

EXHIBIT 1

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

**HIV AND HEPATITIS POLICY
INSTITUTE, *et al.***

Plaintiffs,

v.

**UNITED STATES DEPARTMENT
OF HEALTH AND HUMAN SERVICES, *et
al.***

Defendants.

Case No. 1:22-cv-2604-JDB

BRIEF OF AMICI OF AIMED ALLIANCE, *ET AL.* ON BEHALF OF PLAINTIFFS

Date: February 9, 2023

Lloyd Liu
Hilary Holt LoCicero
BENNETT LOCICERO & LIU LLP
1707 L Street NW
Suite 1030
Washington, DC 20036
Tel: (202) 880-2129
Fax: (202) 747-2807
lliu@blfirm.com
hhlocicero@blfirm.com

Counsel for Amicus Curiae Aimed Alliance

TABLE OF CONTENTS

TABLE OF AUTHORITIES **ii**

CORPORATE DISCLOSURE STATEMENT..... **1**

IDENTITY AND INTERESTS OF AMICI CURIAE..... **1**

INTRODUCTION AND SUMMARY OF ARGUMENT **9**

ARGUMENT..... **12**

 I. HHS’s Interpretation on Copay Accumulators in the 2021 NBPP is Inconsistent with the ACA. 12

 II. Counting Copay Assistance Towards Consumers’ Annual Cost Sharing Limit Does Not Conflict with the 2004 IRS Notice..... 14

 III. Implementation of Copay Accumulators Has National Health Policy Implications. 16

 A. Copay Assistance Is Life Saving Support for Consumers. 17

 B. HHS’s Interpretation of Cost Sharing and Copayment Assistance in the 2021 NBPP Has Resulted in the Erosion of Consumer Protections Provided Under the ACA. 18

 C. Copay Accumulators Threaten the Health Stability of Consumers. 20

 D. Copay Assistance Helps Lower Health Care Costs. 21

CONCLUSION **21**

TABLE OF AUTHORITIES**Cases**

Chevron U.S.A. v. NRDC., 467 U.S. 837 (1984). 12

Statutes

26 U.S.C. § 223..... 16
 42 U.S. Code § 18022..... 9, 18, 20
 42 U.S.C. § 18116(a) 20
 45 C.F.R. § 146.121 20
 45 C.F.R. § 147.104(e)..... 20
 45 C.F.R. § 147.110 20
 45 C.F.R. § 155.20 9, 13
 45 C.F.R. § 156.22 18

Other Authorities

112 Million Americans Struggle to Afford Healthcare, West Health (Mar. 31, 2022),
<https://www.westhealth.org/press-release/112-million-americans-struggle-to-afford-healthcare/>. 10
Affordable Care Act (ACA), Healthcare.gov <https://www.healthcare.gov/glossary/affordable-care-act/>. 9
 Aimed Alliance & Center for Health Law and Policy Innovation at Harvard Law School, March 25, 2022 Letter to CCIO, <https://aimedalliance.org/wp-content/uploads/2023/01/Aimed-Alliance-and-CHLPI-2022-Non-EHB-Analysis-.pdf> 19
 Beena Jimmy & Jimmy Jose, *Patient Medication Adherence: Measures in Daily Practice*, 26 Oman Med. J. 155 (2011) <https://doi.org/10.5001/omj.2011.38> 20
Chronic Disease Management, Healthcare.gov, <https://www.healthcare.gov/glossary/chronic-disease-management/> 20
 Cother Hajat, et al., *Clustering and Healthcare Costs With Multiple Chronic Conditions in a US Study*, 8 Frontiers in Public Health 1 (2021), <https://doi.org/10.3389/fpubh.2020.607528>. 17
Discount, Cambridge Dictionary. 14
FAQs About Affordable Care Act Implementation (May 26, 2015),
<https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part-XXVII-MOOP-2706-FINAL.pdf>..... 9
Frequently Asked Questions (FAQs) about Affordable Care Act (ACA) Implementation Part 40, Department of Labor (Aug. 26, 2019), <https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-40>..... 1, 13
 Halsted R. Holman, *The Relation of the Chronic Disease Epidemic to the Health Care Crisis*, 2 ACR Open Rheumatology 167 (2020)
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7077778/>. 17
Impact of Legislation Protecting Patient Assistance Programs on Health Insurance Premiums, Global Healthy Living Foundation, <https://ghlf.org/copay-assistance-protection/#1661361152997-efccff49-e20d>..... 21

Internal Revenue Bulletin: 2004-33..... 12, 14

IRS Publication 969: Health Savings Accounts and Other Tax-Favored Health Plans (2022).... 15

Michal Shani, et al., *Associations of Chronic Medication Adherence with Emergency Room Visits and Hospitalizations*, 37 J. Gen. Internal Medicine 1060 (2022), <https://doi.org/10.1007/s11606-021-06864-9>..... 21

Out-of-pocket maximum/limit, Healthcare.gov, <https://www.healthcare.gov/glossary/out-of-pocket-maximum-limit/#:~:text=For%20the%202023%20plan%20year,and%20%2417%2C400%20for%20a%20family> 9, 10

