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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.

Office of Civil Rights
Administrative Complaint
In re: Anthem Silver Level QHPs in Wisconsin

I. Complainant

The Center for Health Law and Policy Innovation
Harvard Law School
Wasserstein Caspersen Clinical Building
1585 Massachusetts Ave.
Suite 3130
Cambridge, MA 02138

AIDS Resource Center of Wisconsin
820 North Plankinton Avenue
Milwaukee, WI 53203

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 healthcare and nutritious, affordable food; to reduce health disparities; to develop community advocacy capacity; and to promote more equitable and effective healthcare and food systems.[1]

The AIDS Resource Center of Wisconsin is home to the ARCW Medical Center - Wisconsin's largest and fastest growing HIV health care system. Through its integrated medical, dental and mental health clinics along with its pharmacy and dedicated social services that include food pantries, a legal program, and social work case management, more than 3,300 HIV patients in Wisconsin gain the health care and social services they need for long-term survival with HIV disease from ARCW. ARCW is also a leading provider of innovative and aggressive prevention services to help at-risk individuals stay free of HIV.

II. Defendant

Anthem, the parent company of Anthem BlueCross BlueShield, is headquartered in Indianapolis, Indiana with average annual revenue of $67.9 billion.[2]

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[1] *Health Law and Policy*, CENTER FOR HEALTH LAW AND POLICY INNOVATION, http://www.chlpi.org/health-law-and-policy/ (last visited Apr. 21, 2016).

[2] Anthem *See 2014 Annual Report*, ANTHEM at 11, http://media.corporate-ir.net/media_files/IROL/13/130104/2014AR/export7/pdfs/Anthem_2014AR.pdf (average annual revenue for 2010, 2011, 2012, 2013, and 2014 together).

III. Jurisdiction

The complaint is filed pursuant to Section 1557 of the Patient Protection and Affordable Care Act ("ACA"), codified at 42 U.S.C. § 18116. The Office of Civil Rights ("OCR") has jurisdiction to enforce violations of this statute.[3] Under Section 1557, health insurance companies cannot discriminate against customers on grounds prohibited by Section 504 of the Rehabilitation Act, i.e., on the basis of disability.[4] OCR also enforces Section 504.[5]

Additionally, under 45 C.F.R. § 156.800, the Department of Health and Human Services ("HHS") is tasked with imposing sanctions on plans in federally-facilitated Marketplaces—such as the Wisconsin Marketplace—that do not abide by the relevant regulatory and legal standards. These standards include those codified in Section 1311 of the ACA, 42 U.S.C. § 18031, which prevents health insurance companies from employing practices that have the effect of discouraging individuals with costly health needs from enrolling in their plans.[6] Based on authority granted by Section 1311,[7] HHS has promulgated prescription benefits plan requirements for certification in federally-assisted Marketplaces. Because Anthem's Wisconsin QHPs fail the standards laid out in such regulations, HHS has the authority under 45 CFR § 156.800 to take enforcement action.[8]

IV. Preliminary Statement

A panel of experts under the aegis of the United States Department of Health and Human Services has developed and promulgated federally recognized HIV treatment guidelines.[9] These Guidelines recommend six drug treatment regimens for treatment-naïve patients. The Silver-level Anthem plans offered on

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[3] Enforcement mechanisms available under the Americans with Disabilities Act (ADA) and Section 504 of the Rehabilitation Act (Section 504) are available for § 1557. *See* 42 U.S.C. § 18116; 45 C.F.R. § 92.301.

[4] 29 U.S.C. § 794 (2015).

[5] 45 C.F.R § 84.6(a) (2016).

[6] The Secretary of HHS is responsible for ensuring that insurance plans not be certified for the Marketplace if they "employ marketing practices or benefit designs that have the effect of discouraging the enrollment in such plan by individuals with significant health needs." 42 U.S.C. § 18031(c)(1)(A) (2015).

[7] *See* 42 U.S.C. § 18031(c)(1) (2015).

