HIV Health Care Access Working Group

December 1, 2016

Center for Consumer Information and Insurance Oversight
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201
Submitted via email to: FFEcomments@cms.hhs.gov

To Whom It May Concern:

The HIV Health Care Access Working Group (HHCAWG) appreciates the opportunity to comment on the *2018 Letter to Issuers in the Federally-Facilitated Marketplaces*.

In conjunction with responding to the draft *2018 Letter to Issuers*, we thought it was important to **reiterate the need for CMS to enforce the strong patient non-discrimination provisions contained in the Patient Protection and Affordable Care Act.** Based on our review of the Qualified Health Plans (QHPs) offered in the federally facilitated Marketplaces over the past four years, it appears that plan design discriminating against those living with chronic conditions, such as HIV and Hepatitis C (HCV), is increasingly pervasive. This trend is highlighted by several high profile departures from the Marketplaces, including issuers who offered QHPs that included strong access to care for people living with HIV. We are extremely supportive of the statements included in the draft *2018 Letter to Issuers* regarding plan design and what constitutes discriminatory practices but are concerned that these protections are not adequately enforced against discriminatory issuers.

Our comments regarding the draft *2018 Letter to Issuers* are brief in light of the extensive comments we submitted in response to the *HHS Notice of Benefit and Payment Parameters for 2018.* Our comments and recommendations below are organized by the letter section as requested.

Chapter 1: Certification Process for Qualified Health Plans

Section 1: QHP Application and Certification Process

iv. CMS Review of QHP Applications

We are concerned that there has not been significant analysis of QHPs to identify plans that are discriminating against those living with chronic conditions. We ask that CMS take into account recognized standards of care, such as the Federal *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*[1], when evaluating compliance with ACA

[1] *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents,* U.S. DEPT. OF HEALTH & HUMAN SERVICES PANEL ON ANTIRETROVIRAL GUIDELINES FOR ADULTS AND ADOLESCENTS – AWORKING GROUP OF THE OFFICE OF AIDS RESEARCH ADVISORY COUNCIL (OARAC), https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf (last visited Nov. 28 2016).

requirements. QHPs should not only provide adequate access to recognized standards of care, but also not impose discriminatory cost sharing or utilization management barriers to access these treatments.

We are also concerned that issuers are exploiting actuarial value requirements to discriminate against those living with chronic conditions. While a QHP may satisfy the actuarial value requirements of the ACA, the higher cost sharing differential imposed places those living with HIV and HCV at a financial disadvantage. We urge CMS to review QHPs to ensure that those living with chronic conditions such as HIV and HCV receive roughly the equivalent actuarial value as other enrollees.

Chapter 2: Qualified Health Plan and Stand-Alone Dental Plan Certification Standards

Section 3. Network Adequacy

iv. Network Transparency

We strongly support the pilot projects for 2017 to display provider networks according to the breadth of providers relative to other QHP provider networks to help consumers identify the plans that will best meet their medical needs. We urge CMS to expand this pilot to more states for 2018. We also urge CMS to expand the classification to include other specialists, including HIV and infectious disease specialists as well as behavioral health providers, as early as possible but certainly in 2018.

v. Specialty Access

We strongly support the proposal to assess consumer access to higher cost specialist providers. We commend CMS for the recognition that enrollees living with chronic health conditions need robust networks of specialists to appropriately address their conditions. QHPs are barred from employing marketing practices or benefit designs that may discourage enrollment of individuals with high cost health needs.[2]A lack of specialist providers is another tactic employed to dissuade individuals with chronic conditions, like HIV, from enrolling in certain QHPs. In the past several years we have seen issuers decline to contract with leading specialists, potentially to discourage high cost enrollees from selecting their plans. Additional CMS oversight of specialty access is necessary to prevent such selective networking.

We urge CMS to begin monitoring QHP specialist networks relative to other QHPs in the same service area, especially for consumer access to HIV and infectious disease specialists.

Section 4. Essential Community Providers

We are concerned that some QHPs continue to avoid contracting with Ryan White providers and likely other Essential Community Providers. We strongly urge requiring QHPs to identify the Essential Community Providers by ECP provider type in their online directories. In addition, we

[2] 45 C.F.R. §156.225(b)

urge CMS to publish ECP reviews and the justifications submitted by QHPs. At a minimum reviews should be available for plans not meeting the minimum ECP coverage requirements.

Section 10. Discriminatory Benefit Design

i. EHB Discriminatory Benefit Design

We are concerned that, despite the prohibition found in 45 CFR 156.125(a) against benefit design that discriminates on the basis of disability, many issuers are developing formularies designed to deter people living with HIV from enrolling in their QHPs. For example, in Wisconsin for plan year 2016, Anthem's Silver QHP offerings failed to cover twelve of the sixteen primary drugs necessary to prescribe HIV treatment regiments recommended by the Federal *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*[3] at the time. Further, of the twenty-five commonly prescribed HIV drugs on the market in 2016, Anthem's QHP offerings covered only six. This inadequate coverage highlights that issuers continue to design formularies to drive away enrollees living with chronic health needs, effectively discriminating against them.

