

## **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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### **RE: DISCRIMINATORY PHARMACY BENEFITS DESIGN IN HUMANA QUALIFIED HEALTH PLANS OFFERED IN ILLINOIS**

#### **COMPLAINANTS**

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The Center for Health Law and Policy Innovation of Harvard Law School (CHLPI) is a non-profit organization which advocates for legal, regulatory, and policy reforms to improve the health of underserved populations, with a focus on the needs of low-income people living with chronic conditions and disabilities; CHLPI is also a clinical teaching program of Harvard Law School. The organization has offices in Cambridge, MA and Jamaica Plains, MA.

The AIDS Foundation of Chicago is a non-profit organization whose mission is to mobilize communities to create equity and justice for people living with and vulnerable to HIV and related chronic diseases.

#### **DEFENDANTS**

Humana, headquartered in Louisville, Kentucky, reporting annual revenue of \$54.29 billion for 2015.<sup>1</sup>

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<sup>1</sup> Humana, Inc., “2015 Annual Report” at 2, available at: <http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NjEzNDA3fENoaWxkSUQ9MzI3MDc3fFR5cGU9MQ==&t=1>

## **JURISDICTION**

Within the U.S. Department of Health and Human Services (HHS), the Office of Civil Rights (OCR) enforces nondiscrimination regulations that apply to programs, services, and activities receiving HHS Federal financial assistance. Among the laws enforced by OCR is Section 504 of the Rehabilitation Act of 1973, which prohibits discrimination against otherwise qualified individuals on the basis of disability.<sup>2</sup> OCR also enforces Section 1557 of the Patient Protection and Affordable Care Act (ACA), which prohibits discrimination in the provision of Marketplace health insurance plans.<sup>3</sup>

Under 45 C.F.R. § 85.61(d) OCR is required to “accept and investigate all complete complaints for which it has jurisdiction.” Section 1557 regulations describe OCR’s enforcement authority. Pursuant to 45 C.F.R. § 92.301, “the enforcement mechanisms under Title VI, Title IX, the Age Act, or Section 504 apply for violations of Section 1557.” Cases of noncompliance may result in suspension, termination, or refusal to grant or continue Federal financial assistance.<sup>4</sup> Humana offers QHPs on the Illinois health insurance exchanges and is therefore subject to OCR jurisdiction.<sup>5</sup> The enforcement mechanisms available under Section 504 apply for the purposes of Section 1557, meaning that OCR may determine if civil rights have been violated and whether enforcement proceedings should be initiated.<sup>6</sup>

## **BACKGROUND**

Discrimination within health programs can contribute to increased health disparities, unequal resource distribution, and poor health outcomes. Left unchecked, discriminatory plan design destroys the fair playing field underlying the competitive insurer incentives on which the ACA is premised. In pursuit of a more equitable health care system, and in recognition of the needs of our most vulnerable populations, the ACA incorporated broad protections for consumers against exclusions, denials, and other forms of discrimination on the basis of race, color, national origin, disability, age, sex, gender identity, and sexual orientation.<sup>7</sup> Among

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<sup>2</sup> 29 U.S.C. § 701.

<sup>3</sup> 42 U.S.C. § 18116.

<sup>4</sup> *See* Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31376-01, 31439 (May 18, 2016) (interpreting the newly promulgated 45 C.F.R. § 92.301).

<sup>5</sup> 45 C.F.R. § 92.2(a).

<sup>6</sup> *See* 42 U.S.C. § 18116.

<sup>7</sup> *See* 45 C.F.R. § 156.200(e) (“A QHP issuer must not, with respect to its QHP, discriminate on the basis of race, color, national origin, disability, age, sex, gender identity or sexual orientation.”)

the most vulnerable of these protected classes are individuals living with HIV, who have historically been denied coverage due to this preexisting condition.<sup>8</sup>

The Rehabilitation Act of 1973 prohibits disability discrimination by federal agencies or contractors or by employers that receive federal funding. Jurisprudence interpreting the Rehabilitation Act of 1973 has consistently adjudged individuals living with HIV/AIDS to be disabled.<sup>9</sup> Among other things, Section 1557 of the ACA extends the protections of the Rehabilitation Act to the ACA Marketplaces, barring all discriminatory insurance practices on the grounds of disability, including on the basis of HIV status. Section 1331 of the ACA affords additional protections against discrimination for individuals living with HIV. Section 1331(c)(2)(B) requires a state to “[make] suitable allowances for differences in health care needs of enrollees,” and explicitly bars “discrimination on the basis of pre-existing conditions or other health status-related factors.” Section 1331 of the ACA thereby establishes a general prohibition on any plan benefit design that serves to discourage enrollment for individuals with high cost conditions. Similarly, 45 C.F.R. § 147.104(e) prohibits insurers from “employ[ing] marketing or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs.”

The Complainants have monitored trends in state Marketplaces for the past two years of open enrollment, analyzing the impact that cost-sharing, coverage, and transparency may have on potential enrollees living with HIV.<sup>10</sup> The Complainants’ QHP assessment centered on twenty-four of the most commonly prescribed antiretroviral HIV drugs on the market. HIV is a chronic illness that can be treated but not cured. If HIV is not treated, it can progress to AIDS and dramatically shorten individuals’ lives. Individuals need to remain on treatment and take antiretroviral drugs every day for the rest of their lives in order to maintain the benefits of treatment.<sup>11</sup>

The 24 commonly prescribed antiretroviral HIV drugs assessed by drugs can be classified into 6 groups: Nucleoside Reverse Transcriptase Inhibitors (“NRTIs”), Non-Nucleoside Reverse Transcriptase Inhibitors (“NNRTIs”), Protease Inhibitors (“PIs”), Integrase Strand Transfer Inhibitors (“INSTIs”), Entry Inhibitors (“EIs”) and

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<sup>8</sup> The ACA bans coverage denials based on preexisting conditions, *see* 80 Fed. Reg. 72192, 72192 (Nov. 18, 2015).

