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.

OFFICE OF CIVIL RIGHTS
ADMINISTRATIVE COMPLAINT

Office of 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 Pharmacy Benefit Practices in Humana Louisiana Qualified Health Plans

I. Complainants

CrescentCare is a federally-qualified health center (FQHC) designed to provide quality health services to individuals, couples and families that seek a "medical home" in the Greater New Orleans area. CrescentCare offers comprehensive health and wellness services to the community. CrescentCare works to advocate for empowerment, to safeguard the rights and dignity of individuals, and to provide for an enlightened public. CrescentCare has served the Greater New Orleans area for over 30 years, originally operating as NO/AIDS Task Force, which remains a specialized division of CrescentCare that is uniquely focused on HIV/AIDS.

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 a clinical teaching program of Harvard Law School and is located in Cambridge, Massachusetts.

II. Defendants

Humana Inc., offers Qualified Health Plans (QHPs) in Louisiana under the name Humana. Humana is headquartered in Louisville, Kentucky and reported over $54 billion in revenues in 2015.[1]

[1] http://phx.corporate-ir.net/phoenix.zhtml?c=92913&p=irol-reportsannual

III. Jurisdiction

Within the U.S. Department of Health and Human Services, the Office of Civil Rights (OCR) enforces nondiscrimination regulations that apply to programs, services, and activities receiving HHS Federal financial assistance. Among the laws enforced by OCR is Section 504 of the Rehabilitation Act of 1973, which prohibits discrimination against otherwise qualified individuals on the basis of disability.[2] OCR also enforces Section 1557 of the Patient Protection and Affordable Care Act (ACA), which provides that an individual shall not be subjected to discrimination on the grounds prohibited under Section 504 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.[3]

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

IV. Preliminary Statement

Section 1557 of the Patient Protection and Affordable Care Act (ACA) prohibits discrimination on the basis of disability, a category which includes individuals living with HIV. Per Section 1557, insurers offering contracts for insurance on the marketplace and receiving federal funds through the form of premium tax credits are prohibited from discriminating against individuals living with HIV. Humana currently offers contracts for insurance on the Louisiana marketplace and is thus subject to the requirements of Section 1557. Humana is also subject to Section 1311 of the ACA, which requires that plan benefits design shall not have the effect of discouraging individuals with significant health needs from enrolling in that health plan.

Humana's current drug benefit design places most common HIV medications on the highest formulary tier, subjecting patients seeking those medications to a level of cost-sharing that

[2] 29 U.S.C. § 701.
[3] 42 U.S.C. § 18116.
[4] *See* Nondiscrimination in Health Programs and Activities, 81 FR 31376-01, 31439 (May 18, 2016) (interpreting the newly promulgated 45 C.F.R. § 92.301).
[5] 45 C.F.R. § 92.2(a).
[6] *See* 42 U.S.C. § 18116.

renders their insurance benefit meaningless. By placing HIV medications on the highest drug-pricing tier, Humana's drug benefit practices deny individuals living with HIV meaningful access to these medications, violating Section 1557 of the ACA. Additionally, the prescription drug benefit designs offered by Humana constitute discrimination against those individuals by effectively discouraging them from enrolling in the plan.

V. Factual Background

A. CHLPI QHP Analysis

CHLPI conducted an analysis of the prescription drug formularies and cost structure of all 17 Silver-Level Qualified Health Plans operating in Louisiana in 2016.[7] Humana offers one Silver-Level plan. The single QHP offered by Humana, the Silver 3800/Louisiana HMOx plan, is structured in such a way so as to discourage people living with HIV from enrolling or staying on this plan.

B. Recommended Treatment for HIV

CHLPI's assessment centered on twenty-four of the most commonly prescribed antiretroviral HIV drugs on the market. HIV is a chronic illness that can be treated but not cured. If HIV is not treated, it can progress to AIDS and dramatically shorten individuals' lives. Individuals need to remain on treatment and take antiretroviral drugs every day for the rest of their lives in order to maintain the benefits of treatment.[8]