Frequently, issuers are declining to cover single tablet regimens for HIV based on cost. The treatment benefits these combination tablets present over their component medications in terms of adherence and successful outcomes is significant. In addition, the cost to enrollees is often greater when they are required to take multiple medications with multiple copayments instead of a single tablet regimen with a single copayment. The omission of these regimens is especially egregious in light of the Federal *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*[4] which recommend several of these single tablet regimens.

We urge CMS to provide guidance to the States stating that QHPs that prevent access to federally recommend standards of care, such as the HIV treatment regimens recommended in the Federal *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*[5] violate EHB. This omission is a violation of EHB because it results in plan benefit design aimed at discriminating against those living with a disability, namely HIV.

ii. QHP Discriminatory Benefit Design

We strongly support the continued review of each QHP with regard to estimated out-of-pocket costs for standard treatment protocols for certain chronic, high cost conditions, including bipolar disease, diabetes, hepatitis C, HIV, multiple sclerosis, opioid dependence, rheumatoid arthritis, and schizophrenia. Despite CMS guidance to the contrary, many issuers continue to employ adverse tiering and impose higher cost sharing on those living with HIV when compared to others living chronic conditions that require similar sustained treatment. These benefit designs

[3] *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*, U.S. DEPT. OF HEALTH & HUMAN SERVICES PANEL ON ANTIRETROVIRAL GUIDELINES FOR ADULTS AND ADOLESCENTS – AWORKING GROUP OF THE OFFICE OF AIDS RESEARCH ADVISORY COUNCIL (OARAC), https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf (last visited Nov. 28 2016).
[4] *Id.*
[5] *Id.*

discourage those living with HIV and HCV from enrolling in these issuer's QHPs, thereby discriminating against them.

We appreciate the recognition that the existence of other plans with similar features within a market does not ensure that a benefit design is not discriminatory. As CMS uses an outlier approach, an assessment will not identify discriminatory benefit designs if a majority of QHPs within a service area employ benefit designs that provide poor or inadequate coverage for high cost populations. We urge CMS to continue to monitor QHPs for these discriminatory benefit designs. We appreciate that CMS expressly retains the right to identify a benefit design as discriminatory even if it is not flagged in the outlier analysis. We note that for chronic conditions such as HIV and HCV, it is well documented that QHPs have employed discriminatory benefit designs, through adverse tiering and unjustifiable utilization management restrictions, to discourage enrollment of consumers living with significant health needs. We urge CMS to supplement the outlier analysis with an objective analysis to determine if those living with HIV and HCV have meaningful access to necessary services and treatment. Specifically, we urge CMS to ensure that QHPs provide affordable coverage for fundamental drugs that constitute the clinical standards of care for chronic conditions such as HIV and HCV.

We support CMS requiring issuers to provide clinical evidence supporting plan designs which have less generous benefits for specific populations. We urge CMS to publish these justifications submitted by issuers. At a minimum, these justifications should be available for issuers flagged in the outlier analysis.

Section 11. Prescription Drugs

We commend CMS for its ongoing monitoring of issuer compliance with EHB prescription drug requirements, and its recognition that prescription drug reviews are an essential component in preventing discrimination on the basis of health conditions.

i. Formulary Outlier Review

We strongly support CMS performing an outlier analysis of each QHP's formulary compared to other plans seeking certification. We commend CMS for adding antivirals/anti-hepatitis C (HCV) agents to the list of USP categories for 2018 plan year review.

We urge CMS to consider expanding beyond an outlier review, to identify when the majority of issuers in a Marketplace offer discriminatory coverage of these agents. As an outlier approach will not identify discriminatory utilization management trends where all QHPs seeking certification employ similar tactics to discourage enrollment by those with chronic health conditions, an objective approach is needed. We urge CMS to analyze where the majority of QHPs subject a particular USP category and class to prior authorization or step therapy requirements to determine if these plans discriminate against those living with HIV and HCV.

