January 27, 2022

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

The Honorable Chiquita Brooks- LaSure
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: Comments on *HHS Notice of Benefit and Payment Parameters for 2023* Proposed Rule, CMS-9911-P
RIN 0938-AU65

Dear Secretary Becerra and Administrator Brooks-LaSure:

We appreciate the opportunity to comment on the Health and Human Services' (HHS) proposed 2023 Notice of Benefit and Payment Parameters (NBPP) rule. The 126 organizations signing this letter represent millions of people living with serious, complex chronic illness in the United States. The Biden administration has made progress increasing access to health care and coverage, but more is needed to ensure that people living with chronic illness are able to get the ongoing care they need. We are extremely disappointed that the proposed 2023 NBPP rule does not include any reference to copay accumulator adjustment policies, which financially benefit insurance issuers and pharmacy benefit managers while making crucial treatments unaffordable for patients. ***We strongly urge you to address this issue in the final rule by requiring that insurers and Pharmacy Benefit Managers (PBMs) count all copayments made by or on behalf of an enrollee toward the enrollee's annual deductible and out-of-pocket limit.***

Discriminatory Practice (Section 156.125)

The proposed NBPP for 2023 seeks to refine Section 156.125 of the Affordable Care Act (ACA), directly addressing the issue of discriminatory benefit design, intending to ensure that insurance plans do not discriminate against people living with chronic illness. While we support CMS' intention to ensure that benefit design reflects clinical evidence rather than an effort to discriminate against people with high health care needs, ***we strongly urge CMS to also prohibit use of copay accumulator adjustment policies, which discriminate against people living with chronic illness.***

Copay accumulator adjustment policies undermine ACA protections prohibiting insurers from charging people with pre-existing conditions more than healthier enrollees. Copay assistance is generally only available for specialty or medications without a medically equivalent generic, which are used by people with serious, complex chronic illness. These policies subvert the benefit of co-pay assistance, thereby discriminating against people living with chronic conditions. People with low incomes and people of

color are more likely to be living with a chronic illness,[1] and therefore, these policies target the most vulnerable patients, enabling insurance issuers to engage in what amounts to "backdoor" underwriting of insurance policies for people who require specialty or brand medications. While CMS notes that adverse tiering is discriminatory and that drug coverage and formulary placement are important factors to determine whether a plan is discriminating against people with chronic illness, copay accumulator adjustment policies put critical drugs out of reach, even when covered.

Standardized Benefit Design (Section 156.201) Does Not Solve the Problem of Copay Accumulator Adjustment Policies

We strongly support the proposal to reinstate standardized benefit plans with flat dollar copayments for all prescription drug tiers, including specialty and non-preferred brand tiers. However, we are concerned that the dollar amounts for specialty and non-preferred brand medications – while a significant improvement at every metal level over the high coinsurance amounts found in current marketplace plans - remain too high for many patients struggling to afford their medications without copay assistance. Research has shown that over 70% of patients will not fill a prescription when their copayment reaches $250 (the amount proposed for specialty medications in gold level standard plans), and even at half that amount ($125), 55% of patients will opt against filling a new prescription.[2]

The copay amounts proposed for standard plans ranges from $150 - $350 per fill. And because most plans charge coinsurance post-deductible (proposed at $2,000 - $9,100), people living with chronic illness will still face very steep out-of-pocket costs that make adhering to a treatment plan difficult, if not impossible without copay assistance. ***We urge CMS to strengthen this proposal by 1) ensuring that patient copay assistance is counted toward the deductible and out-of-pocket limit; and 2) excluding all specialty drugs from the deductible to make medications more affordable to patients who utilize this category of prescription to maintain their health.***

Copay Assistance Helps Patients Afford Prescriptions and Stay Healthy

Patient copay assistance is a lifeline for our patients to afford critical, life-saving medications. As insurers have shifted more and more costs to enrollees – especially those who rely on specialty and brand medications – with higher deductibles and increasing coinsurance, many people living with chronic illness must rely on financial assistance to help cover the costs of their prescription drugs and remain adherent to their prescribed treatments. While most enrollees will never hit an out-of-pocket limit of $9,100 (the proposed amount for 2023), people managing a chronic illness requiring specialty or non-preferred brand medications may be forced to pay this amount *every single year*, often in the first few months of the year.[3,4] Since most Americans do not have an extra $9,100 after they pay their health

