June 24, 2024

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Julie Su
Acting Secretary
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

The Honorable Janet Yellen
Secretary
U.S. Department of Treasury
1500 Pennsylvania Ave, NW
Washington, DC 20220

Re: Revised Rule Governing Use of Copay Accumulator Adjustment Programs

Dear Secretaries Becerra, Su, and Yellen:

The All Copays Count Coalition (ACCC) comprises national and state-based 501c3 non-profit, non-partisan patient advocacy and provider organizations representing millions of people living with serious and complex chronic illness. The people we represent need full and ongoing access to medical care, including specialty medications, to treat their conditions and to keep them healthy. They rely on health insurance to protect them from high out-of-pocket costs and ensure they can get the care they need. Today, 76 organizational members of the ACCC write to urge you to **ensure that any revision of the cost-sharing rule related to copay accumulator adjustment policies includes clear, commonsense protections guaranteeing that copayments made by or on behalf of an enrollee are counted as payments toward their annual cost-sharing contributions.** We also request a meeting on this topic at your earliest convenience.

Pursuant to the United States District Court of the District of Columbia's 2023 decision in *HIV & Hepatitis Policy Institute et al v U.S. Department of Health and Human Services* (HHS), HHS

declared its intention to revise 45 CFR 156.130(h). The 2020 Notice of Benefit and Payment Parameters provision currently requires insurers and pharmacy benefit managers (PBMs) to count copay assistance provided by prescription drug manufacturers towards the enrollee's annual cost-sharing limit unless it is used for a drug that has an available and medically appropriate generic equivalent. As the Departments undertake this rule revision, we urge you to:

1. **Build on the existing rule – We urge the Departments to maintain the protections included in the 2020 Notice of Benefit and Payment Parameters.** Since 2019, 21 states, the District of Columbia and Puerto Rico have enacted state laws that use similar language and/or build on similar principles included in this rule. These laws require insurers and pharmacy benefit managers (PBMs) to count copay assistance payments they receive on an enrollee's behalf toward that enrollee's annual deductible and out-of-pocket limit. This both protects patients' access to treatment and ensures that insurers and PBMs are using payments they receive to provide health care for patients as intended by the Affordable Care Act. We have attached the relevant language from these statutes to this letter.

2. **Ensure that copay assistance counts for medically appropriate medications** – The 2020 Notice of Benefit and Payment Parameters provision only allows copay accumulator adjustment policies to be used when there is an available and medically appropriate generic alternative. A few states have enacted total prohibitions on copay accumulator adjustment policies (our preferred approach), and we have seen no evidence that this has resulted in substantial steering or increased premiums.[1] Almost all copay assistance is used for specialty and high-cost brand medications for which insurers and PBMs employ extensive utilization management tools to ensure that they are medically appropriate for a given enrollee.

   We also note that, although generic alternatives are usually priced lower than the branded drug, the difference may be minimal from a patients' perspective, and it is not always the case they are placed on a lower cost-sharing tier, so enrollees may not gain the benefit of that price difference. Furthermore, prescription drugs formularies may not always prefer the generic alternatives over the branded medication. **We respectfully request that the Departments do not allow the use of copay accumulator adjustment policies for the preferred version of a medication, whether that is the brand or the generic. If the preferred version of the treatment is not medically appropriate for the patient, then the Departments should apply an exception to prohibit the use of copay accumulator adjustment policies for the version of the treatment the patient requires.**

3. **Health Savings Accounts-High Deductible Health Plan (HSA-HDHP) carve-outs** –The 2021 revision to 45 CFR 155.130(h) was justified as a response to IRS concerns that use of

[1] The AIDS Institute, *Copay Assistance Does Not Increase Premiums*, May 2023, https://www.theaidsinstitute.org/copays/copay-assistance-does-not-increase-premiums.

