ALL COPAYS COUNT COALITION

Randy Pate
Director, Center for Consumer Information and Insurance Oversight
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

RE: Copay Assistance Provisions in the 2021 Notice of Benefit and Payment Parameters

Dear Mr. Pate:

On behalf of the undersigned members of the All Copays Count Coalition (ACCC), we appreciate the opportunity to submit comments to the Department of Health and Human Services (HHS) in response to the proposed 2021 Notice of Benefit and Payment Parameters (NBPP). ACCC is a diverse representation of patient and provider groups united to serve the interests of beneficiaries with chronic and serious health conditions that rely on copay assistance to make medically necessary drug treatments affordable.

Our comments below focus on the section of the regulation that seeks to revise §156.130(h), which addresses how direct support offered by drug manufacturers to enrollees for specific prescription drugs are treated with regard to accrual towards the annual limitation on cost sharing. In short, we believe the proposal disregards the needs of patients, giving issuers the discretion to count drug copayment assistance towards the annual limitation on cost sharing regardless of the availability of a generic equivalent. If finalized as proposed, HHS will also thwart the administration's commitment to meaningfully reduce out-of-pocket costs for patients with serious, chronic diseases. ***We strongly urge HHS to withdraw this proposal and leave in place the provision established in the 2020 Notice of Benefit and Payment Parameters.***

Copay Assistance for Medically Necessary Prescriptions Helps Protect Patients

The decision not to enforce the 2020 NBPP provision requiring issuers to count drug copayment assistance towards the annual limitation on cost sharing in the absence of a generic equivalent directly conflicts with the Affordable Care Act's (ACA) statutory intent to protect patients and promote affordable care. While patients are hopeful for the development of new, innovative treatments and generic alternatives, currently there are few lower-cost and generic options available for chronic and complex diseases such as arthritis, multiple sclerosis, cancer, HIV, among others.

As a result of rising healthcare costs, copay assistance has become a necessity for many patients to afford their medications. In 2020, a plan with a deductible of at least $1,400 is considered to be a high deductible health plan (HDHP); however, the average deductible for a silver-level qualified health plan this year is $4,600. When coupled with coinsurance of 30-50 percent for a specialty drug placed on the highest formulary tiers, it becomes clear that a patient's monthly bill could easily add up to thousands of dollars.[1] As proposed, the provision adds an additional financial burden for the most vulnerable patients

[1] Robert Wood Johnson Foundation. March 2019. Cost Sharing for Drugs Rises Sharply at Higher Tiers.

who have no option to select a lower cost drug, and who are already facing high out-of-pocket costs in their health care plan.

Two years ago, the administration made a commitment to lower prescription drug and out-of-pocket costs for people in the United States.[2] If patient cost-sharing is too high, patients will not be able to afford their medications and may be forced to delay or forgo treatment. There is a direct correlation between patient cost and treatment adherence; as out-of-pocket costs increase, so do prescription abandonment rates: when patient costs hit the $250 mark, over 70 percent of new patients walk away from the pharmacy empty handed.[3] A Kaiser Family Foundation survey found that of the patients who cited cost as a barrier to medication, 20 percent didn't fill a prescription while another 12 percent skipped doses or rationed pills.[4] For many of the patients represented by ACCC, delaying or forgoing treatment is likely to result in severe deterioration of their condition or even death. Copay assistance is a lifeline for patients who otherwise would not be able to afford their drugs because of the high out-of-pocket costs.

Moreover, the issuer's decision not to count copay amounts paid via manufacturer copay assistance raises questions about whether issuers are collecting the amount of copay assistance twice, effectively surpassing the maximum out-of-pocket threshold. Issuers with such policies continue to collect the copay assistance paid by manufacturers, which accrues toward the issuer's profits for the year, in addition to the copays paid by the patients.

Copay Assistance Does Not Cause Market Distortion

In the proposed rule, HHS reiterates a concern that consumers who select a higher-cost brand name drug over an equally effective, generic drug cause market distortion. Such a concern is, by definition, an impossibility when no generic equivalent is available. Moreover, a substantial body of research shows that when a lower-cost drug is available, providers and patients generally select that option, and that prescription purchases using copay assistance programs for drugs with generic equivalents represent less than 1 percent of the market.

