ADMINISTRATIVE COMPLAINT

Office of Civil Rights, U.S. Department of Health and Human Services
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Washington, D.C. 20201

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Atlanta, GA 30303-8909

RE: DISCRIMINATORY PHARMACY BENEFITS DESIGN IN SELECT QUALIFIED HEALTH PLANS OFFERED IN FLORIDA

COMPLAINANTS

The AIDS Institute
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The National Health Law Program
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The AIDS Institute (TAI) is a national nonprofit AIDS agency focusing on public policy, research, advocacy, and education. It began as a grass roots community mobilization effort in the mid1980s and was incorporated in 1992. TAI has offices in Tampa, Florida and Washington, DC, and has been a leading voice both in Florida and nationally in ensuring people with HIV and other chronic diseases, such as hepatitis, have access to quality and affordable health care.

Founded in 1969, the National Health Law Program ("NHeLP") protects and advances the health rights of low-income and underserved individuals. It is the oldest non-profit of its kind. NHeLP advocates, educates, and litigates at the federal and state levels to further its mission.
DEFENDANTS

Coventry Health Care, Inc., which offers Qualified Health Plans (QHPs) in Florida under the name CoventryOne, is wholly owned by Aetna, which reported over $47 billion in revenue for 2013.¹

Cigna is headquartered in Bloomfield, Connecticut, reporting $32 billion in revenue for 2013.²

Humana is headquartered in Louisville, Kentucky, reporting over $41 billion in revenue for 2013.³

Preferred Medical is headquartered in Coral Gables, Florida. Its 2013 annual report is not available.

JURISDICTION

This complaint is filed pursuant to Section 1557 of the Patient Protection and Affordable Care Act (ACA), codified at 42 U.S.C. § 18116. Section 1557 prohibits federal health programs, activities, and contracts of insurance sold through the health insurance Marketplaces from discriminating against individuals living with disabilities, including HIV and AIDS. The HHS Office of Civil Rights (OCR) has primary responsibility for ensuring compliance with Section 1557 through investigations and enforcement action. Although the HHS OCR has primary oversight over Section 1557, the Department of Justice (DOJ) has coordinating responsibility pursuant to Executive Order 12250.⁴

PRELIMINARY STATEMENT

Under the ACA, health insurers may no longer discriminate on the basis of disability. Section 1557 and other ACA provisions prohibit discriminatory health insurance practices, including plan benefit designs which discourage enrollment of persons with significant health needs, including people living with HIV and AIDS.

The AIDS Institute conducted an analysis (available here; hard copy attached) of the prescription drug formularies and cost structure for all silver-level Qualified Health Plans (QHPs) operating in Florida. The analysis found that, of the 36 plans reviewed, the QHPs offered by CoventryOne, Cigna, Humana, and Preferred Medical charge

inordinately high co-payments and co-insurance for medications used in the treatment of HIV and AIDS.\(^5\) Other plans available through the Marketplace offer HIV/AIDS medications in a range of tiers and cost sharing structures.

- **CoventryOne** places all HIV drugs on Tier 5, including generics (with a 40% co-insurance after a $1,000 Rx deductible) and most require prior authorization.
- **Cigna** places all HIV drugs on Tier 5, including generics (in some plans with a 40% co-insurance after deductible ranging from $0 to $2,750).
- **Humana** places all HIV drugs on Tier 5, including generics (with a 50% co-insurance after a $1,500 Rx deductible).
- **Preferred Medical** places all HIV drugs on a Specialty Tier, including generics, and requires 40% co-insurance. It is unclear which require prior authorization.

The QHP drug benefits offered by CoventryOne, Cigna, Humana, and Preferred Medical impose overly restrictive utilization management which unduly limits access to commonly used HIV/AIDS medications. Moreover, by placing all HIV/AIDS medications, including generics, on the highest cost-sharing tier, CoventryOne, Cigna, Humana, and Preferred Medical discourage people living with HIV and AIDS from enrolling in those health plans – a practice which unlawfully discriminates on the basis of disability.