<sup>9</sup> *See Chalk v. United States Dist. Ct.*, 840 F.2d 701 (9th Cir. 1988); *Doe v. Dalton Elementary Sch. Dist. No. 148*, 694 F. Supp. 440 (N.D. Ill. 1988); *Robertson v. Granite City Community Unit Sch. Dist. No. 9*, 684 F. Supp. 1002 (S.D. Ill. 1988); *Doe v. Centinela Hosp.*, No. CV 87-2514 PAR(PX), 1988 WL 81776 (C.D. Cal. June 30, 1988); *Martinez v. School Bd.*, 675 F. Supp. 1574 (M.D. Fla. 1987); *Doe v. Belleville Pub. Sch. Dist.*, 672 F. Supp. 342 (S.D. Ill. 1987); *Ray v. School Dist. of DeSoto County*, 666 F. Supp. 1524 (M.D. Fla. 1987); *Thomas v. Atascadero Unified Sch. Dist.*, 662 F. Supp. 376 (C.D. Cal. 1987); *American Fed’n of Gov’t Employees v. United States Dep’t of State*, 662 F. Supp. 50 (D.D.C. 1987); *Shuttleworth v. Broward County*, 649 F. Supp. 35 (S.D. Fla. 1986).

<sup>10</sup> The report compiled by the Complainants regarding the 2016 Illinois Silver Level QHPs is published at: <http://www.chlpi.org/download/3098/>

<sup>11</sup> *See About HIV/AIDS*, CENTERS FOR DISEASE CONTROL AND PREVENTION (last updated Dec. 6, 2015), <http://www.cdc.gov/hiv/basics/whatishiv.html>.

Single-Tablet Regimens (“STR”), which combine various drugs into one multi-component product.<sup>12</sup>

Under the aegis of the United States Department of Health and Human Services and in conformance with recognized health needs of HIV patients and developments in HIV medications, an expert panel publishes recommended treatment regimens for HIV that constitute the prevailing standard of care.<sup>13</sup> The Guidelines are meant to be used broadly by providers who work with HIV-positive patients.<sup>14</sup> Under these Guidelines, there are six treatment regimens used for adult and adolescent treatment-naïve patients (i.e., those who have not taken HIV medications before):<sup>15</sup>

1. dolutegravir<sup>16</sup> + (abacavir + lamivudine)<sup>17</sup> = Triumeq (STR).
2. dolutegravir + Truvada (tenofovir DF plus emtricitabine)<sup>18,19</sup>
3. elvitegravir<sup>20</sup> + cobicistat<sup>21</sup> + tenofovir alafenamide<sup>22</sup> + emtricitabine = Genvoya (STR)
4. elvitegravir + cobicistat + (tenofovir DF + emtricitabine) = Stribild (STR)
5. raltegravir<sup>23</sup> + Truvada (tenofovir DF plus emtricitabine)
6. darunavir<sup>24</sup> + ritonavir<sup>25</sup> + Truvada (tenofovir DF plus emtricitabine)

Thus, in order to ensure the ability of providers to prescribe treatment consistent with the prevailing standard of care, formularies should provide access to at least sixteen primary drugs or combination products.<sup>26</sup> Having an exceptions process to

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<sup>12</sup> See *Anti-HIV Drug Classes and Names*, NAM-AIDSMAP, <http://www.aidsmap.com/Anti-HIV-drug-classes-and-names/page/1254942/>.

<sup>13</sup> See generally *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*, DEPARTMENT OF HEALTH AND HUMAN SERVICES, <https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf> [hereinafter *Guidelines*]. In July 2016, the panel updated and revised the Guidelines. In order to match the appropriate Guideline provisions to those in effect during the majority of the relevant plan year, this Complaint references the version of the Guidelines in effect as of January 2016.

<sup>14</sup> See *id.* at A-1

<sup>15</sup> See *id.* at F-3.

<sup>16</sup> Dolutegravir is an integrase inhibitor (INSTI) with a brand name product Tivicay.

<sup>17</sup> Abacavir alone is a Nucleoside Reverse Transcriptase Inhibitor (NRTI) with a brand name of Ziagen. Lamivudine alone is also a NRTI with the brand name of Epivir. Abacavir + lamivudine together are an NRTI with a brand name Epzicom.

<sup>18</sup> Tenofovir disoproxil fumarate (DF) alone is an NRTI with the brand name Viread. Emtricitabine is an NRTI with a brand name of Emtriva. Tenofovir DF plus emtricitabine is an NRTI with the brand name Truvada.

<sup>19</sup> In certain cases where emtricitabine is part of the combination drug, lamivudine can be substituted.

<sup>20</sup> Elvitegravir is an integrase inhibitor (INSTI) with a brand name product Vitekta.

<sup>21</sup> Cobicistat is a pharmacokinetic enhancer with a brand name of Tybost.

