August 13, 2019

The Honorable Alex M. Azar II
Secretary, U.S. Department of Health and Human Services
200 Independence Avenue, SE
Washington, DC 20201

Re: Nondiscrimination in Health and Health Education Programs or Activities [HHS–OCR–2019–0007] [RIN 0945–AA11]

Dear Secretary Azar:

The 122 undersigned members of the **I Am Essential** coalition of patient and community organizations, representing millions of patients and their families, are very concerned that the proposed revisions to the regulations implementing § 1557 of the Affordable Care Act (ACA) will undermine critical patient protections guaranteed by the ACA and may result in lost access to health care, including prescription medications, for people with serious and chronic health care conditions. We respectfully urge you to withdraw this proposed rule.

Section 1557 of the ACA was designed to ensure that health insurance is equally available for all, no matter their health status or health needs. Under § 1557, Americans are protected from discrimination on the basis of race, color, national origin, sex, disability and age by health programs and activities operated or funded by the federal government, including but not limited to Qualified Health Plans offered through the ACA marketplaces. These landmark protections are critical to fulfilling the requirement of preventing discrimination based on pre-existing health conditions and access to the health care that every American deserves.

Patient Protections in Regulations and Guidance

While the law is the foundation for these protections and still remains in effect, **I Am Essential** and others have been instrumental in ensuring that the implementing regulations and guidance meet beneficiaries' needs and provide clarity for all stakeholders regarding compliance. These regulations have brought significant gains in access to comprehensive, affordable, and transparent health care, including prescription drug coverage. If finalized, the proposed rule's changes would reduce the existing regulatory clarity, introduce unnecessary complications and

confusion with respect to compliance with ACA § 1557, and risk harmful effects for patients.

Under the current regulations implementing § 1557, 42 CFR § 92.207 makes clear that covered entities providing or administering health-related insurance or other health-related coverage are prohibited from taking the following actions on the basis of race, color, national origin, sex, age, or disability:

- Denying, canceling, limiting, or refusing to issue or renew a health insurance policy;
- Denying or limiting coverage of a health insurance claim;
- Imposing additional cost sharing or other limitations or restrictions on coverage; and
- Using discriminatory marketing practices or insurance benefit designs.

The existing regulatory clarifications and reinforcement of the above prohibitions are crucial to ensure equal access to health care for people with chronic health care conditions. **The proposed rule would completely remove the regulatory provision that clarifies these important protections under the law. We are deeply concerned that the proposed removal of this provision, if finalized, will increase the likelihood that insurers will seek to use benefit designs that discriminate against people with serious and chronic health care conditions.** Eliminating the regulatory provision that expressly clarifies these critical protections would create confusion and could lead to a proliferation of plan benefit designs and marketing practices that impermissibly seek to attract healthier enrollees and drive away enrolleeswith serious health care conditions. Such practices could leave people with serious and chronic health care conditions without the coverage they need to gain access to lifesaving health care and treatment.

Unfortunately, we have observed that some insurance plans continue to limit beneficiary access to critical medications in discriminatory ways. Eliminating the existing regulations that clarify and reinforce the prohibitions on discriminatory benefit design and marketing may make it harder for individuals to enforce their rights. Even with ACA requirements, state and federal regulators have approved plans with the following discriminatory features:

- Placing all or almost all medications to treat a certain condition on the highest cost tier;
- Not covering all the necessary or treatment guideline recommended medications;
- Charging excessive beneficiary cost-sharing for brand and "specialty" medications, including extremely high coinsurance and deductibles;
- Applying excessive utilization management techniques - such as prior authorization and step therapy requirements - targeting treatments for specific diseases;
- Removing medications from their formularies mid-year, a practice that is particularly harmful to patients on established regimens or whose condition requires a specific treatment.

Such practices, often targeted at specific chronic and serious conditions, not only make it difficult to gain access to necessary medications, but also discourage people living with those conditions from enrolling in these plans. To stop plans from engaging in these

practices and ensure beneficiaries have a choice of plans through which they can access the care and treatment they need, § 1557 and its implementing regulations must be maintained and properly enforced.

