Form Approved: OMB No. 0990-0269.
See OMB Statement on Reverse.

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
Robert	Greenwald

HOME PHONE	WORK PHONE
( )	(617) 390-2584

STREET ADDRESS	CITY
122 Boylston Street	Jamaica Plain

STATE	ZIP	E-MAIL ADDRESS *(If available)*
MA	02130	rgreenwa@law.harvard.edu

Are you filing this complaint for someone else? ☒ Yes ☐ No

If Yes, against whom do you believe the disrimination was directed?

FIRST NAME	LAST NAME
See Attached	See attached

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)*: See attached

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

See Attached

STREET ADDRESS	CITY

STATE	ZIP	PHONE
		( )

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

See attached

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)*

See attached

Please sign and date this complaint.

SIGNATURE Robert Greenwald DATE 09/06/2016

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 Heatlh 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.** To mail a complaint see reverse page for OCR Regional addresses.

PSC Media Arts (301) 443-1090 EF

(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
Kevin	Costello
HOME PHONE	WORK PHONE
( )	(617) 390-2578
STREET ADDRESS	CITY
122 Boylston Street	Jamaica Plain
STATE / ZIP	E-MAIL ADDRESS *(If available)*
MA / 02130	kcostello@law.harvard.edu

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)*

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 ☐ Not Hispanic or Latino

RACE *(select one or more)*

☐ American Indian or Alaska Native ☐ Asian ☐ Native Hawaiian or Other Pacific Islander ☐ Black or African American ☐ White ☐ Other *(specify)*:

PRIMARY LANGUAGE SPOKEN *(if other then 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.

Region I - CT, ME, MA, NH, RI, VT
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

Region II - NJ, NY, PR, VI
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

Region III - DE, DC, MD, PA, VA, WV
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

Region IV - AL, FL, GA, KY, MS, NC, SC, TN
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

Region V - IL, IN, MI, MN, OH, WI
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

Region VI - AR, LA, NM, OK, TX
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

Region VII - IA, KS, MO, NE
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

Region VIII - CO, MT, ND, SD, UT, WY
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

Region IX - AZ, CA, HI, NV, AS, GU, The U.S. Affiliated Pacific Island Jurisdictions
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

Region X - AK, ID, OR, WA
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

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

Marisa Smith, Regional Manager
Office for Civil Rights
U.S. Department of Health and Human Services
1301 Young Street, Suite 1169
Dallas, TX 75202

RE: DISCRIMINATORY PLAN BENEFIT DESIGNS IN TEXAS SILVER QUALIFIED HEALTH PLANS

I. COMPLAINANTS

The Center for Health Law and Policy Innovation of Harvard Law School (CHLPI) 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 illnesses and disabilities. CHLPI works with consumers, advocates, community-based organizations, health and social services professionals, food providers and producers, government officials, and others to expand access to high-quality health care and nutritious, affordable food; to reduce health disparities; to develop community advocacy capacity; and to promote more equitable and effective health care and food systems.

II. DEFENDANT

Humana (the Defendant) is headquartered in Louisville, Kentucky, reporting $54 billion in revenue for 2015.[1]

III. JURISDICTION

This complaint is filed pursuant to Section 1557 of the Patient Protection and Affordable Care Act (ACA).[2] 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

[1] Humana, *2015 Annual Report* (Feb. 2016), http://phx.corporate-ir.net/phoenix.zhtml?c=92913&p=irol-reportsannual.
[2] 42 U.S.C. § 18116; 45 C.F.R. § 92.101.

government.[3] This anti-discrimination clause applies to insurers operating on federal- or state-based insurance Marketplace exchanges.[4] The Defendant here is subject to Section 1557 under 45 C.F.R. § 92.2(a) because it offers a QHP on the Texas health insurance Marketplace.