<sup>22</sup> Tenofovir alafenamide is a prodrug of the NRTI tenofovir.

<sup>23</sup> Raltegravir is an integrase inhibitor (INSTI) with a brand name product Isentress.

<sup>24</sup> Darunavir is a protease inhibitor (PI) with a brand name product Prezista.

<sup>25</sup> Ritonavir is a PI with a brand name product Norvir.

<sup>26</sup> These 16 primary drugs are as follows:

- Tivicay (brand name) – dolutegravir (no generic version available);

the formulary through which an individual can attempt to access coverage for a drug not on the formulary is not enough. This is true because of the uncompensated cost to providers of going through the prior authorization process,<sup>27</sup> because this coverage is not guaranteed,<sup>28</sup> and because the process of obtaining this coverage is opaque.

Doctors choose which drugs to prescribe to their HIV patients based on a range of factors, including co-occurring illnesses,<sup>29</sup> medical history and tolerance. Studies have shown the importance of adherence in maintaining an undetectable viral load, and the greater likelihood of adherence to STRs than to standard multiple pill regimens.<sup>30</sup> Therefore, it is important for patients to have access through their insurance plans to STRs—which are pharmacologically distinct—as well as various single-drug and combination tablets so that they and their doctors can create optimal treatment plans.

It is important to note that these drug regimens are not interchangeable. HIV is a complex disease and treatment options must take into account co-infecting conditions as well as concerns regarding a patient’s medication adherence. Before initiating treatment, physicians must take into account multiple factors, including drug interactions, coexisting comorbid conditions and side effect profiles. Therefore, it is important that doctors be able to provide treatment based on patients’ needs, not on availability under a particular insurance plan. There are

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- abacavir (generic name) – also available in sulfate form as brand name Ziagen;
  - lamivudine (generic name) – also available as brand name Epivir;
  - Epzicom (brand name) - abacavir + lamivudine;
  - Trumeq (brand name) – STR of dolutegravir + (abacavir + lamivudine);
  - tenofovir DF (generic name) – also available as brand name Viread;
  - Emtriva (brand name) – emtricitabine (no generic version available); but note that lamivudine may be substituted in certain circumstances;
  - Truvada (brand name) – tenofovir DF + emtricitabine;
  - Vitekta (brand name) – elvitegravir – (no generic version available);
  - Tybost (brand name) – cobicistat – (no generic version available);
  - Descovy (brand name) - tenofovir alafenamide + emtricitabine;
  - Genvoya (brand name) - STR of elvitegravir + cobicistat + (tenofovir alafenamide + emtricitabine);
  - Stribild (brand name) - STR of elvitegravir + cobicistat + (tenofovir DF + emtricitabine);
  - Isentress (brand name) – raltegravir (no generic version available);
  - Prezista (brand name) – darunavir - (no generic version available);
  - ritonavir (generic name for tablet) – also available in tablet / capsule / solution form as brand name Norvir.

<sup>27</sup> See James L. Raper et al., *Uncompensated Medical Provider Costs Associated with Prior Authorization for Prescription Medications*, 51 CLINICAL INFECTIOUS DISEASES 718, 720 (2010) (providing the amount of time, on average, health care workers spent on prior authorization in a study).

<sup>28</sup> See *id.*

<sup>29</sup> See *id.* at J-1.

<sup>30</sup> See, e.g., S. Scott Sutton et al., *Single- Versus Multiple-Tablet HIV Regimens: Adherence and Hospitalization Risk*, 4 AM. J. MANAGED CARE 242, 244 (2006).

multiple classes of drugs, and which drug should be selected from a particular class depends on specific patient characteristics. Importantly, doctors are instructed to consider the number of doses per day a patient should take in addition to what type of drug they should be prescribed.<sup>31</sup> Accordingly, STRs are preferred under the guidelines because of the ease of taking only one pill per day and the vitally important benefits of greater treatment adherence. Because different STRs include different drug combinations,<sup>32</sup> it is critical that insurance coverage provides options for providers to prescribe appropriate treatment for patients.

## LEGAL STANDARD

Section 1557 is the antidiscrimination provision of the ACA. It prohibits discrimination on the ground of race, color, national origin, sex, age, or disability under “any health program or activity, any part of which is receiving Federal financial assistance . . . or under any program or activity that is administered by an Executive agency or any entity established under [Title I of ACA].”<sup>33</sup> Section 1557 prohibits discrimination not only in federally funded health programs, but also in ACA Marketplaces.

Section 1557 applies to “any health program or activities, any part of which is receiving Federal financial assistance.”<sup>34</sup> Federal financial assistance is expansively designed to include “credits, subsidies or contracts of insurance.”<sup>35</sup> As such, Section 1557’s inclusion of “credits” and “subsidies” shows that its antidiscrimination provision covers private insurance companies who receive any federal tax credits or subsidies under the ACA.

