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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE FOR CIVIL RIGHTS (OCR)

DISCRIMINATION COMPLAINT

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

YOUR FIRST NAME	YOUR LAST NAME
Robert	Greenwald

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

STREET ADDRESS	CITY
122 Boylston Street	Jamaica Plain

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

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

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

FIRST NAME	LAST NAME
See Attached	See attached

I believe that I have been (or someone else has been) discriminated against on the basis of:

☐ Race / Color / National Origin ☐ Age ☐ Religion ☐ Gender *(Male/Female)*

☒ Disability ☐ Other *(specify)*: See attached

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

See Attached

STREET ADDRESS	CITY

STATE	ZIP	PHONE
		( )

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

See attached

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

See attached

Please sign and date this complaint.

SIGNATURE Robert Greenwald DATE 09/06/2016

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

PSC Media Arts (301) 443-1090 EF

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

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

☐ Braille ☐ Large Print ☐ Cassette tape ☐ Computer diskette ☐ Electronic mail ☐ TDD

☐ Sign language interpreter *(specify language)*:

☐ Foreign language interpreter *(specify language)*: ☐ Other:

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

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

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

PERSON / AGENCY / ORGANIZATION / COURT NAME(S)

DATE(S) FILED | CASE NUMBER(S) *(If known)*

To help us better serve the public, please provide the following information for the person you believe was discriminated against (you or the person on whose behalf you are filing).

ETHNICITY *(select one)*

☐ Hispanic or Latino ☐ Not Hispanic or Latino

RACE *(select one or more)*

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

PRIMARY LANGUAGE SPOKEN *(if other then English)*

HOW DID YOU LEARN ABOUT THE OFFICE FOR CIVIL RIGHTS?

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

Region I - CT, ME, MA, NH, RI, VT
Office for Civil Rights
Department of Health & Human Services
JFK Federal Building - Room 1875
Boston, MA 02203
(617) 565-1340; (617) 565-1343 (TDD)
(617) 565-3809 FAX

Region II - NJ, NY, PR, VI
Office for Civil Rights
Department of Health & Human Services
26 Federal Plaza - Suite 3313
New York, NY 10278
(212) 264-3313; (212) 264-2355 (TDD)
(212) 264-3039 FAX

Region III - DE, DC, MD, PA, VA, WV
Office for Civil Rights
Department of Health & Human Services
150 S. Independence Mall West - Suite 372
Philadelphia, PA 19106-3499
(215) 861-4441; (215) 861-4440 (TDD)
(215) 861-4431 FAX

Region IV - AL, FL, GA, KY, MS, NC, SC, TN
Office for Civil Rights
Department of Health & Human Services
61 Forsyth Street, SW. - Suite 3B70
Atlanta, GA 30323
(404) 562-7886; (404) 331-2867 (TDD)
(404) 562-7881 FAX

Region V - IL, IN, MI, MN, OH, WI
Office for Civil Rights
Department of Health & Human Services
233 N. Michigan Ave. - Suite 240
Chicago, IL 60601
(312) 886-2359; (312) 353-5693 (TDD)
(312) 886-1807 FAX

Region VI - AR, LA, NM, OK, TX
Office for Civil Rights
Department of Health & Human Services
1301 Young Street - Suite 1169
Dallas, TX 75202
(214) 767-4056; (214) 767-8940 (TDD)
(214) 767-0432 FAX

Region VII - IA, KS, MO, NE
Office for Civil Rights
Department of Health & Human Services
601 East 12th Street - Room 248
Kansas City, MO 64106
(816) 426-7277; (816) 426-7065 (TDD)
(816) 426-3686 FAX

Region VIII - CO, MT, ND, SD, UT, WY
Office for Civil Rights
Department of Health & Human Services
1961 Stout Street - Room 1426
Denver, CO 80294
(303) 844-2024; (303) 844-3439 (TDD)
(303) 844-2025 FAX

