

October 3, 2022

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services (HHS)
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, D.C. 20201

RE: Comments on Notice Proposed Rulemaking for ACA Section 1557 *Nondiscrimination in Health Programs and Activities* [HHS-OS-2022-0012]

Dear Secretary Becerra:

We, the undersigned 71 organizations, on behalf of millions of patients and American consumers who live with complex conditions such as HIV, autoimmune diseases, cancer, diabetes, lupus, hemophilia, mental illness, hepatitis, and neurological conditions write to comment on the Proposed Rulemaking for ACA Section 1557 *Nondiscrimination in Health Programs and Activities*. The patients we represent appreciate all you are doing to ensure that healthcare can be accessible and delivered in a nondiscriminatory manner. When properly implemented and fully enforced, this rule will help improve health outcomes and promote increased equity and address some of the barriers racial and ethnic communities and others confront as they access healthcare. While there are several components of the *Proposed Rule* that seek to ensure there is no discrimination on the basis of race, color, national origin, sex, age, or disability in health programs that many of us will comment on elsewhere, this letter focuses on those issues that primarily impact access to prescription drugs.

As detailed below, we are extremely pleased that you have taken meaningful steps to improve upon current regulations to ensure that people are not discriminated against in healthcare. In several instances, you have proposed to restore protections that had been included in the past but later withdrawn. In other instances, you have provided further clarity on what constitutes discrimination. In any instance, we emphasize that the law and whatever is finalized in regulation must be strictly enforced. While you have prioritized the importance of nondiscrimination in healthcare, too often we have witnessed insurers that continue to discriminate against people, particularly those who experience serious health conditions, but no action is taken at either the state or federal levels. We urge you to devote the necessary resources to investigate complaints and benefit design that can lead to discrimination and take the proper enforcement against violators. It is only when that occurs will the law and regulations be truly meaningful to patients.

The comments below address the following areas:

- 1) Scope of Proposed Nondiscrimination Regulations;
- 2) Proposed Discrimination through Benefit Design;
- 3) Proposed Discrimination through Excessive Utilization Management;
- 4) Discrimination of Copay Accumulator Adjustment Programs;

- 5) Potential Discrimination of Value Assessments; and
- 6) Need for Enforcement.

Scope of Proposed Nondiscrimination Regulations

We are pleased that HHS has proposed to reinstate the scope of Section 1557 to cover HHS' health programs and activities and clarifies its nondiscrimination requirements to health insurance issuers that receive federal financial assistance, directly or indirectly along with every health program or activity administered by the Department; every program or activity administered by a Title I entity and Medicare Part B.

We were extremely disappointed that the 2020 regulation was narrowed to pertain only to just one section of the ACA and certain directly funded entities. We believe Congress intended the non-discrimination provisions for all federal healthcare programs and activities. We support the definition in the proposed rule of HHS programs that provide federal financial assistance that would be subject to the rule to include Medicaid and CHIP, Medicare Part A, Medicare Part B, Medicare Part C (Medicare Advantage), Medicare Part D (drug coverage), and HHS grant programs. Likewise, we also support the definition of "health program or activity" to mean "any project, enterprise, venture or undertaking to provide or administer health-related services, health insurance coverage, or other health-related coverage; provide assistance to persons in obtaining health-related services, health insurance coverage, or other health-related coverage; provide clinical, pharmaceutical, or medical care; engage in health research; or provide health education for health care professionals or others." And, further, that it would pertain to all activities and operations of the entities.

Finally, we were extremely disappointed that the 2020 rule concluded that health insurance was not healthcare. We strongly support the proposal "to apply this rule to all the operations of a recipient entity principally engaged in the provision or administration of health insurance coverage or other health-related coverage."

Proposed Discrimination through Benefit Design

While we realize that discrimination in plan benefit design is also regulated under essential health benefits and HHS has clearly defined specific examples of presumptive discrimination, including adverse drug tiering, we are pleased that the proposed rule again includes "benefit design" and "marketing practices" as areas in which 1557 pertains.

We support your general definition of benefit design to "include, but are not limited to, 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); medical management standards (including medical necessity standards); provider network design; and reimbursement rates to providers and standards for provider admission to participate in a network." Similarly, we support your definition of marketing practices to "broadly include, for example, activities designed to encourage individuals to participate or enroll in particular health plans or certain types of plans, or to discourage them from doing so, and activities that steer or attempt to steer individuals towards or away from a particular plan or certain types of plans."

One area that we are particularly supportive of is that you intend to apply the nondiscrimination

in benefit design not only to products offered by a covered entity but also “indirect mechanisms that affect the implementation of a benefit design within the covered entity’s control, such as utilization management practices, provider reimbursement, contracting out to third party-contractors such as PBMs.” Since PBMs play a key role in determining which drugs are on a formulary, cost-sharing and tiering, utilization management and pharmacy access, we are extremely supportive of this provision. For far too long PBMs have escaped proper regulation.

