Form Approved: OMB No. 0990-0269.
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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

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

RE: DISCRIMINATORY PRESCRIPTION DRUG BENEFIT DESIGNS IN QUALIFIED HEALTH PLANS IN ALABAMA

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.

AIDS Alabama is a non-profit organization with offices in Birmingham and Mobile, Alabama, whose mission is to help people with HIV/AIDS live healthy, independent lives and to prevent the spread of HIV. The organization focuses on housing, supportive services, policy and advocacy, HIV prevention education, and free and confidential HIV testing.

II. DEFENDANT

Humana, headquartered in Louisville, Kentucky, with annual revenue of $54 billion 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 government.[3] As clarified by the Anti-Discrimination Regulations implementing Section

[1] *Humana Reports Fourth Quarter 2015 Financial Results; Provides 2016 Financial Guidance*, HUMANA, phx.corporate-ir.net/External.File?item...t=1, (last viewed Apr. 4, 2016).
[2] 42 U.S.C. § 18116 (2012).
[3] *Id.* at § 18116(a).

1557,[4] this includes those insurers operating through a federal- or state-established Exchange.[5] The Anti-Discrimination Regulations implementing Section 1557 also note that the Office for Civil Rights (OCR) of the Department of Health and Human Services (HHS) is responsible for investigations and enforcement action concerning discriminatory behavior that violates the ACA.[6]

IV. PRELIMINARY STATEMENT

CHLPI and AIDS Alabama file this complaint to notify OCR of discriminatory HIV benefit designs employed by Humana. Approximately 20,000 Alabamians are living with HIV.[7] Humana has designed Qualified Health Plans (QHPs) that violate Sections 1311 and 1557 of the ACA by preventing these individuals from having "meaningful access"[8] to critical HIV medications. CHLPI and AIDS Alabama encourage OCR to invoke its mandate under the ACA and act to put an end to the discriminatory practices of this insurer.

CHLPI and AIDS Alabama conducted an investigation of silver-level QHP benefit designs in Alabama for 2016, looking at a variety of factors that would affect the selection of a QHP by healthcare consumers living with HIV, including coverage and cost of key medications.[9] In this complaint, we focus on the formulary benefit design for the common regimens recommended as the standard of care for treatment-naïve patients (*i.e.*, those who have not taken HIV medications before) in the Federal *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*,[10] as well as Atripla, which was previously recommended as a standard of care in the *Guidelines* and has been maintained as a treatment for a number of HIV patients.

Both of the QHPs offered by Humana by far the most expensive and restrictive for HIV treatment medications in Alabama. This QHP benefit design placing the costs of life saving medications back onto vulnerable enrollees violates the anti-discrimination protections of the ACA in three ways. First, Humana adversely tiers its HIV medications, placing even generic HIV medications on the highest level of "specialty" cost-sharing, making obtaining 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

[4] 80 Fed. Reg. 54172 (Sept. 8, 2015).
[5] *Id.* at 54173.
[6] 81 Fed. Reg. 31376, 31440 (May 18, 2016).
[7] Quarterly Report: 2015 – Volume 4, ALABAMA PUBLIC HEALTH, http://www.adph.org/aids/assets/HIV_AIDS_Report_4th_Quarter_2015.pdf (last visited Mar. 21, 2016).
[8] *See Alexander v. Choate*, 469 U.S. 287 (1985).
[9] Available at http://www.chlpi.org/plan-assessment/.
[10] *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*, U.S. DEPT. OF HEALTH & HUMAN SERVICES PANEL ON ANTIRETROVIRAL GUIDELINES FOR ADULTS AND ADOLESCENTS – A WORKING GROUP OF THE OFFICE OF AIDS RESEARCH ADVISORY COUNCIL (OARAC), https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf (last visited Mar. 30, 2016).

medications, placing an undue burden on HIV-infected individuals in relation to others with similar chronic health conditions.

