



I am essential

January 15, 2016

The Honorable Sylvia Mathews Burwell
Secretary of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

Re: Comments on *Draft 2017 Letter to Issuers in the Federally-facilitated Marketplaces*

Dear Madame Secretary:

We, the 124 undersigned patient and community organizations representing millions of patients and their families are pleased to submit comments on the [*Draft 2017 Letter to Issuers in the Federally-facilitated Marketplaces*](#). The comments below are reflective of the experiences patients who we represent have encountered as they have utilized the qualified health plans (QHPs) over the past two years. We submit them for your consideration as we all work to improve upon the patient experience and health outcomes, particularly for those with serious and chronic health conditions as they access prescription medications.

The **I Am Essential** coalition recently submitted [comments](#) signed by 124 organizations on the *Notice of Benefit and Payment Parameters for 2017 Proposed Rule*. They focused on 1) the proposed Standard Benefits Option; 2) protecting access to prescription drugs; 3) continuity of care; and 4) payments made to QHP enrollees on behalf of third parties. As requested, we will not repeat the points included in those comments, but instead concentrate on other issues addressed in *Draft 2017 Letter to Issuers*.

Need for Enforcement

Before addressing the specifics in the *Draft 2017 Letter to Issuers*, **we would like to reiterate the need for the Centers for Medicare and Medicaid Services (CMS) to enforce the strong patient nondiscrimination provisions contained in the Affordable Care Act (ACA)**. Based on three years of plan data and the experiences of patients, we believe several issuers continue to violate the ACA by discriminating against people with chronic conditions and other serious illnesses through their plan design. We are extremely supportive of the statements included in previous *Notice of Benefit and Payment Parameters* and the current draft and past *Letter to Issuers* regarding plan design and what constitutes discriminatory practices. Nonetheless, we have seen little evidence that actual enforcement is happening. While we are pleased with the

patient protections included in the *Draft 2017 Letter to Issuers*, to be meaningful, they still need to be enforced.

Nondiscrimination & Federal Civil Rights Laws

We are pleased that in the *Draft 2017 Letter to Issuers*, CMS reminds issuers that several federal civil rights laws and Section 1557 of the ACA also govern QHPs, and are enforced by the Office of Civil Rights (OCR). CMS notes that OCR proposed the “Nondiscrimination in Health Programs and Activities” rule in September 2015. However, that rule has not been finalized and the proposed rule did not detail which plan benefit design practices constitute discrimination against beneficiaries. In a [letter](#) signed by 197 organizations, the **I Am Essential** coalition commented, “In order to protect beneficiaries and to provide clarity to state and federal regulators, now and in the future, HHS must provide a clear definition of what constitutes discrimination.”

To date, we have not seen any evidence that OCR is enforcing these nondiscrimination patient protections. Enforcement is made more difficult since the rule has not been finalized and the proposed rule lacks the specifics needed. **Therefore, we urge OCR to move to finalize a rule that includes specific examples of discriminatory plan design so that it can be meaningfully enforced.**

Discriminatory Benefit Design

EHB Discriminatory Benefit Design

We are supportive of CMS’ identification of certain issuer practices that through their plan design effectively discriminate against or discourage enrollment by certain beneficiaries, such as those with serious or chronic health conditions. This includes when “an issuer places most or all drugs that treat a specific condition on the highest cost formulary tiers.”

Since there has been ample evidence that issuers are engaging in these practices, there needs to be greater enforcement by CMS and the states to ensure this type of discrimination does not occur. While CMS states that “enforcement of this standard is largely conducted by the States,” in order for the ACA patient protections to be realized, the states need the necessary resources and analytical tools to assist in enforcement. Additionally, it is CMS’ ultimate responsibility to ensure that actual plan review and enforcement occurs, and if it is not happening, to step in to ensure that it does.

QHP Discriminatory Benefit Design

We are pleased that CMS plans to consider a number of plan design elements to determine if an issuer is discriminating against individuals on the basis of their health status and other factors, or “employing marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs pursuant to 45 CFR 156.225.” CMS indicates again that it will analyze outlier tests to examine cost-sharing and out-of-pocket costs associated with standard treatment protocols for certain conditions, and review a plan’s cost-sharing structure. In years past, we have noted that an outlier analysis can be faulty if all issuers engage in such practices. Therefore, we are pleased that the *Draft 2017 Letter to Issuers* notes

that “CMS retains the right to identify a benefit design as discriminatory even if it is not flagged in the outlier analysis.”