**DISCUSSION**

I. ACA anti-discrimination protections

Prior to the ACA, health insurance companies routinely discriminated against people living with HIV and AIDS. Plans denied coverage to individuals with pre-existing conditions including HIV and could exclude from their coverage treatment for those conditions. Additionally, insurance companies imposed annual and lifetime caps on benefits, which disproportionately affected people living with HIV and AIDS. The ACA intends to put an end to these discriminatory practices. The ACA requires guaranteed issue of coverage in the individual and small group health insurance markets so that no one can be denied health insurance due to a preexisting condition.\(^6\) Health insurers may no longer exclude coverage of a preexisting condition.\(^7\) The ACA further prohibits discrimination against individual participants and beneficiaries based on health status or medical condition,\(^8\) and it prevents insurers from imposing annual or lifetime limits on benefits.\(^9\)

The ACA contains additional provisions barring discriminatory plan benefit design, establishing that a Qualified Health Plan may “not employ marketing practices or benefit

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\(^6\) 42 U.S.C. § 300gg-1.

\(^7\) Id.

\(^8\) 42 U.S.C. § 300gg-4.

designs that *have the effect of discouraging the enrollment in such plan by individuals with significant health needs.* AACA regulations prohibit discrimination on the basis of race, color, national origin, disability, age, sex, gender identity, or sexual orientation.

The ACA requires all QHPs to provide prescription drug coverage as an essential health benefit (EHB). Under HHS regulations, health plans that provide EHBs “must cover at least the greater of (1) one drug in every United States Pharmacopeial Convention (USP) category and class or (2) the same number of prescription drugs in each USP category and class as the state’s EHB benchmark plan.” A QHP fails to meet the essential health benefits standard and can be decertified if the insurer employs a discriminatory benefits design.

**A. Section 1557 protections**

Most significantly, the ACA applies several existing federal anti-discrimination and civil rights statutes, including the Rehabilitation Act, to the QHPs offered through the health insurance Marketplaces. Prior to the ACA, private health insurance plans were not subject to the Rehabilitation Act, which prohibits discrimination in federal programs against persons living with disabilities, including HIV and AIDS. Under the ACA’s Section 1557, the Rehabilitation Act now expressly applies to the “contracts of insurance” available in the Marketplaces:

An individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.), the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.), or section 794 of title 29 [the Rehabilitation Act], be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title (or amendments).

Section 1557 expressly identifies “credits, subsidies, [and] contracts of insurance” as federal financial assistance to make clear that each trigger its application. Unlike Section 1557, Title VI, Title IX, and the Rehabilitation Act either explicitly exclude or have been interpreted in some circumstances to exclude contracts of insurance as a form of federal financial assistance. A contract of insurance that is federal financial

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10 42 U.S.C. § 18031(c)(a)(emphasis added); see also 45 C.F.R. §156.225(b).
11 45 C.F.R. § 156.200(e).
13 45 C.F.R. § 156.122.
14 45 C.F.R. § 156.125(a).
16 Because “contracts of insurance” are not excluded in the statutory text of Section 504 [of the Rehabilitation Act] but in its regulations, there have been conflicting decisions about whether the
assistance is any contract of insurance that is funded, entered into, administered, or
guaranteed by the federal government. Thus, an insurance company in a Marketplace
that receives federally-subsidized payments such as through premium tax credits is
covered by Section 1557.

Section 1557 specifically references the enforcement mechanisms “provided for” and
“available under” Title VI, Title IX, Section 504, and the Age Discrimination Act (“the Age
Act”). Disparate impact claims are allowed under the civil rights statutes referenced by
Section 1557. Because Section 1557 incorporates the enforcement mechanisms in
those statutes, it too must be interpreted to provide for complaints brought on behalf of
an individual, a class, or by a third party.

B. The Rehabilitation Act

The Rehabilitation Act prohibits programs and services which receive federal funds from
discriminating against persons with disabilities.