Humana's HIV benefits design in Alabama was particularly egregious, especially compared to its competitors and its treatment of other medications. Of the eight Silver QHPs available on Alabama's Marketplace in 2016, only Humana's plans placed virtually all of the necessary components of all the recommended HIV medications on its highest formulary tier, requiring a co-insurance payment of 50% for most medications – an amount that comprises almost one-fifth of median household income in Alabama for the recommended treatment regimens.[11] The unnecessarily high cost of HIV medications under Humana's formulary design is highlighted by comparison to costs for immune suppressant and wakefulness medications. Despite the similarities in cost, duration, and frequency, all of these medications for other conditions are placed on lower formulary tiers, and comprise 1-4% percent of an Alabamian's median household income.

V. RELEVANT LAW

A. Purpose of the Affordable Care Act

People with HIV have historically faced discrimination throughout the healthcare system.[12] The ACA aims to put an end to this discrimination, requiring coverage for pre-existing conditions[13] and prohibiting discrimination[14] against people with disabilities. The ACA recognizes that we must all bear the costs of supporting the health of our fellow citizens – under its holistic model, healthy individuals who might not have purchased insurance are now required to do so; in exchange, health insurers must cover those previously excluded from coverage.

To this end, the ACA provides that insurers shall not discriminate against or deny benefits to individuals with disabilities.[15] Yet Humana is doing just that – designing its QHPs such that popular HIV medications are burdened with prohibitive costs and effectively deterring people with HIV from participating in these plans. While reaping the benefits of the ACA, then, Humana is shirking its concurrent responsibilities under the Act to provide people with disabilities with non-discriminatory "meaningful access"[16] to their health care financing.

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[11] According to the U.S. Census, the median household income in Alabama is $41,657. *Quickfacts: Alabama*, U.S. CENSUS BUREAU, http://www.census.gov/quickfacts/table/PST045215/01 (last visited Mar. 30, 2016).
[12] *See, e.g.*, Gregory M. Herek et al., *HIV-Related Stigma and Knowledge in the United States: Prevalence and Trends, 1991-1999*, J. AM. PUB. HEALTH 371 (2002).
[13] 80 Fed. Reg. 72192, 72192 (Nov. 18, 2015).
[14] 42 U.S.C. § 18116.
[15] *Id.*
[16] *See Choate*, 469 U.S. at 287.

B. Anti-Discrimination Protections in the Affordable Care Act

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.[17] Section 1557 applies directly to federal- and state-based Marketplaces,[18] and therefore applies to Alabama Silver QHP insurers, including Humana. Section 1557 also reinforces the anti-discrimination protections in the ACA by explicitly prohibiting discrimination based on disability.[19] The stipulation that HIV is a categorical disability has also been upheld in relevant case law; persons with HIV disease, both symptomatic and asymptomatic, have physical impairments "that substantially limit one or more major life activities" and are, therefore, protected by the law.[20]

The ACA clearly establishes protections from discrimination for people living with HIV who enroll in a silver QHP in Alabama. Section 1557 provides for enforcement through the mechanisms available under existing anti-discrimination laws, regulations, and policies.[21] The mechanisms relevant to this complaint derive from Section 504 of the Rehabilitation Act,[22] 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."[23]

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.[24] The Supreme Court has specified that the relevant inquiry under the Rehabilitation Act is for determining if discrimination has occurred is whether "meaningful access" has been provided to individuals with disabilities.[25] The meaningful access inquiry asks "whether those with disabilities are as a practical matter able to access benefits to which they are legally entitled."[26]

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**

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[17] 42 U.S.C. § 18116; 45 C.F.R. § 92.101.
[18] 45 C.F.R. § 92.4.
[19] 45 C.F.R. § 92.205.
[20] *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, available at https://www.ada.gov/archive/hivqanda.txt (last visited, Jul. 15, 2016).
[21] 80 Fed. Reg. at 54172-54221.
[22] 42 U.S.C. § 18116(b).
[23] 45 C.F.R. § 84.52(j).
[24] 42 U.S.C. § 12132 (2006).
[25] *See Choate*, 469 U.S. at 287.
[26] *Henrietta D. v. Bloomberg*, 331 F.2d 261, 273 (2003).