Region IX - AZ, CA, HI, NV, AS, GU, The U.S. Affiliated Pacific Island Jurisdictions
Office for Civil Rights
Department of Health & Human Services
90 7th Street, Suite 4-100
San Francisco, CA 94103
(415) 437-8310; (415) 437-8311 (TDD)
(415) 437-8329 FAX

Region X - AK, ID, OR, WA
Office for Civil Rights
Department of Health & Human Services
2201 Sixth Avenue - Mail Stop RX-11
Seattle, WA 98121
(206) 615-2290; (206) 615-2296 (TDD)
(206) 615-2297 FAX

Burden Statement

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

ADMINISTRATIVE COMPLAINT

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

Barbara Holland, Regional Manager
Office for Civil Rights
U.S. Department of Health and Human Services
150 S. Independence Mall West
Suite 372, Public Ledger Building
Philadelphia, PA 19106-9111

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

I. COMPLAINANTS

The Center for Health Law and Policy Innovation of Harvard Law School (CHLPI) is a non-profit organization that 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.

The AIDS Law Project of Pennsylvania is a nonprofit, public-interest law firm providing free legal assistance to people with HIV/AIDS and those affected by the epidemic. The firm educates the public about AIDS-related legal issues, trains case management professionals to become better advocates for their HIV-positive clients, and works at local, state and national levels to achieve fair laws and policies.

II. DEFENDANT

UPMC is a health care provider and insurer based in Pittsburgh, Pennsylvania, with its insurance division reporting $5.7 billion in revenue for 2015.[1]

III. JURISDICTION

This complaint is filed pursuant to Section 1557 of the Patient Protection and Affordable Care Act (ACA), codified at 42 U.S.C. § 18116.[2] Section 1557 prohibits health plans sold through the

[1] UPMC Insurance Division, "2015 Annual Report," (2016) available at https://www.upmchealthplan.com/about/UPMC15_AnnualReport.pdf.
[2] 42 U.S.C. § 18116 (2012).

health insurance Marketplaces from discriminating against individuals living with disabilities, including HIV. As elucidated by the anti-discrimination regulations implementing Section 1557 (the Anti-Discrimination Regulations), this anti-discrimination mandate reaches those insurers operating through a federal- or state-established health insurance Marketplace.[3]

The U.S. Department of Health and Human Service (HHS) Office for Civil Rights (OCR) has primary responsibility for ensuring compliance with Section 1557 through investigations and enforcement actions.[4,5] Under 45 C.F.R. § 85.61(d), OCR is required to "accept and investigate all complete complaints for which it has jurisdiction." 45 C.F.R. § 92.301 additionally provides that "[t]he enforcement mechanisms available for and provided under Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, Section 504 of the Rehabilitation Act of 1973, or the Age Discrimination Act of 1975 shall apply for purposes of Section 1557." Noncompliance can result in suspension, termination, or refusal to grant or continue federal financial assistance.[6] OCR has primary oversight over Section 1557, although the Department of Justice (DOJ) has coordinating responsibility pursuant to Executive Order 12250.[7] UPMC offers Qualified Health Plans (QHPs)[8] on Pennsylvania's federally-facilitated Marketplace and is therefore subject to OCR jurisdiction.

IV. PRELIMINARY STATEMENT

Under the ACA, health insurers may not discriminate on the basis of disability. Section 1557 and other ACA provisions prohibit discriminatory health insurance practices, including plan benefit designs which discourage enrollment of persons with significant health needs, including people living with HIV.

Approximately 35,000 people in Pennsylvania are living with HIV, with the state ranking 10th in the nation in the number of new HIV diagnoses per year.[9, 10] Due to the complexities and rapid evolution in HIV treatment standards, HHS maintains a document called *Guidelines for the Use*

