



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
OFFICE FOR CIVIL RIGHTS (OCR)  
**DISCRIMINATION COMPLAINT**



If you have questions about this form, call OCR (toll-free) at:  
1-800-368-1019 (any language) or 1-800-537-7697 (TDD)

YOUR FIRST NAME		YOUR LAST NAME	
HOME PHONE ( )		WORK PHONE ( )	
STREET ADDRESS			CITY
STATE	ZIP	E-MAIL ADDRESS (If available)	

Are you filing this complaint for someone else?  Yes  No  
If Yes, against whom do you believe the discrimination was directed?

FIRST NAME	LAST NAME
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I believe that I have been (or someone else has been) discriminated against on the basis of:  
Race / Color / National Origin    Age     Religion     Gender (Male/Female)  
Disability    Other (specify): \_\_\_\_\_

Who do you think discriminated against you (or someone else)?  
PERSON/AGENCY/ORGANIZATION

STREET ADDRESS		CITY
STATE	ZIP	PHONE ( )

When do you believe that the discrimination took place?  
LIST DATE(S)

Describe briefly what happened. How and why do you believe you (or someone else) were discriminated against? Please be as specific as possible. (Attach additional pages as needed)

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Please sign and date this complaint.  
SIGNATURE: *Robert Greenwald*    DATE: \_\_\_\_\_

Filing a complaint with OCR is voluntary. However, without the information requested above, OCR may be unable to proceed with your complaint. We collect this information under authority of Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973 and other civil rights statutes. We will use the information you provide to determine if we have jurisdiction and, if so, how we will process your complaint. Information submitted on this form is treated confidentially and is protected under the provisions of the Privacy Act of 1974. Names or other identifying information about individuals are disclosed when it is necessary for investigation of possible discrimination, for internal systems operations, or for routine uses, which include disclosure of information outside the Department for purposes associated with civil rights compliance and as permitted by law. It is illegal for a recipient of Federal financial assistance from Health and Human Services (HHS) to intimidate, threaten, coerce, or discriminate or retaliate against you for filing this complaint or for taking any other action to enforce your rights under Federal civil rights laws. You are not required to use this form. You also may write a letter or submit a complaint electronically with the same information. To submit an electronic complaint, go to our web site at: [www.hhs.gov/ocr/discrimhowtofile.html](http://www.hhs.gov/ocr/discrimhowtofile.html). To mail a complaint see reverse page for OCR Regional addresses.

(The remaining information on this form is optional. Failure to answer these voluntary questions will not affect OCR's decision to process your complaint.)

**Do you need special accommodations for us to communicate with you about this complaint (check all that apply)?**

Braille  Large Print  Cassette tape  Computer diskette  Electronic mail  TDD

Sign language interpreter (specify language): \_\_\_\_\_

Foreign language interpreter (specify language): \_\_\_\_\_

Other: \_\_\_\_\_

**If we cannot reach you directly, is there someone we can contact to help us reach you?**

FIRST NAME		LAST NAME	
HOME PHONE ( )		WORK PHONE ( )	
STREET ADDRESS		CITY	
STATE	ZIP	E-MAIL ADDRESS (If available)	

**Have you filed your complaint anywhere else? If so, please provide the following. (Attach additional pages as needed.)**

PERSON / AGENCY / ORGANIZATION / COURT NAME(S)

DATE(S) FILED	CASE NUMBER(S) (If known)
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**To help us better serve the public, please provide the following information for the person you believe was discriminated against (you or the person on whose behalf you are filing).**

ETHNICITY (select one)  Hispanic or Latino RACE (select one or more)  American Indian or Alaska Native  Asian  Native Hawaiian or Other Pacific Islander

Not Hispanic or Latino  Black or African American  White  Other (specify): \_\_\_\_\_  
PRIMARY LANGUAGE SPOKEN (if other than English) HOW DID YOU LEARN ABOUT THE OFFICE FOR CIVIL RIGHTS?

**To mail a complaint, please type or print, and return completed complaint to the OCR Regional Address based on the region where the alleged discrimination took place.**

<b>Region I - CT, ME, MA, NH, RI, VT</b> Office for Civil Rights Department of Health & Human Services JFK Federal Building - Room 1875 Boston, MA 02203 (617) 565-1340; (617) 565-1343 (TDD) (617) 565-3809 FAX	<b>Region V - IL, IN, MI, MN, OH, WI</b> Office for Civil Rights Department of Health & Human Services 233 N. Michigan Ave. - Suite 240 Chicago, IL 60601 (312) 886-2359; (312) 353-5693 (TDD) (312) 886-1807 FAX	<b>Region IX - AZ, CA, HI, NV, AS, GU, The U.S. Affiliated Pacific Island Jurisdictions</b> Office for Civil Rights Department of Health & Human Services 90 7th Street, Suite 4-100 San Francisco, CA 94103 (415) 437-8310; (415) 437-8311 (TDD) (415) 437-8329 FAX
<b>Region II - NJ, NY, PR, VI</b> Office for Civil Rights Department of Health & Human Services 26 Federal Plaza - Suite 3313 New York, NY 10278 (212) 264-3313; (212) 264-2355 (TDD) (212) 264-3039 FAX	<b>Region VI - AR, LA, NM, OK, TX</b> Office for Civil Rights Department of Health & Human Services 1301 Young Street - Suite 1169 Dallas, TX 75202 (214) 767-4056; (214) 767-8940 (TDD) (214) 767-0432 FAX	<b>Region X - AK, ID, OR, WA</b> Office for Civil Rights Department of Health & Human Services 2201 Sixth Avenue - Mail Stop RX-11 Seattle, WA 98121 (206) 615-2290; (206) 615-2296 (TDD) (206) 615-2297 FAX
<b>Region III - DE, DC, MD, PA, VA, WV</b> Office for Civil Rights Department of Health & Human Services 150 S. Independence Mall West - Suite 372 Philadelphia, PA 19106-3499 (215) 861-4441; (215) 861-4440 (TDD) (215) 861-4431 FAX	<b>Region VII - IA, KS, MO, NE</b> Office for Civil Rights Department of Health & Human Services 601 East 12th Street - Room 248 Kansas City, MO 64106 (816) 426-7277; (816) 426-7065 (TDD) (816) 426-3686 FAX	
<b>Region IV - AL, FL, GA, KY, MS, NC, SC, TN</b> Office for Civil Rights Department of Health & Human Services 61 Forsyth Street, SW. - Suite 3B70 Atlanta, GA 30323 (404) 562-7886; (404) 331-2867 (TDD) (404) 562-7881 FAX	<b>Region VIII - CO, MT, ND, SD, UT, WY</b> Office for Civil Rights Department of Health & Human Services 1961 Stout Street - Room 1426 Denver, CO 80294 (303) 844-2024; (303) 844-3439 (TDD) (303) 844-2025 FAX	

**Burden Statement**

Public reporting burden for the collection of information on this complaint form is estimated to average 45 minutes per response, including the time for reviewing instructions, gathering the data needed and entering and reviewing the information on the completed complaint form. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: HHS/OS Reports Clearance Officer, Office of Information Resources Management, 200 Independence Ave. S.W., Room 531H, Washington, D.C. 20201.

## **ADMINISTRATIVE COMPLAINT**

Office for Civil Rights, U.S. Department of Health and Human Services  
200 Independence Avenue, S.W., Room 509F  
Washington, D.C. 20201

Timothy Noonan, Regional Manager, Region IV  
Office for Civil Rights, U.S. Department of Health and Human Services  
Sam Nunn Atlanta Federal Center, Suite 16T70  
61 Forsyth St, S.W.  
Atlanta, GA 30303-8909

### **RE: DISCRIMINATORY PRESCRIPTION DRUG BENEFIT DESIGNS IN HUMANA QUALIFIED HEALTH PLANS IN TENNESSEE**

#### **I. COMPLAINANTS**

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.