Section 1557 specifically delineates the design of insurance plan benefits as a potentially discriminatory practice.[5] Section 1557, in turn, provides that an individual shall not be subjected to discrimination on the grounds prohibited under Section 504 of the Rehabilitation Act of 1973 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.[6] Section 504 of the Rehabilitation Act of 1973 prohibits discrimination against otherwise qualified individuals on the basis of disability.[7]

The Department of Health and Human Services (HHS) Office for Civil Rights (OCR) is granted authority to investigate potentially discriminatory behavior and to enforce compliance with Section 1557.[8] "OCR is responsible for enforcement with respect to benefit design issues under Section 1557."[9] Further, 45 C.F.R. § 92.301 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." Under 45 C.F.R. 85.61(d), OCR is required to "accept and investigate all complete complaints for which it has jurisdiction." Cases of noncompliance may result in suspension, termination, or refusal to grant or continue Federal financial assistance.[10] Should the enforcement efforts of OCR fall on deaf ears, it can and should refer the matter to the Department of Justice for litigation.[11]

IV. PRELIMINARY STATEMENT

This complaint is filed to notify OCR of discriminatory benefit designs employed by Humana on the Texas Marketplace. Approximately 82,745 Texans are currently living with HIV,[12]and Humana has designed Qualified Health Plans (QHPs) that violate Sections 1311 and 1557 of the ACA by preventing these individuals from "meaningful access"[13] to comprehensive health care coverage that meets their health needs. CHLPI

[3] 42 U.S.C. § 18116(a); 45 C.F.R. § 92.101.
[4] 45 C.F.R. § 92.4.
[5] 45 C.F.R. § 92.207(b)(2).
[6] 42 U.S.C. § 18116.
[7] 29 U.S.C. § 701.
[8] 80 Fed. Reg. 54172-54221 (Sept. 8, 2015).
[9] 81 Fed. Reg. 31376-01, 31440 (May 18, 2016).
[10] *See, e.g.*, 45 C.F.R. §§ 302(c), 80.8, 84.6.
[11] 81 Fed. Reg. at 31376-01 ("OCR has the authority to refer cases to DOJ for litigation where efforts at compliance have been unsuccessful.")
[12] Texas HIV Surveillance Report: 2015 Annual Report, TX DEP'T. OF HEALTH, (July 11, 2016) https://www.dshs.texas.gov/hivstd/reports/HIVSurveillanceReport.pdf.
[13] *See Alexander v. Choate*, 469 U.S. 287 (1985).

requests OCR to invoke its mandate under the ACA, and put an end to the discriminatory practices of this insurer.

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 Texas. 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.[14] 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.[15]

In Texas, CHLPI, along with state partners, 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*,[16] as well as other commonly used HIV medications in the 2016 silver level QHPs available on the Texas 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 Texas 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.[17]

In Texas, CHLPI reviewed the coverage of all recommended treatment regimens by the 2016 Silver Qualified Health Plans (QHPs) on the Texas Marketplace. CHLPI also considered the coverage of Atripla, a STR which is not currently recommended for antiretroviral-naïve patients but is widely used in the United States.[18] CHLPI found that several of these plans are unaffordable for many people living with HIV in Texas using the federally recommended treatment regimens. The QHP offered by Humana, Humana Silver 3800/Houston HMOx, is among one of the most expensive and restrictive for HIV medications in the Texas Marketplace. Humana covered virtually all HIV medications, and all relevant HIV medications recommended by the Federal Guidelines, on its highest tier of its formulary. By covering these medications on the highest tier, Humana is, in effect, restricting access because this tier requires very high cost sharing. This "adverse tiering" and cost discrimination penalizes people living with HIV. Humana, in Texas, is using these plan benefit designs to discourage people living with HIV (who are often costly to insure) from enrolling in its silver QHP.

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[14] Center for Health Law & Policy Innovation, *2016 Qualified Health Plan Assessments* (Dec. 2015), http://www.chlpi.org/plan-assessment.

[15] *Id*.