No otherwise qualified individual with a disability . . . shall, solely by reason
of her or his disability, be excluded from the participation in, be denied the
benefits of, or be subjected to discrimination under any program or activity
receiving Federal financial assistance or under any program or activity
conducted by any Executive agency or by the United States Postal
Service.¹⁸

Under regulations implementing Section 504, programs subject to the Rehabilitation Act
may not “provide benefits or services in a manner that limits or has the effect of limiting
the participation of qualified persons with disabilities.”¹⁹

Persons living with HIV fall within the definition of “disabled” under regulations
implementing the Rehabilitation Act, where disability is defined as:

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regulations properly exclude it. Compare Moore v. Sun Bank of North Florida, 923 F.2d 1423, 1429-32
(11th Cir. 1991) (finding that because Section 504 did not expressly exclude contracts of insurance or
guaranty, regulations containing the exclusion were invalid as inconsistent with congressional intent and
that the contract at issue did in fact constitute federal financial assistance) with Gallagher v. Croghan
Colonial Bank, 89 F.3d 275 (6th Cir. 1996) (holding that based on the Section 504 regulation’s exclusion
of contracts of insurance or guaranty as federal financial assistance, a bank’s receipt of reimbursement
for default loans was not federal financial assistance and thus the bank was not subject to the
Rehabilitation Act).

¹⁷ Dep’t of Justice, Title VI Legal Manual (2001),
http://www.justice.gov/crt/about/cor/coord/vimanual.php#B (stating that Title VI regulations “may validly
prohibit practices having a disparate impact on protected groups, even if the actions or practices are not
intentionally discriminatory”)(citing Guardians Ass’n v. Civil Serv. Comm’n, 463 U.S. 582, 582 (1983) and
Alexander v. Choate, 469 U.S. 287, 293 (1985)); Dep’t of Justice, Title IX Legal Manual (2001),
http://www.justice.gov/crt/about/cor/coord/ixlegal.php#2 (citing cases and stating “[i]n furtherance of
[Congress’s] broad delegation of authority [to implement Title IX’s prohibition of sex discrimination], federal
agencies have uniformly implemented Title IX in a manner that incorporates and applies the disparate
impact theory of discrimination.”).

¹⁹ 45 C.F.R. § 84.52(a)(iv).
(i) A physical or mental impairment that substantially limits one or more of the major life activities of such individual;
(ii) A record of such an impairment; or
(iii) Being regarded as having such an impairment.\textsuperscript{20}

Under long settled case law that even asymptomatic persons living with HIV are considered disabled and thus protected under federal anti-discrimination laws.\textsuperscript{21}

C. Applicability of the ADA safe harbor provision for insurers

The Americans with Disabilities Act (ADA) offers protections to persons with disabilities, in employment and public accommodation.\textsuperscript{22} The ADA is generally read in conjunction with the Rehabilitation Act.\textsuperscript{23} While the Rehabilitation Act applies exclusively federal funded programs and services, the ADA applies to private entities in areas such as employment, public accommodations, commercial facilities, and transportation.\textsuperscript{24}

The ADA’s protections have previously been held by courts to apply to the sale, but not the content of private health insurance plans.\textsuperscript{25} The ADA contains a safe harbor provision that protects insurers, stating that its protections do not prohibit, “an insurer, hospital or medical service company, health maintenance organization, or any agent, or entity that administers benefit plans, or similar organizations from underwriting risks, classifying risks, or administering such risks that are based on or not inconsistent with State law.”\textsuperscript{26}

However, the ADA’s safe harbor provision is not a license for health insurers to discriminate. Insurers may not employ this safe harbor provision as “subterfuge” to circumvent anti-discrimination protections.\textsuperscript{27} Courts have held that insurers do not have to provide actuarial data to justify coverage limits but those limits must be based upon actual or reasonably predictable risks.\textsuperscript{28} Instead, “the issue is whether the classifications made in the plan are rational ones or merely a pretext to effectuate a form of discrimination.”\textsuperscript{29} In fact, “what is needed is a rational nexus, based on underwriting experience, between the formation of the plan and the classifications made.”\textsuperscript{30}