Nashville CARES is a non-profit organization with offices in Nashville, Tennessee, whose mission is to end the HIV epidemic in middle Tennessee. The organization focuses on education, advocacy, and support for those at risk for or living with HIV, including prevention, counseling, and testing.

#### **II. DEFENDANTS**

Humana Health Plan, Inc., headquartered in Louisville, Kentucky, with annual revenue of \$54 billion for 2015.<sup>1</sup>

#### **III. JURISDICTION**

This complaint is filed pursuant to Section 1557 of the Patient Protection and Affordable Care Act (ACA).<sup>2</sup> The ACA provides that “an individual shall not ... be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity” that enters into a “contract of insurance” with the federal government.<sup>3</sup> As elucidated by the anti-discrimination regulations implementing Section 1557 (the Anti-Discrimination

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<sup>1</sup> Humana. *Annual Report - 2015*, HUMANA, <http://phx.corporate-ir.net/phoenix.zhtml?c=92913&p=irol-reportsannual>, (Feb. 18, 2016).

<sup>2</sup> 42 U.S.C. § 18116 (2012).

<sup>3</sup> *Id.* at § 18116(a).

Regulations), this anti-discrimination mandate reaches those insurers operating through a federal- or state-established health insurance exchange.<sup>4</sup>

Section 1557 specifically delineates the design of insurance plan benefits as a potentially discriminatory practice.<sup>5</sup> Section 1557 provides that under any health program or activity, any part of which is receiving federal financial assistance, or any entity established under Title I of the ACA or its amendments, an individual shall not be subjected to discrimination on grounds prohibited under Section 504 of the Rehabilitation Act of 1973.<sup>6</sup> Section 504 of the Rehabilitation Act of 1973 prohibits discrimination against otherwise qualified individuals on the basis of disability.<sup>7</sup> Under Section 504 and attendant case law, HIV is considered a categorical disability.<sup>8</sup>

The Department of Health and Human Services (HHS) Office for Civil Rights (OCR) is granted authority to investigate potentially discriminatory behavior in the health insurance context and to enforce compliance with Section 1557.<sup>9,10</sup> Under 45 C.F.R. § 85.61(d), OCR is required to “accept and investigate all complete complaints for which it has jurisdiction.” 45 C.F.R. § 92.301 additionally provides that “[t]he enforcement mechanisms available for and provided under Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, Section 504 of the Rehabilitation Act of 1973, or the Age Discrimination Act of 1975 shall apply for purposes of Section 1557.” Noncompliance can result in suspension, termination, or refusal to grant or continue federal financial assistance.<sup>11</sup> Should the efforts of OCR to enforce Section 1557 not result in compliance on the part of the insurer, it can refer the matter to the Department of Justice for litigation.<sup>12</sup>

#### IV. PRELIMINARY STATEMENT

This complaint is filed to notify OCR of discriminatory benefit designs employed by Humana on the Tennessee Marketplace. Approximately 16,802 Tennesseans are currently living with HIV,<sup>13</sup> and Humana has designed Qualified Health Plans (QHPs) that violate Sections 1311 and 1557 of the ACA by preventing these individuals from “meaningful access”<sup>14</sup> to comprehensive health care coverage that meets their health needs. CHLPI and Nashville CARES request OCR to invoke its mandate under the ACA, and put an end to the discriminatory practices of this insurer.

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<sup>4</sup> 80 Fed. Reg. 54172, 54173 (Sept. 8, 2015).

<sup>5</sup> 45 C.F.R. § 92.207(b)(2).

<sup>6</sup> 42 U.S.C. § 18116.

<sup>7</sup> 29 U.S.C. § 701.

<sup>8</sup> *Social Security For People Living With HIV*, SOCIAL SECURITY, (last visited Jul. 15, 2016), available at <https://www.ssa.gov/pubs/EN-05-10019.pdf>

<sup>9</sup> 80 Fed. Reg. at 54172-54221.

<sup>10</sup> 81 Fed. Reg. 31376-01, 31440 (May 18, 2016) (“OCR is responsible for enforcement with respect to benefit design issues under Section 1557.”).

<sup>11</sup> *See, e.g.*, 45 C.F.R. §§ 80.8, 84.6, and 302(c).

<sup>12</sup> 81 Fed. Reg. at 31376-01 (“OCR has the authority to refer cases to DOJ for litigation where efforts at compliance have been unsuccessful.”)

<sup>13</sup> HIV Disease/STD Surveillance Reports - 2014, TN DEP’T. OF HEALTH, (Oct. 23, 2015) available at <https://www.tn.gov/health/article/hiv-data>.

<sup>14</sup> *See Alexander v. Choate*, 469 U.S. 287 (1985).

In a recent series of reports, CHLPI analyzed trends in HIV medication coverage and costs in the 2016 silver level QHPs in state Marketplace exchanges, including Tennessee. As a result of its work, CHLPI has seen an alarming national trend towards decrease in coverage and an increase in consumer cost sharing for these treatments.<sup>15</sup> These trends discourage individuals with HIV from enrolling in these QHPs. The issues around cost and coverage of key medications also raise the chances of serious health consequences for enrollees who are unable to afford necessary care.<sup>16</sup>

In Tennessee, CHLPI, along with Nashville CARES, reviewed the coverage of all the common regimens recommended as the standard of care for treatment-naïve patients in the Federal *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*,<sup>17</sup> as well as other commonly used HIV medications in the 2016 silver level QHPs available on the Tennessee Marketplace. CHLPI found that the federally-recommended treatment regimens are disproportionately unaffordable to individuals living with HIV under the benefit plan designs of several insurers offering QHPs on the Tennessee Marketplaces. Silver-level QHPs were chosen for review because they are “the marketplace standard,” meaning that subsidies to lower income enrollees are calculated on the premiums the silver QHPs and certain cost sharing subsidies are available only if an enrollee has selected a silver QHP.<sup>18</sup>

All of the three QHPs offered by Humana (Humana Silver 3800/Nashville PPOx, Humana Silver 3800/Memphis PPOx, and Humana Silver 3800/Knoxville PPOx) are among the most expensive and restrictive for accessing HIV treatment medications in Tennessee. This QHP benefit design placing the costs of life saving medications back onto vulnerable enrollees and violates the anti-discrimination protections of the ACA in three ways. First, Humana adversely tiers its HIV medications, placing virtually all relevant HIV medications on the highest level of “specialty” cost-sharing, which in turn makes necessary treatment objectively unaffordable for the average person living with HIV. Secondly, the high cost sharing renders HIV medications so expensive on Humana QHPs that beneficiaries are rationally discouraged from joining their plans in the first place, or forced to migrate to other insurers, as a means of reducing the insurance company’s financial burden. Third, Humana singles out HIV medications from other medications, placing an undue burden on HIV-infected individuals in relation to others with similar chronic health conditions.

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<sup>15</sup> Center for Health Law & Policy Innovation, *2016 Qualified Health Plan Assessments* (Dec. 2015), available at <http://www.chlpi.org/plan-assessment>.

<sup>16</sup> *Id.*

<sup>17</sup> U.S. Dept. of Health & Human Services Panel on Antiretroviral Guidelines for Adults and Adolescents – A Working Group of the Office of AIDS Research Advisory Council (OARAC), *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents: When to Start: Initial Combination Regimens for the Antiretroviral-Naïve Patient* (last visited Jul. 15, 2016), available at [https://aidsinfo.nih.gov/contentfiles/lvguidelines/aa\\_recommendations.pdf](https://aidsinfo.nih.gov/contentfiles/lvguidelines/aa_recommendations.pdf).

<sup>18</sup> *Qualified Health Plan*, Obamacare Facts, (last visited Jul. 20, 2016), available at <http://obamacarefacts.com/insurance-exchange/qualified-health-plan/>.