employ discriminatory benefit designs, though the Regulations remain silent on whether insurers 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."[27] 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."[28]

Section 1311

As a separate issue, the trends uncovered in CHLPI and AIDS Alabama'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."[29] 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."[30] State regulators in Alabama 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.[31]

C. Compliance Reviews and Enforcement Authority

OCR has the primary responsibility for enforcement of the civil rights protections in the ACA. Under 45 C.F.R. 85.61(d), OCR is required to "accept and investigate all complete complaints for which it has jurisdiction." 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." Cases of noncompliance may result in suspension, termination, or refusal to grant or continue Federal financial assistance.[32] Should the

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[27] *2017 Letter to Issuers in the Federally-facilitated Marketplaces*, U.S. DEPT. OF HEALTH & HUMAN SERVICES Pg. 45 available at https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2017-Letter-to-Issuers-2-29-16.pdf (February 29, 2016).
[28] 80 Fed. Reg. 10750-01, 10823 (Feb. 27, 2015).
[29] ACA § 1311(c)(1)(A).
[30] *See* 80 Fed. Reg. at 10823.
[31] *Regulations Enforced by OCR*, U.S. DEPT. OF HEALTH & HUMAN SERVICES available at http://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/laws/index.html (last visited Jul. 15, 2016),.
[32] *See, e.g.*, 45 C.F.R. §§ 80.8, 84.6, 302(c).

enforcement efforts of OCR fall on deaf ears, it can and should refer the matter to the Department of Justice for Litigation.[33]

VI. FACTS AND ANALYSIS

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

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

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[33] Fed. Reg. 31376-01, 31440 (May 18, 2016) ("OCR has the authority to refer cases to DOJ for litigation where efforts at compliance have been unsuccessful.")

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

[35] 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).

[36] *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).

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

[38] *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).

[39] *See Guidelines*, supra note 10, at K-5.

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

[41] *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.

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.[42] The Guidelines are meant to be used broadly by providers who work with HIV-positive patients.[43] 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):[44]

1. dolutegravir[45] + (abacavir + lamivudine)[46] = Triumeq (STR).
2. dolutegravir + Truvada (tenofovir DF plus emtricitabine)[47,48]
3. elvitegravir[49] + cobicistat[50] + tenofovir alafenamide[51] + emtricitrabine = Genvoya (STR)
4. elvitegravir + cobicistat +(tenofovir DF + emtricitrabine) = Stribild (STR)
5. raltegravir[52] + Truvada (tenofovir DF plus emtricitabine)
6. darunavir[53] + ritonavir[54] + 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.[55] Having an exceptions process to the formulary through which an individual can

[42] *See generally Guidelines*, *supra* note 10.
[43] *See id.* at A-1
[44] *See id.* at F-3.
[45] Dolutegravir is an integrase inhibitor (INSTI) with a brand name product Tivicay.
[46] 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.
[47] 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.
[48] In certain cases where emtricitabine is part of the combination drug, lamivudine can be substituted.
[49] Elvitegravir is an integrase inhibitor (INSTI) with a brand name product Vitekta.
[50] Cobicistat is a pharmacokinetic enhancers with a brand name of Tybost.
[51] Tenofovir alafenamide is a prodrug of the NRTI tenofovir.
[52] Raltegravir is an integrase inhibitor (INSTI) with a brand name product Isentress.
[53] Darunavir is a protease inhibitor (PI) with a brand name product Prezista.
[54] Ritonavir is a PI with a brand name product Norvir.
[55] 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);

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,[56] because this coverage is not guaranteed,[57] 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,[58] 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.[59] 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.[60] 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:

- 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.

[56] *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).
[57] *See Guidelines*, *supra* note 10.
[58] *See id.* at J-1.
[59] *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).
[60] *See Tivicay*, POSITIVELY AWARE, http://www.positivelyaware.com/tivicay (last visited Apr. 20, 2016).

