

October 3, 2022

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

Melanie Fontes Ranier
Director, Office for Civil Rights
U.S. Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

Attention: 1557 NPRM (RIN 0945-AA17)

Secretary Becerra and Director Ranier,

The All Copays Count Coalition (ACCC), on behalf of the 57 undersigned organizations, appreciates the opportunity to provide comments in response to the proposed rule on Section 1557 of the Affordable Care Act (ACA). We applaud the Administration for taking action to address discriminatory practices in health programs and activities and wish to highlight several practices that are clearly discriminatory based on the proposed rule that unfairly target the most financially vulnerable patients with serious and chronic health conditions.

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 treatment 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 and restrictive formularies that limit access to specialty medications. And once approved, patients often face skyrocketing deductibles and steep cost-sharing requirements, as well as discriminatory practices that prevent them from accessing needed specialty and brand medications.

Specifically, we would like to highlight the significance of proposed paragraph (b)(2) which would prohibit marketing practices or benefit designs that discriminate on the basis of race, color, national origin, sex, age, or disability. As the proposed rule states: "By clarifying that health insurance and other health-related coverage must not employ discriminatory benefit design or marketing practices, proposed paragraph (b)(2) would further the ACA's goals of expanding access to affordable and quality health care and would be consistent with existing departmental regulations governing health insurance and other health-related coverage that similarly prohibit such discriminatory practices."

We urge you to finalize this proposal, which we hope will address several discriminatory practices specifically targeting the patients we represent:

- **Copay accumulator adjustor programs:** With deductibles and out-of-pocket costs soaring, many patients with serious and chronic conditions rely on financial assistance from drug companies and non-profits to afford and adhere to their medications. Unfortunately, many insurers are taking assistance intended for patients; they do not count the amount provided by copay assistance programs toward a patient's deductible and out-of-pocket (OOP) maximum.

- **Copay maximizer programs:** In copay maximizer programs, patients are told that their medications are no longer considered essential health benefits, and to avoid having to pay the full cost of their medications, they have to enroll in a special program. The program then resets their monthly out-of-pocket requirement for their drugs to match 1/12th of the maximum co-pay assistance that a manufacturer offers to extract the maximum amount of co-pay assistance. Again, none of these payments are counted towards the patient's deductible and OOP maximum.
- **Alternative funding models:** This practice is used by large group and self-insured (or ERISA) health plans, with the help of outside brokers. It occurs when a plan removes all high-cost drugs from their coverage and then refers patients to manufacturer Patient Assistance Programs (PAPs) to get access to their treatments for free since they are no longer covered by their insurance. Not all patients qualify, plus these short-term programs cannot be relied on for an entire year nor do they provide the ancillary services and supplies needed to actually take the medication.

These practices typically target patients with high-cost health needs, treating them differently due to their disability, which is discriminatory. When people with chronic illness are unable to adhere to their treatment, they risk worsening their health—in some cases, irreversibly. These practices undermine coverage for pre-existing conditions, hurt patient access to medicines, decrease drug adherence, and even cost our health care system more money in the long run.

Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in a health program or activity, **any part of which is receiving Federal financial assistance**, including credits, subsidies, or contracts of insurance. The private insurance plans, PBMs and brokers employing these strategies meet the newly proposed definition of “covered entity.” Individuals represented by the patient groups listed below meet the statutory definition of “disability” as defined at 28 CFR 35.108, because unfortunately, they live with a disease that limits a major life activity, including the operation of a major bodily function. We strongly support the proposed definition of “covered entity” as well as the definition of “disability.”

In order not to be overly prescriptive or unintentionally inconsistent, HHS does not define the term “benefit design” but rather provides examples, such as coverage, exclusions, and limitations of benefits; prescription drug formularies; cost sharing (including copays, coinsurance, and deductibles); utilization management techniques (such as step therapy and prior authorization); etc. Co-pay accumulator adjustor programs, co-pay maximizer programs, and alternative funding models all clearly fall within the types of benefit designs and marketing practices, and we encourage you to explicitly include these practices in the examples of discrimination that will be prohibited when this rule is finalized.

Finally, we agree that “robust enforcement of such nondiscrimination requirements for health insurance and other health-related coverage practices is critical to ensure individuals’ ability to receive the health services they need, unencumbered by discriminatory conduct.” We urge you to finalize the policies in the proposed rule as soon as possible and to robustly enforce these protections.

Respectfully,

All Copays Count Coalition

AIDS Foundation of Chicago
Alaska Hemophilia Association
Alliance for Patient Access
Alpha-1 Foundation
American Liver Foundation

Arthritis Foundation
Bleeding Disorders Association of South Carolina
Bleeding Disorders Foundation of North Carolina
California Chronic Care Coalition
Cancer Support Community
CancerCare
Chronic Care Policy Alliance
CLL Society
Coalition of Skin Diseases
Cystic Fibrosis Research Institute
Diabetes Leadership Council
Diabetes Patient Advocacy Coalition
Gateway Hemophilia Association
Haystack Project
HealthyWomen
Hemophilia Alliance
Hemophilia Association of New Jersey
Hemophilia Association of the Capital Area
Hemophilia Council of California
Hemophilia Federation of America
Hemophilia Foundation of Michigan
Hemophilia Foundation of Southern California
Hemophilia of Indiana
Hemophilia of Iowa
HIV + Hepatitis Policy Institute
Immune Deficiency Foundation
Lone Star Bleeding Disorders Foundation
Looms for Lupus
Lupus and Allied Diseases Association, Inc.
Midwest Hemophilia Association
Multiple Sclerosis Association of America
National Eczema Association
National Hemophilia Foundation
National MS Society
National Pancreas Foundation
New England Bleeding Disorder Advocacy Coalition
New England Hemophilia Association
New York State Bleeding Disorders Coalition
Oklahoma Hemophilia Foundation
Pacific Northwest Bleeding Disorders
Patient Access Network (PAN) Foundation
Project Sleep
Society of Dermatology Physician Assistants
Southwestern Ohio Hemophilia Foundation
Spondylitis Association of America
Susan G. Komen
Tennessee Hemophilia Bleeding Disorder Foundation
Texas Central Bleeding Disorders
The AIDS Institute
The Assistance Fund

Virginia Hemophilia Foundation
Western Pennsylvania Bleeding Disorders Foundation