## V. RELEVANT LAW

### A. Anti-Discrimination Protections in the Affordable Care Act

#### 1. Section 1557

Under Section 1557, the ACA clearly establishes protections from discrimination based on race, color, national origin, disability, age, sex, gender identity, or sexual orientation.<sup>19</sup> Section 1557 applies directly to federal- and state-based Marketplaces,<sup>20</sup> and therefore applies to Tennessee Silver QHP insurers. Section 1557 also reinforces the anti-discrimination protections in the ACA by explicitly prohibiting discrimination based on disability.<sup>21</sup> The stipulation that HIV is a categorical disability has also been upheld in relevant case law; persons with HIV, both symptomatic and asymptomatic, have physical impairments “that substantially limit one or more major life activities” and are, therefore, protected by the law.<sup>22</sup>

The ACA clearly establishes protections from discrimination for people living with HIV who enroll in a silver QHP in Tennessee. Section 1557 provides for enforcement through the mechanisms available under existing anti-discrimination laws, regulations, and policies.<sup>23</sup> The mechanisms relevant to this complaint derive from Section 504 of the Rehabilitation Act,<sup>24</sup> which utilizes a definition of disability from the Americans with Disabilities Act. This definition classifies HIV as a “physical or mental impairment that substantially limits one or more of the major life activities of [an] individual.”<sup>25</sup>

Additionally, although Section 1557 does not expressly 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>26</sup> The Supreme Court has specified that the relevant inquiry under the Rehabilitation Act for determining if discrimination has occurred is whether “meaningful access” has been provided to individuals with disabilities.<sup>27</sup> The meaningful access inquiry asks “whether those with disabilities are as a practical matter able to access benefits to which they are legally entitled.”<sup>28</sup>

The Anti-Discrimination Regulations indicate that insurers must make reasonable modifications in policies, practices, and procedures to avoid disability-based discrimination, unless doing so would fundamentally change the nature of the program. Moreover, the Anti-Discrimination

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<sup>19</sup> 42 U.S.C. § 18116; 45 C.F.R. § 92.101.

<sup>20</sup> 45 C.F.R. § 92.4.

<sup>21</sup> *Id.* at § 92.205.

<sup>22</sup> *See, e.g., Bragdon v. Abbott*, 524 U.S. 624 (1998); U.S. Dep’t. of Justice Disability Rights Section, *Questions and Answers: The Americans with Disabilities Act and Persons with HIV*, ADA.Gov, (last visited, Jul. 15, 2016) available at <https://www.ada.gov/archive/hivqanda.txt>.

<sup>23</sup> 80 Fed. Reg. at 54172-54221.

<sup>24</sup> 42 U.S.C. § 18116(b).

<sup>25</sup> 45 C.F.R. § 84.52(j).

<sup>26</sup> 42 U.S.C. 12132 (2006).

<sup>27</sup> *See Choate*, 469 U.S. at 287.

<sup>28</sup> *Henrietta D. v. Bloomberg*, 331 F.2d 261, 273 (2003).

Regulations state that covered entities may not employ discriminatory benefit designs, though remains silent on whether issuers may place all drugs to treat a single medical condition on the plan's highest cost-sharing tier. HHS has made its intention on this benefits design practice clear elsewhere, such as in its *2017 Letter to Issuers and Notice of Benefit and Payment Parameters*. HHS notes that "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>29</sup> HHS 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>30</sup>

## 2. Section 1311

As a separate issue, the trends uncovered in CHLPI's analysis indicate that state regulators are not enforcing the ACA anti-discrimination protections outlined in Section 1311 of the ACA, which prohibits "marketing practices or benefit designs that have the effect of discouraging enrollment in such plan by individuals with significant health needs."<sup>31</sup> The Centers for Medicare and Medicaid Services (CMS) has interpreted 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>32</sup> State regulators in Tennessee have yet to enforce Section 1311 protections for people living with HIV. OCR, however, has enforcement authority for activities administered by any entity established under Title I of the ACA, which includes state Marketplace exchanges.<sup>33</sup>

## VI. DISCUSSION

### A. Recommended Treatment for HIV

HIV is a chronic illness that can be treated but not cured. 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>34</sup> Strict adherence to Antiretroviral Therapy (ART)<sup>35</sup> can stop the progression of HIV and prevent its transmission to others.<sup>36</sup> One multi-country study has found, for instance,

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<sup>29</sup> U.S. Dept. of Health & Human Services, *2017 Letter to Issuers in the Federally-facilitated Marketplaces*, Pg. 45 (February 29, 2016) available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2017-Letter-to-Issuers-2-29-16.pdf>.

<sup>30</sup> 80 Fed. Reg. 10750-01, 10823 (Feb. 27, 2015).

<sup>31</sup> ACA § 1311(c)(1)(A).

<sup>32</sup> See 80 Fed. Reg. at 10823.

<sup>33</sup> U.S. Dept. of Health & Human Services, *Regulations Enforced by OCR*, (last visited Jul. 15, 2016), available at <http://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/laws/index.html>.

<sup>34</sup> See *About HIV/AIDS*, CENTERS FOR DISEASE CONTROL AND PREVENTION (last updated Dec. 6, 2015), <http://www.cdc.gov/hiv/basics/whatishiv.html>.

<sup>35</sup> ART is comprised of a combination of HIV medicines taken as a daily HIV regimen. See *Overview of HIV Treatments*, AIDS.GOV, <https://www.aids.gov/hiv-aids-basics/just-diagnosed-with-hiv-aids/treatment-options/overview-of-hiv-treatments/> (last visited Apr. 10, 2016).

<sup>36</sup> See PE Sax et al., *Adherence to antiretroviral treatment and correlation with risk of hospitalization among commercially insured HIV patients in the United States*, 7 PLOS ONE 2 (2012); J.J. Parienti et al., *Better adherence with once-daily antiretroviral regimens: a meta-analysis*, 48 CLIN. INFECT. DIS. 484 (Feb. 2009).

that early initiation of ART resulted in a 96% reduction in HIV transmission.<sup>37</sup> These outcomes are beneficial both to affected individuals and to the health system at large, which must bear the costs of sicker, larger populations of individuals with AIDS. There are a total of 25 commonly prescribed antiretroviral HIV drugs on the market. They 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 Single Tablet Regimens (STRs).<sup>38</sup>

HIV is an incredibly complex disease that presents and develops differently in different patients. Therefore, it is important that doctors be able to provide treatment plans based on patients’ needs, not on availability under a particular insurance plan. Which drug should be selected from a particular class depends on 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 take.<sup>39</sup> Accordingly, STRs are preferred because of the ease of taking only one pill per day and the important benefits of greater treatment adherence.<sup>40</sup> Because different STRs include different drug combinations,<sup>41</sup> it is important that doctors be able to prescribe any STR to a patient in case a given one is not preferable because of a patient’s characteristics or reaction.

There are recommended treatment regimens produced by an expert panel under the aegis of the United States Department of Health and Human Services in conformance with recognized health needs of HIV patients and developments in HIV medications.<sup>42</sup> The Guidelines are meant to be used broadly by providers who work with HIV-positive patients.<sup>43</sup> Under these Guidelines, there are currently six treatment regimens used for adult and adolescent treatment-naïve patients (i.e., those who have not taken HIV medications before):<sup>44</sup>

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<sup>37</sup> Myron S. Cohen et al., *Prevention of HIV-1 Infection with Early Antiretroviral Therapy*, 365 N. ENGL. J. MED. 493 (2001).

<sup>38</sup> See *Anti-HIV Drug Classes and Names*, NAM-AIDSMAP, <http://www.aidsmap.com/Anti-HIV-drug-classes-and-names/page/1254942/> (last visited Apr. 20, 2016).

<sup>39</sup> See *Guidelines*, supra note 17, at K-5.

<sup>40</sup> See *id.* at K1-K2.

