

Insurers and PBMs contend that use of copay assistance drives up drug costs and health spending. The facts suggest otherwise. First, copay assistance is not offered for the vast majority of prescriptions for branded drugs with generic alternatives. In fact, recent data shows that for all commercial market claims for products that have copay assistance, only 3.4 percent of assistance being used is for branded drugs that may have a generic alternative. If copay assistance programs were driving patients away from generic alternatives, then this share would be significantly higher. Second, when patients cannot access the medications they need, it ends up costing the health system *more* money due to complications and worsening health. Research has found that the cost of patients not receiving optimal medication therapy is over $528 billion each year in the United States.

Repealing §156.130(h) and clarifying that insurers must count any assistance paid by or on behalf of a patient toward their annual deductible and out-of-pocket limit, as 14 states and Puerto Rico have now done, is the simplest way to protect all patients' access to treatment and ensure that patients – rather than insurers – benefit from manufacturer copay assistance.

With the health and welfare of patients being our common goal, the undersigned members of the ACCC respectfully urge CMS to consider addressing the permissibility of CAAPs in the 2024 NBPP or sooner and we request the opportunity to meet with you directly about this issue. Please do not hesitate to contact Rachel Klein, Deputy Executive Director of The AIDS Institute, at rklein@taimail.org to schedule a meeting or ask any questions.

Respectfully,

AIDS Foundation Chicago
AIDS United
Aimed Alliance
Alliance Community Healthcare Inc.
Alliance for Patient Access
ALPHA-1 FOUNDATION
American Academy of HIV Medicine
American Cancer Society Cancer Action Network
American College of Rheumatology
Arthritis Foundation

Association for Clinical Oncology
Association for Women in Rheumatology
Bleeding Disorders Foundation of North Carolina
Cancer Support Community
Cancer*Care*
Chronic Care Policy Alliance
CLL Society
Coalition of State Rheumatology Organizations
Color of Crohn's and Chronic Illness
Crohn's & Colitis Foundation
Cystic Fibrosis Foundation
Cystic Fibrosis Research Institute
Derma Care Access Network
Dermatology Nurses' Association
Diabetes Leadership Council (DLC)
Diabetes Patient Advocacy Coalition (DPAC)
Epilepsy Foundation
Foundation For Sarcoidosis Research
FORCE: Facing Our Risk of Cancer Empowered
Gaucher Community Alliance
Georgia AIDS Coalition
Georgia Equality
Georgia Watch
Global Healthy Living Foundation
Haystack Project
HealthyWomen
Hemophilia Council of California
Hemophilia Federation of America
Hemophilia Of Georgia
HIV + Hepatitis Policy Institute
HIV Dental Alliance
HIV Medicine Association
ICAN, International Cancer Advocacy Network
Immune Deficiency Foundation
Infusion Access Foundation
International Foundation for AiArthritis
Jewish Democratic Women's Salon
Legal Action Center
Looms for Lupus
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
Mesothelioma Applied Research Foundation
MLD Foundation
Multiple Sclerosis Association of America

Multiple Sclerosis Foundation
NASTAD
National Eczema Association
National Hemophilia Foundation
National Infusion Center Association
National Multiple Sclerosis Society
National Organization for Rare Disorders
National Psoriasis Foundation
NCODA
New Georgia Project Action Fund
Partnership to Advance Cardiovascular Health
Patient Access Network (PAN) Foundation
Pulmonary Hypertension Association
Rheumatology Nurses Society
Susan G. Komen
The AIDS Institute
The Assistance Fund
The Headache and Migraine Policy Forum
Western Pennsylvania Bleeding Disorders Foundation

CC: Dr. Ellen Montz, Deputy Administrator & Director, CCIIO;
Jeff Wu, Deputy Director for Policy, CCIIO