[16] *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* U.S. DEP'T OF HEALTH & HUMAN SERVICES PANEL ON ANTIRETROVIRAL GUIDELINES FOR ADULTS AND ADOLESCENTS – A WORKING GROUP OF THE OFFICE OF AIDS RESEARCH ADVISORY COUNCIL (OARAC), (last visited Jul. 15, 2016), available at https://aidsinfo.nih.gov/contentfiles/lvguidelines/aa_recommendations.pdf.

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

[18] Horberg, M. & Klein, D, *An update on the use of Atripla in the treatment of HIV in the United States* HIV/AIDS (June 18, 2010).

This restriction of access to HIV medications contradicts the purpose and spirit of the Affordable Care Act (ACA), which is to create meaningful access to health care for all Americans regardless of health status. Insurers on the Marketplace benefit from the ACA's individual mandate and subsidies. Eighty-seven percent of individuals enrolled in a 2015 Marketplace plan qualified for an advance premium tax credit from the federal government.[19] These insurers are benefiting from certain parts of the ACA while disrespecting its purpose by discouraging those with chronic health conditions from enrolling, or by penalizing those who do enroll.

V. RELEVANT LAW

A. Anti-Discrimination Protections under the ACA

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.[20] Section 1557 applies directly to federal- and state-based Marketplaces,[21] and therefore applies to Texan Silver QHP insurers. Section 1557 also reinforces the anti-discrimination protections in the ACA by explicitly prohibiting discrimination based on disability.[22] 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.[23]

The ACA clearly establishes protections from discrimination for people living with HIV who enroll in a silver QHP in Texas. Section 1557 provides for enforcement through the mechanisms available under existing anti-discrimination laws, regulations, and policies.[24] The mechanisms relevant to this complaint derive from Section 504 of the Rehabilitation Act,[25] 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."[26]

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

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[19] *ASPE Research Brief* U.S. DEP'T OF HEALTH AND HUMAN SERVICES, (Feb. 9, 2015), https://aspe.hhs.gov/sites/default/files/pdf/33776/ib_APTC.pdf.
[20] 42 U.S.C. § 18116; 45 C.F.R. § 92.101.
[21] 45 C.F.R. § 92.4.
[22] *Id.* at § 92.205.
[23] *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) https://www.ada.gov/archive/hivqanda.txt.
[24] 80 Fed. Reg. at 54172-54221.
[25] 42 U.S.C. § 18116(b).
[26] 45 C.F.R. § 84.52(j).

denied the benefits of, or be subject to discrimination under" any health program or activity.[27] 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.[28] The meaningful access inquiry asks "whether those with disabilities are as a practical matter able to access benefits to which they are legally entitled."[29]

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 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."[30] 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." [31]

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."[32] 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." [33] State regulators in Texas 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.[34]

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[27] 42 U.S.C. 12132 (2006).
[28] *See Choate*, 469 U.S. at 287.
[29] *Henrietta D. v. Bloomberg*, 331 F.2d 261, 273 (2003).
[30] *2017 Letter to Issuers in the Federally-facilitated Marketplaces,* U.S. DEP'T OF HEALTH AND HUMAN SERVICES, Pg. 45 (February 29, 2016) https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2017-Letter-to-Issuers-2-29-16.pdf.
[31] 80 Fed. Reg. 10750-01, 10823 (Feb. 27, 2015).
[32] ACA § 1311(c)(1)(A).
[33] *See* 80 Fed. Reg. at 10823.
[34] *Regulations Enforced by OCR*, U.S. DEP'T OF HEALTH AND HUMAN SERVICES (last visited Jul. 15, 2016), http://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/laws/index.html.

IV. 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.[35] Strict adherence to Antiretroviral Therapy (ART)[36] can stop the progression of HIV and prevent its transmission to others.[37] One multi-country study has found, for instance, that early initiation of ART resulted in a 96% reduction in HIV transmission.[38] 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).[39]

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.[40] Accordingly, STRs are preferred because of the ease of taking only one pill per day and the important benefits of greater treatment adherence.[41] Because different STRs include different drug combinations,[42] 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

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

[36] 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).