<sup>41</sup> See *Antiretroviral Drugs Used in the Treatment of HIV Infection*, UNITED STATES FOOD AND DRUG ADMINISTRATION (last updated Oct. 8, 2015), <http://www.fda.gov/ForPatients/Illness/HIVAIDS/Treatment/ucm118915.htm>.

<sup>42</sup> See generally *Guidelines*, supra note 17.

<sup>43</sup> See *id.* at A-1

<sup>44</sup> See *id.* at F-3.



1. dolutegravir<sup>45</sup> + (abacavir + lamivudine)<sup>46</sup> = Triumeq (STR).
2. dolutegravir + Truvada (tenofovir DF plus emtricitabine)<sup>47,48</sup>
3. elvitegravir<sup>49</sup> + cobicistat<sup>50</sup> + tenofovir alafenamide<sup>51</sup> + emtricitabine = Genvoya (STR)
4. elvitegravir + cobicistat + (tenofovir DF + emtricitabine) = Stribild (STR)
5. raltegravir<sup>52</sup> + Truvada (tenofovir DF plus emtricitabine)
6. darunavir<sup>53</sup> + ritonavir<sup>54</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 must currently provide access to sixteen primary drugs.<sup>55</sup> Having an exceptions process to the formulary through which an individual can attempt to access coverage for a drug not on the formulary, prescribed before enrollment, is not enough. This is true because of the uncompensated cost to providers of going through the prior authorization process,<sup>56</sup> because this coverage is not guaranteed,<sup>57</sup> and because the process of obtaining this coverage is opaque.

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<sup>45</sup> Dolutegravir is an integrase inhibitor (INSTI) with a brand name product Tivicay.

<sup>46</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>47</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>48</sup> In certain cases where emtricitabine is part of the combination drug, lamivudine can be substituted.

<sup>49</sup> Elvitegravir is an integrase inhibitor (INSTI) with a brand name product Vitekta.

<sup>50</sup> Cobicistat is a pharmacokinetic enhancers with a brand name of Tybost.

<sup>51</sup> Tenofovir alafenamide is a prodrug of the NRTI tenofovir.

<sup>52</sup> Raltegravir is an integrase inhibitor (INSTI) with a brand name product Isentress.

<sup>53</sup> Darunavir is a protease inhibitor (PI) with a brand name product Prezista.

<sup>54</sup> Ritonavir is a PI with a brand name product Norvir.

<sup>55</sup> These 16 primary drugs are as follows:

- Tivicay (brand name) – dolutegravir (no generic version available);
- 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;
- Triumeq (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>56</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>57</sup> See *Guidelines*, supra note 17.

Doctors choose which drugs to prescribe to their HIV patients based on a range of factors, including co-occurring illnesses,<sup>58</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>59</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.

For broad treatment purposes, it is not sufficient that one drug in a particular class may be covered. For example, Isentress and Tivicay are both in the INSTI class. However, Tivicay is specifically recommended to individuals who have resistance to older drugs such as Isentress and to those who are likely to have greater adherence if they are prescribed a once-daily drug, rather than a multi-dose drug such as Isentress.<sup>60</sup> An individual who is currently on Isentress and becomes resistant must be able to switch to Tivicay, necessitating that both medications be covered by his or her insurer, despite being in the same class.

Because compound medications are not interchangeable with their components, physicians prefer to prescribe certain branded medications to achieve the recommended treatment regimens. For example, physicians will seek to prescribe Triumeq, as opposed to Tivicay plus Ziagen and Epivir or Tivicay plus Epzicom. Translating the recommended treatment regimens into their preferred brand formulations results in the following regimens:

1. Triumeq
2. Tivicay + Truvada
3. Genvoya<sup>61</sup>
4. Stribild
5. Isentress + Truvada
6. Prezista + Norvir + Truvada

We base our cost calculations off the combination of branded medications that the majority of physicians would describe at the best way of achieving the recommended treatment regimens. This means prioritizing use of compound medications and STRs to minimize pill load in order to improve adherence and positive outcomes.

## **B. Discriminatory Plan Benefit Design in Humana QHPs on the Tennessee Marketplace**

Insurance plan benefit design can be a form of discrimination when targeted at preventing certain groups from accessing needed care, services, and treatment. Section 1557 explicitly prohibits insurers from using discriminatory benefit designs.<sup>62</sup> For example, CMS, when interpreting the

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<sup>58</sup> See *id.* at J-1.

<sup>59</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 (206).

<sup>60</sup> See *Tivicay*, POSITIVELY AWARE, <http://www.positivelyaware.com/tivicay> (last visited Apr. 20, 2016).

<sup>61</sup> Genvoya was not FDA approved during the open enrollment for the 2016 QHPs. Therefore, it was not included on formularies or in the calculations for this complaint. It has since been added.

<sup>62</sup> 45 C.F.R. § 92.207(b)(2).

responsibilities of insurers under the ACA, noted that “if an issuer places most or all drugs that treat a specific condition on the highest cost formulary tiers [a practice known as adverse tiering], that plan design might effectively discriminate against, or discourage enrollment by, individuals who have those conditions.”<sup>63</sup> The minimal requirements for what prescription drug benefits a health plan must provide in order to be certified under the ACA are set forth in 45 C.F.R. §156.122. 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.

Though not directly binding on the 2016 plans being discussed, these regulations serve as a metric for where QHPs on the marketplace *ought* to be, and the kind of pharmaceutical access that should be provided to their beneficiaries. To provide “appropriate access to drugs”, Humana must make affordable and accessible the HIV medications comprising accepted treatments—such as the federal recommended HIV treatment regimens. In Tennessee, Humana is one of several insurers whose silver QHPs have plan benefit designs that show clear adverse tiering and cost discrimination limiting access to those precise regimens.

### *1. Adverse Tiering*

Adverse tiering is a mechanism insurance companies use to discourage people with high-cost chronic diseases from selecting their plans by structuring drug formularies such that the necessary medication regimens for that disease, including generics, are in the tier with the highest cost sharing.<sup>64</sup> A study out of the Harvard School of Public Health found that the difference in out-of-pocket HIV drug costs between those plans which used adverse tiering and other plans was stark. Enrollees who dealt with adverse tiering had an average annual cost per drug of more than triple that of enrollees in plans that did not adversely tier (\$4,892 vs. \$1,615), with a nearly \$2,000 difference per year even for generic drugs.<sup>65</sup> Even after factoring in the lower premiums and the ACA’s cap on out-of-pocket spending, the study estimates that a person with HIV would pay more than \$3,000 for treatment annually under a plan that practices adverse tiering than in another plan.<sup>66</sup>

Humana, in all three of its 2016 silver QHP offerings, covers all but one of the medications included in the federally recommended treatment regimens (Genvoya, Isentress, Prezista, Stribild, Tivicay, Triumeq, and Truvada) on their highest formulary tier. This is their “specialty

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<sup>63</sup> 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>.

<sup>64</sup> Douglas B. Jacobs & Benjamin D. Sommers, *Using Drugs to Discriminate — Adverse Selection in the Insurance Marketplace*, 372 N.E. J. Med. 399, 401 (2015).

<sup>65</sup> *Id.*

<sup>66</sup> *Id.*

tier”, with 50% coinsurance or 40% coinsurance when filled via a preferred network pharmacy. Norvir, which must be taken in conjunction with Prezista and Truvada, was on a lower tier. This ensures that an individual living with HIV in Tennessee on any of Humana’s silver-level QHPs is paying for a high level of cost-sharing.

## 2. *High Cost-Sharing*

Because Humana tiers almost all relevant HIV medications on its highest formulary tier, enrollees often have to shoulder half of the cost of their prescriptions. One medication, Norvir, is available for only a \$50 copayment but must be taken with two medications that come with 50% coinsurance. This cost sharing percentage translates into high out of pocket prices at the pharmacy register. Objectively, the “sticker price” for HIV medications is unaffordable for the average enrollee in Tennessee.