The 24 commonly prescribed antiretroviral HIV drugs assessed by drugs can be classified into 6 groups: Nucleoside Reverse Transcriptase Inhibitors ("NRTIs"), Non-Nucleoside Reverse Transcriptase Inhibitors ("NNRTIs"), Protease Inhibitors ("PIs"), Integrase Strand Transfer Inhibitors ("INSTIs"), Entry Inhibitors ("EIs") and Single-Tablet Regimens ("STR"), which combine various drugs into one multi-component product.[9]

Under the aegis of the United States Department of Health and Human Services and in conformance with recognized health needs of HIV patients and developments in HIV medications, an expert panel publishes recommended treatment regimens for HIV that constitute the prevailing standard of care.[10] The Guidelines are meant to be used broadly by providers who

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[7] The full assessment report is available on CHLPI's website. *See* http://www.chlpi.org/plan-assessment/

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

[9] *See Anti-HIV Drug Classes and Names*, NAM-AIDSMAP, http://www.aidsmap.com/Anti-HIV-drug-classes-and-names/page/1254942/.

[10] *See generally Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*, DEPARTMENT OF HEALTH AND HUMAN SERVICES, https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf [hereinafter Guidelines]. In July 2016, the panel updated and revised the Guidelines. In order to match the appropriate Guideline provisions to those in

work with HIV-positive patients.[11] Under these Guidelines, there are six treatment regimens used for adult and adolescent treatment-naïve patients (i.e., those who have not taken HIV medications before):[12]

1. dolutegravir[13] + (abacavir + lamivudine)[14] = Triumeq (STR).
2. dolutegravir + Truvada (tenofovir DF plus emtricitabine)[15,16]
3. elvitegravir[17] + cobicistat[18] + tenofovir alafenamide[19] + emtricitrabine = Genvoya (STR)
4. elvitegravir + cobicistat +(tenofovir DF + emtricitrabine) = Stribild (STR)
5. raltegravir[20] + Truvada (tenofovir DF plus emtricitabine)
6. darunavir[21] + ritonavir[22] + Truvada (tenofovir DF plus emtricitabine)

Thus, in order to ensure the ability of providers to prescribe treatment consistent with the prevailing standard of care, formularies should provide access to sixteen primary drugs or combination products.[23] Having an exceptions process to the formulary through which an

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effect during the majority of the relevant plan year, this Complaint references the version of the Guidelines in effect as of January 2016.

[11] *See id.* at A-1.

[12] *See id.* at F-3.

[13] Dolutegravir is an integrase inhibitor (INSTI) with a brand name product Tivicay.

[14] 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.

[15] 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.

[16] In certain cases where emtricitabine is part of the combination drug, lamivudine can be substituted.

[17] Elvitegravir is an integrase inhibitor (INSTI) with a brand name product Vitekta.

[18] Cobicistat is a pharmacokinetic enhancer with a brand name of Tybost.

[19] Tenofovir alafenamide is a prodrug of the NRTI tenofovir.

[20] Raltegravir is an integrase inhibitor (INSTI) with a brand name product Isentress.

[21] Darunavir is a protease inhibitor (PI) with a brand name product Prezista.

[22] Ritonavir is a PI with a brand name product Norvir.

[23] 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);
- 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.

individual can attempt to access coverage for a drug not on the formulary is not enough. This is true because of the uncompensated cost to providers of going through the prior authorization process,[24] because this coverage is not guaranteed,[25] 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,[26] 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.[27] Therefore, it is important for patients to have access through their insurance plans to STRs—which are pharmacologically distinct—as well as various single-drug and combination tablets so that they and their doctors can create optimal treatment plans.

It is important to note that these drug regimens are not interchangeable. HIV is a complex disease and treatment options must take into account co-infecting conditions as well as concerns regarding a patient's medication adherence. Before initiating treatment, physicians must take into account multiple factors, including drug interactions, coexisting comorbid conditions and side effect profiles. Therefore, it is important that doctors be able to provide treatment based on patients' needs, not on availability under a particular insurance plan. There are multiple classes of drugs, and which drug should be selected from a particular class depends on specific patient characteristics. Importantly, doctors are instructed to consider the number of doses per day a patient should take in addition to what type of drug they should be prescribed.[28] Accordingly, STRs are preferred under the guidelines because of the ease of taking only one pill per day and the vitally important benefits of greater treatment adherence. Because different STRs include different drug combinations,[29] it is critical that doctors are able to prescribe any STR for a patient.