Per 45 C.F.R. §156.122(e), plans "must allow enrollees to access prescription drug benefits at in-network retail pharmacies" unless the prescribed drug "is subject to restricted distribution by the U.S. Food and Drug Administration" or "requires special handling, provider coordination, or

patient education that cannot be provided by a retail pharmacy." Many benefit designs for 2017, however, require that all drugs on a specialty tier be dispensed through a specialty pharmacy, regardless of whether they meet either exception. Further, many plans subject certain drugs in a class to "limited distribution" through specialty pharmacies while allowing other drugs to be accessed through retail pharmacies without any apparent clinical justification. For example, Humana's 2017 drug list for AZ, GA, IL, IN, KS, KY, LA, MI, MS, NV, PR, and WI limits three single tablet regimens – Atripla, Complera, and Odefsey – to only specialty pharmacy distribution, but allows three others – Genvoya, Stribild, and Triumeq – to be distributed at retail pharmacies.[6] This practice is not within the narrowly defined exception to the mail order opt out articulated in 45 C.F.R. §156.122(e) as there is no safety or special handling justification for treating the first three single tablet regimens differently from the latter three. We urge CMS to review QHPs to ensure that limited distribution designations are not being used to avoid compliance with the mail order opt out requirement. We also urge CMS to require issuers to, at a minimum, submit justifications explaining why these medications require services that cannot be provided by retail pharmacies.

We appreciate the previous guidance in the *HHS Notice of Benefit and Payment Parameters for 2016*[7] that prohibits an issuer from making a medication mail order only except when a (1) the drug is subject to restricted distribution by the U.S. Food and Drug Administration or (2) the drug requires special handling, provider coordination, or patient education that cannot be provided by a retail pharmacy.[8] Nevertheless, as illustrated above, we are receiving reports from a variety of jurisdictions that issuers are keeping the more expensive HIV and HCV medications as mail order only. This stands in contrast to the decades of retail pharmacies successfully dispensing HIV medications and the several years of retail pharmacies successfully dispensing newer HCV medications.

Mail order only medication dispensing creates continuity issues for people living with chronic conditions such as HIV and HCV. Oftentimes, infectious disease specialists will work closely with local retail pharmacies to provide coordinated care for these complex patients that cannot be delivered through mail order pharmacies. Low income enrollees who move or may not be at home if the dispensing pharmacy requires a patient signature face the prospect of treatment interruptions, causing serious health consequences. A mail order only restriction may also discourage enrollment by, and therefore discriminate against, transient individuals and those who wish to keep their conditions confidential. Additionally, patients may not be able to wait for the prescription to be filled by a mail order pharmacy.

ii. Clinical Guideline-Based Review of Prescription Drug Coverage

We strongly support the continued review of QHP coverage of, and the associated cost sharing for, drugs recommended in nationally-recognized clinical guidelines for the list of conditions, including HIV and HCV. The Department of Health and Human Services Guidelines for the Use of Antiretroviral Therapy in Adults and Adolescents and for Pediatric HIV infection are widely

[6] Humana, *2017 Humana Drug List, available at* http://apps.humana.com/marketing/documents.asp?file=2839551.
[7] 80 Fed. Reg. 10749, 10820-22 (Feb. 27, 2015).
[8] 45 C.F.R. §156.122(e)(1)(i)-(ii).

recognized as setting the standard of care for HIV treatment in the U.S.[9] The American Association for the Study of Liver Disease and the Infectious Diseases Society of America Recommendations for Testing, Managing, and Treating Hepatitis C are widely recognized as setting the standard of care for HCV in the U.S.[10]

iii. Review of Tier Placement of Prescription Drugs Recommended for Treatment of Specific Medical Conditions

We strongly support the review of cost sharing tier placement for a class or classes of drugs used to treat certain conditions. Some QHPs continue to place all or most of the antiretroviral drugs on the highest cost sharing tiers. A recent analysis conducted by the National Alliance of State & Territorial AIDS Directors found that thirty-four percent of all 2016 QHPs placed the most effective and modern HIV treatments, single tablet regiments, on the highest cost-sharing "specialty" tier[11]. This is despite CMS guidance in the *2016 and 2017 Letter to Issuers in the Federally-facilitated Marketplaces* that it is discriminatory to place all single tablet regimens on a specialty tier to discourage those living with HIV from enrolling[12]. We urge CMS to monitor closely for adverse tiering and to require corrective action when adverse tiering is identified.

Adverse tiering makes necessary treatment objectively unaffordable for people living with HIV and HCV. A recent study from the Harvard School of Public Health found that the difference in out-of-pocket costs for HIV treatments between plans that utilize adverse tiering and those that do not was significant. Enrollees in plans that adversely tiered HIV medications had an average annual cost per drug of more than triple that of enrollees in plans that do not adversely tier ($4,892 vs. $1,615), with a nearly $2,000 difference per year even for generic drugs.[13] The study estimates that a person living with HIV will end up paying upwards of $3,000 more annually for treatment under a plan that employs adverse tiering than under a plan that does not.[14] Even if an enrollee pays up to the out-of-pocket cap, they remain responsible for monthly premiums. This presents low income enrollees with an impossible financial barrier to necessary treatments.

In light of the data from 2016 as well as initial reports from 2017, we stress that an adverse tiering review has tremendous utility for identifying discriminatory benefit designs and is crucial for preserving access to care for those living with chronic conditions. As our 2016 data noted an alarming trend of decreased coverage coupled with increased cost sharing, it is imperative that discriminatory benefit designs are identified quickly, and that CMS requires corrective action when adverse tiering is identified.