The prices negotiated between insurers to pharmaceutical companies for medications are proprietary information and therefore not publicly available. However, there are several public indexes that provide a framework by which drug prices can be determined. The Average Wholesale Price (AWP) index is valuable, but considered an inflated cost estimate, since it does not accommodate for negotiation between parties. The Big 4 Price, on the other hand, is the amount paid by four government agencies—the Department of Veterans Affairs, the Department of Defense, the Public Health Service, and the U.S. Coast Guard—and includes large, negotiated discounts. Because of the purchasing and negotiating power of these agencies, Big 4 Price is considered a relatively low estimate of the price paid by private insurance companies.<sup>67</sup> In this analysis, we use the Big 4 pricing index to conservatively estimate costs for private insurers. However, the actual prices paid by insurers and passed on to consumers are likely to be even higher than the estimates presented here.

As discussed above, Humana covers all but one of the medications included in the federally recommended treatment regimens (Genvoya, Isentress, Prezista, Stribild, Tivicay, Triumeq, and Truvada) on their highest formulary tier. This is their “specialty tier”, with 50% coinsurance or 40% coinsurance when filled via a preferred network pharmacy. Norvir, which must be taken in conjunction with Prezista and Truvada, was on tier 3, requiring a copayment of only \$50. These cost sharing requirements result in a person living with HIV spending \$556.06 to 1,211.21 per month per treatment regimen.<sup>68</sup>

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<sup>67</sup> Dept. of Veterans Affairs, *Determining the Cost of Pharmaceuticals for a Cost-Effectiveness Analysis*, (last visited Jul. 15, 2016), available at <http://www.herc.research.va.gov/include/page.asp?id=pharmaceutical-costs>.

<sup>68</sup> See Appendix—Table 1 for data on cost of treatment for each treatment regimen and QHP offered by Humana.

<b>Humana 3800 Silver-level QHPs</b>	<b>Monthly Cost of Regimen (Big 4 Prices)</b>	<b>Cost of Regimen (Co-Insurance)</b>	<b>Annual Cost of Regimen</b>
Tenofovir/Emtricitabine ( <b>Truvada</b> ) + Raltegravir ( <b>Isentress</b> )	\$1,112.12	\$556.06	\$6,672.72
Tenofovir/Emtricitabine ( <b>Truvada</b> ) + Dolutegravir ( <b>Tivicay</b> )	\$1,712.43	\$856.22	\$10,274.58
Tenofovir/Emtricitabine + Elvitegravir/Cobicistat (co-formulated as <b>Stribild</b> )	\$2,422.41	\$1,211.21	\$14,534.46
Tenofovir/Emtricitabine + Elvitegravir/Cobicistat (co-formulated as <b>Genvoya</b> )	\$2,422.34	\$1,211.17	\$14,534.04
Tenofovir/Emtricitabine ( <b>Truvada</b> ) + Darunavir ( <b>Prezista</b> ) + Ritonavir ( <b>Norvir</b> )	\$1,630.36	\$815.27	\$9,783.24
Abacavir/Lamivudine + Dolutegravir (co-formulated as <b>Triumeq</b> )	\$2,184.73	\$1,092.37	\$13,108.38

To place these numbers in context, the median household income in Tennessee is \$44,361.<sup>69</sup> For an individual diagnosed with HIV on a Humana silver-level QHP in Tennessee, their pharmaceuticals *alone* will cost upwards of 15% of their income.<sup>70</sup> Even if a beneficiary only pays to the out-of-pocket cap (\$6,660, only slightly less than the federal limit<sup>71</sup>) they are still responsible for their monthly premiums (an average of \$276 per month across all Humana plans), and whatever costs accrue from other medical services. Altogether, this means that individuals with HIV enrolled in Humana plans in the state of Tennessee are spending a prohibitive 24.5% of their income on healthcare costs alone. For many, paying the first several months of cost sharing is prohibitive, so they never spend enough to receive the protections of the out of pocket cap. With a 55% proposed rate increase for the Tennessee exchange in 2017, it seems that Tennessee’s HIV population will only see their barriers to appropriate care grow.<sup>72</sup>

### 3. Exploiting Actuarial Value

Prime facie high cost-sharing is not the only way for a plan benefit design to discriminate against those with chronic conditions such as HIV. Despite the ACA’s intent to provide access to health care for Americans living with disabilities, insurers can offer discriminatory plan benefit designs because of the way in which actuarial value, the standard upon which they are judged, is calculated. The ACA’s requirement for silver-level insurance plans on the Marketplaces is an actuarial value of 70%, which means the insurer is expected to pay 70% of health care expenses

<sup>69</sup> American Community Survey, “Median Household Income (in 2014 Inflation-Adjusted Dollars)”, (last visited Jul. 15, 2016), available at <http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?src=bkmk>.

<sup>70</sup> See *infra*, Table 3.

<sup>71</sup> Bob Herman, *CMS moves forward with rule on out-of-pocket limits*, (Sept. 15, 2015), available at <http://www.modernhealthcare.com/article/20150915/NEWS/150919927>.

<sup>72</sup> Louise Norris, *Tennessee health insurance exchange / marketplace* (Jul. 7, 2016), available at <https://www.healthinsurance.org/tennessee-state-health-insurance-exchange/>.

while enrollees in that plan pay 30% (via deductibles, copayments, and co-insurance).<sup>73</sup> The actuarial value for a plan is calculated as an average across all enrollees.

Because of the nature of the actuarial value goal as an average, insurers can choose between offering plans that are equitable between the healthy and the sick or favoring healthy enrollees by pushing more costs onto vulnerable populations. QHPs can be structured to have a higher premium or deductible and lower cost sharing across all conditions, or a lower premium and higher cost sharing for certain conditions. Both can have the same actuarial value and meet the ACA's requirement, but the latter is more liable to disproportionately affect people with chronic conditions.<sup>74</sup>

Humana's QHPs are financed heavily through cost sharing, which disproportionately penalizes people with chronic conditions who need long-term access to expensive treatments (*e.g.*, STRs and newer antiretroviral treatments). Insurers offering plans on the silver Marketplace can structure plan benefit designs in this way because their average, actuarial value is still 70%, even though people living with HIV could likely end up paying much more. Because of the very high costs of HIV medication, it is likely that Humana enrollees living with HIV receive an actuarial value closer to 50% (if they use out of network pharmacies) or 60% (if they use in network pharmacies) than the promised 70%. As a result, Humana is able to lower its premiums and probably deliver higher actuarial values to healthy enrollees, making it more attractive to enrollees who are cheaper to insure while discouraging "undesirable" sicker enrollees.

To close this loophole, the actuarial value of QHPs should be further restricted. In addition to the requirement that the average value be 70%, silver QHPs should limit the percentage that any individual with a silver QHP could bear to a certain range around that average value. This would ensure that people living with chronic diseases would not be unfairly penalized by insurers who game the system of actuarial value.

#### *4. Humana's Plan Design Does Not Reflect Market Standards*

Humana's discriminatory benefit design does not reflect a necessity of the healthcare market in the state of Tennessee. For example, UnitedHealthcare (UHC) which offered three silver-level plans on the Tennessee Marketplace in 2016, placed Isentress, Norvir, Prezista, Stribild, Tivicay, Triumeq, and Truvada on its Tier 2 and 3, the "mid-range" tiers of its formulary. This significantly reduces the cost-sharing to its plan members—UHC's CompassPlus QHPs charge \$40-80 co-payments for pharmaceuticals on Tier 2 and 3 respectively, while its HSA Plan offers 0% cost sharing for the components of these treatment regimens.

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<sup>73</sup> Kaiser Family Foundation, *What the Actuarial Values in the Affordable Care Act Mean* (April 2011), available at <https://kaiserfamilyfoundation.files.wordpress.com/2013/01/8177.pdf>.