[37] *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).

[38] Myron S. Cohen et al., *Prevention of HIV-1 Infection with Early Antiretroviral Therapy*, 365 N. ENGL. J. MED. 493 (2001).

[39] *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).

[40] *See Guidelines*, supra note 17, at K-5.

[41] *See id.* at K1-K2.

[42] *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.

recognized health needs of HIV patients and developments in HIV medications.[43] The Guidelines are meant to be used broadly by providers who work with HIV-positive patients.[44] 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):[45]

1. dolutegravir[46] + (abacavir + lamivudine)[47] = Triumeq (STR).
2. dolutegravir + Truvada (tenofovir DF plus emtricitabine)[48,49]
3. elvitegravir[50] + cobicistat[51] + tenofovir alafenamide[52] + emtricitrabine = Genvoya (STR)
4. elvitegravir + cobicistat +(tenofovir DF + emtricitrabine) = Stribild (STR)
5. raltegravir[53] + Truvada (tenofovir DF plus emtricitabine)
6. darunavir[54] + ritonavir[55] + 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.[56] Having an exceptions process to the formulary through which an individual can

[43] *See generally Guidelines*, *supra* note 17.
[44] *See id.* at A-1
[45] *See id.* at F-3.
[46] Dolutegravir is an integrase inhibitor (INSTI) with a brand name product Tivicay.
[47] 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.
[48] 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.
[49] In certain cases where emtricitabine is part of the combination drug, lamivudine can be substituted.
[50] Elvitegravir is an integrase inhibitor (INSTI) with a brand name product Vitekta.
[51] Cobicistat is a pharmacokinetic enhancers with a brand name of Tybost.
[52] Tenofovir alafenamide is a prodrug of the NRTI tenofovir.
[53] Raltegravir is an integrase inhibitor (INSTI) with a brand name product Isentress.
[54] Darunavir is a protease inhibitor (PI) with a brand name product Prezista.
[55] Ritonavir is a PI with a brand name product Norvir.
[56] 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 lamuvidine may be substituted in certain circumstances;
- Truvada (brand name) – tenofovir DF + emtricitabine;
- Viteka (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);

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,[57] because this coverage is not guaranteed,[58] 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,[59] 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 regiments.[60] 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.[61] 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[62]
4. Stribild
5. Isentress + Truvada
6. Prezista + Norvir + Truvada

- 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.

[57] *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).
[58] *See Guidelines*, supra note 16.
[59] *See id.* at J-1.
[60] *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).
[61] *See Tivicay*, POSITIVELY AWARE, http://www.positivelyaware.com/tivicay (last visited Apr. 20, 2016).
[62] 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.

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. Humana's Discriminatory Benefit Design in Texas

In Texas, the Defendant is one of several insurers whose Silver QHPs have plan benefit designs that show clear adverse tiering and cost discrimination. Humana's Silver QHP covers all medications considered in the analysis, but all but one medication are on its highest formulary tier with 50% coinsurance, depending on whether the enrollee uses a preferred network pharmacy. The remaining medication, Norvir, must be taken in conjunction with two medications that Humana requires 50% coinsurance for. This 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 Texas. The monthly out-of-pocket cost of an HIV treatment regimen for a consumer with Humana's plan could range from $764 to $1,087.[6364] Because Humana tiers almost all relevant HIV medications on its highest formulary tier, enrollees often have to shoulder 50% of the cost of their prescriptions. Data on cost of treatment for each treatment regimen can be found in the Appendix.

C. Effects of The Defendant's Discriminatory Plan Benefit Designs

The plan benefit designs of the Defendant are discriminatory in nature and adversely impact both public health and people living with HIV in Texas. Because of the structure of its formulary design as applied to HIV medications, the Defendant places a heavy burden on individuals living with HIV enrolled in its QHP and raises significant public health concerns.