1. Triumeq
2. Tivicay + Truvada
3. Genvoya[61]
4. Stribild
5. Isentress + Truvada
6. Prezista + Norvir + Truvada

We base our cost calculations on 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 Prescription Drug Benefit Designs in Alabama

By designing its QHPs[62] in a manner that prevents people with HIV from achieving "meaningful access" to medically necessary treatment, Humana is discriminating against people with HIV – behavior that is not only unfair to these individuals, but can also have serious public health consequences and undermine the goals of the ACA.

Humana offers two silver-level plans through Alabama's Marketplace – Silver 3800/Birmingham PPOx and Silver 3800/Huntsville PPOx. Humana plans include 5 tiers for medication: Tiers 1 – 4 require copayments of $10, $40, $80, and $160 for a 30-day supply; Tier 5 requires a coinsurance rate of 50% of the cost of the medicine. Under both plans, all but one of the branded medications used to achieve the recommended HIV treatment regimens,[63] as well as the popular STR Atripla, are placed on Tier 5, meaning that individuals with HIV and AIDS will pay 50% coinsurance rates for these medications. The monthly costs to enrollees for the federally recommended regimens on Humana's silver plans range from $699.74 to $856.22,[64] comprising 16-19 percent of the Alabama median monthly household income.[65]

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[61] 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.

[62] *See* APPENDIX.

[63] One medication, Norvir, is on tier 3. Norvir, however, cannot be taken on its own. It must be taken with Truvada and Prezista, both of which are placed on tier 5.

[64] 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. 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.

[65] Median household income is $43,511 annually, or $4,456.83 per month. *See* Quickfacts: Alabama, UNITED STATES CENSUS BUREAU, http://www.census.gov/quickfacts/table/IPE120214/01,00 (last visited Mar. 21, 2016).

The discriminatory nature of Humana's benefit designs is particularly apparent when compared with the pricing for other types of medications, such as immune suppressant and wakefulness medications Imuran, Trexall, Zortress, Azasan, and Nuvigil. These medications are regularly prescribed in accordance with a daily regimen similar to that of HIV medications.[66] In contrast to the recommended HIV ARTs, which were all placed on Tier 5, only one of the immune suppressant and wakefulness medications, Zortress, was tiered to require a 50% coinsurance rate. Humana has placed the majority of these medications on Tiers 2–3, which require copayments of $40–80.

C. Humana's Plan Design Does not Reflect Market Standards[67]

In addition to Humana, there are two other insurers that offer 2016 silver-level plans in Alabama – Blue Cross Blue Shield of Alabama and UnitedHealthcare. Both of those insurers offer coverage of the same recommended treatment regimens at significantly lower cost to their enrollees. Additionally, neither tiers almost all key HIV medications on their highest formulary tier.

BlueCross Blue Shield of Alabama offers 4 QHPs – Blue Select Silver, Blue Value Saver, Blue Saver Silver, and Blue Secure Silver. BlueCross Blue Shield of Alabama plans include 4 tiers for medications: The majority of plans require copayments ranging from $25 - $425 for a 30-day supply; Blue Select Silver requires a 20% coinsurance payment for its Tier 4 medications. The four QHPs offered by Blue Cross Blue Shield of Alabama place the recommended HIV branded medications on tier 2, otherwise classified as a Preferred Brand Drug, requiring fixed co-payments of $55, $65, or $75 per medication for a 30-day supply, depending on the plan. This means an enrollee will only pay up to 4% of the Alabama median monthly household income to access his or her treatment.

UnitedHealthcare offers three silver plans in Alabama -- Silver Compass 4000, Silver Compass 5000, and Silver Compass HS 3600. The Silver Compass 4000 and 5000 plans feature 4 tiers, with copayments ranging from $10 - $160. These plans place the recommended HIV branded medications on tiers 2 and 3, requiring fixed co-payments of $40 or $80 per medication for a 30-day supply. This means an enrollee will only pay up to 2.7% of the Alabama median monthly household income to access his or her treatment.Under the other plan offered by UnitedHealthcare in Alabama, Silver Compass HAS 3600, customers pay an annual deductible of $3,600 for all medications.