<sup>74</sup> *Cost-Sharing*, Health Coverage Guide, (last visited Jul. 15, 2016), available at <http://healthcoverageguide.org/reference-guide/benefits-providers-and-costs/cost-sharing/>.

UnitedHealthcare Compass Plus QHPs	Monthly Cost of Regimen (Big 4 Prices)	Cost of Regimen	Annual Cost of Regimen
Tenofovir/Emtricitabine ( <b>Truvada</b> ) + Raltegravir ( <b>Isentress</b> )	\$1,211.99	\$80	\$960
Tenofovir/Emtricitabine ( <b>Truvada</b> ) + Dolutegravir ( <b>Tivicay</b> )	\$1,712.43	\$120	\$1,440
Tenofovir/Emtricitabine + Elvitegravir/Cobicistat (co-formulated as <b>Stribild</b> )	\$2,422.41	\$80	\$960
Tenofovir/Emtricitabine + Elvitegravir/Cobicistat (co-formulated as <b>Genvoya</b> )	\$2,422.34	***	***
Tenofovir/Emtricitabine ( <b>Truvada</b> ) + darunavir ( <b>Prezista</b> ) + ritonavir ( <b>Norvir</b> )	\$1,630.36	\$120	\$1,440
Abacavir/ <b>Lamivudine</b> (still NRTIs) + Dolutegravir (co-formulated as <b>Triumeq</b> )	\$2,184.73	\$50	\$600

\*\*\* Genvoya was not included in the UnitedHealthcare formulary at the time of CHLPI's assessment.

Not only are the above numbers a significantly smaller percentage of the Tennessee median household income (1-2%) but UHC's plans also offer lower premiums, and lower out-of-pocket caps than Humana's—thereby reducing the comparative cost of HIV treatment for their beneficiaries. As is apparent, this is a significant drop in cost from the same HIV drug regimens as covered under Humana's three QHPs, even though the plans are offered on the same Marketplace.<sup>75</sup> It can be inferred, then, that Humana's high cost-sharing and exploitation of actuarial value with regard to HIV drugs is a deviation from market necessity—therefore, there must non-business-related reasons for Humana to structure its plan thusly.

### C. Specific Discriminatory Aversion to HIV Regimens, Through Comparator Drug Therapies

Placing the majority of recommended HIV medications on the highest drug formulary tier is not a business necessity for Humana. Other medications covered by Humana have similar costs but are placed on lower formulary tiers, giving enrollees greater access to their needed treatments. The disparity in formulary tiering for medications at similar costs suggests that Humana purposefully designed the 2016 silver QHPs to discourage enrollment of people living with HIV.

As noted above, Humana covers all but one relevant HIV medication (Genvoya, Isentress, Prezista, Stribild, Tivicay, Triumeq, and Truvada) on their highest, specialty drug formulary tier, with 50% coinsurance, or 40% coinsurance when filled via a preferred network pharmacy. By covering these medications on the highest tier, the insurer is, in effect, restricting access. This

<sup>75</sup> It is worth noting that UHC is withdrawing from the Tennessee Marketplace by the end of the year. See WATE 6 Staff, *UnitedHealthcare leaving health exchange in Tennessee* (Apr. 19, 2016) <http://wate.com/2016/04/19/unitedhealthcare-leaving-health-exchange-in-tennessee/>.

“adverse tiering” and cost discrimination penalizes people living with HIV; These plan benefits are *de facto* designed to discourage people living with HIV (who are often costly to insure) from enrolling in their silver QHPs.

CHLPI considered a number of non-HIV medications—Saphris<sup>76</sup>, Invega<sup>77</sup>, Sabril<sup>78</sup>, Alecensa<sup>79</sup>, Inlyta<sup>80</sup>, Temodar<sup>81</sup>, Xenazine<sup>82</sup>, Zyprexa Zydis<sup>83</sup>, and Tykerb<sup>84</sup>—to compare to the HIV medications covered under Humana QHPs. These represent an array of drugs used to treat psychiatric disorders such as schizophrenia and bipolar disorder (Saphris, Invega, Zyprexa Zydis), various cancers (Alecensa, Inlyta, Temodar, Tykerb), and the symptoms of Huntington’s disease (Xenazine). These medications are similar to HIV medications because the conditions they treat are chronic, long-term, and require a daily or twice-daily dose.<sup>85</sup> Additionally, these medications, like HIV treatment regimens, are more expensive end of the spectrum, with Big 4 prices ranging from over \$750 per thirty pills, to almost \$1,200.<sup>86</sup> Despite similar pricing, Humana covers the majority of these drugs on tier 4, rather than the specialty tier 5, meaning that they are less restricted than the HIV medications.

## VII. RELIEF REQUESTED

CHLPI and Nashville CARES request that OCR use its authority to investigate these violations of the ACA and to ensure meaningful access to health care for people living with HIV in Tennessee. Similar violations in Florida, where insurers were charging high copayments and coinsurance for HIV medications, have resulted in large fines and settlements.<sup>87</sup>

CHLPI and Nashville CARES request that OCR require Humana to adjust their Silver QHPs to be non-discriminatory toward people living with HIV. This would ensure that people living with

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<sup>76</sup> *Asenapine (Saphris)*, NATIONAL ALLIANCE ON MENTAL ILLNESS, (last visited, Jul. 15, 2016), available at [https://www.nami.org/Learn-More/Treatment/Mental-Health-Medications/Asenapine-\(Saphris\)](https://www.nami.org/Learn-More/Treatment/Mental-Health-Medications/Asenapine-(Saphris)).

<sup>77</sup> *Paliperidone (Invega)*, NATIONAL ALLIANCE ON MENTAL ILLNESS, (last visited, Jul. 15, 2016), available at [http://www.nami.org/Learn-More/Treatment/Mental-Health-Medications/Paliperidone-\(Invega\)](http://www.nami.org/Learn-More/Treatment/Mental-Health-Medications/Paliperidone-(Invega)).

<sup>78</sup> *Sabril Medication Guide*, FOOD & DRUG ASS’N, (Jul. 11, 2013), available at <http://www.fda.gov/downloads/Drugs/DrugSafety/UCM180720.pdf>.

<sup>79</sup> *Alecensa*, GENETECH, (last visited, Jul. 15, 2016), available at <http://www.gene.com/patients/medicines/alecensa>.

<sup>80</sup> *Inlyta Prescribing Information*, Pfizer, (Aug., 2014), <http://labeling.pfizer.com/ShowLabeling.aspx?id=759>.

<sup>81</sup> *Temozolomide (Temodar)*, AMERICAN BRAIN TUMOR ASSOCIATION, (last visited, Jul. 15, 2016), available at <http://www.abta.org/secure/resource-one-sheets/temozolomide-1.pdf>.

<sup>82</sup> Tatiana Yero and Jose A. Rey, *Tetrabenazine (Xenazine), An FDA-Approved Treatment Option For Huntington’s Disease-Related Chorea*, P&T., 33(12): 690–694. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2730806/>

<sup>83</sup> *Zyprexa Zydis Medication Guide*, FOOD & DRUG ASS’N, (Aug. 8, 2013), available at [http://www.fda.gov/ohrms/dockets/ac/08/briefing/2008-4399b1-05%20\(Zyprexa%20\(olanzapine\)%20Labeling\).pdf](http://www.fda.gov/ohrms/dockets/ac/08/briefing/2008-4399b1-05%20(Zyprexa%20(olanzapine)%20Labeling).pdf).

<sup>84</sup> *Tykerb*, BREASTCANCER.ORG (Nov. 5, 2015), available at [http://www.breastcancer.org/treatment/targeted\\_therapies/tykerb](http://www.breastcancer.org/treatment/targeted_therapies/tykerb).

<sup>85</sup> Centers for Disease Control and Prevention, *HIV in the United States: At a Glance* (Sept. 29, 2015), available at <http://www.cdc.gov/hiv/statistics/overview/ataglance.html>.