Proposed Discrimination through Excessive Utilization Management

The proposed rule not only adds back the protections that were removed in the 2020 rule but recognizes some of the harmful issuer and PBM practices that patients face as they seek to access prescription medications. One such area that the proposed rule identifies as potential discrimination is the use of excessive utilization management techniques that issuers and PBMs employ that limit access to the prescription drugs their providers prescribe to treat or prevent illness.

As described in the proposed rule’s preamble, utilization management can include prior authorization, step therapy (or “fail-first”), and durational or quantity limits. While OCR states that utilization management controls “are standard industry practices that are permitted under Section 1557” we are pleased that you have added:

“as long as they are applied in a neutral, nondiscriminatory manner and are not otherwise prohibited under other applicable Federal and state law. Excessive use or administration of utilization management tools that target a particular condition that could be considered a disability or other prohibited basis could violate Section 1557. For example, prescription drug formularies that place utilization management controls on most or all drugs that treat a particular condition regardless of their costs without placing similar utilization management controls on most or all drugs used to treat other conditions may be discriminatory under this section. Similarly, benefit designs that place utilization management controls on most or all services that treat a particular disease or condition but not others may raise concerns of discrimination. Where there is an alleged discriminatory practice or action, the covered entity would be expected to provide a legitimate, nondiscriminatory reason, based on clinical evidence, for the practice.”

We are pleased that you have recognized the growing use of utilization management, particularly as it relates to prescription drugs. Consider the following: an analysis conducted by Avalere of employer and exchange plans use of utilization for brand name drugs in 2020 found that over 50 percent of the drugs in certain therapeutic classes of drugs were subject to utilization management. For example, drugs treating depression, rheumatoid arthritis, multiple sclerosis, and psoriasis all had over 50 percent of their drugs subject to utilization management.¹ The trend of utilization management is growing. Over the years 2014 to 2020 the use of step therapy in the commercial market grew 546 percent for HIV drugs, 478 percent for cardiovascular drugs, and 220 percent for multiple sclerosis drugs. Over the same years, the growth of utilization management in commercial plans grew by 478 percent for cardiovascular drugs and 309 percent for multiple myeloma drugs.²

¹ Tiernan Meyer, Rebecca Yip, Yonatan Mengesha, Damali Santiesteban, Richard Hamilton, “Utilization Management Trends in the Commercial Market, 2014–2020,” Avalere Health, November 14, 2021, <https://avalere.com/wp-content/uploads/2021/11/UM-Trends-in-the-Commercial-Market.pdf>.

² Ibid.

Discrimination by Instituting Copay Accumulator Adjustment Programs

While you have provided examples of potential discrimination in benefit design to include excessive utilization management, and mention cost-sharing as a potential benefit design that can be used to discriminate, we urge you to specifically identify copay accumulator adjustment programs and similar programs as discriminatory and, therefore, must be prohibited.

Copay accumulator adjustment programs are harmful policies instituted by insurers and PBMs that do not apply copay assistance towards beneficiaries' out-of-pocket costs and deductibles. Insurers and PBMs take the copay assistance provided by drug companies that is meant for the patients but are not counting it toward the patient's deductible and out-of-pocket cost obligations. Frequently they are doing it without the patient knowing. People pick up their drug in the beginning of the year but later in the year, they learn that the copay assistance was not counting and they are forced to come up with the money, which could be thousands of dollars, to pick up their prescription.

These policies also allow insurers to "double dip" and increase their revenue by receiving patient copayments twice.

Another scheme that PBMs are implementing is to designate certain higher priced "specialty" medicines as "non-essential" and then raise the cost-sharing to ensure that they collect all of the patient assistance offered by the manufacturer but do not count it towards the beneficiary's cost-sharing obligation. Under this arrangement, the plans often collect payments far exceeding the out-of-pocket maximum. If the beneficiary does not participate in this scheme, they are forced to pay higher cost-sharing and it will not count towards their out-of-pocket maximum.

These practices are discriminatory because they are only being applied to people who have serious and chronic health conditions who rely on prescription drugs.

Potential Discrimination of Value Assessments

We are very pleased that you have raised the issue of the potential discriminatory nature of certain value assessments in deciding healthcare coverage. Their use is increasing particularly as it relates to prescription drug coverage, utilization management, and cost-sharing decisions. As you have correctly stated some value assessments "make use of methods for calculating value that penalize individuals or groups of individuals on the basis of race, color, national origin, sex, age, or disability (e.g., by placing a lower value on life-extension for a group of individuals based on a protected basis or via inappropriate adjustment of clinical end points on the basis of a protected basis under Section 1557), they may violate this part."