The out-of-pocket limit for Humana's silver plans is $6,300, Summary of Benefits and Coverage: What this Plan Covers & What it Costs, Humana Insurance Company, http://apps.humana.com/marketing/documents.asp?file=2601404 (last visited Mar. 30, 2016). People with HIV would have to pay exorbitant monthly costs for at least four months before arriving at that amount; if unable to meet these costs, they would risk losing insurance before they reached the cap amount. Although the Ryan White program covers co-insurance and copayments on HIV medication for people with HIV, these stopgap measures should not be used to justify irrational and discriminatory benefits designs.

[66] *Rheumatoid Arthritis – Diagnosis and Treatment*, MAYO CLINIC, http://www.mayoclinic.org/diseases-conditions/rheumatoid-arthritis/home/ovc-20197388 (last visited Apr. 10, 2016.

[67] *See* APPENDIX.

We include these insurers in this complaint for two reasons: first, as is apparent, the cost sharing required by both other insurers 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. First, the formulary plan design of Humana's competitors suggest that a reasonable plan can be offered that does not discriminate against individuals living with HIV by placing all of their medications on the higher formulary tiers and requiring high cost sharing to obtain those medications. The cost sharing differential infers 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.

Second, as the *only* insurers offering QHPs in Alabama, these insurers all operate within a small, closed healthcare ecosystem. When one insurer discriminates against a certain type of consumer, the remaining insurers are forced to disproportionately bear the costs of those consumers, which can lead to a spiraling effect on ever increasing cost sharing as insurers attempt to avoid this burden. 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. For example, United Healthcare recently announced that they will be withdrawing from most Marketplaces, included Alabama, 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.

VII. RELIEF REQUESTED

People with HIV have a right to access QHPs that do not discriminate against them on account of their disability. CHLPI and AIDS Alabama urge OCR to investigate the HIV drug benefit designs of Humana.

CHLPI and AIDS Alabama request that OCR pursue several next steps. First, we request that OCR review HIV prescription drug benefit designs of QHPs offered by Humana for discriminatory design that prevents "meaningful access" to healthcare financing. Where such discriminatory benefit design occurs, CHLPI and AIDS Alabama request that OCR work with local regulators to require that Humana adjust its plans; this insurer should also be required to engage in an outreach and enrollment campaign directed at individuals with HIV, in order to mitigate the damage of its discriminatory practices.

To ensure that insurers do not revert to these discriminatory practices, we encourage OCR to engage in ongoing monitoring of these insurers, with a focus on both tiering and costs associated with HIV-related medications and treatments. Additionally, OCR should seek civil monetary penalties for continued non-compliance with civil rights protections.

CHLPI and AIDS Alabama are available to provide any assistance necessary to ensure that people living with AIDS in Alabama are provided with meaningful access to healthcare, as mandated under the ACA.

Respectfully Submitted,

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APPENDIX: HIV Prescription Drug Pricing

