September 30, 2013

Leon Rodriguez, Director
Office for Civil Rights
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Room 509F, HHH Building
Washington, D.C. 20201

Attention: 1557 RFI (RIN 0945-AA02)

Dear Mr. Rodriguez:

The signatories to this letter appreciate the opportunity to provide information as the Office for Civil Rights begins the process of drafting regulations to implement the nondiscrimination requirements articulated in Section 1557 of the Patient Protection and Affordable Care Act of 2010 (ACA) (42 U.S.C. 18116). The above referenced RFI solicits information on a number of issues arising under Section 1557, including the issue that relates to our concerns, "Examples of health programs and activities, including less common types of programs."

This letter is addressed specifically to the use and proliferation of specialty tiers as part of the design and management of prescription drug benefits offered through ACA mandated or related health programs and services, including the Title 1 Health Insurance Marketplaces.

Section 1557 of the ACA prohibits discrimination on the basis of race, color, national origin, sex, age, or disability. As stated in the Federal Register notice, Section 1557 is consistent with and promotes several of the Administration's and Department's key initiatives that promote health and equal access to health care.

> *Section 1557 provides that an individual shall not be excluded from participation in, be denied the benefits of, or be subjected to discrimination on the grounds prohibited under Title VI of the Civil Rights Act of 1964 (Title VI), 42 U.S.C. 2000d et seq. (race, color, national origin), Title IX of the Education Amendments of 1972 (Title IX), 20 U.S.C. 1681 et seq. (sex), the Age Discrimination Act of 1975 (Age Act), 42 U.S.C. 6101 et seq. (age), or Section 504 of the Rehabilitation Act of 1973 (Section 504), 29 U.S.C. 794 (disability), under any health program or activity, any part of which is receiving Federal financial assistance, or under any program or activity that is administered by an Executive Agency or any entity established under Title I of the Affordable Care Act or its amendments. Section 1557*

> *states that the "enforcement mechanisms provided for and available under" Title VI, Title IX, Section 504, or the Age Act shall apply for purposes of violations of Section 1557. The Department is responsible for developing regulations to implement Section 1557.*

Specialty tiers are prescription drug formulary management tools that insurers and payers use to limit their liability and increase the beneficiaries' share of the costs of certain prescription drugs (sometimes referred to as specialty drugs). These specialty drugs generally include prescription medicines that are used to treat complex, chronic conditions. Specialty tiers commonly include drugs that are injected, infused, or inhaled. They may require refrigeration, compounding, or other "special" handling.

Unlike the standard tiers, which have fixed copayments, specialty tiers require that beneficiaries pay coinsurance – a percentage of the drug price. Studies have documented specialty tier coinsurance of over 50% of the purchase and handling price. A 2009 report published by AARP noted that specialty drug prices increase at three times the rate of inflation, with annual costs to patients ranging from $5,000 to $300,000 per year. As a rule, the drugs on specialty tiers generally have no equivalent on lower tiers, generic or branded.

Specialty tiers are cost shifting mechanisms. They are driven by cost alone. Drugs are assigned to specialty tiers by virtue of their higher cost profiles. The "specialty" designation of these drugs and tiers is not based upon need or efficacy relative to the other tiers. Specialty tiers are designed to limit payer/insurer financial exposure. They do not advance quality care. They do not increase access to medications. They do not protect the patient. They protect profit margins with no consideration given to the impact on access, or quality of outcomes for patients.

Specialty tiers are inherently discriminatory. In theory and in practice, specialty tiers are the antithesis of the philosophical, legal and regulatory underpinnings that are the hallmark of legitimate, good faith, non-discriminatory practices. Specialty tiers are an example of *a priori* discrimination based upon disease state, treatment modality, and ability to pay. Secondarily, specialty tiers discriminate against certain demographic groups that disproportionately experience lower family incomes, incidence or prevalence of certain diseases, and access to early medical intervention.

Specialty tier coinsurance is an economic burden that delays treatment, compromises the ability of physicians to prescribe essential medications, increases medication non-adherence, and increases the risk for avoidable hospitalizations and re-hospitalizations, medical complications, and amenable mortality.

In closing, we applaud the desire of the Office for Civil Rights to elicit information from the public as it begins the rulemaking process. However, our human and fiscal resources are far too limited to provide the level of evidence necessary to make a sound legal, medical and societal case against specialty tiers.

Therefore, given the extraordinary harm to the health and economic well-being of America's patients, workers, employers, clinicians and institutional providers, we ask the Office for Civil Rights to employ the full powers of the federal government to investigate, case find, and collect and analyze data regarding the impact and outcomes of specialty tiering formulary management.

We look forward to continuing to work with the Secretary of Health and Human Services and the President to assure that the Patient Protection and Affordable Care Act is successfully implemented and maximizes American potential.

Sincerely,

AIDS United
Alliance for Patient Advocacy
American Association of Diabetes Educators
American Autoimmune-Related Diseases Association
Arthritis Foundation
Association of Black Cardiologists
Asthma and Allergy Foundation of America
Blue Ribbon Advocacy Alliance
Community Access National Network
National Council of Asian and Pacific Islander Physicians
National Fibromyalgia & Chronic Pain Association
National Health Council
National Lung Cancer Partnership
National Minority AIDS Council
National Minority Quality Forum
National Multiple Sclerosis Society
OWL-The Voice of Midlife and Older Women
Prevent Cancer Foundation

Crohn's & Colitis Foundation
Epilepsy Foundation
GBS/CIDP Foundation International
Global Healthy Living Foundation
HealthHIV
Immune Deficiency Foundation
Lung Cancer Alliance
Lupus Foundation of America
Men's Health Network
Mental Health America
National Alliance on Mental Illness
National Council for Behavioral Health
Project ReDirect-DC
Pulmonary Hypertension Association
Scleroderma Foundation
Sjögren's Syndrome Foundation
South Carolina HIV/AIDS Council
The AIDS Institute
The Myositis Association
The National Grange
U.S. Pain Foundation
US Pain
Veterans Health Council
Vietnam Veterans of America