[24] *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).
[25] *See id.*
[26] *See id.* at J-1.
[27] *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).
[28] https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/11/what-to-start
[29] http://www.fda.gov/ForPatients/Illness/HIVAIDS/Treatment/ucm118915.htm

C. Humana's Drug Benefit Design

Under Humana's Silver 3800/Louisiana HMOx plan, individuals are subject to a $3,800 medical deductible and a $6300 out of pocket cap.[30] Drugs are placed on one of 5 tiers with varying levels of copayments and/or coinsurance:

Tier 1 – Preferred generic drugs ($10-$25 copayments)
Tier 2 – Non-preferred generic drugs ($20-$50 copayments)
Tier 3 – Preferred brand name drugs ($50-$125 copayments)
Tier 4 – Non-preferred brand name drugs (50% coinsurance)
Tier 5 – Specialty drugs (50% coinsurance)

Humana places 17 of the 24 covered HIV medications on the tier 5/specialty drug tier. Additionally, almost all (23 of 24) medications are quantity-limited, and four of the medications require prior authorization. As an example, common STR medications are tiered as follows:

Drug Name	Tier	Monthly Price Estimate[31]	Monthly Cost Estimate to Enrollee[32]
Atripla	Tier 5 (quantity limit, prior authorization required)	$1,399.47	$699.00
Tivicay	Tier 5 (quantity limit)	$818.61	$409.00
Triumeq	Tier 5 (quantity limit)	$1,520.93	$760.00
Stribild	Tier 5 (quantity limit)	$1,528.59	$764.00
Complera	Tier 5 (quantity limit, prior authorization required)	$1,421.53	$710.00
Truvada	Tier 5 (quantity limit)	$893.82	$446.00
Prezcobix	Tier 5 (quantity limit)	$736.72	$368.00
Isentress	Tier 5 (quantity limit, prior authorization required)	$750.40	$375.00
Abacavir	Tier 2 (quantity limit)	$375.57	$187.00

[30] The information in this Complaint reflects data collected during the 2016 open enrollment process between November 1, 2015 and January 31, 2016. It is consistent with the assessment report published on CHLPI's website. *See* http://www.chlpi.org/plan-assessment/

[31] The monthly cost is based on pricing information from the Big Four Price Federal Ceiling Price Program. Congress established the program under the Veterans Health Care Act of 1992. The program is a separate brand-name drug discount program for the four largest federal purchasers of pharmaceuticals: Veterans Affairs, Department of Defense, Public Health Service, and the Coast Guard. "The Big Four account for more than 95 percent of purchases made under Federal Supply Schedule contracts. The law sets a cap on the prices that manufacturers can charge the four agencies based on a measure of average manufacturer prices and inflation. The price to the Big Four for a brand-name drug is the lower of the FSS price or the cap." *See* http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/64xx/doc6481/06-16-prescriptdrug.pdf at 16. The pricing index is available at http://www1.va.gov/nac/index.cfm?template=Search_Pharmaceutical_Catalog.

[32] The monthly cost to the enrollee was calculated using the Big Four index price and coinsurance rate for the specific drug.

Under the legal standards set forth in the ACA and other statutes, these tiering practices deny individuals living with HIV meaningful access to these medications.

VI. Legal Standards

A. Purpose of the ACA

The ACA expands health insurance coverage dramatically and ensures access for vulnerable populations, including those with disabilities and significant health needs.[33] The ACA includes many provisions to accomplish these goals, including prohibitions on the denial of coverage based on preexisting conditions. Insurers also may not exclude preexisting conditions from coverage.[34] The law further prohibits discrimination based on health status or medical condition[35] and dictates that insurers may not institute annual or lifetime limits on benefits.[36] The ACA further requires insurers offering QHPs in a state Marketplace to provide prescription drug coverage as an Essential Health Benefit (EHB).[37]

These provisions inform the unacceptable discriminatory nature of Humana's plan benefit design. Individuals in Louisiana living with HIV are a vulnerable population, and the ACA's intention was to expand coverage and access to these individuals. Humana's Louisiana QHP enrollees living with HIV should benefit from meaningful EHB prescription drug coverage. Yet, because of Humana's adverse tiering practices, they are prevented from having meaningful access to these medications. Thus, Humana's plan benefits design also violates the specific non-discrimination provisions of the ACA, Sections 1311 and 1557.