Sara R. Collins, Lauren A. Haynes, Relebohile Masitha, *The State of U.S. Health Insurance in 2022*, The Commonwealth Fund (Sept. 29, 2022), <https://www.commonwealthfund.org/publications/issue-briefs/2022/sep/state-us-health-insurance-2022-biennial-survey>. 10

Statutory Interpretation: Theories, Tools, and Trends, Congressional Research Service (updated May 18, 2022). 12

Thomas Sullivan, *HHS Final Rule a Win for Copay Accumulator Adjustment Programs*, Pol’y & Med. Rockpointe Pub., (July 7, 2022), <https://www.policymed.com/2020/07/hhs-final-rule-a-win-for-copay-accumulator-adjustment-programs.html>. 15

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and U.S. District Court for the District of Columbia LCvR 7(o)(5), Aimed Alliance makes the following disclosures: Aimed Alliance is a 501(c)(3) not-for-profit health policy organization. Aimed Alliance is managed by an independent Board of Directors and has no parent corporation, and no publicly held company has 10 percent or greater ownership in Aimed Alliance. The organization’s principal place of business is in the District of Columbia.¹

IDENTITY AND INTERESTS OF AMICI CURIAE

Aimed Alliance is a 501(c)(3) not-for-profit health policy organization whose mission is to protect and enhance the rights of health care consumers and providers. Aimed Alliance advances policies to ensure that consumers and health care providers, can make informed and individually appropriate decisions without third-party interference from health insurers and their agents. Aimed Alliance leads and participates in policy-focused coalition activities to advance its mission. Members of Aimed Alliance’s policy coalition include health care consumers and professionals, more than 20 not-for-profit organizations, and 12 commercial supporters. Aimed Alliance’s organizational positions are established by its independent board of directors in accordance with its public interest mission.

¹ Pursuant to Fed. R. App. P. 29(a)(4)(E) and U.S. District Court for the District of Columbia LCvR 7(o)(5), amici curiae state that no counsel for a party authored this brief in whole or in part, and no party or counsel for a party contributed money intended to fund the preparation or submission of this brief. No person other than amici curiae, their members, or their counsel contributed money intended to fund the preparation or submission of this brief.² This policy applies to ACA exchange plans, and non-grandfathered individual and group health plans. *Frequently Asked Questions (FAQs) about Affordable Care Act (ACA) Implementation Part 40*, Department of Labor (Aug. 26, 2019), <https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-40>.

The ADAP Advocacy Association (aaa+®)(ADAP) is a national nonprofit organization that works to promote and enhance the AIDS Drug Assistance Programs (ADAPs) and improve access to care for persons living with HIV/AIDS. ADAP works with advocates, community, health care, government, patients, pharmaceutical companies, and other stakeholders to raise awareness, offer patient educational programs, and foster greater community collaboration.

Advocacy & Awareness for Immune Disorders Association (AAIDA) is a nonprofit organization dedicated to patients living with immune conditions and overlapping conditions with a focus on advocacy campaigns and educational initiatives. AAIDA also provides patients and health care providers assistance with insurance denials and medication assistance programs available across the United States.

Any Positive Change Inc. is nonprofit organization focused on drug user health, providing no-cost harm reduction services, information, education, resources, and referrals to the people of Lake County, California.

The Association of Community Cancer Centers (ACCC) is a community of cancer centers — representing members nationwide from all care delivery settings: comprehensive cancer programs, health systems, academic centers, community cancer programs, and private practices.

The Autoimmune Association is the world's leading nonprofit organization dedicated to autoimmune awareness, advocacy, education, and research. Children with Diabetes is a nonprofit organization dedicated to providing education and support to families living with type 1 diabetes, who are often adversely impacted by co-pay accumulators.

The Chronic Care Policy Alliance (CCPA) is a network of state and regional advocacy organizations advancing public policy that improves the lives of those living with chronic

conditions and diseases. Dedicated to achieving better access to quality, affordable health care, CCPA brings together advocates who share common goals and lends its experience in legislative action and public policy creation to support statewide and regional networking development.

The Coalition of State Rheumatology Organizations (CSRO) is comprised of over 40 state and regional professional rheumatology societies whose mission is to advocate for excellence in the field of rheumatology, ensuring access to the highest quality of care for the management of rheumatologic and musculoskeletal disease. The coalition serves practicing rheumatologists and their patients. Its interest as an amicus is simple: it wants to ensure that its patients can fully benefit from all of the Affordable Care Act's critical patient protections, and allowing copay assistance to count towards deductibles and out-of-pocket limits helps meet that goal.

Community Access National Network (CANN), formerly Ryan White CARE Act Title II Community AIDS National Network, is a nonprofit, non-partisan organization whose mission is to define, promote, and improve access to health care services and supports for people living with HIV/AIDS and/or viral hepatitis through advocacy, education, and networking. CANN's coalition-based work centers on the patient experience in navigating various aspects of health care; analyzing public policy impacts on patient access to care; and educating industry partners, policymakers, and other stakeholders as to the key issues patients self-identify as the most important to them.