We are supportive that CMS will review out-of-pocket costs associated with standard treatment protocols of certain chronic and high cost medical conditions. For 2017, it has identified only five medical conditions that will be subject to this review. We encourage CMS to expand the list of conditions for which it will conduct a review since there are so many more health conditions, and patients with those conditions need the same protections. Again, while we are pleased CMS indicates it will conduct these reviews, based on the last three plan years, we are not finding evidence that the reviews are occurring and action is being taken against issuers.

Prescription Drugs

We are supportive of CMS’ intent to review adequate prescription drug coverage in QHPs by conducting a 1) formulary outlier review; 2) clinical guidelines-based review; and 3) review of tier placement of prescription drugs recommended of specific medical conditions. We are pleased that CMS states it will review for “an unusually high number of drugs that are subject to prior authorization and/or step therapy requirements in a particularly United States Pharmacopeia (USP) category or class.” While we are pleased CMS will review a plan’s drug coverage in order to determine if it meets clinical guidelines for the treatment of specific medical conditions, it is only doing so for nine conditions. Beneficiaries rely on Marketplace plans for many more health conditions, and adequate drug coverage is necessary for them to have meaningful access to care. We urge CMS to review all plans for adequate drug coverage for all medical conditions. We are also pleased that CMS will review for unusually high cost-sharing requirements for specific drugs.

We are particularly pleased that CMS has stated that it is “concerned about adverse tiering, which occurs when a formulary benefit design assigns most or all drugs in the same therapeutic class needed to treat a specific chronic, high cost medical condition to a high cost-sharing tier.” We agree with CMS that this practice, which is being employed by many issuers across the country, is potentially discriminatory.

Formulary Drug List and Formulary Lookup Tool

We are very supportive of the transparency requirements that CMS reiterates all plans must utilize to help patients select an appropriate QHP that best meets their needs. This includes an accurate and up-to-date machine readable drug list that includes tiering, utilization management and pharmacy network requirements. We agree with CMS that “the formulary drug list must be published in a manner that is easily accessible to plan enrollees, prospective enrollees, the state, the Marketplace, CMS, OPM and the general public.”

Out-of-Pocket Cost Comparison Tool

In order for beneficiaries to select a QHP that best meets their health needs and for them to know what their out-of-pocket costs will be for a certain medication or medical service, CMS should require plans to include a true out-of-pocket cost comparison tool. A beneficiary should be able to know what their estimated costs for a specific drug regimen will be in advance. This is particularly important for plans that utilize co-insurance rather than co-pays. A beneficiary has no idea what the patient costs of a drug will be when plans use co-insurance. We believe these

plans fail to meet the necessary plan transparency requirements, and may steer beneficiaries to plans that charge patients excessive costs for medications. This could be rectified if the out-of-pocket cost comparison tool was a true cost tool, similar to what is used by Medicare Part D.

In many instances access to prescription medications by Marketplace beneficiaries has been limited by some issuers through a variety of means, including restricted formularies, excessive cost-sharing and medical utilization management tools, such as prior authorizations, step therapy, and others. As CMS itself has stated, some of these practices violate the ACA and are discriminatory, especially against beneficiaries who have chronic or other serious health conditions. We believe that through a proper and meaningful state and federal review processes, these practices can be eliminated. CMS and most states must review every QHP for a number of important elements; there is no reason why they cannot review them for these important patient protections, as well. They should not rely only on patient grievances and complaints. We call upon CMS and the states to enforce the important patient protections included in the ACA and other laws.

Thank you very much.