1. Impact for Humana Enrollees Living with HIV

Based on the estimated monthly cost calculations and median household income data for Texas taken from the U.S. Census,[65] a Texan with HIV on Humana's Silver QHP would spend up to 26% of his or her income on a federally recommended HIV treatment regimen. These costs are unacceptable and may prevent enrollees living with HIV from benefitting from their health insurance coverage in the same manner as non disabled individuals enrolled in the same plan.

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[63] Prices paid by insurers (or by their intermediaries – pharmacy benefit managers) to pharmaceutical companies for medications are not publicly available. Several indexes exist that provide information about drug prices. Two such indexes that are widely used are the Average Wholesale Price (AWP) and the Big 4 Price. AWP is considered an inflated cost estimate. The Big 4 Price 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. For this reason, it is considered a very low estimate of the price paid by private insurance companies. *See* Department of Veterans Affairs, *Determining the Cost of Pharmaceuticals for a Cost-Effectiveness Analysis* (last visited April 4, 2016), available at http://www.herc.research.va.gov/include/page.asp?id=pharmaceutical-costs.In this analysis, we use the Big 4 pricing index to conservatively estimate costs for private insurers. The actual prices paid by insurers and passed on to consumers are likely to be even higher than the estimates presented here.

[64] Calculated using Big 4 pricing.

[65] *Median Household Income by State (Texas) – Single-Year Estimates*, U.S. CENSUS BUREAU, (last visited March 22, 2016) https://www.census.gov/hhes/www/income/data/statemedian.

The current cost of STRs and newer HIV medications on Texas Silver QHP offered by the Defendant restricts meaningful access to effective treatment. Meaningful access is critical both to improving health outcomes for people living with HIV *and* to preventing the transmission of HIV. Without consistent, affordable access to appropriate treatments, people living with HIV in Texas are more likely to get sick and more likely to transmit the virus to others, increasing the number of people in need of HIV treatment.

2. Public Health Impacts

One of the main goals of ART is to suppress the HIV virus in a person's bloodstream.[66] This viral suppression can take, for someone beginning ART, between 3 and 6 months. Once suppressed, if a person continues with consistent treatment, their risk of sexually transmitting the virus to another person is reduced by 96%. If a person stops ART, their viral load will increase up to a level above suppression.[67] In order to minimize new infections, current HIV cases must be properly managed and as many individuals as possible must achieve viral suppression and remain virally suppressed.

HIV is an incredibly complex disease that presents and develops differently in different patients. It is important that doctors be able to provide treatment plans based on patients' needs, not based on availability under a particular insurance plan. There are multiple classes of drugs, and which drug should be selected from a particular class depends on patient characteristics. For example, until the recent development of STRs, an ART regimen consisted of taking a combination of three or more drugs every day.[68] As expected, the simplified STR regimen is associated with increased treatment adherence rates. Patients are more likely to consistently take their medication and maintain viral suppression if their treatment regimen is one pill per day.[69,70] However, multiple pill regimens might still be preferred in some cases due to a patient's resistance testing results, drug toxicity, drug-drug interaction, and virologic efficacy.[71] To achieve widespread viral suppression, neither STR nor multiple pills may be treated as interchangeable, even within a drug class.[72]

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[66] *HIV Treatment When to Start: Choosing an HIV Regimen* NATIONAL INSTITUTES OF HEALTH AIDSINFO, (Feb. 24, 2016) https://aidsinfo.nih.gov/education-materials/fact-sheets/21/53/what-to-start--selecting-a-first-hiv-regimen.

[67] *HIV/AIDS Care Continuum* AIDS.GOV, (March 6, 2015) https://www.aids.gov/federal-resources/policies/care-continuum.

[68] *Id.*

[69] Armstrong, B., Chan, D. J., Stewart, M. J., Fagan, D., & Smith, D, *Single Tablet Regimen Usage and Efficacy in the Treatment of HIV Infection in Australia* (Sept. 20, 2015), AIDS RESEARCH AND TREATMENT.