The Connecticut Oncology Association is the sole professional support organization for Connecticut practicing oncologists and their practices, including practice administration and clinical teams. Community Oncology Alliance (COA) is a nonprofit organization dedicated to

advocating for the complex care and access needs of patients with cancer and the independent community oncology practices that serve them. COA's mission is to ensure that patients with cancer receive the highest quality, most affordable, and most accessible cancer care in their own communities where they live and work, regardless of their racial, ethnic, demographic, or socioeconomic status. COA is the only nonprofit organization in the United States dedicated solely to independent community oncology practices, which serve the majority of Americans receiving cancer treatment.

Equitas Health is a federally designated community health center and one of the largest LGBTQ+ and HIV/AIDS serving health care organizations in the country. Each year, it serves tens of thousands of patients in Ohio, Texas, Kentucky, and West Virginia, and since 1984, it has been working to advance "care for all."

The EveryLife Foundation for Rare Diseases empowers the rare disease patient community to advocate for impactful, science-driven legislation and policy that advances the equitable development of and access to lifesaving diagnoses, treatments, and cures. Rare disease patients often rely on copay assistance programs to ensure they can afford to access their medications.

Fabry Support & Information Group is a national, nonprofit organization that provides resources to those diagnosed with Fabry and their caregivers, including free education about Fabry disease, clinical trial opportunities, improved scientific learnings, consumer rights and practical issues surrounding those living with this chronic, life-threatening condition. The Fabry community is being impacted by insurers' growing use of copay accumulator programs that divert assistance away from those suffering while rewarding insurers who are supposedly providing maximum value to their vulnerable customers.

Gaucher Community Alliance is a nonprofit patient advocacy organization representing the interests of patients and families living with all types of Gaucher disease. Gaucher disease is a rare genetic disease that allows a certain fat to build up in certain organs, bones, and in some cases the brain. The FDA-approved treatments for this disease allow its patients to live a quality life in most cases. These treatments can be expensive and are often unaffordable without copay assistance. Its community needs action to protect its patients and allow them to remain on treatment by counting all dollars of copay assistance toward the annual cost sharing limits.

The Georgia AIDS Coalition is a not-for-profit organization created in 1989 to act as an educational resource for the formation and articulation of public policy regarding HIV infection, Hepatitis, Tuberculosis, and sexually transmitted infections. Copay cards have assisted HIV+ individuals and PrEP clients in meeting deductibles or out-of-pocket maximums on their insurance. Restricting manufacturer copay assistance from counting toward a patient's annual out-of-pocket maximum makes medication unaffordable for individuals leading to treatment interruption, increases in viral load, and decreases in the health status of individuals.

The Global Healthy Living Foundation is a 501(c)(3) nonprofit organization whose mission is to improve the quality of life for people with chronic illnesses (such as arthritis, osteoporosis, migraine, psoriasis, asthma, alopecia, inflammatory bowel disease, and cardiovascular disease) by advocating for improved access to health care at the community, state, and federal levels, and amplifying education and awareness efforts within its social media framework.

The Global Liver Institute saves lives by empowering patient advocates to collaborate with policymakers, clinicians, and industry to drive the liver health field forward. Healthy Men Inc. (HMI) is a nonprofit organization dedicated to advancing the health interests of boys, men,

and their families that works to support adoption of male-friendly approaches to health care and wellness services for boys and men. Its interest in this case stems from the core precept that making medications, particularly advanced technology medications, affordable is fundamental to access.

Hemophilia Federation of America (HFA) is a community-based, grassroots advocacy organization that assists, educates, and advocates for people with hemophilia, von Willebrand disease, and other rare bleeding disorders. Bleeding disorders are serious, life-long, and expensive. Individuals and families who live with these health conditions require quality and affordable health care coverage, and protection from onerous and unpredictable out-of-pocket costs.

ICAN, International Cancer Advocacy Network, is a cancer patient advocacy organization and 501(c)(3) charitable organization based in Phoenix, Arizona. ICAN specializes in direct patient navigation, clinical trials matching, molecular profiling matching, public policy advocacy, and health equity advocacy. One of the issues that ICAN focuses on in its public policy advocacy is addressing the negative implications of copay accumulators.

Infusion Access Foundation (IAF) is an inclusive community of individuals with different illnesses united by a common goal: to reliably access the right care at the right time to manage the burdens of chronic disease at the lowest possible cost. It supports the community to advocate with one voice that reaches policymakers. As a nonprofit, IAF's purpose is to support the people that are underserved by the health care system every day so they can fight together for treatment.

The International Foundation for Autoimmune & Autoinflammatory Arthritis is a not-for-profit organization whose mission is to advance education, advocacy, and research for those impacted by autoimmune and autoinflammatory arthritis (AiArthritis) diseases through peer-led

guidance, collaboration, and resources that are driven by patient-identified issues and patient-infused solutions. AiArthritis advances policies that ensure that treatment decisions remain made between the patient and their medical team to maintain continuity of care.

Founded in 1969, the National Health Law Program (NHeLP) is a public interest organization dedicated to improving access to quality health care, including prescription drugs, for low-income and underserved individuals. To achieve its mission, NHeLP advocates, educates, and litigates at the federal and state levels.