<sup>86</sup> Assuming recommended dosage for adults, this is the Big 4 price for a one month supply of each medication.

<sup>87</sup> The AIDS Institute and the National Health Law Program, “Re: Discriminatory Pharmacy Benefits Design in Select Qualified Health Plans Offered in Florida (May 29, 2014).



HIV enrolled in a QHP from any of these three insurers would be able to manage their condition free from cost discrimination and adverse tiering.

CHLPI and Nashville CARES request that OCR also review the HIV prescription drug benefit designs of all Silver QHPs offered on the Tennessee Marketplace to ensure compliance with the ACA's anti-discrimination clause. CHLPI and Nashville CARES also request that OCR investigate why the Tennessee Department of Insurance, responsible for approving insurance plans on the Marketplace, has allowed these plans to be offered on Tennessee's exchange. OCR should provide oversight and guidance to ensure discriminatory plans are not approved in the future.

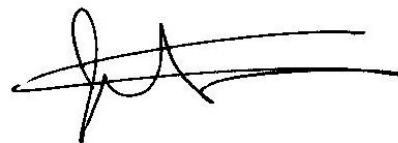
People living with HIV have the right to access health care that does not discriminate against them on account of their disability. CHLPI and Nashville CARES urge OCR to investigate the HIV drug benefit designs of Humana in the Tennessee Marketplace. CHLPI and Nashville CARES are available to provide any assistance necessary to ensure that people living with HIV in Tennessee are provided meaningful access to health care, as mandated under the ACA.

Respectfully Submitted,

September 6, 2016



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**APPENDIX**

**Table 1. TN Humana Silver-Level Plans, HIV HHS-Recommended Drug Coverage**

<b>Plan</b>	<b>Drug</b>	<b>Tier</b>	<b>Co Insurance</b>	<b>Big 4 Price</b>	<b>Average Cost w/Co-Insurance</b>	<b>Yearly Co-Insurance</b>	<b>Yearly Out of Pocket Cap</b>	<b>Monthly Indiv. Premium</b>	<b>Median TN Income</b>	<b>Annual Cost (OoP + Prem.) as % of TN Median Income</b>
<b>Silver 3800/ Nashville PPOx</b>	Genvoya	5	50%	\$1,528.52	\$764.26	\$9,171.12	\$6,350.00	\$311.00	\$44,361.00	29.1%
<b>Silver 3800/ Nashville PPOx</b>	Isentress (raltegravir)	5	50%	\$109.15	\$54.58	\$654.90	\$6,350.00	\$311.00	\$44,361.00	22.7%
<b>Silver 3800/ Nashville PPOx</b>	Norvir (ritonavir)	3	\$50	\$35.90	\$50	\$600	\$6,350.00	\$311.00	\$44,361.00	1.3%
<b>Silver 3800/ Nashville PPOx</b>	Prezista (darunavir)	5	50%	\$700.64	\$350.32	\$4,203.84	\$6,350.00	\$311.00	\$44,361.00	22.7%
<b>Silver 3800/ Nashville PPOx</b>	Stribild (cobicistat/elvitegravir/ emtricitabine/tenofovir)	5	50%	\$1,528.59	\$764.30	\$9,171.54	\$6,350.00	\$311.00	\$44,361.00	29.1%
<b>Silver 3800/ Nashville PPOx</b>	Tivicay (dolutegravir)	5	50%	\$818.61	\$409.31	\$4,911.66	\$6,350.00	\$311.00	\$44,361.00	22.7%
<b>Silver 3800/ Nashville PPOx</b>	Triumeq (abacavir/dolutegravir/lam ivudine)	5	50%	\$2,184.09	\$1,092.37	\$9,125.58	\$6,350.00	\$311.00	\$44,361.00	38.0%
<b>Silver 3800/ Nashville PPOx</b>	Truvada (emtricitabine/tenofovir)	5	50%	\$893.82	\$446.91	\$5,362.92	\$6,350.00	\$311.00	\$44,361.00	22.7%
<b>Silver 3800/ Memphis PPOx</b>	Genvoya	5	50%	\$1,528.52	\$764.26	\$9,171.12	\$6,350.00	\$256.00	\$44,361.00	27.6%
<b>Silver 3800/ Memphis PPOx</b>	Isentress (raltegravir)	5	50%	\$109.15	\$54.58	\$654.90	\$6,350.00	\$256.00	\$44,361.00	21.2%

<b>Silver 3800/ Memphis PPOx</b>	Norvir (ritonavir)	3	\$50	\$35.90	\$50	\$600	\$6,350.00	\$311.00	\$44,361.00	1.3%
<b>Silver 3800/ Memphis PPOx</b>	Prezista (darunavir)	5	50%	\$700.64	\$350.32	\$4,203.84	\$6,350.00	\$256.00	\$44,361.00	21.2%
<b>Silver 3800/ Memphis PPOx</b>	Stribild (cobicistat/elvitegravir/ emtricitabine/tenofovir)	5	50%	\$1,528.59	\$764.30	\$9,171.54	\$6,350.00	\$256.00	\$44,361.00	27.6%
<b>Silver 3800/ Memphis PPOx</b>	Tivicay (dolutegravir)	5	50%	\$818.61	\$409.31	\$4,911.66	\$6,350.00	\$256.00	\$44,361.00	21.2%
<b>Silver 3800/ Memphis PPOx</b>	Triumeq (abacavir/dolutegravir/lam ivudine)	5	50%	\$2,184.09	\$1,092.37	\$9,125.58	\$6,350.00	\$256.00	\$44,361.00	36.5%
<b>Silver 3800/ Memphis PPOx</b>	Truvada (emtricitabine/tenofovir)	5	50%	\$893.82	\$446.91	\$5,362.92	\$6,350.00	\$256.00	\$44,361.00	21.2%
<b>Silver 3800/ Knoxville PPOx</b>	Isentress (raltegravir)	5	50%	\$109.15	\$54.58	\$654.90	\$6,350.00	\$260.00	\$44,361.00	21.3%
<b>Silver 3800/ Knoxville PPOx</b>	Norvir (ritonavir)	3	\$50	\$35.90	\$50	\$600	\$6,350.00	\$311.00	\$44,361.00	1.3%
<b>Silver 3800/ Knoxville PPOx</b>	Prezista (darunavir)	5	50%	\$700.64	\$350.32	\$4,203.84	\$6,350.00	\$260.00	\$44,361.00	21.3%
<b>Silver 3800/ Knoxville PPOx</b>	Stribild (cobicistat/elvitegravir/ emtricitabine/tenofovir)	5	50%	\$1,528.59	\$764.30	\$9,171.54	\$6,350.00	\$260.00	\$44,361.00	27.7%
<b>Silver 3800/ Knoxville PPOx</b>	Tivicay (dolutegravir)	5	50%	\$818.61	\$409.31	\$4,911.66	\$6,350.00	\$260.00	\$44,361.00	21.3%
<b>Silver 3800/ Knoxville PPOx</b>	Triumeq (abacavir/dolutegravir/lam ivudine)	5	50%	\$2,184.09	\$1,092.37	\$9,125.58	\$6,350.00	\$260.00	\$44,361.00	36.4%

<b>Silver 3800/ Knoxville PPOx</b>	Truvada (emtricitabine/tenofovir)	5	50%	\$893.82	\$446.91	\$5,362.92	\$6,350.00	\$260.00	\$44,361.00	23.5%
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**Table 2. TN Humana Silver-Level Plans, Comparator Drug Classes**