[3] 80 Fed. Reg. 54172, 54173 (Sept. 8, 2015).
[4] *Id.* at 54172-221.
[5] 81 Fed. Reg. 31376-01, 31440 (May 18, 2016) ("OCR is responsible for enforcement with respect to benefit design issues under Section 1557.").
[6] *See, e.g.*, 45 C.F.R. §§ 80.8, 84.6, and 302(c).
[7] Exec. Order No. 12,250, 3 C.F.R. § 298 (1980).
[8] UPMC's silver-level QHPs include: UPMC Health Plan Advantage Silver $0/$50 – Partner Network, UPMC Health Plan Advantage Silver $0/$50–Premium Network, UPMC Health Plan Advantage Silver $0/$50–Select Network, UPMC Health Plan Advantage Silver $1750/$30–Partner Network, UPMC Health Plan Advantage Silver $1750/$30–Premium Network, UPMC Health Plan Advantage Silver $1750/$30–Select Network, UPMC Health Plan Advantage Silver $3250/$10–Partner Network, UPMC Health Plan Advantage Silver $3250/$10 – Premium Network, UPMC Health Plan Advantage Silver $3250/$10–Select Network, UPMC Health Plan Advantage Silver HSA $2600/20%–Partner Network, UPMC Health Plan Advantage Silver HSA $2600/20%–Premium Network, and UPMC Health Plan Advantage Silver HSA $2600/20%–Select Network.
[9] Bureau of Epidemiology, Pennsylvania Department of Health. "Annual HIV Surveillance Summary," (2015) available at http://www.health.pa.gov/My%20Health/Diseases%20and%20Conditions/E-H/HIV%20And%20AIDS%20Epidemiology/Documents/2015%20Annual%20HIV%20Surveillance%20Summary%20Report.pdf.
[10] Centers for Disease Control and Prevention. "Pennsylvania – 2015 State Health Profile." (2015) available at http://www.cdc.gov/nchhstp/stateprofiles/pdf/pennsylvania_profile.pdf

of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents.[11] This is a living document that is updated as new research and treatment options become available. Under the *Guidelines*, HIV clinicians are advised to consider multiple factors when making an individualized treatment plan for their patients. The clinician should consider such factors as pill burdens, comorbidities, and avoid adverse drug interactions. Single-tablet regimens are often preferred by providers and patients for their simplicity of use and likelihood of adherence. Due to these considerations as well as patient and provider choice, HIV treatments are not interchangeable. Requiring all patients to begin with the least expensive treatment before providing coverage for newer more expensive treatments is contrary to current federal guidelines, which calls for individualized treatment plans.

Despite the new prohibition against disability discrimination, there has been an alarming decrease in coverage around necessary HIV treatment regimens concurrent with increased cost sharing. CHLPI, with the assistance of the AIDS Law Project, conducted an analysis of the prescription drug formularies and cost structure for all silver-level QHPs operating in Pennsylvania in 2016.[12] The analysis found that all of UPMC's silver-level QHPs exhibited discriminatory plan design in the form of "adverse tiering" – placing the most common and up-to-date HIV medications in a coverage tier with a high co-pay or co-insurance.[13] Other plans available through the Pennsylvania Marketplace offer enrollees living with HIV more medications in a range of tiers and cost-sharing structures.[14]

The QHP drug benefits offered by UPMC impose overly cost-restrictive tiering which unduly limits access to commonly used HIV medications. This adverse tiering discourages people living with HIV from enrolling in UPMC's health plans - a practice which unlawfully discriminates on the basis of disability. For example, the *Guidelines* recommend clinicians prescribe one of several front-line regimens for treating treatment-naïve patients. These treatment regimens utilize either a single-tablet or a combination of drugs. Under all of UPMC's silver-level QHPs, all recommended front-line regimens require consumers to pay 50% co-insurance for all but one medication (and that medication must be taken with two other medications that require 50% co-insurance).[15] This contrasts sharply with Aetna's silver-level QHPs which cover all five regimens on tiers with co-pays of either $40 or $75.[16]

V. RELEVANT LAW

A. The Affordable Care Act's Anti-Discrimination Protections

Prior to the ACA, health insurance companies routinely discriminated against people living with HIV. Plans denied coverage to individuals with pre-existing conditions including HIV and could exclude from their coverage treatment for those conditions. Additionally, insurance companies