The National Infusion Center Association (NICA) is a nonprofit organization formed to support non-hospital, community-based infusion centers caring for patients in need of provider-administered medications. To improve access to medical benefit drugs that treat complex, rare, and chronic diseases, it works to ensure that patients can access these drugs in safe and cost-effective alternatives to hospital care settings. In service of that goal, NICA supports policies that improve drug affordability for beneficiaries, increase price transparency, reduce disparities across care settings, and foster patient access to the highest-quality, lowest-cost setting. For these reasons, NICA has a keen interest in ensuring that these insurer programs cannot be used in the exchanges.

The National Consumers League (NCL) is a private, nonprofit advocacy group representing consumers on marketplace and workplace issues. It is the nation's oldest consumer organization, founded in 1899. Headquartered in Washington, DC, today NCL provides government, businesses, and other organizations with the consumer's perspective on concerns including child labor, privacy, food safety, and health care. Its position is that maximizers cannot stand.

National Oncology State Network is a nonprofit action organization established by state leaders collaborating on emerging state issues in order to strengthen cancer care and policy across the country.

The Rheumatology Nurses Society (RNS) is a nonprofit professional nursing and advanced practice provider (APP) organization representing registered nurses, nurse practitioners, physician assistants, and other health care professionals who are engaged in clinical practice, education, research, and advocacy for the care of adult and pediatric patients with rheumatic diseases. Often, its members not only provide clinical care to rheumatology patients, but also help them navigate the overwhelming utilization management requirements and financial burdens of autoimmune disease. Its members know from firsthand experience that high out-of-pocket costs lead to treatment non-adherence. For that reason, RNS has taken a strong position against the use of these programs by insurers.

Triage Cancer is a national, nonprofit organization that provides free education on the legal and practical issues that may impact individuals diagnosed with cancer and their caregivers, through events, materials, and resources. Triage Cancer also continuously advocates for the health care, finances, insurance, employment, and consumer rights of those diagnosed with cancer and their caregivers. As a nonprofit organization focused on mitigating financial toxicity for individuals diagnosed with cancer, the Triage Cancer believes that the use of copay accumulator programs prevents those who are already struggling with the financial ramifications of a cancer diagnosis from getting the care and treatment they need.

Aimed Alliance and its fellow amici submit this brief in support of Plaintiffs' Motion for Summary Judgment and prayer for relief. The amici have a strong interest in this case given that each organization works and advocates to promote and protect the rights of patients and health

care consumers. If this case proceeds, the amici and other patient advocates will undertake public awareness, consumer and professional education, and advocacy activities to disseminate the facts of this case and the Court's holding. In doing so, it will help the public to better understand their copayment obligations and the manner in which they are impacted by the practices and programs of health plans that prey upon uninformed health care consumers.

INTRODUCTION AND SUMMARY OF ARGUMENT

The Patient Protection and Affordable Care Act (ACA) is designed to increase access to health insurance, bolster consumer protections, and make health coverage fairer and more affordable. *Affordable Care Act (ACA)*, Healthcare.gov, <https://www.healthcare.gov/glossary/affordable-care-act/>. As such, the ACA establishes an annual limit on cost sharing that all health plans subject to the ACA must comply with. FAQs About Affordable Care Act Implementation (Part XXVII) (May 26, 2015), <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part-XXVII-MOOP-2706-FINAL.pdf>. Notably, the ACA defines “cost sharing” to include “deductibles, coinsurance, copayments, or similar charges” and the statute does not establish limitations with respect to who can pay such cost sharing amounts. 42 U.S.C. § 18022(c)(3)(A)(i). Moreover, the definition of cost sharing as implemented by 45 C.F.R. § 155.20 explicitly recognizes that cost sharing expenditures may be paid by *or on behalf of* the enrollee.

This annual limit on cost sharing, referred to as the out-of-pocket maximum, is the most a plan enrollee can be required to pay for covered services in a plan year. *Out-of-pocket maximum/limit*, Healthcare.gov, <https://www.healthcare.gov/glossary/out-of-pocket-maximum-limit/#:~:text=For%20the%202023%20plan%20year,and%20%2417%2C400%20for%20a%20fa>

mily. For 2023, the out-of-pocket maximum is \$9,100 for individuals and \$18,200 for families. *Id.*

While the annual out-of-pocket maximum is intended to reduce the financial burden of obtaining health care, many insured individuals and families nevertheless struggle to afford their health care expenses. According to a 2022 survey, an estimated 44 percent of American adults struggle to afford health care. *112 Million Americans Struggle to Afford Healthcare*, West Health, (Mar. 31, 2022), <https://www.westhealth.org/press-release/112-million-americans-struggle-to-afford-healthcare/>. A separate 2022 survey published by the Commonwealth Fund found that 46 percent of respondents skipped or delayed care because of cost. Sara R. Collins, Lauren A. Haynes, Relebohile Masitha, *The State of U.S. Health Insurance in 2022*, The Commonwealth Fund (Sept. 29, 2022), <https://www.commonwealthfund.org/publications/issue-briefs/2022/sep/state-us-health-insurance-2022-biennial-survey>. Skipping, delaying, or otherwise rationing care can have devastating consequences for individuals' health, especially those living with chronic and serious conditions.