Covered Entities

The existing regulation implementing § 1557 makes clear that the statute's anti-discrimination protections apply to entities receiving federal financial assistance from HHS, as well as every health program or activity administered by HHS and every health program or activity administered by an entity under Title I of the ACA. The proposed regulation includes changes that, if finalized, would appear to reflect an effort to significantly restrict the application of § 1557 in two ways:

1) First, the proposed rule would remove existing provisions that create definitional clarity regarding the key term "health program or activity" and would impose new interpretations that seem designed to limit the extent to which many health insurance companies and plans would be subject to the anti-discrimination rules.
2) Second, the proposed rule would revise the regulatory provisions relating to the rule's application in a manner that may seek to limit the scope of coverage by stating that the regulations apply to any program or activity administered by HHS *under Title I of the ACA*, where the existing regulations expressly confirm the rule's application to "every health program or activity administered by the Department."

These proposed changes, if finalized, would increase the risk of health insurers developing and implementing benefit designs and marketing practices that discriminate against patients with serious and chronic health care conditions. We believe that all health care products sold by insurers who receive federal financial assistance should be subject to the ACA's non-discrimination protections, not just those products that receive financial assistance. This would leave millions of people without the health care protections they need and currently have.

Health insurance is inextricably linked with the provision of health care. Insurers design benefits, define medical management and other utilization criteria, build provider networks, and create payment structures. Thus, through these mechanisms, insurance companies establish the very infrastructure through which patients gain access to lifesaving care. Discrimination in any part of the health care system, of which insurers are a critical component, has a reverberating impact throughout the system, and will result in people not getting care they need.

Eliminating Oversight & Enforcement

Several provisions of the proposed rule would undermine protections against discrimination by making it more difficult for people to learn about their rights and to report a violation. The proposed regulation would remove 45 CFR § 92.7 requiring covered entities to establish a grievance procedure for patients to report discrimination, designate a staff person responsible for coordinating § 1557 responsibilities, and inform people about their right not to be discriminated against. It may also make it more difficult for patients to enforce their

rights in court and to receive compensatory damages when warranted. These proposed changes would have the combined effect of reducing anti-discrimination claims, while increasing the likelihood that a patient will be subject to discriminatory action. HHS itself acknowledges that, "an unknown number of persons are likely not aware of their right to file complaints with the Department's Office for Civil Rights and some unknown subset of this population may suffer remediable grievances, but will not complain to OCR absent notices informing them of the process."[1]

The proposed rule delegates all enforcement authority to the Director of the Office for Civil Rights, including receiving complaints, investigating complaints, and adjudicating claims. The ACA's anti-discrimination protections are critically important, especially for people with serious, chronic illness and disabilities. The multi-prong enforcement mechanism currently in place includes plan review, certification, and monitoring by state and federal regulators. It also allows individuals who experience discrimination to file both administrative and judicial complaints. This comprehensive approach to enforcement of § 1557 provides checks and balances and avenues of redress that cannot be achieved if sole enforcement authority lies with the Director of the Office for Civil Rights. Such a change would likely result in complaints of discriminatory behavior going unanswered and unresolved. Without a robust enforcement mechanism, the HHS certification of compliance with § 1557 becomes an empty shell.

Together, these proposed changes to notice and enforcement may substantially gut the impact of § 1557 by making it more difficult for patients to know their rights, report discriminatory actions, and remedy situations where they are not provided equal access to health care under the law.

Conclusion

The ACA has provided health coverage and improved access to care for tens of millions of Americans living with chronic and serious health conditions, many of whom were previously uninsured or underinsured. Additionally, the law established new patient protections for these newly insured individuals and for almost all others in the health care system. This includes a prohibition on preexisting condition exclusions, requiring coverage of essential health benefits, an annual limit on out-of-pocket costs, prohibiting discriminatory benefit design, preventing the utilization of discriminatory marketing practices, and expanding federal civil rights protections and clarifying the application of those laws to health insurance and health care.

While those protections still exist in the law, HHS has proposed to remove several existing regulations that will result in reduced clarity, increased confusion, and greater opportunities for insurers and others to advance policies, practices, and benefit designs that discriminate against people with serious and chronic conditions. Congress passed the ACA to end discriminatory practices in health care through robust and broadly applicable nondiscrimination protections. We object to any effort to roll back those protections or to

[1] 84 Federal Register 27883.

disturb the regulations that clarify and reinforce these protections' scope and application.