[8] Under this regulation, HHS is authorized to impose several types of sanctions upon QHP issuers in a Federally-facilitated Exchange that fail to meet Exchange standards, including civil penalties and decertification. *See* 45 C.F.R. §156.800(a) (2016).

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

the Wisconsin Marketplace fail to cover fully-three quarters of the sixteen primary drugs necessary to prescribe these regimens. HIV is a complex disease, and individuals need to be able to have access to a range of medications, particularly single tablet regimens ("STRs"), which generally increase adherence and viral suppression. Anthem covers *no* STR recommended by the Guidelines.

Anthem plans effectively discriminate against individuals with HIV by not providing them with meaningful access to lifesaving medications in violation of Section 1311 and Section 1557 of the ACA, and related regulations. By not covering the vast majority of the HIV medications encompassed by the Guidelines, the Anthem plans have the effect of discouraging individuals with a high-cost disease -- HIV -- from enrolling in the plan. Anthem provides extensive and adequate coverage of drugs for another type of chronic illness: hypertension. A comparison of Anthem's treatment access for individuals with hypertension as compared to individuals with HIV leads to the conclusion that the Anthem plans discriminate in violation of Section 1311 and Section 1557 of the ACA.

The Complainants request that OCR first investigate Anthem's WI Marketplace offerings and the process by which this plan benefit design was reached. The Complainants also ask OCR to take all necessary steps to remedy illegal acts, including suspending, terminating, or refusing to grant or continue federal financial assistance to the Defendant. Finally, Complainants ask OCR to enforce civil monetary penalties, and if necessary, decertify the Anthem plans as authorized by 45 C.F.R. § 156.800.

V. Facts

A. <u>HIV treatment is complex</u>.

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.[10]

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 STRs.[11]

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

[11] *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).

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.[12] Accordingly, STRs are preferred because of the ease of taking only one pill per day and the important benefits of greater treatment adherence.[13] Because different STRs include different drug combinations,[14] it is important that doctors be able to prescribe any STR to a patient in case a given one is not preferable because of a patient's characteristics or reaction.

There are recommended treatment regimens produced by an expert panel under the aegis of the United States Department of Health and Human Services in conformance with recognized health needs of HIV patients and developments in HIV medications.[15] The Guidelines are meant to be used broadly by providers who work with HIV-positive patients.[16] 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):[17]

1. dolutegravir[18] + (abacavir + lamivudine)[19] = Triumeq (STR).
2. dolutegravir + Truvada (tenofovir DF plus emtricitabine)[20,21]
3. elvitegravir[22] + cobicistat[23] + tenofovir alafenamide[24] + emtricitrabine = Genvoya (STR)
4. elvitegravir + cobicistat +(tenofovir DF + emtricitrabine) = Stribild (STR)
5. raltegravir[25] + Truvada (tenofovir DF plus emtricitabine)
6. darunavir[26] + ritonavir[27] + Truvada (tenofovir DF plus emtricitabine)

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[12] *See Guidelines*, *supra* note 9, at K-5.
[13] *See id.* at K1-K2.
[14] *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.
[15] *See generally Guidelines*, *supra* note 9.
[16] *See id.* at A-1
[17] *See id.* at F-3.
[18] Dolutegravir is an integrase inhibitor (INSTI) with a brand name product Tivicay.
[19] 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.
[20] 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.
[21] In certain cases where emtricitabine is part of the combination drug, lamivudine can be substituted.
[22] Elvitegravir is an integrase inhibitor (INSTI) with a brand name product Vitekta.
[23] Cobicistat is a pharmacokinetic enhancers with a brand name of Tybost.
[24] Tenofovir alafenamide is a prodrug of the NRTI tenofovir.
[25] Raltegravir is an integrase inhibitor (INSTI) with a brand name product Isentress.