[70] Antinori, A., Angeletti, C., Ammassari, A., Sangiorgi, D., Giannetti, A., Buda, S., Girardi, E., & Degli Esposti, L. *Adherence in HIV-positive patients treated with single-tablet regimens and multi-pill regimens: findings from the COMPACT study* (Nov. 11, 2012), JOURNAL OF THE INTERNATIONAL AIDS SOCIETY.

[71] *See Guidelines*, supra note 16.

[72] American Academy of HIV Medicine, *Strategies for Health Insurers to Optimize Coverage for People with HIV*
(Feb. 2014), http://www.hivma.org/uploadedFiles/HIVMA/Policy_and_Advocacy/Policy_Priorities/Healthcare_Reform_Implementation/Comments_on_Health_Care_Reform_Implementation/Optimize_Coverage_for_People_with_HIV.pdf.

D. Discriminatory Plan Benefit Design Practices

Since the Defendant places all key HIV medications on its highest formulary tier and requires high coinsurance for its highest tier, it has created a plan that is hostile to enrollees living with HIV. As such, it is likely guilty of discriminatory plan benefit design practices, including high cost sharing, adverse tiering, and exploiting actuarial value.

1. *High Cost Sharing*

At the most basic level, the cost sharing required by insurers practicing discriminatory benefit design is problematic because it renders these medications unaffordable. Although the ACA requires a cap on out of pocket payments, high cost sharing requirements can prevent individuals from enjoying the protections of the cap by requiring them to meet it within the first several months of the year. For low income individuals, finding the funds to pay several thousand dollars in the first few months of their insurance plan can be challenging.

High cost sharing is not an absolute requirement to provide health insurance in Texas. Competitors, such as Blue Cross Blue Shield and United Healthcare, charged much lower copayments for the same medications. For example, Blue Cross Blue Shield required its enrollees to pay $50-60 per month for most HIV medications, with some newer medications priced at $100-120. The insurers who offer more reasonable cost sharing requirements demonstrate that it is not a business requirement to require very high cost sharing for all HIV medications.

2. Adverse Tiering

Some insurers, including the Defendant, are instead practicing discriminatory plan design such as 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.[73] 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.[74] 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.[75]

3. Exploiting Actuarial Value

[73] Douglas B. Jacobs & Benjamin D. Sommers, *Using Drugs to Discriminate — Adverse Selection in the Insurance Marketplace*, 372 N.E. J. MED. 399, 401 (2015).
[74] *Id.*
[75] *Id.*

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 marketplace exchanges is an actuarial value of 70%, which means the insurer is expected to pay 70% of health care expenses while enrollees in that plan pay 30% (via deductibles, copayments, and co-insurance).[76] 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, or a lower premium and higher cost sharing. 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.[77]

Humana's QHP is financed primarily 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.

E. Discriminatory Plan Benefit Design Practices have Problematic Policy Implications

By discouraging those with HIV from enrolling in its QHP, Humana causes clustering of individuals with HIV in a smaller number of plans and insurers. This creates financial disincentives for insurers that are currently abiding by ACA anti-discrimination mandates. Ultimately, without legal intervention the higher costs inflicted on law-abiding insurers through clustering will lead them to raise premiums or alter their benefit designs in ways similar to Humana. Both United Healthcare and Aetna, two major national

[76] Kaiser Family Foundation, *What the Actuarial Values in the Affordable Care Act Mean* (April 2011) https://kaiserfamilyfoundation.files.wordpress.com/2013/01/8177.pdf.
[77] *Cost-Sharing*, Health Coverage Guide, (last visited Jul. 15, 2016) http://healthcoverageguide.org/reference-guide/benefits-providers-and-costs/cost-sharing/.

insurers, have already announced that they will be withdrawing from most Marketplaces because of the difficulty of competing in this market. Therefore, if Section 1557 is not enforced against Humana, adverse selection will lead to a "race to the bottom," where savvy insurers will require individuals with HIV to pay increasingly more for their medications.