B. ACA Non-Discrimination Provisions

The principles underlying the purpose of the ACA are captured expressly in Sections 1311 and 1557. Sections 1311 and 1557 explicitly prohibit insurers offering plans on a marketplace from discriminating against individuals in a protected class, and also prohibit insurers from designing plan benefits in such a way as to discourage individuals with significant health needs from effectively enrolling in those plans. Humana's plan benefit design for the QHP it offers on the Louisiana marketplace violates both of these ACA requirements.

[33] *See* https://www.aier.org/research/understanding-affordable-care-act
[34] 42 U.S.C. § 300gg-1.
[35] 42 U.S.C. § 300gg-4.
[36] 42 U.S.C. § 300gg-11.
[37] 42 U.S.C. § 18116.

i. *Section 1311*

Section 1311 of the ACA states:

> The Secretary shall, by regulation, establish criteria for the certification of health plans as qualified health plans. Such criteria shall require that, to be certified, a plan shall, at a minimum—meet marketing requirements, and not employ marketing practices or benefit designs that have the effect of discouraging the enrollment in such plan by individuals with significant health needs.[38]

Individuals living with HIV have "significant health needs" as determined by the Americans with Disabilities Act. Although "significant health needs" is not explicitly defined by the statute, a useful tool for understanding the individuals included in this category is the definition of a protected class in disability law. The Americans with Disabilities Act defines a disability with respect to an individual as: a physical or mental impairment that substantially limits one or more major life activities of such individual; a record of such an impairment; or being regarded as having such an impairment. Individuals living with HIV meet these criteria and are therefore members of the protected class. As summarized by the Civil Rights Division of the U.S. Department of Justice:"[p]ersons with HIV, both symptomatic and asymptomatic, have physical impairments that substantially limit one or more major life activities or major bodily functions and are, therefore, protected by the law."[39] Thus, Section 1311 of the ACA applies directly to the drug treatment regimens necessary for individuals living with HIV.

The drug tiering used by Humana results in the effective discouragement of enrollment for individuals living with HIV. An analysis utilizing average median household income is illustrative of how individuals living with HIV are discouraged due to the high costs of the medications. The average median household income for Louisiana in 2015 was $40,462,[40] or $3,371.83 per month. Given the out-of-pocket costs associated with Humana's plan, we estimate that an enrollee would spend over 22% of her monthly income for just one drug (Stribild). The enrollee would have to pay the full coinsurance rate for Stribild for nine months before she reaches the ACA annual out-of-pocket maximum. This level of cost-sharing tied to a single drug is unreasonable, especially in a context where the entire class of drugs is similarly treated. Individuals living with HIV are thus effectively discouraged from enrolling in Humana's Silver-Level QHP, in violation of Section 1311.

[38] 42 U.S.C. § 18042.
[39] US Department of Justice, Civil Rights Division, Questions and Answers: The Americans with Disabilities Act and Persons with HIV/AIDS, http://www.ada.gov/aids/ada_q&a_aids.htm.
[40] *See* https://www.census.gov/hhes/www/income/data/statemedian/ (using 3-year average Medians).

ii. *Section 1557*

Additionally, Section 1557 of the ACA reads:

> Except as otherwise provided for in this title (or an amendment made by this title), an individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.), the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.), or section 794 of title 29, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title (or amendments). The enforcement mechanisms provided for and available under such title VI, title IX, section 794, or such Age Discrimination Act shall apply for purposes of violations of this subsection.[41]

Section 1557 incorporates the enforcement mechanisms of several statutes including Title VI, Title IX, the Rehabilitation Act, and the Age Discrimination Act.[42] For individuals living with HIV, Section 1557's prohibition on discrimination based on the grounds prohibited by the Rehabilitation Act is most relevant.

C. The Rehabilitation Act

The Rehabilitation Act mandates that "[n]o otherwise qualified individual with a disability . . . shall, solely by reason of her or his disability, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance."[43] The regulation implementing Section 504 provides that subject programs may not "provide benefits or services in a manner that limits or has the effect of limiting the participation of qualified persons with disabilities." 45 C.F.R. § 84.52(a)(iv).