Thus, in order to ensure the ability of providers to prescribe treatment consistent with the prevailing standard of care, formularies must provide access to sixteen primary drugs or combination products.[28] Having an exceptions process to the formulary through which an individual can attempt to access coverage for a drug not on the formulary, prescribed before enrollment, is not enough. This is true because of the uncompensated cost to providers of going through the prior authorization process,[29] because this coverage is not guaranteed,[30] and because the process of obtaining this coverage is opaque.[31]

Doctors choose which drugs to prescribe to their HIV patients based on a range of factors, including co-occurring illnesses,[32] 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.[33] 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.

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

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

[28] These 16 primary drugs or combination products 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.

[29] *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).

[30] *See id.*

[31] *See* section VII.D, *infra*, on transparency.

[32] *See id.* at J-1.

[33] *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).

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, and Anthem covers one of the drugs—Isentress. 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.[34] An individual who is currently on Isentress and becomes resistant would not be able to switch to Tivicay if that individual were insured by Anthem.

B. Anthem does not cover the majority of the most important HIV drugs.

Of the 25 commonly prescribed HIV drugs on the market, the Anthem Qualified Health Plans ("QHPs") offered on the Wisconsin Marketplace cover only six.[35] Anthem's QHP's cover Atripla, which is an STR; Isentress, which is an INSTI; Kaletra, which is a PI; Truvada, which is an NNRTI; Selzentry, which is an EI; and Ziagen, which is an NRTI.[36, 37]

Further, of the sixteen primary drugs encompassed by the federal treatment Guidelines, Anthem's Silver QHP in Wisconsin fails to cover 12.[38,39] As discussed above, STRs are generally preferred as a treatment method. Because Anthem covers only one STR, which is not one that is included in the federal treatment Guidelines, doctors whose HIV-positive patients are on Anthem would not able to abide either by federal treatment guidelines or general treatment guidelines

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[34] *See Tivicay*, POSITIVELY AWARE, http://www.positivelyaware.com/tivicay (last visited Apr. 20, 2016).

[35] *See* CHLPI WI QHP Assessment Report at: http://www.chlpi.org/download/3132/

[36] *See Four Tier Formulary*, ANTHEM BLUECROSS BLUESHIELD at 18-19 *available at* https://fm.formularynavigator.com/MemberPages/pdf/2016WISelectHIX_7020_Full_1592.pdf [hereinafter *Anthem Formulary*].

[37] It bears noting that some antiviral drugs that Anthem has chosen to cover on its formulary are explicitly warned against and labeled as *not* recommended for certain populations by the Guidelines. For example, Anthem's Wisconsin QHP formulary covers the generic NNRTI nevirapine on tier 4. The Guidelines explicitly warn against use of nevirapine in treatment naïve patients, because it is "[a]ssociated with serious and potentially fatal toxicity" and because it "did not meet non-inferiority criteria" in comparison to similar drugs. *See* Guidelines, *supra* n. 9 at Table 9.

[38] One of those 16 drugs -- Genvoya -- was the subject of a November 18, 2015 statement by the U.S. Department of Health and Human Services' Panel on Antiretroviral Guidelines for Adults and Adolescents, announcing that it intended to include elvitegravir/cobicistat/tenofovir alafenamide/emtricitabine as a Recommended regimen for certain HIV patients. While this statement was released after the start of the 2016 Open Enrollment period for QHPs, the Complainants note that Anthem has failed to cover Genvoya in its Silver-level Wisconsin QHP formulary in the intervening months.

[39] The only three of the sixteen drugs covered by Anthem's formulary are: lamivudine, Viread and Isentress. Anthem's Wisconsin Silver QHPs also fail to include Truvada on their formulary. However, Anthem's formulary does include coverage for the brand name version of tenofovir DF (called Viread) as well as lamuvidine, which can be substituted for emtricitabine in the recommended regimens. Thus, because the component parts of Truvada (with an acceptable substitution) are covered, the Complainants do not include it in the tally of non-covered drugs.

to choose medication regiments that include fewer doses of medications. Additionally, due to the special disease characteristics of HIV discussed above, the lack of coverage means that doctors cannot use the full range of HIV medication to find an appropriate treatment regimen for a particular patient.