Generic drugs account for nearly 90 percent of all prescriptions written today.[5] In reaction to the concern that manufacturer coupons incentivize brand-name drugs over generics, the fact is that the overwhelming majority (87 percent) of copay assistance programs are for drugs that have no generic equivalent.[6] The 13 percent of branded drugs for which generic equivalent products were available in a USC Schaeffer analysis accounted for only 0.05 percent of all prescriptions filled.[7]

Another analysis conducted by IQVIA presents further evidence that the revision to this rule may be a disproportionate reaction to a perceived problem.[8] Prescription payment claims analyzed from 2013 to

[2] US Department of Health & Human Services. May 2018. American Patients First: The Trump Administration blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs.
[3] IQVIA. May 2019. Medicine Use and Spending in the US; A Review of 2018 outlook to 2023.
[4] Kaiser Family Foundation. February 2019. Health Tracking Poll, Prescription Drugs.
[5] Association for Accessible Medicines. 2017. Generic Drug Access & Savings in the U.S.
[6] Van Nuys, K., Joyce, G., Ribero, R., Goldman, D.P. February 2018. A Perspective on Prescription Drug Copayment Coupons. Leonard D Schaeffer Center for Health Policy & Economics.
[7] IMS Institute for Healthcare Informatics. February 2014. Patient Savings Program Use Analysis
[8] IQVIA. Fact Sheet. An Evaluation of Copay Card Utilization in Brands After Generic Competitor Launch

2017 revealed that of the total commercial market, copay cards for products that had lost exclusivity made up only 0.4 percent of the volume.
In fact, in the 2020 NBPP HHS agreed that manufacturer copay assistance, when used for a brand name drug without a generic equivalent, would not distort the market, because there is no lower-cost option from which to steer patients. When that same rule was finalized HHS noted, "Where there is no generic equivalent available or medically appropriate, it is less likely that the manufacturer's coupon would disincentivize a lower cost alternative and thereby distort the market."[9]

If Left to the Discretion of Issuers, Copay Accumulators Will Spread Further
Codifying permission for issuers to exclude manufacturer copay assistance from patients' annual cost-sharing limits, regardless of the availability of an equivalent generic, all but guarantees that this will become the new standard of practice. Following the Tri-Agency FAQ issued in August 2019 indicating HHS would delay enforcement of the final rule, an issuer that had previously aligned its policy to comply with the requirements of the 2020 NBPP promptly issued an addendum, reverting to broadly banning all copay assistance without exception.[10] This provides evidence that if granted the flexibility, more issuers will in fact prohibit copay assistance.

The Source of Money to Pay Health Care Costs Does Not Reduce Health Care Costs
At section 1302(c)(3)(A), HHS suggests that amounts paid via manufacturer copay assistance should be excluded from the definition of cost-sharing because the existence of manufacturer copay assistance reduces the patients' cost-sharing obligation. We disagree with the reasoning HHS offers in this section; the existence of financial assistance does not change the patients' cost-sharing obligation. Rather, it merely helps the patient meet that obligation, similar to a gift from a family member, income from a job, lottery winnings, or a tax refund. Given the exorbitant and increasing costs that patients with severe, chronic illnesses must pay for their health care, we urge HHS to focus its efforts – in furtherance with this administration's stated goal – on reducing out-of-pocket costs for patients rather than limiting where patients are able to find the resources to pay for their care.

The coalition urges HHS to reconsider revising §156.130(h) as proposed and uphold the patient protections intended by the law to ensure patients can access their prescription medications without undue financial burden. We look forward to working with you to ensure patient access to needed medications. Should you have any questions please contact Rachel Klein, Deputy Executive Director at the AIDS Institute, at RKlein@taimail.org.

Sincerely,

All Copays Count Coalition Steering Committee
Anna Hyde, Vice President of Advocacy and Access, Arthritis Foundation
Kim Czubaruk, Senior Director of Policy and Advocacy, Cancer Support Community
Kim Calder, Senior Director of Health Policy, National Multiple Sclerosis Society
Kollet Koulianos, Senior Director Payor Relations, National Hemophilia Foundation
Rachel Klein, Deputy Executive Director, The AIDS Institute

[9] Health & Human Services. April 2019. Patient Protection and Affordable Care Act; HHS Notice of Benefit & Payment Parameters for 2020.
[10] The AIDS Institute. February 2020. Copay Accumulators and 2020 Qualified Health Plans.

All Copays Count Coalition Members

Aimed Alliance
Alliance for Patient Access
American Association of Clinical Urologists
American Autoimmune Related Diseases Association
American College of Rheumatology
American Kidney Fund
American Liver Foundation
Association of Women in Rheumatology
Axis Advocacy
CancerCare
Children with Diabetes
Chronic Disease Coalition
Coalition of State Rheumatology Organizations
Crohn's & Colitis Foundation
Cystic Fibrosis Engagement Network
Derma Care Access Network
Diabetes Patient Advocacy Coalition
Epilepsy Foundation
GBS|CIDP Foundation International
Good Days
Hemophilia Federation of America
HIV + Hepatitis Policy Institute
Huntington's Disease Society of America
Immune Deficiency Foundation
International Myeloma Foundation
Little Hercules Foundation
LUNGevity Foundation
MLD Foundation
Multiple Sclerosis Association of America
National Diabetes Volunteer Leadership Council
National Organization for Rare Disorders
National Pancreas Foundation
Patient Access Network (PAN) Foundation
Patient Services, Inc.
Project Sleep
Pulmonary Hypertension Association
Spondylitis Association of America
U.S. Hereditary Angioedema Association