To help privately insured consumers obtain medically necessary treatments prescribed by their health care providers, drug manufacturers developed programs commonly referred to as “copay assistance programs.” These programs are designed to provide direct financial assistance to qualifying consumers by covering a portion of their prescription drug cost sharing requirements. Originally, these assistance programs helped consumers by both lowering the cost of their prescription drugs at the pharmacy counter *and* contributing towards their plans' annual cost sharing limit. In other words, they helped consumers afford their treatments at the point of sale and helped them progress toward reaching their annual out-of-pocket maximums. In response to these programs, insurance companies and those who manage their prescription drug plans have

adopted policies that prohibit consumers from counting the copay assistance provided by a manufacturer toward their deductibles and annual out-of-pocket maximums.

The policies, known as copay accumulator programs, result in health insurance companies “double dipping” to the detriment of consumers by collecting both the copay assistance provided by the manufacturer and the out-of-pocket payments from the patient after the assistance is exhausted. As explained in more detail herein, health plans have also used this concept to develop various other, sometimes coercive, schemes that negatively impact health care consumers. Because of these policies, it effectively takes health care consumers longer to reach their annual out-of-pocket maximums than if the assistance initially counted toward their plans’ annual cost sharing limits. Ultimately, this increases insured consumers’ annual health care costs. This is contrary to the ACA’s statutory text and also directly contradicts and undermines the ACA’s intent of fair and affordable health care coverage.

To protect health care consumers, patient advocacy organizations, health policy organizations, and other nonprofits advocated for HHS to clarify that all cost sharing by or on behalf of insured individuals for a deductible, copay, coinsurance or similar charge should be counted towards their pharmacy cost sharing and annual limits. In its 2021 NBPP, however, HHS revised 45 C.F.R. § 156.130(h) to permit health plans to exclude drug manufacturer copay assistance from counting towards an insured consumer’s cost sharing limits. Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans, 85 Fed. Reg. 29,164 (May 14, 2020) [hereinafter *2021 NBPP*]. In seeking to justify this abrupt change from prior policy, HHS pointed to the possibility that requiring plans to count manufacturer copay assistance towards the out-of-pocket maximum could conflict with Internal Revenue Service (IRS) guidance from 2004 (2004

IRS Notice) regarding eligibility of enrollees in high deductible health plans (HDHPs) to contribute to health savings accounts (HSAs) when manufacturer copayment assistance is involved. Internal Revenue Bulletin: 2004-33.

This Court should set aside the 2021 NBPP to the extent it permits insurers to implement copay accumulator programs and similar programs that exclude manufacturer assistance from annual cost sharing limits because (1) it is inconsistent with the ACA; (2) it cannot be justified by the 2004 IRS Notice; and (3) allowing health plans to implement copay accumulators has important national health policy implications. Therefore, on behalf of health care consumers, caregivers, and health care providers, the amici respectfully ask this Court to grant Plaintiffs' prayer for relief and find that the ACA requires all cost sharing by or on behalf of consumers to count towards their annual cost sharing limits.

ARGUMENT

I. HHS's Interpretation on Copay Accumulators in the 2021 NBPP is Inconsistent with the ACA.

Statutes must be interpreted with the ordinary meaning of the text that Congress intended. *Chevron U.S.A. v. NRDC*, 467 U.S. 837 (1984). Agencies may only provide a reasonable interpretation when the statute is silent or ambiguous. *Id.* See also *Statutory Interpretation: Theories, Tools, and Trends*, Congressional Research Service, p. 41 (updated May 18, 2022). Moreover, if an agency attempts to interpret a silent or ambiguous statute, this Court may only provide deference to the agency's interpretation so long as the interpretation is reasonable. *Id.*

In the 2021 NBPP, HHS stated that whether manufacturer copay assistance falls under the definition of "cost sharing" is "subject to interpretation." On the one hand, HHS reasoned that "[t]he value of the direct manufacturer support could be viewed as not representing costs incurred by or charged to enrollees. Instead, such amounts could be viewed as representing a reduction, by

drug manufacturers, in the amount that the enrollee is required to pay at the point of sale to obtain the drug.” Under this viewpoint, manufacturer copay assistance would not be deemed as cost sharing, and as such, it would not be mandated to count towards a consumer’s annual cost-sharing limits. On the other hand, HHS also stated that “if a consumer is responsible for a \$50 co-pay for a brand name drug, the consumer cannot obtain the drug at the point of sale without providing the full \$50 (whether with \$50 cash, or \$30 cash with the \$20 coupon).” *2021 NBPP*. Under the latter example, copay assistance is counted towards the consumer’s annual cost sharing limits because the entire \$50 is considered a cost incurred by the consumer to access their medication.

HHS essentially concluded that both interpretations are consistent with the law and, thus, each state and issuer may elect to use either interpretation.² *Id.* However, concluding that both interpretations are consistent with the definition of cost sharing contradicts the plain language of the ACA and is unreasonable.