Section 1557 cross-references Section 504 of the Rehabilitation Act, which prohibits disability discrimination in federally funded programs.<sup>36</sup> Section 1557 also references Title VI, prohibiting discrimination based on race, color, or national origin; Title IX, prohibiting sex discrimination; and the Age Discrimination Act of 1975. Thus, Section 1557 is firmly grounded in prior civil rights laws. Although Section 1557 does not define prohibited discrimination, it adopts the language of the Rehabilitation Act regarding disability discrimination, providing that an individual or entity shall not be “excluded from participation in, be denied the benefits of, or be subject to discrimination under” any health program or activity.<sup>37</sup> The use of this language “seems to evidence an intent that Section 1557’s anti-discrimination mandate is to be interpreted consistently with that of Title VI, Title IX, Section 504, and Age Discrimination Act, all of which have implemented

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<sup>31</sup> <https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/11/what-to-start>

<sup>32</sup> <http://www.fda.gov/ForPatients/Illness/HIVAIDS/Treatment/ucm118915.htm>

<sup>33</sup> 42 U.S.C. § 18116.

<sup>34</sup> 42 U.S.C. § 12132.

<sup>35</sup> *Id.*

<sup>36</sup> 29 U.S.C. § 794(a).

<sup>37</sup> 42 U.S.C. § 12132.

regulations that prohibit both disparate impact, as well as intentional discrimination.”<sup>38</sup>

Although OCR need not make out even a prima facie case of disparate impact under either the Affordable Care Act or the Rehabilitation Act to justify administrative enforcement of these regulations,<sup>39</sup> the principles discerned from disparate impact jurisprudence provide a useful backdrop against which the discrimination alleged here can be viewed.<sup>40</sup> In *Alexander v. Choate*, the Court looked to whether “meaningful access” had been provided to the plaintiff, finding that “to assure meaningful access, reasonable accommodations in the [plaintiff’s] program or benefit may have to be made.”<sup>41</sup> The Court recognized that a balance must be struck between “the statutory rights of the handicapped to be integrated into society and the legitimate interests of federal grantees in preserving the integrity of their programs: while a grantee need not be required to make ‘fundamental’ or ‘substantial’ modifications to accommodate the handicapped, it may be required to make ‘reasonable’ ones.”<sup>42</sup> Interpreting this standard further, the Ninth Circuit has concluded that the question is whether the required services have been provided “in an effective manner.”<sup>43</sup> This “effective manner” may be understood comparatively, in which case a benefit design is ineffective if it does not provide disabled individuals with the same opportunities to benefit from the services that are available to others.<sup>44</sup>

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<sup>38</sup> Sidney D. Watson, *Section 1557 of the Affordable Care Act: Civil Rights, Health Reform, Race, and Equity*, 55 How. L.J. 855, 872 (2012).

<sup>39</sup> “Disparate impact” refers to an evidentiary methodology that differs from “disparate treatment” with respect to the need to prove intent to discriminate. “In contrast to a disparate-treatment case, where a ‘plaintiff must establish that the defendant had a discriminatory intent or motive,’ a plaintiff bringing a disparate-impact claim challenges practices that have a ‘disproportionately adverse effect on [a protected class]’ and are otherwise unjustified by a legitimate rationale.” *Texas Dep’t of Hous. & Cmty. Affairs v. Inclusive Communities Project, Inc.*, 135 S. Ct. 2507, 2513 (2015) quoting *Ricci v. DeStefano*, 557 U.S. 557, 577 (2009). The Complainants here urge OCR to commence administrative enforcement against Humana by undertaking the investigation necessary to discern why it has designed its plan benefits in the manner it has. Such an investigation is warranted in any event to discover whether Humana harbored a discriminatory intent, as required in the context of a disparate treatment cause of action, or whether Humana can offer a legitimate, non-discriminatory justification for the impact of its design, as would be examined in the context of a disparate impact cause of action. Whatever the underlying reason for Humana’s plan benefit design, its treatment and effect on people living with HIV/AIDS, viewed in light of the publicly available information referenced in this Complaint, merits administrative enforcement by OCR.

<sup>40</sup> It is worth noting that in the parallel context of private enforcement of Section 1557, OCR has interpreted Section 1557 to allow for disparate impact causes of action, even if this methodology is not directly here at issue. “OCR interprets Section 1557 as authorizing a private right of action for claims of disparate impact discrimination on the basis of any of the criteria enumerated in the legislation.” Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31376-01, 31440 (interpreting the newly promulgated 45 C.F.R. § 92.301).

<sup>41</sup> *Alexander v. Choate*, 469 U.S. 287, 301 (1985).

<sup>42</sup> *Id.*, 469 U.S. at 300.

<sup>43</sup> *Katie A., ex rel. Ludin v. Los Angeles Cty.*, 481 F.3d 1150, 1159 (9th Cir. 2007).

<sup>44</sup> See Leslie Pickering Francis & Anita Silvers, *Debilitating Alexander v. Choate: “Meaningful Access” to Health Care for People with Disabilities*, 35 FORDHAM URB. L.J. 447, 475 (2008).

In addition to Section 1557, Section 1311 of the ACA also prohibits the employment of “marketing practices or benefit designs that have the effect of discouraging enrollment in such plan by individuals with significant health needs.”<sup>45</sup> CMS thus interprets the ACA’s antidiscrimination provisions to apply specifically to instances where issuers place “most or all drugs that treat a specific condition on the highest cost tiers.”<sup>46</sup>

## DISCUSSION

### **I. Humana deters individuals living with HIV from enrolling in their plans by placing the majority of HIV medications as specialty drugs in its highest cost-sharing tier.**

By disproportionately placing life-prolonging, single-sourced drugs (i.e., drugs for which there is no generic equivalent) in tiers with high consumer cost-sharing, Humana discriminates against individuals with conditions such as HIV/AIDS. Structuring cost-sharing design in such a manner places an undue burden on individuals living with specific chronic conditions, who have no alternative but to pay the exorbitant costs required to receive their necessary treatments.