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[9] AIDSinfo.org. Clinical Guidelines Portal. Online at: https://aidsinfo.nih.gov/guidelines.
[10] Hcvguidelines.org. HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C. Online at: http://www.hcvguidelines.org/full-report-view
[11] National Alliance of State & Territorial AIDS Directors, *Discriminatory Design: HIV Treatment in the Marketplace*, available at https://www.nastad.org/sites/default/files/Discriminatory-Design-HIV-Treatment-in-the-Marketplace.pdf
[12] Department of Health & Human Services, *2016 Letter to Issuers in the Federally-facilitated Marketplaces*, Pg. 37 (February 20, 2015) available at https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2016-Letter-to-Issuers-2-20-2015-R.pdf
[13] Douglas B. Jacobs & Benjamin D. Sommers, *Using Drugs to Discriminate – Adverse Selection in the Insurance Marketplace*, 372 N.E. J. Med 399, 401 (2015).
[14] *Id.*

We welcome the opportunity to discuss and provide guidance to CMS regarding the factors relevant to an adverse tiering review. A review of adverse tiering should focus on whether the drugs recommended in the relevant recognized standards of care are covered, what tier they are placed on, as well as any unjustified utilization management requirements imposed. Additionally, CMS should not only consider the tier drugs are placed on, but also consider the overall cost imposed on the enrollee. As an example, some QHPs may differentiate between four tiers yet require the same out-of-pocket cost for the highest two tiers. Such a distinction may obscure the fact that recommended treatments, while not on the highest tier, are still being subjected to discriminatory cost sharing.

We also urge CMS to also consider the importance of transparency in drug tiering. For low income enrollees living with HIV and HCV, the cost of their medications is a significant factor in choice of plan. QHPs that require coinsurance rather than copayments for the highest tiers confuse this choice, as a prospective enrollee will not be able to find out how much their necessary medications will cost until after they are enrolled. We urge CMS to consider the effect of placing HIV and HCV medications in tiers that require coinsurance rather than copayments on people living with chronic health conditions.

Section 12. Supporting Informed Choice/Meaningful Difference

We support CMS applying a more standardized approach to evaluating meaningful difference among an issuer's QHP products. Taking steps to ensuring meaningful differences among QHP options is important to improve consumer options, reduce confusion among enrollees and streamline the enrollment process.

Chapter 3: Consumer Support Tools and Public Information

Section 2. Formulary Drug List and Formulary Lookup Tool

We are concerned that the requirements of 45 CFR 156.122(d) are not being sufficiently enforced. We have received numerous reports during open enrollment for the 2017 QHPs from multiple states that formulary links displayed on healthcare.gov are either broken or outdated. Additionally, it is often the case that, despite the requirement that a formulary list all covered drugs, coverage information is incomplete and may only be accessed by calling the issuer directly. We urge CMS to consistently monitor this requirement to ensure than the formulary drug list URLs submitted by issuers are functioning, up to date, and complete.

Thank you again for the opportunity to comment on the draft letter to issuers. We appreciate the ongoing responsiveness to the challenges experienced by QHP enrollees with HIV and others and hope to soon see stronger enforcement of these policies. We look forward to continuing to work with HHS to ensure the ACA works as intended for people with HIV and others with serious chronic conditions. Please contact the HHCAWG co-chairs Robert Greenwald with the Treatment Access Expansion Project (rgreenwa@law.harvard.edu), Amy Killelea with the

National Alliance of State & Territorial AIDS Directors (akillelea@nastad.org), or Andrea Weddle with the HIV Medicine Association (aweddle@hivma.org) if we can be of assistance.

Submitted on behalf of the HHCAWG Steering Committee,

Treatment Access Expansion Project | National Alliance of State and Territorial AIDS Directors | American Academy of HIV Medicine | AIDS Action Baltimore | AIDS Action Committee of MA | AIDS Alliance for Women, Infants, Children, Youth & Families | AIDS Foundation of Chicago | The AIDS Institute | APLA Health | AIDS Treatment Data Network | AIDS United | Association of Nurses in AIDS Care | Community Access National Network | Communities Advocating Emergency AIDS Relief (CAEAR) Coalition | Gay Men's Health Crisis | Georgia AIDS Coalition | Harlem United | Health and Disability Advocates | HealthHIV | HIVictorious, Inc. | HIV Medicine Association | HIV Prevention Justice Alliance | Housing Works | Los Angeles LGBT Center | Moveable Feast | National Minority AIDS Council | The National Working Positive Coalition| Project Inform | San Francisco AIDS Foundation | South Carolina Campaign to End AIDS| Treatment Action Group | VillageCare