Medication	Tier	Monthly Cost for Insured	AWP	Big 4 Price	AL Median Monthly Income	Percentage of Monthly Income
Blue Cross Blue Shield of Alabama						
Blue Select Silver, Blue Value Saver						
Atripla	2	$65	$2,869.80	$1,399.47	$4,456.83	1.5%
Truvada and Isentress	2,2	$65 + $65	$1,759.73 + $1,545.07	$893.82 + $750.40	$4,456.83	3%
Truvada and Tivicay	2,2	$65 + $65	$1,759.73 + $1,707.26	$893.82 + $818.61	$4,456.83	3%
Stribild	2	$65	$3,244.80	$1,528.59	$4,456.83	1.5%
Truvada, Prezista, and Norvir	2,2	$65 + $65 + $65	$1,759.73 + $1,226.55 + $35.90	$893.82 + $700.64 + $35.90	$4,456.83	4%
Triumeq	2	$65	$2,889.30	$2,174.09	$4,456.83	1.5%
Blue Saver Silver						
Atripla	2	$55	$2,869.80	$1,399.47	$4,456.83	1.2%
Truvada and Isentress	2,2	$55 + $55	$1,759.73 + $1,545.07	$893.82 + $750.40	$4,456.83	2.4%
Truvada and Tivicay	2,2	$55 + $55	$1,759.73 + $1,707.26	$893.82 + $818.61	$4,456.83	2.4%
Stribild	2	$55	$3,244.80	$1,528.59	$4,456.83	1.2%
Truvada, Prezista, and Norvir	2,2	$55 + $55 + $55	$1,759.73 + $1,226.55 + $35.90	$893.82 + $700.64 + $35.90	$4,456.83	4%
Triumeq	2	$55	$2,889.30	$2,174.09	$4,456.83	1.2%
Blue Secure Silver						
Atripla	2	$75	$2,869.80	$1,399.47	$4,456.83	1.7%
Truvada and Isentress	2,2	$75 + $75	$1,759.73 + $1,545.07	$893.82 + $750.40	$4,456.83	3.4%
Truvada and Tivicay	2,2	$75 + $75	$1,759.73 + $1,707.26	$893.82 + $818.61	$4,456.83	3.4%
Stribild	2	$75	$3,244.80	$1,528.59	$4,456.83	1.7%
Truvada, Prezista, and Norvir	2,2	$75 + $75 + $75	$1,759.73 + $1,226.55 + $35.90	$893.82 + $700.64 + $35.90	$4,456.83	4%
Triumeq	2	$75	$2,889.30	$2,174.09	$4,456.83	1.7%
Humana						
Silver 3800/Birmingham PPOx, Silver 3800/Huntsville PPOx						

Medication	Tier	Monthly Cost for Insured	AWP	Big 4 Price	AL Median Monthly Income	Percentage of Monthly Income
Atripla	5	$699.74	$2,869.80	$1,399.47	$4,456.83	16%
Truvada and Isentress	5,5	$409.31 + $375.20	$1,759.73 + $1,545.07	$893.82 + $750.40	$4,456.83	18%
Truvada and Tivicay	5,5	$409.31 + $446.91	$1,759.73 + $1,707.26	$893.82 + $818.61	$4,456.83	19%
Stribild	5	$764.30	$3,244.80	$1,528.59	$4,456.83	17%
Truvada, Prezista, and Norvir	5,5, and 3	$409.31 + $350.32 + $50	$1,759.73 + $1,226.55 + $35.90	$893.82 + $700.64 + $35.90	$4,456.83	18%
Triumeq	5	$1,087.05	$2,889.30	$2,174.09	$4,456.83	24%
UnitedHealthcare						
Silver Compass 4000, Silver Compass 5000						
Atripla	2	$40	$2,869.80	$1,399.47	$4,456.83	0.9%
Truvada and Isentress	2,2	$40 + $40	$1,759.73 + $1,545.07	$893.82 + $750.40	$4,456.83	1.8%
Truvada and Tivicay	2,3	$40 + $80	$1,759.73 + $1,707.26	$893.82 + $818.61	$4,456.83	2.7%
Stribild	3	$80	$3,244.80	$1,528.59	$4,456.83	1.8%
Truvada, Prezista, and Norvir	2,2, 2	$40 + $40 + $40	$1,759.73 + $1,226.55 + $35.90	$893.82 + $700.64 + $35.90	$4,456.83	2.7%
Triumeq	2	$40	$2,889.30	$2,174.09	$4,456.83	0.9%
Silver Compass HSA 3600						
Atripla	N/A	$3600 Annual	$2,869.80	$1,399.47	$4,456.83	N/A
Truvada and Isentress	N/A	$3600 Annual	$1,759.73 + $1,545.07	$893.82 + $750.40	$4,456.83	N/A
Truvada and Tivicay	N/A	$3600 Annual	$1,759.73 + $1,707.26	$893.82 + $818.61	$4,456.83	N/A
Stribild	N/A	$3600 Annual	$3,244.80	$1,528.59	$4,456.83	N/A
Truvada, Prezista, and Norvir	N/A	$3600 Annual	$1,759.73 + $1,226.55 + $35.90	$893.82 + $700.64 + $35.90	$4,456.83	N/A
Triumeq	N/A	$3600 Annual	$2,889.30	$2,174.09	$4,456.83	N/A