Humana deters potential enrollees living with HIV by placing 16 of the 24 most common HIV medications on its highest cost-sharing tier. Though tiers 4 and 5 both require 50% coinsurance, tier 5 is reserved for “specialty drugs” while tier 4 includes “non-preferred brand-name drugs. . . . often with a preferred generic alternative.”<sup>47</sup> There is no discernible difference between tiers 4 and 5 of the formulary, and many of the brand name drugs on tier 4 actually lack generic alternatives, contrary to tier 4’s description. The sheer optics of placing these drugs on the highest tier serves no rational business purpose other than to dissuade individuals living with HIV from enrolling in their plan, particularly when nearly every other insurer offering plans on the marketplace in Illinois offers the medications at a far lower out-of-pocket cost.

Additionally, potential enrollees are not afforded the tools to calculate the potential monthly costs of their HIV treatment regimen. Humana’s plan design lacks transparency in that individuals are required to pay half the price of nearly all HIV medications. In comparison to published co-pay rates, individuals have no way of

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<sup>45</sup> 42 U.S.C. § 18031(c)(1)(A).

<sup>46</sup> See Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016, 80 FR 10750-01, 10823 (Feb. 27, 2015). See also CMS, 2017 Letter to Issuers in the Federally-facilitated Marketplaces (Feb. 29, 2016) available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2017-Letter-to-Issuers-2-29-16.pdf> (“if an issuer places most or all drugs that treat a specific condition on the highest cost formulary tiers, that plan design might effectively discriminate against, or discourage enrollment by, individuals who have those conditions.”)

<sup>47</sup> See 2016 Humana Drug List for Rx Plus, available at <http://apps.humana.com/marketing/documents.asp?file=2614807>

knowing what the costs of their medication will be prior to their enrollment. Coinsurance tends to quickly increase cost to the consumers by making them responsible for a sizable portion of the cost of expensive medication. Additionally, it is practically impossible for consumers with coinsurance to calculate the actual cost sharing owed before attempting to purchase their prescriptions.

## II. Humana fails to provide affordable access to HIV medications by making HIV treatment regimens cost-prohibitive.

Humana’s formulary fails to provide an adequate selection of affordable HIV treatments.<sup>48</sup> As discussed at length above, HIV treatment regimens are not interchangeable and formularies should allow broad access to affordable treatment options. Choice of regimen should be driven by clinical considerations, treatment guidelines, and patient and provider choice, rather than cost. As shown in Figure 1 below, for an individual enrolled in Humana’s Illinois QHP, the monthly cost of life-saving, necessary medication is astronomical, ranging between 8 - 14% of an average monthly Illinoisian income for a single treatment regimen.

**Figure 1 – Percentage of Income Necessary for Guideline Treatment**

<u>Regimen</u>	<u>Monthly Cost-Sharing Estimate for Humana Enrollee<sup>49</sup></u>	<u>% of Median Income<sup>50</sup></u>
<b>Triumeq</b>	<b>\$608</b>	<b>12.7%</b>
<b>Truvada + Tivicay</b>	<b>\$684</b>	<b>14.3%</b>
<b>Stribild</b>	<b>\$611</b>	<b>12.8%</b>
<b>Truvada + Isentress</b>	<b>\$377</b>	<b>7.9%</b>
<b>Prezista + Norvir + Truvada</b>	<b>\$682</b>	<b>14.3%</b>

<sup>48</sup> Beginning January 1, 2017 all issuers must ensure that their formulary drug list meets the following criteria:

“(1) Covers a range of drugs across a broad distribution of therapeutic categories and classes and recommended drug treatment regimens that treat all disease states, and does not discourage enrollment by any group of enrollees; and

(2) Provides appropriate access to drugs that are included in broadly accepted treatment guidelines and that are indicative of general best practices at the time.” 45 C.F.R. §156.122.

<sup>49</sup> Estimation of monthly cost-share is necessary, as Humana does not make public its actual proprietary drug prices for enrollees. These are conservative cost estimates, as they are based on published “Big Four” drug prices. The “Big Four” are the four largest federal purchasers of pharmaceuticals: the Department of Veterans Affairs (VA), the Department of Defense (DoD), the Public Health Service, and the Coast Guard. The Big Four Pharmaceutical Catalog is available at:

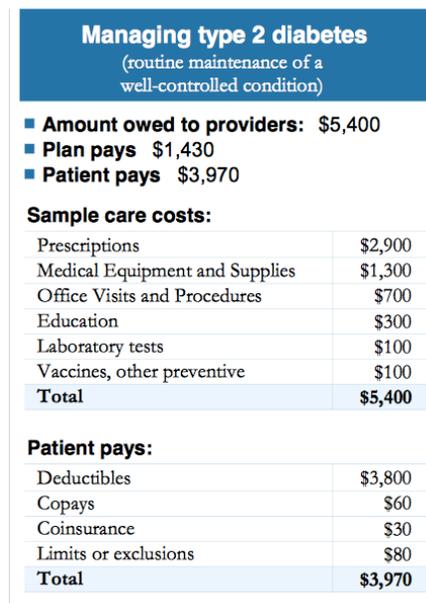
[http://www1.va.gov/nac/index.cfm?template=Search\\_Pharmaceutical\\_Catalog](http://www1.va.gov/nac/index.cfm?template=Search_Pharmaceutical_Catalog)

Complainants note that this cost estimate is also conservative because it utilizes the lower, in-network 40% cost-sharing responsibility, rather than the higher, out-of-network 50% coinsurance level. For enrollees unable to use network pharmacies, the cost-sharing burden will be that much more difficult.