As previously discussed, the Americans with Disabilities Act defines the class of "persons with disabilities," and individuals living with HIV are included in this class. Court have also

[41] Id.
[42] *See* Nondiscrimination in Health Programs and Activities, 81 FR 31376-01, 31439 (May 18, 2016) (interpreting the newly promulgated 45 C.F.R. § 92.301).
[43] 29 U.S.C. § 794(a).

recognized that "HIV infection does fall well within the general definition set forth" by regulations implementing Section 504 of the Rehabilitation Act.[44]

VII. Discussion

A. Humana's Louisiana QHPs Adversely Affects Individuals Living with HIV as Compared to Patients Seeking Similarly-Situated Medications

i. *Comparison to similarly-situated drug*

Although OCR need not make out even a prima facie case of disparate impact under either the Affordable Care Act or the Rehabilitation Act to justify administrative enforcement of these regulations,[45] the principles discerned from disparate impact jurisprudence provide a useful backdrop against which the discrimination alleged here can be viewed.[46] In *Alexander v. Choate*, the Court looked to whether "meaningful access" had been provided to the plaintiff, finding that "to assure meaningful access, reasonable accommodations in the [plaintiff's] program or benefit may have to be made."[47] The Court recognized that a balance must be struck between "the statutory rights of the handicapped to be integrated into society and the legitimate interests of federal grantees in preserving the integrity of their programs: while a grantee need not be required to make 'fundamental' or 'substantial' modifications to accommodate the handicapped, it may be required to make 'reasonable' ones."[48] Interpreting this standard further, the Ninth Circuit has concluded that the question is whether the required services have been

[44] *Bragdon v. Abbott*, 524 U.S. 624, 633 (1998) (analyzing HIV in the context of 45 CFR § 84.3(j)(2)(i) (1997), regulations issued by the Department of Health, Education, and Welfare interpreting Section 504 of the Rehabilitation Act).

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

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

[47] *Alexander v. Choate*, 469 U.S. 287, 301 (1985).

[48] *Id*. at 300.

provided "in an effective manner."[49] This "effective manner" may be understood comparatively, in which case a benefit design is ineffective if it does not provide disabled individuals with the same opportunities to benefit from the services that are available to others.[50]

It is worth noting in this vein that HHS has enacted a regulation, to take effect on January 1, 2017, that will require insurance companies to "(1) [c]over[] a range of drugs across a broad distribution of therapeutic categories and classes and recommended drug treatment regimens that treat all disease states, and do[] not discourage enrollment by any group of enrollees; and (2) [p]rovide[] appropriate access to drugs that are included in broadly accepted treatment guidelines and that are indicative of general best practices at the time."[51] This regulation will require insurance companies to provide meaningful access to medications for disabled individuals because it will connect formulary requirements to the Guidelines, which constitute the continually updated prevailing clinical standard of care.[52] In order to judge whether Humana is providing "appropriate access," it is helpful to compare the cost-sharing treatment of HIV drugs to similarly-situated drugs used to treat other conditions.

Nuvigil is a medication used to treat various chronic sleep disorders.[53] The dosing pattern and regime for Nuvigil is similar to HIV medications, most commonly taken as a daily single pill.[54] Based on wholesale price, one would expect the enrollee costs for Nuvigil to be similar to HIV medications. Nuvigil's wholesale cost for the recommended dosage is similar, on average, to HIV medications. The Average Wholesale Price[55] per month of Nuvigil is $729.60.[56] Humana's Silver-Level plan places Nuvigil on Tier 3, meaning that enrollees pay $50 retail co-payments or $125 mail-order co-payments for a monthly prescription. These sums are small compared to the monthly payments enrollees are required to pay for HIV medications – as high as $764 per month. *See supra* at Section V(C). Beyond the objective difficulty of affording monthly HIV prescriptions on Humana's QHP, the difference in tiering decisions between Nuvigil and HIV

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[49] *Katie A., ex rel. Ludin v. Los Angeles Cty.*, 481 F.3d 1150, 1159 (9th Cir. 2007).

[50] *See* Leslie Pickering Francis & Anita Silvers, *Debilitating Alexander v. Choate: "Meaningful Access" to Health Care for People with Disabilities*, 35 FORDHAM URB. L.J. 447, 475 (2008).

[51] 45 C.F.R. § 156.122(a)(3)(iii)(H).