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[1] The Center for American Progress. Fact Sheet: Health Disparities by Race and Ethnicity. (May 7, 2020). https://www.americanprogress.org/article/health-disparities-race-ethnicity/

[2] IQVIA. *Medicine Use and Spending in the U.S: A review of 2018 and Outlook to 2023.* (May 9, 2019). https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-use-and-spending-in-the-us-a-review-of-2018-and-outlook-to-2023

[3] Center for Consumer Information and Insurance Oversight, *Affordability in the Marketplace Remains an Issue for Moderate Income Americans.* (January 2021). https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/Impact-Premium-Affordability.pdf

[4] K. Hempstead. *Marketplace Pulse: Cost-Sharing in the Marketplace, 2021*. Robert Wood Johnson Foundation, (June 28, 2021), https://www.rwjf.org/en/library/research/2021/06/marketplace-pulse-cost-sharing-in-the-marketplace-2021.html

insurance premium, rent or mortgage, food, transportation, childcare, and other basic needs, copay assistance is often the only way they can afford the medication they need, even if they have insurance.[5]

Some descriptions liken copay assistance to a coupon or a discount for prescription drugs. However, it is important to note that unlike a coupon or discount, copay assistance does not reduce the amount that enrollees are charged by their insurance plan for a prescription drug; rather, it is a source of financial aid to help patients pay the cost-sharing their insurance plan requires to fill their prescription. And unlike other large out-of-pocket costs for covered services, cost-sharing for a prescription drug must be paid in full for a person to receive the product, rather than being billed afterwards. This poses an insurmountable financial barrier for many patients with devastating potential consequences.

As noted above, extensive research documents that high out-of-pocket costs are associated with prescription abandonment – over 70% of new patients will walk away from a prescription when faced with a copayment of $250 or more.[6] For patients with a serious condition like HIV, multiple sclerosis, cancer, epilepsy, hemophilia, or diabetes, delaying or forgoing treatment may result in severe deterioration of their condition, permanent disability or even death. Copay assistance helps patients remain adherent to prescribed treatment, improving or maintaining their health.

Helping patients to remain adherent to medications and treatment regimens lowers costs to the overall healthcare system as well. A recent study found that increasing use of utilization management policies costs healthcare stakeholders $93 billion annually, with patients bearing the brunt through increased cost-sharing.[7] Any economic benefits gained by implementing obstructive policies, including copay accumulator adjustment policies, come at the cost of patients' health.[8]

"Double-Dipping" by Insurers using Copay Accumulator Adjustment Policies

In addition to the harm caused to patients by copay accumulator adjustment policies, these policies subvert the patient protections of the ACA by allowing insurers and PBMs to overcharge enrollees who use copay assistance. The ACA established annual out-of-pocket limits for covered health care services. When enrollees hit the out-of-pocket limit, insurance issuers must fully cover any further health care costs incurred. By not counting copay assistance cost-sharing amounts used to pay for covered services toward annual deductibles and out-of-pocket limits, insurers are able to keep the cost-sharing paid by enrollees, while avoiding assuming responsibility for costs above the out-of-pocket limit. This reduces the overall value of insurance for enrollees with chronic illness and exposes them to ongoing charges for their prescription drugs as well as any other health care they may need during the year.

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[5] Board of Governors of the Federal Reserve System, *Report on the Economic Well-Being of US Households in 2019-May 2020.* https://www.federalreserve.gov/publications/2020-economic-well-being-of-us-households-in-2019-overall-economic-well-being-in-2019.htm

[6] IQVIA. *Medicine Use and Spending in the US: A Review of 2018 and Outlook to 2023.* (May 2019.) Medicine Use and Spending in the US; A Review of 2018 outlook to 2023. A recent patient experience survey showed that of respondents taking prescription medicines with a high-deductible health plan, 52% report one or more episodes of non-adherence in the past year (Patient Experience Survey https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PES-Report_100621_Final.pdf).