The term “cost sharing” as defined by the ACA and implemented at 45 C.F.R. § 155.20 is not ambiguous. The statutory definition explicitly recognizes that cost sharing expenditures, including deductibles, coinsurance, copayments, or similar charges, may be paid by *or on behalf of* the enrollee. 45 C.F.R. § 155.20 (emphasis added). Thus, under a plain reading of the definition, all assistance paid toward a cost sharing item must count towards an individual’s annual limit on cost sharing.

Notwithstanding the plain meaning of the definition of cost sharing, the 2021 NBPP creates unreasonable outcomes. For example, under HHS’s interpretation, financial support provided by

² This policy applies to ACA exchange plans, and non-grandfathered individual and group health plans. *Frequently Asked Questions (FAQs) about Affordable Care Act (ACA) Implementation Part 40*, Department of Labor (Aug. 26, 2019), <https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-40>.

a parent trying to help their adult child with health care costs could also not count towards the child's annual cost sharing limits. Likewise, financial contributions received by consumers from charities or other low-income funding programs could also be excluded from counting towards consumers' annual limit on cost sharing. These outcomes are completely unreasonable, unfair, and impractical.

In addition to conflicting with the plain meaning of the definition of cost sharing, the 2021 NBPP's revisions to 45 C.F.R. § 156.130(h) undermines a primary purpose of the ACA—to make health care more affordable. When a plan adopts a copay accumulator, consumers are required to pay their health plan for an amount the plan has already collected on their behalf. This ultimately increases consumers' overall health care costs, making their health care less affordable.

Lastly, HHS' interpretation that copay assistance is intended as a reduction or a discount to consumers is misguided. *2021 NBPP*. Copay assistance is not a discount. A discount is defined as “a reduction in the usual price.” *Discount*, Cambridge Dictionary, <https://dictionary.cambridge.org/us/dictionary/english/discount>. Here, the cost of the medication does not change when a consumer uses copay assistance, but rather the cost of the medication is paid by two different parties, the drug manufacturer and the consumer.

As such, this Court should not give deference to HHS's interpretation of cost sharing and copay assistance in the 2021 NBPP given that it is inconsistent with the plain language of the ACA and unreasonable.

II. Counting Copay Assistance Towards Consumers' Annual Cost Sharing Limit Does Not Conflict with the 2004 IRS Notice.

On August 16, 2004, the IRS issued the 2004 IRS Notice, a bulletin that contained a set of questions and answers on HSAs and HDHPs. Internal Revenue Bulletin: 2004-33, Q9. In that document, Question 9 asked, “May an individual who is covered by an HDHP and also has a

discount card that enables the user to obtain discounts for health care services or products, contribute to an HSA?” (emphasis added). The IRS provided the following answer:

A-9. Yes. Discount cards that entitle holders to obtain discounts for health care services or products at managed care market rates will not disqualify an individual from being an eligible individual for HSA purposes if the individual is required to pay the costs of the health care (taking into account the discount) until the deductible of the HDHP is satisfied.

In the 2021 NBPP, HHS interpreted the 2004 IRS Notice as extending beyond “discount cards” to manufacturer copay assistance, making an individual enrolled in an HSA-HDHP ineligible for an HSA if they accept copay assistance to help satisfy their cost sharing amounts before their minimum deductible is met. Thomas Sullivan, *HHS Final Rule a Win for Copay Accumulator Adjustment Programs*, Pol’y & Med. Rockpointe Pub., (July 7, 2022), <https://www.policymed.com/2020/07/hhs-final-rule-a-win-for-copay-accumulator-adjustment-programs.html>. Essentially, HHS used a nearly two-decades old *guidance* document – without the force of law – to justify permitting copay assistance to be excluded from consumers’ annual cost sharing limits. HHS reasoned that it would be difficult for health plans to comply with the 2004 IRS Notice and also count copay assistance towards consumers’ annual cost-sharing limits. *2021 NBPP*.

However, HHS’s reliance on the 2004 IRS Notice to justify its interpretation of cost sharing and copay assistance is incorrect for two critical reasons. First, the 2004 IRS Notice only precludes “discount cards” from contributing to an individual’s annual cost-sharing limits. Discount cards and manufacturer copay assistance are not the same thing. Discount cards typically refer to third party programs that are often used as an *alternative* to health insurance. IRS Publication 969: *Health Savings Accounts and Other Tax-Favored Health Plans* (2022). Thus, patients without health insurance can use these discount cards to receive their prescription drugs at a lower cost.

Further, discount cards have no annual cap. In contrast, copay assistance is used by individuals with private health insurance to help offset health plans' annual cost sharing amounts. Copay assistance programs also cap the total annual assistance that an individual may receive. Thus, these two programs and terms are not interchangeable.