We urge you not to renege on the promise of affordable, high-quality care and treatment for everyone, especially those living with chronic and serious health conditions. We respectfully urge you to withdraw this proposed rule.

Sincerely,

A New PATH
Action Wellness
ADAP Advocacy Association
Advocates for Responsible Care (ARxC)
AIDS Alliance for Women, Infants, Children, Youth & Families
AIDS Foundation of Chicago
Aimed Alliance
Allergy & Asthma Network
Alliance for Patient Access
ALS Association
American Association on Health & Disability
American Autoimmune Related Diseases Association (AARDA)
American Behcet's Disease Association
American Cancer Society Cancer Action Network
APS Foundation of America, Inc
Arthritis Foundation
Association of Migraine Disorders
Axis Advocacy
Benedictine Sisters of Erie
Benedictines for Peace
California Chronic Care Coalition
California Health Collaborative
California Hepatitis C Task Force
Caregiver Action Network
Caregiver Voices United
Celiac Disease Foundation
Center for Independence of the Disabled, NY
CHAMP (Coalition for Headache And Migraine Patients)
Chronic Disease Coalition
Chronic Migraine Awareness, Inc.
Community Access National Network (CANN)
Conquer Myasthenia Gravis
Consumers for Quality Care (CQC)
Danielle Byron Henry Migraine Foundation
Dysautonomia International
Easterseals Massachusetts

Epilepsy Foundation
Epilepsy Foundation Greater Southern Illinois
Epilepsy California
Epilepsy Foundation Alaska
Epilepsy Foundation America
Epilepsy Foundation Central & South Texas
Epilepsy Foundation Eastern PA
Epilepsy Foundation Greater Chicago
Epilepsy Foundation Greater Los Angeles
Epilepsy Foundation Iowa
Epilepsy Foundation Maryland
Epilepsy Foundation Metro DC
Epilepsy Foundation Middle and West TN.
Epilepsy Foundation New England
Epilepsy Foundation of Arizona
Epilepsy Foundation of Colorado
Epilepsy Foundation of Delaware
Epilepsy Foundation of Hawaii
Epilepsy Foundation of Indiana
Epilepsy Foundation of Kentuckiana
Epilepsy Foundation of Long Island
Epilepsy Foundation of Michigan
Epilepsy Foundation of Minnesota
Epilepsy Foundation of Mississippi
Epilepsy Foundation of Nevada
Epilepsy Foundation of Oklahoma
Epilepsy Foundation of San Diego County
Epilepsy Foundation of Utah
Epilepsy Foundation of Vermont
Epilepsy Foundation of Virginia
Epilepsy Foundation Ohio
Epilepsy Foundation Oregon
Epilepsy Foundation San Diego County
Epilepsy Foundation Washington
Epilepsy Foundation West Virginia
Foundation for Sarcoidosis Research
Global Healthy Living Foundation
Global Justice Institute, Metropolitan Community Churches
HealthHIV
Hemophilia Federation of America
Hep B United
Hepatitis B Foundation
HIV Medicine Association
International Association of Hepatitis Task Forces

International Foundation for Autoimmune & Autoinflammatory Arthritis
International Pain Foundation
International Pemphigus and Pemphigoid Foundation
Let's Kick ASS AIDS Survivor Syndrome
Let's Talk About Change LLC
LUNGevity Foundation
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
Men's Health Network
Mental Health America
Miles for Migraine
Mirta
MLD Foundation
NAMI South Bay
NAPAFASA
NASTAD
National Alliance on Mental Illness
National Association of Nutrition and Aging Services Programs (NANASP)
National Blood Clot Alliance
National Coalition for LGBT Health
National Eczema Association
National Hemophilia Foundation
National Kidney Foundation
National Multiple Sclerosis Society
National Patient Advocate Foundation
Neuropathy Action Foundation
New Jersey Association of Mental Health and Addiction Agencies, Inc.
Prevent Blindness
Prevent Cancer Foundation
Retired Educator
RetireSafe
San Francisco Women's Cancer Network
Sickle Cell Disease Foundation
Sjogren's Syndrome Foundation
Society for Public Health Education
Susan G. Komen
The AIDS Institute
The Michael J. Fox Foundation for Parkinson's Research
The Migraine Diva
The Myositis Association
Triage Cancer
US Pain Foundation