\textsuperscript{20} 45 C.F.R. § 84.52(j). See also 29 C.F.R. § 1630.2(g).
\textsuperscript{22} 42 U.S.C. §§ 12101-12213.
\textsuperscript{23} Helen L. v. DiDario, 46 F.3d 325 (3d Cir. 1998).
\textsuperscript{24} 42 U.S.C. §§ 12181-12189.
\textsuperscript{25} See Doe v. Mutual of Omaha Ins. Co., 179 F.3d 557 (7th Cir. 1999) (upholding lifetime and annual caps on health insurance, which disproportionately affect people living with HIV and AIDS, because under the ADA “the content of the goods or services offered by a place of public accommodation is not regulated.”).
\textsuperscript{26} 42 U.S.C. § 12201(c)(1).
\textsuperscript{27} 42 U.S.C. § 12201(c)(3).
\textsuperscript{29} Currie, 147 F.Supp.2d at 37.
\textsuperscript{30} Id.
In contrast to the ADA, the Rehabilitation Act contains no safe harbor provision for health insurance companies. And notably, Section 1557 applies the Rehabilitation Act, but not the ADA, to QHPs sold through the Marketplace.31

Section 1557 extends anti-discrimination protections not just to the sale of health insurance plans, but to their content as well. Even if the safe harbor provision did apply to QHPs, as explained below CoventryOne, Cigna, Humana, and Preferred Medical would not be protected because their prescription drug benefit designs exhibit no rational nexus to underwriting risks.

II. Florida QHPs with a discriminatory prescription drug benefit design

Antiretroviral therapy (ART) is recommended for all persons with HIV infection and should be offered to those with early HIV infection.32 Treatment adherence is particularly important for persons living with HIV and AIDS because “even short interruptions of care can threaten health and undermine prevention effects.”33 Notably, higher cost sharing, including copayment and coinsurance, can often result in missing doses or falling out of treatment, which can lead to the development of drug resistance.34 Moreover, prior authorizations result in fewer prescriptions filled and increased non-adherence.35

Some Florida health insurers designate certain medications, including those used in the treatment of HIV/AIDS, as specialty drugs. There is no statutory or regulatory definition of “specialty drugs,” nor is there a common industry standard definition.

Likewise, the practice of tiering medications is becoming increasingly common among health insurers. There is no statutory or regulatory definition for tiering drugs in QHPs, nor is there a common industry standard definition.36 In the absence of guidelines or industry standards, the practice of tiering medications according to required

31 Henrietta D. v. Bloomberg, 331 F.3d 261, 272 (2d Cir. 2003) (claims under the ADA and Rehabilitation Act are treated identically unless one of the differences in the two statutes is pertinent to a claim).
33 Dana P. Goldman, et al., The Prospect Of A Generation Free Of HIV May Be Within Reach If The Right Policy Decisions Are Made, 33 Health Affairs, 430 (2014).
36 The Medicare Part D program contemplates tiering, but requires CMS approval that the prescription drug coverage and any tiering system have an “actuarial bases provided and reasonably and equitably reflect the revenue requirements.” 42 C.F.R. § 423.272(b)(1). Medicare Part D plans must provide an exceptions process to tiering. See 42 C.F.R., §§ 423.104(d)(2), 423.578.
copayments, prior authorization, and quantity limits can lead to abuses that harm medically vulnerable populations such as people with HIV and AIDS.  

A. CoventryOne

CoventryOne offers two silver-level plans through the Federally Facilitated Marketplace (FFM) operating in Florida - Coventry One FL Silver $10 Copay HMO and Coventry One FL Silver $10 Copay HMO Carelink. The plans have the same formularies and pricing structure but feature different provider networks to correspond with the regions in which they are sold.

For most of its health plans offered outside the Marketplace, CoventryOne offers prescription drug coverage in three tiers, with generics in Tier 1 and brand name and some non-preferred drugs in Tier 3. Tier 3 is the highest tier with highest co-pays and deductibles. By contrast, for silver-level plans available through the Marketplace, CoventryOne provides prescription drug coverage in six tiers.

Tier 1A: Lower Cost Preferred Generic Drugs
Tier 1: Preferred Generic Drugs
Tier 2: Preferred Brand Drugs
Tier 3: Non-preferred Brand/Generic Drugs
Tier 4: Preferred Specialty Drugs
Tier 5: Non-preferred Specialty Drugs

CoventryOne designates all HIV drugs as “specialty” drugs. CoventryOne places all its anti-retroviral therapies in Tier 5, including the generic versions of CombiVIR, Epivir, Ziagen, and Zerit, which are widely prescribed anti-retrovirals. Tier 5 drugs require prior authorization, 40% coinsurance, and quantity limits. The company provides no information on total out of pocket expenditures required for enrollees paying “coinsurance.”