VI. Legal Standard

The ACA intended to create an insurance market in which disabled individuals could meaningfully participate. Just as subsidies provide greater choice for middle- and low-income Americans, the anti-discrimination provisions in the ACA ensure greater choice for the millions of Americans living with disabilities and other high-cost illnesses.

Both Section 1557 and Section 1311 provide necessary protections for disabled individuals, including those living with HIV. Section 1557 prohibits discrimination by insurance plans that receive Marketplace subsidies from discriminating against individuals using the Marketplace on the grounds referenced in four preexisting statutes, including Section 504 of the Rehabilitation Act, which is read together with the Americans with Disabilities Act ("ADA").[40] HIV-positive individuals are considered disabled under the ADA,[41] so this anti-discrimination provision applies categorically to individuals with HIV.[42]

Section 1311 prohibits qualified health plans sold on the Marketplace from employing "marketing practices or benefit designs that have the effect of discouraging the enrollment in such plan by individuals with significant health needs."[43] The purpose of this provision is to ensure that disabled individuals have choices in the Marketplace. Stated plainly, insurers cannot discriminate against disabled individuals in their plan structures.[44]

Section 1311 and Section 1557 should be read in the context of the statute as a whole. The ACA was intended to provide insurance coverage to those not being

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[40] *See* 42 U.S.C. § 18116.

[41] *See generally Bragdon v. Abbott*, 524 U.S. 624 (1998).

[42] Historically, the ADA has not prohibited insurance companies from charging disabled individuals higher premiums because of their pre-existing condition status or barring them from purchasing insurance altogether. See 42 U.S.C. § 12201(c) ("Subchapters…shall not be construed to prohibit or restrict--
(1) an insurer…from underwriting risks, classifying risks, or administering such risks that are based on or not inconsistent with State law; or
(2) a person or organization covered by this chapter from establishing, sponsoring, observing or administering the terms of a bona fide benefit plan that are based on underwriting risks, classifying risks, or administering such risks that are based on or not inconsistent with State law[.]") However, other provisions of the ACA do prohibit such practices, and therefore § 1557 generally prohibits discrimination in the provision of health care and health insurance.

[43] 42 U.S.C. § 18031(c)(1)(A).

[44] *See* 42 U.S.C. § 18031; *see also* 45 C.F.R. § 156.125.

served by the current insurance system.[45] The ACA was designed to combat discriminatory insurance practices and ensure that individuals with disabilities and other high-cost health needs had the same access to health insurance as healthy individuals.[46] Section 2704 prohibits insurance companies from barring individuals with pre-existing conditions from enrolling.[47] Section 2701 also prohibits insurance companies from charging higher premiums to individuals with pre-existing conditions.[48] Finally, Section 2711 prohibits insurance companies from placing lifetime or annual caps on medical spending.[49]

Related regulations state that "[a]n issuer does not provide essential health benefits ("EHB") if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions."[50]

Altogether, these anti-discrimination provisions provide comprehensive rights for disabled individuals, who must have the same health care access in Marketplace plans as non-disabled individuals do.

VII. Argument

A. Individuals with HIV do not have meaningful access to life-saving medications.

The ACA prohibits insurance companies from discriminating against individuals on the basis of their status as disabled individuals. Section 1557 prohibits discrimination on the basis of disability.[51] Under Section 1311, this discrimination extends to *discouraging* individuals from enrolling in plans based on health status.[52] A coverage structure that makes it difficult or impossible for individuals with HIV to get access to the drugs they need is discriminatory under both Section 1557 and Section 1311.