Second, HHS's interpretation is inconsistent with the HSA statute and IRS's subsequent guidance, IRS Publication 969. 26 U.S.C. § 223. Under the HSA statute, an individual is eligible to contribute to an HSA if (1) they are enrolled in an HDHP; and (2) while enrolled in the HDHP, they are not covered by any other plan that is not an HDHP and which provides coverage for any benefit which is covered under the HDHP. 26 U.S.C. § 223(c). In addition, IRS Publication 969 states that an individual can contribute to an HSA so long as (1) the individual is not enrolled in Medicare; and (2) not claimed as a dependent on someone else's tax return. IRS Publication 969. As such, an individual is *only* prohibited from contributing to an HSA if (1) they are not enrolled in an HDHP; (2) they are enrolled in Medicare; (3) they are a dependent on someone else's tax return; or (4) they have additional health plan coverage. Neither the HSA statute nor IRS Publication 969 state that if an individual accepts manufacturer copay assistance then they are ineligible to contribute towards their HSA. Thus, there is no apparent or potential conflict as asserted by HHS.

III. Implementation of Copay Accumulators Has National Health Policy Implications.

Subsections A through C below describe the broad, national public health policy implications of allowing health plans to implement copay accumulator programs, and similar schemes where plans accept the cost sharing assistance amounts that manufacturers provide for patients but then refuse to apply those assistance amounts towards the patients' annual cost sharing limits.

A. Copay Assistance Is Life Saving Support for Consumers.

Many critics of copay assistance argue that counting the assistance toward individuals' annual cost sharing limit results in consumers being less invested in their health. This position mischaracterizes the purpose and importance of copay assistance programs, especially with respect to consumers living with rare and chronic conditions. Copay assistance programs are a vital consumer safety net, ensuring that consumers can afford their medications and are not forced to become non-adherent to their treatment plans due to financial cost.

It is estimated that around 50 percent of the United States population is living with a chronic disease. Halsted R. Holman, *The Relation of the Chronic Disease Epidemic to the Health Care Crisis*, 2 ACR Open Rheumatology 167 (2020) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7077778/>. Consumers living with chronic conditions often have increased health care costs compared to consumers without them due to the cost of available treatments, the regular frequency at which medications must be taken and refilled, and frequent provider visits. For instance, one study analyzing a large number of commercial health insurance claims from 2015 found that individuals living with at least two chronic conditions had mean annual health care spending of over \$12,000 to manage their health, nearly double the 2016 annual limit on cost sharing (\$6,850). Cother Hajat, et al., *Clustering and Healthcare Costs With Multiple Chronic Conditions in a US Study*, 8 *Frontiers in Public Health* 1 (2021), <https://doi.org/10.3389/fpubh.2020.607528>. Moreover, data shows that copay assistance is extremely rarely used in instances where a medically appropriate generic alternative therapy is available for the patient.

Thus, copay assistance can be life saving for individuals living with rare and chronic conditions. People with such conditions want to feel healthy, manage their symptoms effectively, and reduce the negative implications their conditions can place on their day-to-day lives. Copay

assistance does not incentivize individuals to be less invested in their health, but rather *more* invested because they are better able to afford their medications and other care and manage their conditions. It ensures these individuals can access their monthly treatments while reducing the possibility of serious financial strain or debt.

B. HHS’s Interpretation of Cost Sharing and Copayment Assistance in the 2021 NBPP Has Resulted in the Erosion of Consumer Protections Provided Under the ACA.

By permitting health plans to exclude manufacturer assistance from counting toward consumers’ annual cost sharing limits, HHS has laid the groundwork for further erosion of the ACA’s core essential health benefit (EHB) protections as plans attempt to access the maximum amount of copay assistance available.

The ACA requires health plans to cover 10 EHBs, one of which is prescription drugs. 42 U.S.C. § 18022(b). In addition, the ACA requires that all cost sharing amounts spent on an EHB, such as prescription drugs, count towards the consumer’s deductible and annual out-of-pocket limit. 45 C.F.R. § 156.22. However, to capitalize on the maximum amount of copay assistance available, many plans have begun to designate certain medications as “non-EHBs” so the plan can coerce the consumer into enrolling in the plans’ specialty medication programs. These non-EHB schemes coerce consumers into enrollment by stating that if they enroll in the specialty medication program, then their out-of-pocket costs for their medication will be minimal; but, if they do not enroll in the program, then they will be responsible for a 30 percent to 100 percent coinsurance that will not count towards their deductible or annual out-of-pocket limit. After patients are essentially forced to enroll in a specialty medication program to avoid high coinsurance payments, the plan helps the individual enroll in a manufacturer copayment assistance program, if they are not already receiving such copayment assistance. Then, once the consumer is enrolled in the copay assistance program, the plan accepts the assistance on behalf of the consumer but does not count

it towards their deductible or annual out-of-pocket limit. *See* Aired Alliance & Center for Health Law and Policy Innovation at Harvard Law School, March 25, 2022 Letter to CCIIO, <https://aimedalliance.org/wp-content/uploads/2023/01/Aimed-Alliance-and-CHLPI-2022-Non-EHB-Analysis-.pdf>.