	<b>Drug</b>	<b>Tier</b>	<b>Co-Pay</b>	<b>Co-Insurance</b>	<b>Big 4 Price/30 pills</b>	<b>Average Cost w/Co-Insurance</b>	<b>Yearly Co-Insurance</b>	<b>Yearly Out of Pocket Cap</b>	<b>Individual Premium</b>	<b>Annual Premium</b>	<b>Median TN Income</b>	<b>Average Total Cost (OoP + Premium) to TN Median Income</b>
<b>Silver 3800/ Nashville PPOx</b>	Saphris	4		50%	\$854.88	\$427.44	\$5,129.28	\$6,350.00	\$311.00	\$3,732.00	\$44,361.00	19.98%
<b>Silver 3800/ Nashville PPOx</b>	Invega	4		50%	\$743.96	\$371.98	\$4,463.76	\$6,350.00	\$311.00	\$3,732.00	\$44,361.00	18.48%
<b>Silver 3800/ Nashville PPOx</b>	Sabril	5		50%	\$1,364.16	\$682.08	\$8,184.96	\$6,350.00	\$311.00	\$3,732.00	\$44,361.00	22.73%
<b>Silver 3800/ Nashville PPOx</b>	Alecensa	n/a		50%	\$1,170.86	\$585.43	\$7,025.16	\$6,350.00	\$311.00	\$3,732.00	\$44,361.00	22.73%
<b>Silver 3800/ Nashville PPOx</b>	Inlyta	5		50%	\$1,164.97	\$582.48	\$6,989.81	\$6,350.00	\$311.00	\$3,732.00	\$44,361.00	22.73%
<b>Silver 3800/ Nashville PPOx</b>	Temodar	n/a		50%	\$989.72	\$494.86	\$5,938.33	\$6,350.00	\$311.00	\$3,732.00	\$44,361.00	21.80%
<b>Silver 3800/ Nashville PPOx</b>	Xenazine	5		50%	\$859.30	\$429.65	\$5,155.78	\$6,350.00	\$311.00	\$3,732.00	\$44,361.00	20.04%
<b>Silver 3800/ Nashville PPOx</b>	Zyprexa Zydis	n/a		50%	\$850.19	\$425.10	\$5,101.14	\$6,350.00	\$311.00	\$3,732.00	\$44,361.00	19.91%
<b>Silver 3800/ Nashville PPOx</b>	Tykerb	5		50%	\$809.07	\$404.54	\$4,854.43	\$6,350.00	\$311.00	\$3,732.00	\$44,361.00	19.36%

<b>Silver 3800/ Memphis PPOx</b>	Saphris	4	50%	\$854.88	\$427.44	\$5,129.28	\$6,350.00	\$256.00	\$3,072.00	\$44,361.00	18.49%
<b>Silver 3800/ Memphis PPOx</b>	Invega	4	50%	\$743.96	\$371.98	\$4,463.76	\$6,350.00	\$256.00	\$3,072.00	\$44,361.00	16.99%
<b>Silver 3800/ Memphis PPOx</b>	Sabril	5	50%	\$1,364.16	\$682.08	\$8,184.96	\$6,350.00	\$256.00	\$3,072.00	\$44,361.00	21.24%
<b>Silver 3800/ Memphis PPOx</b>	Alcensa	n/a	50%	\$1,170.86	\$585.43	\$7,025.16	\$6,350.00	\$256.00	\$3,072.00	\$44,361.00	21.24%
<b>Silver 3800/ Memphis PPOx</b>	Inlyta	5	50%	\$1,164.97	\$582.48	\$6,989.81	\$6,350.00	\$256.00	\$3,072.00	\$44,361.00	21.24%
<b>Silver 3800/ Memphis PPOx</b>	Temodar	n/a	50%	\$989.72	\$494.86	\$5,938.33	\$6,350.00	\$256.00	\$3,072.00	\$44,361.00	20.31%
<b>Silver 3800/ Memphis PPOx</b>	Xenazine	5	50%	\$859.30	\$429.65	\$5,155.78	\$6,350.00	\$256.00	\$3,072.00	\$44,361.00	18.55%
<b>Silver 3800/ Memphis PPOx</b>	Zyprexa Zydis	n/a	50%	\$850.19	\$425.10	\$5,101.14	\$6,350.00	\$256.00	\$3,072.00	\$44,361.00	18.42%
<b>Silver 3800/ Memphis PPOx</b>	Tykerb	5	50%	\$809.07	\$404.54	\$4,854.43	\$6,350.00	\$256.00	\$3,072.00	\$44,361.00	17.87%
<b>Silver 3800/ Knoxville PPOx</b>	Saphris	4	50%	\$854.88	\$427.44	\$5,129.28	\$6,350.00	\$260.00	\$3,120.00	\$44,361.00	18.60%
<b>Silver 3800/ Knoxville PPOx</b>	Invega	4	50%	\$743.96	\$371.98	\$4,463.76	\$6,350.00	\$260.00	\$3,120.00	\$44,361.00	17.10%

<b>Silver 3800/ Knoxville PPOx</b>	Sabril	5	50%	\$1,364.16	\$682.08	\$8,184.96	\$6,350.00	\$260.00	\$3,120.00	\$44,361.00	21.35%
<b>Silver 3800/ Knoxville PPOx</b>	Alcensa	n/a	50%	\$1,170.86	\$585.43	\$7,025.16	\$6,350.00	\$260.00	\$3,120.00	\$44,361.00	21.35%
<b>Silver 3800/ Knoxville PPOx</b>	Inlyta	5	50%	\$1,164.97	\$582.48	\$6,989.81	\$6,350.00	\$260.00	\$3,120.00	\$44,361.00	21.35%
<b>Silver 3800/ Knoxville PPOx</b>	Temodar	n/a	50%	\$989.72	\$494.86	\$5,938.33	\$6,350.00	\$260.00	\$3,120.00	\$44,361.00	20.42%
<b>Silver 3800/ Knoxville PPOx</b>	Xenazine	5	50%	\$859.30	\$429.65	\$5,155.78	\$6,350.00	\$260.00	\$3,120.00	\$44,361.00	18.66%
<b>Silver 3800/ Knoxville PPOx</b>	Zyprexa Zydis	n/a	50%	\$850.19	\$425.10	\$5,101.14	\$6,350.00	\$260.00	\$3,120.00	\$44,361.00	18.53%
<b>Silver 3800/ Knoxville PPOx</b>	Tykerb	5	50%	\$809.07	\$404.54	\$4,854.43	\$6,350.00	\$260.00	\$3,120.00	\$44,361.00	17.98%

**Table 2. TN Humana Silver-Level Plans, HHS-recommended regimens as percentage of Median Household Income**

<b>Humana 3800 Silver-level QHPs</b>	<b>Monthly Cost of Regimen (Big 4 Prices)</b>	<b>Cost of Regimen (Co-Insurance)</b>	<b>Annual Cost of Regimen</b>	<b>Median Household Income TN</b>	<b>Percentage of Median Household Income TN</b>
<b>Tenofovir/Emtricitabine (Truvada) + Raltegravir (Isentress)</b>	\$1,112.12	\$556.06	\$6,672.72	\$44,361.00	15%
<b>Tenofovir/Emtricitabine (Truvada) + Dolutegravir (Tivicay)</b>	\$1,712.43	\$856.22	\$10,274.58	\$44,361.00	23%
<b>Tenofovir/Emtricitabine + Elvitegravir/Cobicistat (co-formulated as Stribild)</b>	\$1,528.59	\$764.30	\$9,171.60	\$44,361.00	21%
<b>Tenofovir/Emtricitabine + Elvitegravir/Cobicistat (co-formulated as Genvoya)</b>	\$1,528.52	\$764.26	\$9,171.12	\$44,361.00	21%
<b>Tenofovir/Emtricitabine (Truvada) + darunavir (Prezista) + ritonavir (Norvir)</b>	\$1,630.36	\$815.27	\$9,783.24	\$44,361.00	22%
<b>Abacavir/Lamivudine + Dolutegravir (co-formulated as Triumeq)</b>	\$2,184.73	\$1,092.37	\$13,108.38	\$44,361.00	30%