As interpreted in *Alexander v. Choate*, Section 504 of the Rehabilitation Act requires covered entities to provide "meaningful access" to the relevant benefit.[53] The benefit guaranteed by Section 1557 is the right to participate in

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[45] *See* Stephen Adams et al., *Understanding the Affordable Care Act*, AM. INST. FOR ECON. RESEARCH (May 8, 2014), https://www.aier.org/research/understanding-affordable-care-act.
[46] *See The Affordable Care Act Helps Americans with Disabilities*, THE WHITE HOUSE, https://www.whitehouse.gov/sites/default/files/docs/the_aca_helps_americans_with_disabilities.pdf (last visited Apr. 20, 2016).
[47] *See* 42 U.S.C. 300gg-3 (2015).
[48] *See* 42 U.S.C. 300gg (2015).
[49] *See* 42 U.S.C. 300gg-11 (2015).
[50] 45 C.F.R. § 156.125 (2016).
[51] *See* 42 U.S.C. § 18116.
[52] *See* 42 U.S.C. § 18031(c)(1).
[53] *See Alexander v. Choate*, 469 U.S. 287, 301 (1995).

and not be discriminated against by "any health program or activity…including contracts of insurance."[54]

Overall, courts have interpreted "meaningful access" as similar to "equal opportunity."[55] The issue is not whether disabled and non-disabled people are able to get the same outcome from a given service, but rather whether disabled people's needs deny them meaningful access to the same services or benefits that non-disabled people retain the same access to.[56]

"Meaningful access" has not been precisely defined in this context. However, where a QHP fails to provide coverage for the fundamental drugs that constitute the clinical standard of care – as defined by HHS Guidelines – for a given chronic illness, it is fair to conclude that the benefit design has the effect of discouraging enrollment by individuals with such health needs, as is prohibited by the ACA.[57] Federal regulators agree -- a new regulation, to take effect on January 1, 2017, requires insurance companies to: "(1) Cover[] 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) Provide[] appropriate access to drugs that are included in broadly accepted treatment guidelines and that are indicative of general best practices at the time."[58]

This regulation will require insurance companies to provide meaningful access to medications for disabled individuals because it will allow them to access drugs that are included in treatment guidelines, and therefore are the ones that doctors believe, based on current science, are likely to improve their patients' conditions.[59]

As described above, Anthem's relevant formulary fails to cover fully **three-quarters** of the sixteen drugs encompassed by the recommendations for treatment-naïve HIV patients in the federal Guidelines. It follows that providers treating Anthem-covered patients with initial HIV diagnoses will not be able prescribe consistent with this federal treatment Guidelines. Such a policy plainly fails to meet *Choate*'s "meaningful access" standard for individuals disabled by an HIV diagnosis. Further, the dearth of coverage creates a strong disincentive for to enroll in Anthem's plans, in violation of Section 1311 of the ACA and related regulations.

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[54] 42 U.S.C. § 18116(a).
[55] Leslie Pickering Francis & Anita Silvers, *Debilitating* Alexander v. Choate*: "Meaningful Access" to Health Care for People with Disabilities*, 35 FORDHAM URB. L.J. 447, 453 (2008).
[56] *Civic Ass'n of the Deaf of New York City, Inc. v. City of New York*, No. 95-8591, 2011 WL 5995182, at *13 (S.D.N.Y. Nov. 29, 2011).
[57] 42 U.S.C. § 18031(c)(1)(A).
[58] 45 C.F.R. § 156.122(a)(3)(iii)(H).
[59] *See Guidelines*, *supra* note 9 at A-1.

B. Anthem's Coverage Benefit Design is Significantly Different for Other Classes of Drugs

In contrast, Anthem *does* provide meaningful access to treatment for another chronic disease: hypertension (or high blood pressure). Hypertension is a chronic illness that is in many ways similar to HIV. It can be controlled with a routine regimen care that is the clinical standard nationwide, but it cannot be cured, and generally needs to be treated for the rest of an individual's life. If hypertension is not controlled, then the individual is more likely to develop severe health problems such as heart attacks, strokes, and kidney disease.[60]