While the question of whether non-EHB schemes are permissible under applicable law is not directly before the Court here, it is critical for this Court to understand that the creation of the non-EHB programs is a result of the specific agency action that *is* at issue in this case—namely, HHS incorrectly determining that plans may collect manufacturer copay assistance from consumers without counting it towards consumers’ annual cost sharing limits. As a result of this determination, plans developed new means of accessing the maximum amount of financial assistance available from third parties, irrespective of the consumer’s financial needs. Ultimately, these schemes limit the scope of the ACA’s EHB protections which, if left unchecked, could impact other EHBs. For example, health plans likewise could adopt a benchmark plan with the least number of services under the EHB category of “maternal and newborn care,” and deem all additional services as non-EHBs. As a non-EHB, the consumer’s costs for these services would not contribute towards their deductibles and annual out-of-pocket limits. This type of erosion is dangerous for many women who experience high-risk pregnancies and need more visits, tests, or ultrasounds than those provided in the benchmark plan.

Moreover, by targeting specific medications for which copay assistance is available and that particular enrollees have been prescribed because of their health status, health factors, health conditions, and/or disabilities, these non-EHB policies undermine and raise significant concerns under the ACA’s important nondiscrimination provisions that are in place to protect patients against discrimination in health care and discriminatory benefit designs. *See, e.g.*, 42

U.S.C. § 18116(a); 42 U.S.C. §§ 18022 (a) - (b)(4); 45 C.F.R. §§ 146.121(a) - (b), 147.104(e) & 147.110. These potential large-scale ramifications all stem from HHS's improper interpretation and cannot be ignored.

C. Copay Accumulators Threaten the Health Stability of Consumers.

As noted above, millions of Americans are living with at least one chronic condition or disease. To manage a chronic condition or disease, an individual often must have regular screenings and check-ups, coordinated treatment and monitoring, and prescription medications, among other health care needs. *Chronic Disease Management*, Healthcare.gov, <https://www.healthcare.gov/glossary/chronic-disease-management/>. All such services generally require some form of cost sharing from consumers until they reach their annual cost sharing limits. Yet, as explained throughout this brief, copay accumulators lead to higher health care expenses for consumers who are subject to them.

When consumers are unable to afford prescription drugs and other health care expenses, they may become nonadherent to their treatment plans. Non-adherence can include consumers stopping their treatments altogether, rationing medications by skipping doses, or limiting medication usage. This can lead to poor health outcomes, including relapses in symptoms and hospitalization, which can increase overall health care costs. Beena Jimmy & Jimmy Jose, *Patient Medication Adherence: Measures in Daily Practice*, 26 Oman Med. J. 155 (2011) <https://doi.org/10.5001/omj.2011.38>.

This is a major reason why copay assistance programs have become so important to patients. When consumers receive the full, intended benefit of copay assistance programs, they are better able to afford their medications, comply with their treatment regimens, and maintain health stability. Health plans that use copay accumulators jeopardize the viability and

sustainability of these vital safety net programs by taking advantage of them, reaping their financial value, and robbing consumers of their full intended benefit.

D. Copay Assistance Helps Lower Health Care Costs.

Organizations that argue copay assistance should not count towards consumers' annual cost sharing limit often claim that if copay assistance is counted towards annual cost sharing limits, then health care costs, such as health insurance premiums, will increase. However, there is evidence that this claim is not true. A recent study by the Global Healthy Living Foundation found that there currently is no statistical difference in premiums between states with laws mandating that copay assistance count towards deductibles and out-of-pocket maximums and those that do not have such laws. *Impact of Legislation Protecting Patient Assistance Programs on Health Insurance Premiums*, Global Healthy Living Foundation, <https://ghlf.org/copay-assistance-protection/#1661361152997-efccff49-e20d>.

Moreover, copay assistance can help reduce long-term health care costs because consumers are more likely to adhere to their treatment plans when they can consistently afford and access their prescribed treatments. Ultimately, treatment adherence reduces the likelihood that consumers will incur costly health care expenditures, such as emergency room visits and hospitalizations. Michal Shani, et al., *Associations of Chronic Medication Adherence with Emergency Room Visits and Hospitalizations*, 37 J. Gen. Internal Medicine 1060 (2022), <https://doi.org/10.1007/s11606-021-06864-9>.

CONCLUSION

For the reasons discussed above, Aired Alliance and its fellow amici support Plaintiffs' motion for summary judgment and prayer for relief. In making its findings in this case, the amici strongly urge the Court to consider the broad, national public health policy implications that arise

from the 2021 NBPP's position on copay accumulators, and the need to protect and uphold important consumer protections created by the ACA.

A judgment in Plaintiffs' favor will enable Aimed Alliance and other patient advocates to undertake important public awareness, consumer and professional education, and advocacy activities to disseminate the Court's holding, support other complaints that relate to the erosion of EHBs, and promote the legislative and regulatory changes necessary to protect consumers.

Dated: February 9, 2023

Respectfully submitted,

/s/ Lloyd Liu

Lloyd Liu

Hilary Holt LoCicero

BENNETT LOCICERO & LIU LLP

1707 L Street NW

Suite 1030

Washington, DC 20036

Tel: (202) 880-2129

Fax: (202) 747-2807

lliu@bllfirm.com

hhlocicero@bllfirm.com

Counsel for Amicus Curiae Aimed Alliance