<sup>50</sup> The 2014 median household income in Illinois was \$57,166 per year (\$4,763.83/month). Source: U. S. Census Bureau, American Community Survey (ACS), 5-Year Estimates. See, <http://factfinder.census.gov>

Though Humana features a yearly out-of-pocket maximum (OOPM) of \$6,300 for an individual plan, individuals living with HIV/AIDS will reach this cap more quickly than individuals living with other chronic diseases with lower-tiered medications. Figure 2 is taken from Humana’s enrollment website to provide an example of costs associated with a diabetes, another chronic, well-controlled condition requiring routine maintenance.<sup>51</sup> As indicated in Figure 2, an enrollee on the HIV treatment regimen of Prezista + Norvir + Truvada would pay more for their medication in five months (\$4,633.33) than an enrollee with diabetes would pay in an *entire year* for all prescriptions and medical services (\$3,970). Many individuals are unlikely to afford such high monthly coinsurance rates without greatly reducing their quality of life. Indeed, given the high single month cost, some individuals may never be able to afford the cash-flow required for even the first month’s supply of their HIV medication, and may simply abandon their prescriptions at the pharmacy. For individuals unable to afford their medications because they are on such a high cost-sharing tier, the OOPM is immaterial and does little to alleviate the effects of such high cost-sharing requirements. Just as Medicare Part D enrollees were forced to pay full coverage within their plan’s “donut hole”, Humana enrollees will bear the financial challenges resulting from inadequate coverage and may never reach their yearly out-of-pocket spending limit because they will forgo their life-saving medications.<sup>52</sup> With such a formulary design, Humana fails to provide “appropriate access to drugs,” as required under 45 CFR §156.122.

**Figure 2 – Humana Enrollment Website**



<sup>51</sup> Source: Humana, “Compare Illinois Health Plan Options”, available at: <https://www.humana.com/individual-and-family/products-and-services/medical-plans/plans-in-illinois/>

<sup>52</sup> See “What is the Donut Hole?” U.S. Medicare (Aug. 9, 2010), available at: <https://blog.medicare.gov/2010/08/09/what-is-the-donut%20hole/>

### **III. Because Humana places all single-tablet regimens on the highest cost-sharing tier, enrollees are at greater risk of non-adherence and resulting life-threatening health consequences with their treatment regimens.**

According to the federal guidelines, non-adherence is the most common cause of treatment failure.<sup>53</sup> Unlike diabetes treatment regimens, which retain their efficacy even after a period of noncompliance, antiretroviral therapy (ART) may become ineffective after even a short interruption in a treatment plan.<sup>54</sup> Because HIV is highly adaptable, any individual period of non-adherence may lead to “emergence of drug resistance and loss of future treatment options.”<sup>55</sup> The guidelines state: “Strict adherence to antiretroviral therapy (ART) is key to sustained HIV suppression, reduced risk of drug resistance, improved overall health, quality of life, and survival, as well as decreased risk of HIV transmission.”<sup>56</sup>

The guidelines cite risk-factors that may lead to non-adherence, including high pill burdens and inaccessibility due to cost.<sup>57</sup> Single-tablet regimens (STRs) are the key to greater adherence, as they require lower pill burdens and are associated with fewer side effects than many of the older treatment regimens. According to the Panel on Antiretroviral Guidelines’ research, “increased patient cost sharing resulted in decreased medical adherence and more frequent drug discontinuation.”<sup>58</sup> Compounding the risks of non-adherence, this research also finds that such practices are not cost-effective: “[F]or patients with chronic diseases, increased cost sharing was also associated with increased use of the medical system.”<sup>59</sup>

With this in mind, it bears emphasis that every STR included in the drugs examined by the Complainants is placed by Humana in its highest cost-sharing tier.<sup>60</sup>

### **IV. In placing most HIV/AIDS medications on the highest cost-sharing tiers, Humana’s drug formulary treats individuals living with HIV/AIDS unfairly.**

Though Humana places nearly all HIV/AIDS medication on the highest cost-sharing tier, they place similarly-situated drugs used to treat other conditions on lower tiers. In doing so, Humana treats individuals living with HIV unfairly, requiring them to pay more for their medications than others must pay for their comparably priced non-HIV medications.

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<sup>53</sup> Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. Available at <http://aidsinfo.nih.gov/contentfiles/lvguidelines/AdultandAdolescentGL.pdf>. Section accessed [Apr. 1, 2016] [i-34]

<sup>54</sup> *Id.*

<sup>55</sup> *Id.* at k-1.

<sup>56</sup> *Id.*

<sup>57</sup> *Id.* at i-34.

<sup>58</sup> *Id.* at k-18.

<sup>59</sup> *Id.*

<sup>60</sup> The Humana formulary assessed by Complainants places Atripla, Triumeq and Stribild on Tier 5.

Figure 3 highlights two chemotherapy drugs as an example.<sup>61</sup> Though comparably priced (according to publicly available wholesale price data),<sup>62</sup> the cost to consumer is only \$50 per month, or 1% of the Illinois median household income. This stands in stark contrast to HIV prescription cost-sharing, which is more than ten times higher as a percentage of income in some cases. This remains true even for a drug like Isentress, which has a significantly lower wholesale price than the lower tiered non-HIV drugs.