According to the guidelines released by the American Heart Association ("AHA"), there are four classes of medications that should be prescribed for individuals with no co-morbidities: Thiazide, Angiotensin-Converting Enzyme ("ACE") Inhibitors, Angiotensin II Receptor Blockers ("ARB"), and Calcium Channel Blockers ("CCB").[61] The drugs are often combined, and they are prescribed and altered based on an individual's characteristics, health needs, and reaction to previous medications.[62]

Anthem covers multiple hypertension drugs in every listed class, meaning that a doctor can pick and choose among suggested treatment guidelines in order to construct a treatment regimen for a particular individual patient with hypertension. These drugs are all made clearly available on various tiers under the Anthem plans, so an individual with hypertension has meaningful access to treatment because she can access multiple drugs in each class of drugs that are commonly prescribed under the AHA treatment guidelines.

Insurance companies that employ discriminatory plan designs restricting individuals with high-cost health needs from enrolling in their plans violate the anti-discrimination provisions of the ACA, as understood in the context of the plan as a whole. A plan that is structured in a way that attracts healthy individuals with relatively low-cost illnesses while not providing adequate coverage for higher-cost individuals with disabilities and other serious health needs violates the ACA.

D. Anthem is not transparent about drug coverage.

Federal law requires a QHP insurer to provide up-to-date, accurate and complete information to the public about its formulary drug coverage and cost-sharing

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[60] *See High Blood Pressure Facts*, CENTERS FOR DISEASE CONTROL AND INFECTION (last updated Feb. 19, 2015), http://www.cdc.gov/bloodpressure/facts.htm.
[61] *See Controlling Hypertension in Adults*, AMERICAN HEART ASSOCIATION AND AMERICAN STROKE ASSOCIATION, http://www.heart.org/idc/groups/heart-public/@wcm/@hcm/documents/downloadable/ucm_461839.pdf (last visited Apr. 20, 2016).
[62] *See id.*

requirements.[63] Formulary information is to be made available "on the plan's public Web site through a clearly identifiable link or tab without requiring an individual to create or access an account or enter a policy number."[64] Anthem's formulary includes a "prior authorization" designation for certain drugs, indicating that an individual must receive prior authorization from a doctor in order to get that drug covered. No HIV drugs have that designation. Therefore, there is no indication that an individual could be prescribed an HIV drug other than the ones listed on the formulary. However, the formulary also indicates that the insurance company may cover a drug that an individual has already been prescribed even if it is not normally covered, and directs the customer to call customer service.[65] However, based on the experience of Complainants, an individual must be enrolled in a plan in order to receive further information. No information about a process in place that would allow an individual currently on an HIV medication not covered to obtain that medication is publicly provided. An individual who is currently prescribed a medication not covered—such as Stribild, which is one of the drugs listed on the federal treatment guidelines—would not be able to know before enrolling in Anthem whether she could obtain coverage of this medication. These type of information barriers are expressly prohibited under the ACA and warrant administrative enforcement by OCR.

E. 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 orientation, gender identity or socioeconomic circumstance, will have unfettered access to high quality, life-extending care, free from stigma and discrimination."[66] 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."[67] 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.

[63] *See* 42 U.S.C. 300gg-15; 45 C.F.R. § 156.122(d)(1).
[64] 45 C.F.R. § 156.122(d)(1)(i).
[65] *See Anthem Formulary*, *supra* note 36 at 1.
[66] *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
[67] *Id.* at 1.

IX. Remedy Requested

The Complainants requests that OCR:

1. Investigate transparency issues, coverage and prior authorization plan design elements of the prescriptions drug benefits in QHPs offered by Anthem;

2. Take all necessary steps to remedy the unlawful conduct of Anthem, including a corrective action plan and targeted outreach and enrollment of people living with HIV and AIDS and to consider suspending, terminating, or refusing to grant or continue federal financial assistance to the Defendant;

3. Seek civil monetary penalties and decertification of the Anthem QHPs, for continued non-compliance with federal civil rights protections, as authorized by 45 C.F.R. § 156.800.

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Dated: September 6, 2016