By providing plans to HIV beneficiaries that mandate the highest levels of cost sharing, Humana beneficiaries are subject to a *de facto* denial of meaningful access to HIV medications. No reasonable HIV drug consumer would choose to enroll or stay on Humana's QHP. Considering that the median monthly income in Texas is $4,381.33, cost sharing between 17-26% of this value is impractical for most Texas residents. As such, beneficiaries on Humana's plans are more likely to stop taking HIV medications, thereby increasing the chances of transmission and raising the expenses incurred by the state. Moreover, as discussed above, Humana's prescription drug benefit design is entirely unreasonable as illustrated by the Texas market norm. For example, insurers such as Aetna require only a $15-40 copayment for the same medications. Other major insurers, such as Molina Marketplace and Blue Cross Blue Shield require copayments of $50-60 for most key HIV medications.

Troublingly, given the demographics of the HIV epidemic, Humana's adverse tiering has a particularly negative impact on groups that have historically experienced discrimination.

VII. RELIEF REQUESTED

CHLPI requests that OCR use its authority to enforce these violations of the ACA and to ensure meaningful access to health care for people living with HIV in Texas. Similar violations in Florida, where insurers were charging high copayments and coinsurance for HIV medications, have resulted in large fines and settlements.[78]

CHLPI requests that OCR require the Defendant to adjust its Silver QHP to be non-discriminatory toward people living with HIV. This would ensure that people living with 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 requests that OCR also review the HIV prescription drug benefit designs of all Silver QHPs offered on the Texas Marketplace to ensure compliance with the ACA's anti-discrimination clause. CHLPI also requests that OCR investigate why the Texas Department of Insurance, responsible for approving insurance plans on the Marketplace, has allowed these plans to be offered on Texas' exchange. OCR should provide oversight and guidance to ensure discriminatory plans are not approved in the future.

To ensure compliance in the future for people living with other chronic diseases, CHLPI requests that OCR work to develop and implement methods for detecting discrimination

[78] The National Health Law Program, *Florida Insurance Commissioner fines Humana $500,000* (Feb. 18, 2016) http://www.healthlaw.org/news/press-releases/470-florida-insurance-commissioner-fines-humana-500000.

in insurance plans offered on federal- or state-based exchanges. These methods should focus on detecting discrimination against vulnerable populations.

Finally, CHLPI requests that OCR require all insurers offering plans on federal- or state-based exchanges to demonstrate meaningful transparency of their prescription drug benefit costs. This would enable consumers to make an informed decision about their health care, which is the original purpose of the Marketplace exchange.

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

Respectfully Submitted,

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APPENDIX

Table 1: Cost of treatment plans on Humana's Silver QHP, in dollars spent per month. Calculated using Big 4 pricing.

Treatment Regimen	Big 4 Pricing of Treatment Regimen	Humana Silver 3800 / Houston HMOx Cost Sharing Requirement	Humana Silver 3800 / Houston HMOx Cost Sharing Payment	Total Humana Silver 3800 / Houston HMOx Cost Sharing Per Year
Atripla	$1,773.42	50%	$886.71	$10,640.52
Truvada and Isentress	$893.82 + $750.40	50% + 50%	$822.11	$9865.32
Truvada and Tivicay	$893.82 + $818.61	50% + 50%	$856.22	$10,274.64
Stribild	$1,528.59	50%	$764.30	$9,171.60
Truvada, Prezista, and Norvir	$893.82 + $700.64 + $35.90	50% + 50% + $50	$842.23	$10,106.76
Triumeq	$2,174.09	50%	$1,087.05	$13,044.60
Genvoya	$1,528.52	50%	$764.26	$9,171.12

Table 2: Percent of median Texas income spent on each treatment plan on Humana's Silver QHP. Calculated using Big 4 pricing.

Treatment Regimen	Humana Silver 3800 / Houston HMOx
Atripla	20%
Truvada and Isentress	18%
Truvada and Tivicay	19%
Stribild	17%
Truvada, Prezista, and Norvir	19%
Triumeq	26%
Genvoya	17%