**Figure 3 – Drug Comparison**

<b>Medication</b>	<b>AWP</b>	<b>Tier</b>
<i>Non-HIV</i>		
<b>Trexall (15 mg)</b>	\$1313	3 - \$50 copay
<b>Leukeran</b>	\$1216	3 - \$50 copay
<i>HIV</i>		
<b>Tivicay (50 mg)</b>	\$1422	5 – 40-50% coinsurance
<b>Prezista (100 mg oral)</b>	\$905	5 – 40-50% coinsurance
<b>Isentress (100 mg tab)</b>	\$386.30	5 – 40-50% coinsurance
<b>Viread (150 mg)</b>	\$1109	5 – 40-50% coinsurance

By providing plans to HIV/AIDS beneficiaries that mandate the highest levels of cost sharing, Humana beneficiaries are subject to a de facto denial of meaningful access to HIV/AIDS medications. Because of the formulary’s design, beneficiaries on Humana’s plans are more likely to stop taking HIV/AIDS medications, thereby increasing the chances of transmission and raising the expenses incurred by the state.

Unambiguously, Humana’s adverse tiering subjects those with HIV and AIDS to discrimination and denies them the benefits of the ACA, in direct violation of Section 1557. Although not expressly excluded from participation in Humana’s health insurance plans, the cost-prohibitive nature of enrollment would lead any reasonable HIV/AIDS drug consumer to avoid or leave Humana’s plans altogether.

<sup>61</sup> See 2016 Humana Drug List for Rx Plus, available at <http://apps.humana.com/marketing/documents.asp?file=2614807>.

<sup>62</sup> Complainants use AWP prices for the purposes of Figure 3, as the intent is not to estimate actual cost, but rather to identify the relative cost of drugs to one another.

**V. Humana is an outlier when compared to the vast majority of QHPs on the Illinois Insurance Exchange, with much higher cost sharing rates for enrollees living with HIV.**

Of the 42 silver plans CHLPI assessed in Illinois, 69% of plans provide the majority of medications and/or middle-tier cost-sharing.<sup>63</sup> Only 7% of plans on the Illinois Marketplace placed HIV medications on the highest tier requiring coinsurance.<sup>64</sup> By categorically placing all STRs in their highest cost sharing tiers, Humana is placing their own financial incentives above ACA mandates. By requiring enrollees to pay far higher cost-sharing than other insurers, Humana discourages individuals with HIV/AIDS from enrolling and staying on their insurance plans, thereby driving this high-cost population to their competitors.

Consider Truvada, an important component of regimens for treatment-naive individuals recommended in the federal guidelines described above. But Truvada is also the only drug available in the United States as pre-exposure prophylaxis (PrEP) for people who are HIV-negative but vulnerable to HIV infection. Access to this medication is particularly important for serodiscordant couples and men who have sex with men (MSM).<sup>65</sup> Of each of the plans offered in Cook County, Humana is the only insurance company that places Truvada on tier 5. All other plans place Truvada on an intermediate tier, usually with cost-sharing in the range of \$40 - \$50. Humana's silver plans require a 50% co-insurance for this medication, for an estimated monthly cost of \$357. The exorbitant monthly cost of Truvada would undoubtedly deter any individual living with HIV from enrolling in Humana's silver plans, but it may also deter MSM and others engaging in activity that may put them at risk for contracting HIV in the future.

In the case of Truvada and most other commonly prescribed HIV medications, Humana's adverse tiering discriminates based on both disability and sexual orientation, both of which are disallowed under Sections 1557 and 1331 of the ACA. Whatever the motivation for Humana's tiering decisions, these are outlier practices – as shown in comparison to the vast majority of QHPs on the Illinois Insurance Exchange – that warrant administrative enforcement. Though courts have held that regulated entities are entitled to make “practical business choices and profit-related decisions”, such business decisions shall not stand should the court find “an available alternative ... practice that has less disparate impact and serves the [entity's] legitimate needs.”<sup>66</sup> In this instance, the majority of silver plans on the Illinois Marketplace place HIV medications on lower tiers, and use co-pays for cost-sharing rather than coinsurance. Humana may defend this adverse tiering as a

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<sup>63</sup> “2016 Plan Analysis for Qualified Health Plans: Illinois” Center For Health Law and Policy Innovation, at 12 – 14, available at: <http://www.chlpi.org/plan-assessment/>

<sup>64</sup> *See id.*

<sup>65</sup> *See* U.S. Public Health Service, “Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2014” at 9, available at <https://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf>

<sup>66</sup> *Texas Dep't of Hous. & Cmty. Affairs v. Inclusive Communities Project, Inc.*, 135 S. Ct. 2507, 2518 (2015)

business necessity, however the majority of its competitors within the very same marketplace did not similarly find it necessary to engage in such discriminatory insurance practices.

This practice creates clustering of individuals with HIV/AIDS in a smaller number of plans and insurers, creating financial disincentives and magnifying risk for insurers that are currently abiding by ACA anti-discrimination mandates. Ultimately, without federal agency intervention, the higher costs inflicted on law-abiding insurers through clustering will lead them to raise premiums or alter cost sharing in ways similar to Humana. Complicity with this type of discriminatory practice allows one insurer to take advantage of the system in a manner that is unfair to other competing insurance companies who remain in compliance with Sections 1557 and 1311. And it is undoubtedly unfair to HIV-positive individuals, who are among those potential enrollees with the greatest health needs, yet are faced with the greatest financial costs. If Section 1557 is not enforced against Humana, it may lead to a “race to the bottom,” where savvy insurers require individuals with HIV/AIDS to pay far more for their medications.