B. Cigna

Cigna offers five silver-level QHPs in Florida: myCigna Copay Assure Silver, myCigna Health Flex 1500, myCigna Health Flex 2750, myCigna Health Flex 5000, and myCigna

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37 See attached chart by The AIDS Institute for a complete listing of the Florida QHP HIV/AIDS drug formulary and tiering structure. See also Katie Keith et al., Nondiscrimination Under the Affordable Care Act, The Center on Health Insurance Reforms, Georgetown University’s Health Policy Institute 13 (July 2013) http://chir.georgetown.edu/pdfs/NondiscriminationUndertheACA_GeorgetownCHIR.pdf.
41 QHPs are required to make the amount of enrollee cost sharing available. 45 C.F.R. § 156.220(d).
Health Savings 3400. Cigna places prescription drugs on 5 Tiers, available through retail or mail order:

Tier 1 - Retail Preferred Generic
Tier 2 - Retail Non-Preferred Generic
Tier 3 - Retail Preferred Brand
Tier 4 - Retail Non-preferred Brand
Tier 5 - Retail Specialty

The company places all HIV/AIDS drugs on Tier 5, including generic versions of Combivir, Retrovir, Trizivir, Viramune, Ziagen, and Zerit, which are widely prescribed anti-retrovirals. In most of its plans, Cigna charges 40-50% co-insurance for Tier 5 drugs after a deductible ranging from $0 to $2,750. Cigna requires prior authorization for these commonly used HIV/AIDS treatment regimens and limits enrollees to only a 30 day supply. The company provides no information on total out-of-pocket expenditures required for enrollees paying "coinsurance."

C. Humana

Humana offers two silver-level QHPs through the Florida Marketplace: Humana Connect Silver 4600/6300 Plan and the Humana Direct Silver 4600/6300 Plan. Humana also has a five tier pricing structure for prescription drugs offered through its Florida QHPs.

Humana places all HIV drugs on Tier 5, including generic versions of Combivir, Epivir, Retrovir, Videx, Viramune, Ziagen, and Zerit. Humana requires enrollees to pay 40-50% co-insurance after a $1,500 Rx deductible. The company requires prior authorization for these commonly used HIV/AIDS treatment regimens and limits enrollees to only a 30 day supply. Humana provides no information on total out of pocket expenditures required for enrollees paying "coinsurance."

D. Preferred Medical

Preferred Medical offers two QHPs through the Florida Marketplace: Preferred Medical Plan Silver Deluxe AX Dade and Preferred Medical Plan Silver Deluxe CX Dade. The company places all HIV drugs on a Specialty Tier, including generic versions of Combivir, Epivir, Retrovir, Ziagen, and Zerit. Preferred Medical requires enrollees pay 40% co-insurance. It is unclear whether all require prior authorization. Preferred Medical provides no information on total out of pocket expenditures required for enrollees paying "coinsurance."

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43 Humana does not directly post the Summary of Benefits and coverage on its website. These documents are available via [www.healthcare.gov](http://www.healthcare.gov).
III. How CoventryOne, Cigna, Humana, and Preferred Medical prescription drug benefit designs compare to other QHPs sold in Florida

The practice of placing all anti-retrovirals on the highest tier is not a market-norm or necessity. Other issuers vary tiering or place HIV drugs on more affordable tiers.\(^{44}\) Below are examples of plans available in Florida with more balanced cost-sharing practices:

- **BlueCross** is the Florida Marketplace issuer with the largest share of plans in the silver market. Blue Cross places most HIV drugs on either Tier 1 or Tier 2, requiring a co-payment of between $10 and $25 for Tier 1 drugs (after a deductible in some cases) and a co-payment of between $40 and $70 for Tier 2 drugs (after a deductible in some cases). Only one drug is on Tier 3 without a generic or alternate form on a lower tier. Tier 3 co-payments range from $70-$100.

- **Ambetter** places most HIV drugs on Tier 1 and Tier 2 and two HIV drugs on Tier 4. Tier 1 co-payments range from $10 to $25 and Tier 2 co-payments range from $50 to $75 (sometimes after meeting a deductible). Tier 4 drug coinsurance ranges from 20% to 30% (after a deductible), with one plan benefit structure using a $250 (after deductible) co-payment.