[7] R, King. *Study: Drug utilization costs health industry $93B a year, with patients bearing most of the cost.* Fierce Healthcare. (August, 4, 2021). https://www.fiercehealthcare.com/payer/study-drug-utilization-costs-health-industry-93b-a-year-patients-bearing-most-cost

[8] R.I. Carlton, T. Bramley, B Nightengale, T. Conner, C Zacker. *Review of Outcomes Associated with Formulary Restrictions: Focus on Step Therapy.* (American Journal of Pharmacy Benefits.) (January, 2010). https://www.aspconline.org/wp-content/uploads/2021/08/Review-of-Outcomes-Associated-With-Formulary.pdf

In other rulemaking, CMS has acknowledged that insurers using copay accumulator adjustment policies are benefiting financially from those payments, subverting the intended benefit to the enrollee. Nonetheless, CMS' position puts the onus on the manufacturer to find new ways to ensure that any benefit from copay assistance provided is accrued to the enrollee, or face penalties.[9] The simplest way to address this concern, however, would be for CMS to restrict the use of copay accumulator adjustment policies, as it did in the 2020 NBPP, ensuring that enrollees get the full benefit of copay assistance intended for them.

Reinstating HHS' Original Position on Copay Assistance

This issue has been addressed by CMS in previous iterations of the NBPP. In the 2020 NBPP, CMS restricted use of copay accumulator adjustment policies, allowing them only in cases where an enrollee used manufacturer copay assistance for a brand drug when a medically-equivalent generic is available. However, HHS reversed course in the 2021 NBPP, allowing issuers to disregard any and all manufacturer copay assistance when determining whether an enrollee has met their annual deductible and/or out-of-pocket limit. This reversal of policy position has put our patients in a precarious position as they make difficult decisions about paying for medicines and paying for other necessities like groceries and rent during a pandemic and rising inflation.

HHS justified the policy reversal as necessary to protect access to tax benefits for people who use Health Savings Accounts (HSAs) with a High Deductible Health Plan (HDHP). A complete reversal of HHS' policy was not needed to protect HSA tax benefits. The IRS has since clarified that its only concern is related to the use of copay assistance to meet the minimum deductible to qualify as an HDHP ($1,400 for an individual or $2,800 for a family).[10] The use of copay assistance for amounts over the minimum deductible does not conflict with its policy related to HSA-eligibility. In its 2020 policy, HHS had already described certain conditions under which it would allow issuers to apply copay accumulator adjustment policies; rather than reverse its policy completely, HHS should have simply allowed plans to implement these policies up to the minimum deductible for enrollees in HSA-eligible plans.

We urge HHS to reconsider its policy allowing insurers and PBMs to adopt copay accumulator adjustment programs. A recent review of 2020 and 2021 marketplace plans reveals that copay accumulator adjustment programs have proliferated in the past two years.[11] These policies disproportionately impact patients with chronic illness, jeopardizing their access to needed care and prescription drugs. We urge HHS to require issuers and pharmacy benefit managers to count patient copay assistance toward a beneficiary's out-of-pocket costs, putting patients' health first.

We appreciate HHS officials and CMS leaders considering the critical needs of our patient community. Please feel free to reach out to Rachel Klein, Deputy Executive Director, The AIDS Institute at

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[9] US Department of Health & Human Services. Establishing Minimum Standards in Medicaid State Drug Utilization Review and Supporting Value-Based Purchasing for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third- Party Liability Requirements. https://www.cms.gov/newsroom/fact-sheets/establishing-minimum-standards-medicaid-state-drug-utilization-review-dur-and-supporting-value-based-0

[10] IRS. Notice 2004-50. Health Savings Accounts – Additional Qs & As. (Revised August 9, 2004). https://www.irs.gov/pub/irs-drop/n-04-50.pdf

[11] Stephanie Hengst. The AIDS Institute. *Copay Accumulator Adjustment Programs: Putting Insurance Company Profits Over Patients*. June 2020. http://www.theaidsinstitute.org/sites/default/files/attachments/AI_CoPay_Accumulator_Adjustment_Brochure_w%20Appendix_FINAL.pdf

rklein@taimail.org should you have any questions. Thank you very much for your consideration of our comments.