#### **VII. Humana continues to employ discriminatory practices against individuals living with HIV, in spite of criticism from experts and authorities against the practice of discriminatory tiering.**

In their recent *Notice of Benefit and Payment Parameters for 2016 Proposed Rule*, the Centers for Medicare and Medicaid Services (CMS) labeled adverse tiering practices as discriminatory, noting:

“if an issuer places most or all drugs that treat a specific condition on the highest cost tiers, we believe that such plan designs effectively discriminate against, or discourage enrollment by, individuals who have those chronic conditions.”<sup>67</sup>

Under Illinois law, the DOI must decide if plans satisfy the federal requirements for sale on the State’s exchange, including the requirement that plans not discriminate against any health conditions such as HIV/AIDS. This gatekeeping role was explicitly assigned to the DOI in the Illinois State Partnership Exchange Blueprint Application, which designates the DOI as the “Appropriate Authority to Perform and Oversee Certification of QHPs [qualified health plans]” under ACA § 1311: “The Illinois Department of Insurance (DOI) has this authority [to perform and oversee certification of QHPs] under the broad powers granted to the Director under 215 ILCS 5/401.”<sup>68</sup> Thus, the DOI must act in conformity with ACA § 1311, which

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<sup>67</sup> 79 Fed. Reg. 70674 (November 26, 2014). Available at <http://www.gpo.gov/fdsys/pkg/FR-2014-11-26/pdf/2014-27858.pdf>.

<sup>68</sup> Illinois State Partnership Exchange Blueprint Application, at 1, available at: [https://www.statereforum.org/system/files/il\\_blueprint\\_application.pdf](https://www.statereforum.org/system/files/il_blueprint_application.pdf)

provides that a State “may not make available any health plan that is not a qualified health plan.”<sup>69</sup> To be a “qualified health plan” a plan must provide “essential health benefits.”<sup>70</sup>

On May 23, 2014, the Illinois Department of Insurance (DOI) issued a bulletin highlighting the importance of issuer compliance with 45 C.F.R. 156.125(a-c), which asserts that “[a]n issuer does not provide EHB (essential health benefits) if its benefit design, or the implementation of its benefit design, discriminates based on...present or predicted disability,” among other health conditions.<sup>71</sup> The bulletin serves to remind all insurers that this prohibition on discrimination applies just as much to HIV/AIDS as other health conditions. The DOI explicitly warns that a QHP engaging in discriminatory plan design or implementation would not be recommended for certification, particularly if the plan fails to provide access to the “recommended” and “alternative” HIV drug regimens listed in HHS’s *Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents*.<sup>72</sup> In spite of this warning, Humana’s discriminatory plan designs remain certified and available for enrollment on the Illinois Marketplace Exchanges.

On January 28, 2015, AFC sent a letter to Bruce D. Broussard, the President and CEO of Humana, informing him of these official statements and urging Humana to immediately amend their formularies “to cover all HIV medications in cost sharing tiers that will allow people with HIV access to these essential medications.”<sup>73</sup> Over a year later, the majority of HIV medications remain on Tier 5 at 50% co-insurance.

## **RELIEF REQUESTED**

The Center for Health Law and Policy Innovation and the AIDS Foundation of Chicago request that OCR:

- I. Review drug plan tiering, cost-sharing structures, quantity limits, and prior authorization requirements for the HIV/AIDS prescription drug benefits in QHPs offered by Humana;
- II. Take all necessary steps to remedy the unlawful conduct of Humana, including a corrective action plan and targeted outreach of people living with HIV;

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<sup>69</sup> 42 U.S.C. § 18031(d)(1)(B)(i).

<sup>70</sup> 42 U.S.C. § 18021(a)(1)(B).

<sup>71</sup> Andrew Boron, Director of Insurance, Company Bulletin CB 2014 – 08, “Discrimination and Qualified Health Plan (QHP) Certification or Recertification for 2015 Plan Year” (May 23, 2014).

<sup>72</sup> U.S. Dep’t of Health and Human Servs., *Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents* (insert date here)

<sup>73</sup> Letter from AIDS Foundation of Chicago to Bruce D. Broussard, President and CEO of Humana, Inc. (dated Jan. 28, 2015).

- III. Suspend, terminate, or refuse to grant or continue federal financial assistance; or seek civil monetary penalties and decertification of the relevant QHP for continued non-compliance with federal civil rights protections.

**CONCLUSION:**

Disproportionately high cost-sharing and coinsurance are not appropriate when they serve as a gatekeeper to access to life saving medications, nor when they are designed to disproportionately burden people living with HIV with unreasonable cost sharing. Plans that practice such benefit design force individuals living with HIV more to pay far more per year than plans with more equitable out of pocket cost structures. This requires people living with HIV to shoulder a significantly larger percentage of their health care costs than other consumers. The failure to effectively stem such unfair and discriminatory plan design is increasingly undermining access to care for many people living with HIV. Without strong state or federal oversight by insurance regulators, the discriminatory plan design trend will likely continue.

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