We wholeheartedly agree.

Some of these value assessment use quality-adjusted life-years (QALYs), which are fundamentally discriminatory towards patients with chronic disease, the elderly, those who are disabled, and historically marginalized patient populations. Because these groups may not ever be able to reach a completely healthy state, their overall gains from the lens of the QALY are lower, and treatments are accordingly wrongly assigned lower value. QALYs are fundamentally also ageist as an elderly person can never secure the same QALY value at full health as a younger person and further, QALYs penalize older people due to shorter life expectancy.

In addition, there is no sound theoretical basis for assuming the QALY effectively captures the value of a treatment. Rather, the diverse experience of individual patients can never be fully conveyed by a single numerical sum/average that assumes uniform value across patient groups. If value is to be placed on human life, patient-centered outcomes should not be amalgamated into one, biased metric.

Since Section 1557 bans discrimination on the basis of age and disability, we believe the use of QALYs in health programs and activities should be prohibited.

Need for Enforcement

Any law or regulation is worthless if it is not properly and fully enforced. Since the enactment of the ACA, patients, particularly those with serious and chronic conditions who rely on prescription medications, have experienced discrimination through benefit design. OCR has highlighted some of them in the past and included others in the proposed regulation. Now it is important that state and federal regulators take the necessary steps to fully enforce the law and regulations. Hopefully, regulators will be given the tools to assist them in these efforts and they can address discrimination as they conduct plan reviews and take enforcement actions against issuers. With the scope of the rule widened they will also need additional resources. We also realize, unfortunately, that often the burden rests with the patients or their caregivers, who while battling their personal health issues have to at the same time battle their insurers and PBMs. We urge you to devote the necessary resources to investigate complaints and benefit design that can lead to discrimination and take the proper enforcement against violators.

We thank you for the opportunity to share these comments and look forward to the new rule's finalization and implementation so that patients can better access their healthcare free of discrimination.

If you have any questions or comments please contact Carl Schmid, Executive Director of the HIV+Hepatitis Policy Institute at cschmid@hivhep.org, or Quardricos Driskell, vice president of Public Policy and Government Affairs of the Autoimmune Association at quardricos@autoimmune.org

Sincerely,

ADAP Advocacy Association
 Advocacy & Awareness for Immune Disorders
 Association (AAIDA)
 Advocacy House Services Inc.
 AIDS Action Baltimore
 AIDS Alabama
 AIDS Alliance for Women, Infants, Children,
 Youth & Families
 AIDS United
 Alliance for Patient Access
 American Behcet's Disease Association (ABDA)
 American Cancer Society Cancer Action

Network
 American Kidney Fund
 Autistic Self Advocacy Network
 Autoimmune Association
 Bienestar Human Services
 California Hepatitis C Task Force
 Cancer Support Community
 Caregiver Action Network
 Caring Ambassadors Program
 Celiac Disease Foundation
 Chronic Care Policy Alliance
 Coalition for Headache and Migraine Patients

Coalition of Skin Diseases	JDRF
Color of Crohn's and Chronic Illness	LUNGeivity Foundation
Community Access National Network	Lupus and Allied Diseases Association, Inc.
Community Oncology Alliance	MLD Foundation
Crohn's & Colitis Foundation	My Brother's Keeper, Inc.
Depression and Bipolar Support Alliance	NASTAD
Diabetes Leadership Council	National Association of Nutrition and Aging Services Programs
Diabetes Patient Advocacy Coalition	National Minority Quality Forum
Dysautonomia International	National Psoriasis Foundation
Equality California	Ohio State Grange
Gaucher Community Alliance	Oregon Rheumatology Alliance
Georgia AIDS Coalition	Partnership to Fight Chronic Disease
Global Coalition on Aging Alliance for Health Innovation	Patients Rising Now
Global Healthy Living Foundation	PlusInc
Global Liver Institute	Prevent Blindness
Good Days	Pulmonary Hypertension Association
HealthHIV	Silver State Equality
HealthyWomen	Solve ME/CFS Initiative
Hemophilia Council of California	The Assistance Fund
Hemophilia Federation of America	The Hepatitis C Mentor and Support Group – HCMSG
HIV+Hepatitis Policy Institute	The Sumaira Foundation
Immune Deficiency Foundation	Triage Cancer
Infusion Access Foundation (IAF)	U.S. Pain Foundation
International Cancer Advocacy Network	Vasculitis Foundation
International Foundation of AiArthritis	

cc: Melanie Fontes Rainer, Director, Office of Civil Rights
 Chiquita Brooks-LaSure, Administrator, Centers for Medicare & Medicaid Services