- **Aetna** places generic versions of HIV drugs Combinvir, Epivir, Retrovir, Videx, Zerit, Ziagen, Viramune on Tier 1.

- **Florida Healthcare Plans (an independent licensee of Blue Cross)** places HIV drugs on Tier 2 and Tier 3, requiring a $10 co-payment for Tier 2 drugs and a $30 co-payment for Tier 3 drugs (after meeting a deductible).

- **Molina** places most drugs on Tiers 1 and 2, with one drug on Tier 3, and two drugs on Tier 4. Tier 1 requires a $20 co-payment and Tier 2 a $55 co-payment. Tiers 3 and 4 require a 30% co-insurance.

IV. Compliance reviews and enforcement authority

While OCR has primary responsibility to monitor and enforce civil rights protections, other agencies and entities also have a role. The Centers for Medicare & Medicaid Services (CMS) conducts compliance reviews of QHPs as part of the certification process for QHP participation in the FFMs. CMS examines compliance with ACA standards, including ACA regulations prohibiting discrimination on the basis of on race, color, national origin, disability, age, sex, gender identity, or sexual orientation; not employing marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs.

In its 2015 Letter to Issuers, the Center for Consumer Information and Insurance Oversight (CCIIO) indicates it will perform an outlier analysis on QHP cost sharing (e.g.,

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\(^{44}\) See attached analysis by The AIDS Institute of Florida QHP drug formularies and tiering structures.
co-payments and co-insurance) as part of the QHP certification application process.\textsuperscript{45} CCIIO further promises to "review plans that are outliers based on an unusually large number of drugs subject to prior authorization and/or step therapy requirements in a particular category and class."

The certification application process does not preclude or replace non-discrimination enforcement by the OCR.\textsuperscript{46} Moreover, given that discrimination is often based on long-standing and pervasive benefit design customs in the insurance industry, looking for outliers will likely prove inadequate in detecting pervasive and endemic patterns of discrimination against persons with HIV/AIDS and others with significant health care needs.

**RELIEF REQUESTED**

The AIDS Institute and the National Health Law Program request that OCR:

1. Review drug plan tiering, cost sharing structures, prior authorization requirements, and supply limits for the HIV/AIDS prescription drug benefits in QHPs offered by CoventryOne, Cigna, Humana, and Preferred Medical;

2. Take all necessary steps to remedy the unlawful conduct of CoventryOne, Cigna, Humana, and Preferred Medical, including a corrective action plan and targeted outreach and enrollment of people living with HIV and AIDS;

3. Require CoventryOne, Cigna, Humana, and Preferred Medical to fund a study of other compensable damages for enrollees living with HIV and AIDS affected by the barriers to accessing prescription drugs. The study should examine issues including, but not limited to, the development of HIV treatment resistance in enrollees, adverse events including hospitalizations resulting from interruptions in treatment, the need for salvage therapy, and overcharges to enrollees living with HIV/AIDS;

4. Seek civil monetary penalties and decertification of the above-named Florida QHPs, for continued non-compliance with federal civil rights protections.


\textsuperscript{46} In a January 16, 2014 letter to the HIV Health Care Access Working Group (on file with The AIDS Institute and the National Health Law Program), CCIIO’s then-director Gary Cohen acknowledged concerns raised by The AIDS Institute and other stakeholders regarding the discriminatory prescription drug benefit cost sharing structures of some QHPs. Cohen noted that consumer complaints regarding benefits and cost sharing could be directed to state departments of insurance or the Call Center for healthcare.gov. However, Cohen neither validates nor denies a discriminatory prescription drug plan benefit design, nor does his advice to advocates preclude OCR from its civil rights monitoring and enforcement responsibilities.
Barriers to care and treatment interruptions can lead to serious, adverse health consequences for people living with HIV/AIDS. The AIDS Institute and the National Health Law Program strongly urge OCR to investigate discriminatory HIV prescription drug benefit designs in Florida, and elsewhere, as expeditiously as possible. We are available to offer any assistance necessary to ensure that people living with HIV/AIDS get full access the health benefits provided under the ACA.

Respectfully submitted,

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