[52] *See Guidelines*, supra note 10 at A-1.

[53] http://www.nuvigil.com/aboutNUVIGIL.aspx

[54] http://www.provigil.com/PDFs/Full_Prescribing_Information.pdf

[55] Average Wholesale Price is "a benchmark that has been used for over 40 years for pricing and reimbursement of prescription drugs for both government and private payers." http://www.drugs.com/article/average-wholesale-price-awp.html The Average Wholesale Price does not include discounts or rebates.

[56] http://www.micromedexsolutions.com.ezp-prod1.hul.harvard.edu/micromedex2/librarian/CS/00950F/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/1E3471/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/redbook.ShowProductSearchResults?SearchTerm=NUVIGIL&searchType=redbookProductName&searchTermId=36522&searchContent=%24searchContent&searchFilterAD=filterADActive&searchFilterRepackager=filterExcludeRepackager&searchPattern=%5Enuvig (using 200 mg dosage option).

medications is striking. By pricing similar drugs so disparately, Humana denies meaningful access to individuals living with HIV and therefore runs afoul of the ACA.

B. Humana's Benefits Design is Divergent From Most Other Insurers Offering QHPs on the Louisiana Marketplace

Humana's plan benefit design is outside of the market norm. Review of the Louisiana market proves that Humana need not tier its HIV drugs as it does in order to be competitive. As discussed above, CHLPI assessed all 17 Silver-Level QHPs offered in the Louisiana Marketplace. The analysis looked at the prescription drug formularies and cost-sharing structures for each plan.

The analysis found that other insurers place HIV medications on tiers subject to significantly lower cost-sharing structures. For example:

- Blue Cross Blue Shield Blue Max Copay plan charges 10% coinsurance, up to $150 per prescription;
- HMO Louisiana offers various plans with co-insurance ranging from 10% to 20%;
- United Healthcare offers several plans with capped co-payments of $160 or less; and
- Vantage offers two plans with capped co-payments of $150 or less.

These insurers are equivalent to Humana in their lack of access to generic versions of the HIV medications, yet Humana requires significantly higher cost-sharing by patients living with HIV enrolled in its QHP. The plan benefit design of Humana's QHP results in patients spending over 20% of their monthly income on a single HIV medication (using current median annual household income data).[57] Patients enrolled in other QHPs with flat co-payments will spend as little as 0.04% of their income on the same medications. When judged against their competitors in the Louisiana Marketplace, Humana's drug benefit design results in the denial of meaningful access to HIV medications and thus violates the ACA.

C. Administrative Enforcement is Necessary

Ensuring access to the drugs at issue in these complaints is worthy of an increased sense of urgency because they are the lynchpin to ending the HIV epidemic domestically. These drugs are not only vital to stabilizing the health and saving the lives of the users themselves, they virtually eliminate the user's ability to transfer the virus to others. In 2010, the federal government issued the nation's first ever National HIV/AIDS Strategy (NAS) for the United States with the stated goal of the United States becoming: "[A] place where new HIV infections are rare and when they do occur, every person, regardless of age, gender, race/ethnicity, sexual

[57] https://www.census.gov/hhes/www/income/data/statemedian/ (using 3-year average Medians).

orientation, gender identity or socioeconomic circumstance, will have unfettered access to high quality, life-extending care, free from stigma and discrimination."[58] The strategy commits the federal government to, *inter alia*, "[i]ncreasing access to care and optimizing health outcomes for people living with HIV; and reducing HIV-related health disparities."[59] Only with vigorous administrative enforcement – led by the Office of Civil Rights – with the promises of the ACA and the federal government's commitment to the National HIV/AIDS strategy be fully realized.

VIII. Relief Requested

CrescentCare and The Center for Health Law and Policy Innovation request that OCR:

I. Review drug plan tiering, cost-sharing structures, quantity limits, and prior authorization requirements for the HIV/AIDS prescription drug benefits in QHPs offered by Humana;

II. Take all necessary steps to remedy the unlawful conduct of Humana, including a corrective action plan and targeted outreach of people living with HIV;

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

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[58] *See* National HIV/AIDS Strategy for the United States at vii, *available at* https://www.aids.gov/federal-resources/national-hiv-aids-strategy/nhas.pdf
[59] *Id.* at 1.

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