copay assistance ran afoul of 2004 IRS guidance related to eligibility to contribute to an HSA. Subsequently, the IRS has made clear that its concern is limited to copay assistance used before an enrollee has hit the minimum deductible required to qualify as an HDHP, (which in 2024 is $1,600 for an individual and $3,200 for family coverage), and that copay assistance may be counted for all cost-sharing above that threshold. It is also important to note that these limits only apply to individuals actively contributing to HSAs. Several states have included language navigating this concern in their state laws. Although we continue to believe that copay assistance is fundamentally different than a coupon, we acknowledge that the Departments may also address this issue in a revised rule. **We respectfully request that, if included in the rule, any provision allowing copay accumulator adjustment policies related to HSAs be limited to people for whom using copay assistance would result in ineligibility to contribute to an HSA; ie, those who are enrolled in an HSA-eligible HDHP *and* are actively contributing to an HSA, and only up to the minimum deductible required to qualify as an HDHP.**

Restricting use of copay accumulator adjustment policies to ensure that people living with serious chronic illness can afford the treatment they need when they have insurance is an important step for HHS to take. Our organizations hear stories every day of patients who, despite paying premiums for plans they believed provided comprehensive health insurance coverage, are unable to afford the treatment they need.

Recently, HHS and Treasury adopted a policy our coalition strongly supports: requiring all prescription drugs covered in individual and small group market plans to be treated as essential health benefits for the purposes of cost-sharing. We have recently heard from patients who, as a result of this policy, have plans reverting from copay maximizer programs to copay accumulator policies. We urge CMS to protect patients by requiring insurers and PBMs to count copay assistance payments they receive on behalf of an enrollee toward that enrollee's annual deductible and out-of-pocket limit.

We request a meeting with you to continue this conversation and provide additional information on the subject. Please feel free to reach out to Rachel Klein, Deputy Executive Director, The AIDS Institute at rklein@taimail.org with availability for a meeting. We thank you for your consideration.

Sincerely,

Accessia Health
AIDS Foundation Chicago
Aimed Alliance
Alliance for Headache Disorders Advocacy
Alliance for Patient Access
Alliance for Women's Health and Prevention
Alpha-1 Foundation
ALS Association
American College of Rheumatology
Arthritis Foundation
Association for Clinical Oncology
Autoimmune Association
Bleeding Disorders Alliance of North Dakota

Bleeding Disorders Foundation of North Carolina
California Chronic Care Coalition
Cancer Support Community
CancerCare
Chronic Care Policy Alliance
Chronic Migraine Awareness, Inc.
CLL Society
Clusterbusters, Inc
Coalition of State Rheumatology Organizations
Community Liver Alliance
Crohn's & Colitis Foundation
Cystic Fibrosis Research Institute
Diabetes Leadership Council
Diabetes Patient Advocacy Coalition
Dravet Syndrome Foundation
Eastern Pennsylvania Bleeding Disorders Foundation
Epilepsy Foundation
Facial Pain Association
Fair Health North Carolina
GO2 for Lung Cancer
Good Days
Haystack Project
Headache and Migraine Policy Forum
Headache Cooperative of the Pacific
HealthyWomen
Hemophilia Alliance
Hemophilia Association of the Capital Area
Hemophilia Council of California
Hemophilia Federation of America
Hereditary Angioedema Association
Hidradenitis Suppurativa Coalition
HIV Medicine Association
HIV+Hepatitis Policy Institute
Hope Charities
ICAN, International Cancer Advocacy Network
Immune Deficiency Foundation
Infusion Access Foundation
Infusion Providers Alliance
Little Hercules Foundation
Looms For Lupus
LUNGevity Foundation
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
MLD Foundation
National Bleeding Disorders Foundation
National Consumers League
National Eczema Association
National Headache Foundation
National Infusion Center Association (NICA)
National MS Society
National Psoriasis Foundation
Nevada Chronic Care Collaborative
Patient Access Network (PAN) Foundation
Pulmonary Hypertension Association
Rheumatology Nurses Society
Society of Dermatology Physician Associates (SDPA)
Southern Headache Society
Spondylitis Association of America
Susan G. Komen
The AIDS Institute
The Headache and Migraine Policy Forum
Triage Cancer
Virginia Hemophilia Foundation