Sincerely,

ADAP Advocacy Association
Advocacy & Awareness for Immune Disorders Association (AAIDA)
Advocates for Responsible Care (ARxC)
AIDS Alabama
AIDS Foundation Chicago
AIDS United
Alliance for Patient Access
Alliance for Safe Biologic Medicines
American Academy of HIV Medicine
American College of Gastroenterology
American College of Rheumatology
American Kidney Fund
American Liver Foundation
Americans for Cures
APLA Health
APS Foundation of America, Inc
Arizona Bleeding Disorders
Arthritis Foundation
Association for Clinical Oncology
Autoimmune Association
Bleeding Disorders Alliance Illinois
Bleeding Disorders Alliance of North Dakota
Bleeding Disorders Association of NENY
Bleeding Disorders Association of South Carolina
Bleeding Disorders Association of South Carolina
California Chronic Care Coalition
Cancer Support Community
Cancer*Care*
Caregiver Action Network
Center for Health Law and Policy Innovation
Chronic Care Policy Alliance
Coalition of State Rheumatology Organizations
Colorectal Cancer Alliance
Community Access National Network (CANN)
Community Oncology Alliance
Connecticut Hemophilia Society
Crohn's & Colitis Foundation
Cystic Fibrosis Research Institute (CFRI)
Depression and Bipolar Support Alliance

Diabetes Leadership Council
Digestive Disease National Coalition
Dystonia Medical Research Foundation
Eastern Pennsylvania Bleeding Disorders Foundation
Florida Hemophilia Association FHA
FORCE - Facing Our Risk of Cancer Empowered
Foundation for Sarcoidosis Research
Gateway Hemophilia Association
GBS|CIDP Foundation International
Georgia AIDS Coalition
Global Healthy Living Foundation
Great Lakes Hemophilia Foundation
Haystack Project
HealthyWomen
Hemophilia Association of the Capital Area
Hemophilia Federation of America
Hemophilia Federation of America
Hemophilia Federation of America
Hemophilia Foundation Of Michigan
Hemophilia Foundation of Southern CA
Hemophilia of Iowa
Hemophilia of North Carolina
Hep B United
Hepatitis B Foundation
HIV + Hepatitis Policy Institute
HIV Dental Alliance
HIV Medicine Association
Human Rights Campaign
ICAN, International Cancer Advocacy Network
Immune Deficiency Foundation
International Association of Providers of AIDS Care
International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis)
International Foundation for Gastrointestinal Disorders
Interstitial Cystitis Association
Little Hercules Foundation
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
Lymphatic Education & Research Network
Mary M. Gooley Hemophilia Center
Medical Advocacy & Outreach
METAvivor
Midwest Hemophilia Association
MLD Foundation
Movement Disorders Policy Coalition

Multiple Sclerosis Association of America
NASTAD
National Alopecia Areata Foundation
National Ataxia Foundation
National Consumers League
National Eczema Association
National Hemophilia Foundation
National Multiple Sclerosis Society
National Pancreas Foundation
National Psoriasis Foundation
National Scleroderma Foundation
NCODA
Nevada Chronic Care Collaborative
New England Hemophilia Association
New York Blood Center
New York City Hemophilia Chapter
New York State Bleeding Disorders Coalition
Pacific Northwest Bleeding Disorders
Parkinson & Movement Disorder Alliance
Patient Access Network (PAN) Foundation
Patient Services, Inc.
PlusInc
Project Sleep
Pulmonary Hypertension Association
Restless Legs Syndrome Foundation
Rheumatology Nurses Society
Sangre de Oro Executive Board Member
Shriver Center on Poverty Law
SisterLove, Inc.
Snake River Hemophilia and Bleeding Disorder, Inc.
Society of Dermatology Physician Assistants
Southwestern Ohio Hemophilia Foundation
Spondylitis Association of America
Susan G. Komen
The 6:52 Project Foundation, Inc.
The AIDS Institute
The Headache and Migraine Policy Forum
The Mended Hearts, Inc
Triage Cancer
US Hereditary Angioedema Association
Virginia Hemophilia Foundation
Vivent Health
Western Pennsylvania Bleeding Disorders Foundation

CC: Ellen Montz, Director, CCIIO