Sincerely,

30 for 30 Campaign

ActionAIDS

ADAP Advocacy Association

Adult Congenital Heart Association

AIDS Alabama

AIDS Alliance for Women, Infants,
Children, Youth & Families

AIDS Foundation of Chicago

The AIDS Institute

AIDS Research Consortium of Atlanta

AIDS Resource Center Ohio

Alliance for Lupus Research

Alliance for the Adoption of Innovations in
Medicine (Aimed Alliance)

Alpha-1 Foundation

Alzheimer's & Dementia Resource Center

American Association on Health and
Disability

American Bechet's Disease Association

American Foundation for the Blind

American Nurses Association

Arthritis Foundation

Asian & Pacific Islander American Health
Forum

Association of Nurses in AIDS Care

California Hepatitis C Task Force

Caregiver Action Network

Caring Ambassadors Program, Inc.

Cascade AIDS Project

Colon Cancer Alliance

Community Access National Network

COPD Foundation

Depression and Bipolar Support Alliance

Easter Seals

Easter Seals Massachusetts

Elder Care Advocacy of Florida

EPIC Long Island (Epilepsy Foundation of
Long Island)

Epilepsy Association of Oklahoma

Epilepsy Foundation

Epilepsy Foundation Central & South Texas

Epilepsy Foundation Heart of Wisconsin
 Epilepsy Foundation North/Central Illinois,
 Iowa, Nebraska
 Epilepsy Foundation Northwest
 Epilepsy Foundation of Alabama
 Epilepsy Foundation of Arizona
 Epilepsy Foundation of Colorado
 Epilepsy Foundation of Connecticut, Inc.
 Epilepsy Foundation of Greater Chicago
 Epilepsy Foundation of Greater Los Angeles
 Epilepsy Foundation of Greater Southern
 Illinois
 Epilepsy Foundation of Hawaii
 Epilepsy Foundation of Indiana
 Epilepsy Foundation of Kentuckiana
 Epilepsy Foundation of Missouri and
 Kansas
 Epilepsy Foundation of Nevada
 Epilepsy Foundation of Northeastern New
 York, Inc.
 Epilepsy Foundation of Vermont
 Epilepsy Foundation of Western Ohio
 Epilepsy Foundation of Western Wisconsin
 Epilepsy-Prall, Inc.
 Federation of Families for Children's
 Mental Health Colorado
 Fight Colorectal Cancer
 FORGE, Inc.
 Georgia AIDS Coalition
 Global Healthy Living Foundation
 Global Liver Institute
 H.E.A.L.S of the South
 HCSP/HCV Advocate
 HealthHIV
 Hemophilia Federation of America
 Hepatitis Foundation International
 HIV Dental Alliance

HIV Medicine Association
 HIV Prevention Justice Alliance
 Hope for a Brighter Day, Inc.
 Hope for a Positive Tomorrow
 Human Rights Campaign
 Immune Deficiency Foundation
 International Foundation for Autoimmune
 Arthritis
 International Pemphigus Pemphigoid
 Foundation
 Lakeshore Foundation
 Los Angeles LGBT Center
 Lupus Foundation of America
 Lupus Foundation of Florida
 Lupus LA
 Lupus Research Institute
 MANA, A National Latina Organization
 March of Dimes
 Marriage Equality USA
 Men's Health Network
 Mental Health America
 Mental Health America of Colorado
 NAMI Alabama
 NAMI North Carolina
 Nashville CARES
 National Alliance for Hispanic Health
 National Alliance of State & Territorial
 AIDS Directors
 National Alliance on Mental Illness
 National Asian Pacific American Families
 Against Substance Abuse
 National Association of Hepatitis Task
 Forces
 National Coalition for LGBT Health
 National Hemophilia Foundation
 National Kidney Foundation
 National LGBTQ Task Force

National Multiple Sclerosis Society
National Organization for Rare Disorders
(NORD)
National Patient Advocate Foundation
National Psoriasis Foundation
National Stroke Association
National Viral Hepatitis Roundtable
New Jersey Association of Mental Health
and Addiction Agencies, Inc.
OWL
PCa Blue
Project ReDirect-DC
RAIN Oklahoma
RetireSafe
Salud USA
SisterLove, Inc.
South Florida Cancer Association
Southern HIV/AIDS Strategy Initiative
(SASI)
Susan G Komen
Unity Fellowship of Christ Church NYC
US Pain Foundation, Inc.
The Veterans Health Council
Vietnam Veterans of America
Virginia Hemophilia Foundation
Wellness and Education Community Health
Action Network
Women Against Prostate Cancer