[11] Panel on Antiretroviral Guidelines for Adults and Adolescents, *Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents*, DEP'T OF HEALTH AND HUMAN SERVS., available at https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf.
[12] Center for Health Law & Policy, Harvard Law School, "2016 Plan Analysis for Qualified Health Plans," (2016), available at http://www.chlpi.org/download/3113/.
[13] *Id.* at 213-248.
[14] *Id.* at 11-12.
[15] *Id.* at 213-248.
[16] *Id.* at 14-25.

imposed annual and lifetime caps on benefits, which disproportionately affected people living with HIV. The ACA was designed, in part, to put an end to these discriminatory practices. The ACA requires guaranteed issue of coverage in the individual and small group health insurance markets so that no one can be denied health insurance due to a preexisting condition.[17] Health insurers may no longer exclude coverage of a preexisting condition.[18] The ACA further prohibits discrimination against individual participants and beneficiaries based on health status or medical condition,[19] and it prevents insurers from imposing annual or lifetime limits on benefits.[20]

The ACA contains additional provisions barring discriminatory plan benefit design, establishing that a Qualified Health Plan may "not employ marketing practices or benefit designs ***that have the effect of discouraging the enrollment in such plan by individuals with significant health needs.***"[21] ACA regulations prohibit discrimination on the basis of on race, color, national origin, disability, age, sex, gender identity, or sexual orientation.[22]

The ACA requires all QHPs to provide prescription drug coverage as an essential health benefit (EHB).[23] Under HHS regulations, health plans that provide EHBs "must cover at least the greater of (1) one drug in every United States Pharmacopeial Convention (USP) category and class or (2) the same number of prescription drugs in each USP category and class as the state's EHB - benchmark plan."[24] A QHP fails to meet the essential health benefits standard and can be decertified if the insurer employs a discriminatory benefits design.[25]

1. Section 1557 Protections

Most significantly, the ACA applies several existing federal anti-discrimination and civil rights statutes, including the Rehabilitation Act, to the QHPs offered through the health insurance Marketplaces. Prior to the ACA, private health insurance plans were not subject to the Rehabilitation Act, which prohibits discrimination in federal programs against persons living with disabilities, including HIV and AIDS. Under the ACA's Section 1557, the Rehabilitation Act now expressly applies to the "contracts of insurance" available in the Marketplaces:

> 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 [the Rehabilitation Act], 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

[17] 42 U.S.C. § 300gg-1.
[18] *Id.*
[19] 42 U.S.C. § 300gg-4.
[20] 42 U.S.C. § 300gg-11.
[21] 42 U.S.C. § 18031 (c)(1)(a)(emphasis added); see also 45 C.F.R. §156.225(b).
[22] 45 C.F.R. § 156.200(e).
[23] 42 U.S.C. § 18022.
[24] 45 C.F.R. § 156.122.
[25] 45 C.F.R. § 156.125(a).

> program or activity that is administered by an Executive Agency or any entity established under this title (or amendments).[26]

Section 1557 expressly identifies "credits, subsidies, [and] contracts of insurance" as federal financial assistance to make clear that each trigger its application. Unlike Section 1557, Title VI, Title IX, and the Rehabilitation Act either explicitly exclude or have been interpreted in some circumstances to exclude contracts of insurance as a form of federal financial assistance.[27] A contract of insurance that is federal financial assistance is any contract of insurance that is funded, entered into, administered, or guaranteed by the federal government. Thus, an insurance company in a Marketplace that receives federally-subsidized payments such as through premium tax credits is covered by Section 1557.[28]

The regulations implementing Section 1557 explicitly prohibit health insurance issuers from having or implementing "benefit designs that discriminate of the basis of . . . disability in a health-related insurance plan or policy, or other health-related coverage."[29] Other regulations implementing the ACA, as noted above, prohibit QHP issuers from employing benefit designs "that will have the effect of discouraging the enrollment of individuals with significant health needs."[30] In providing guidance to QHPs issuers on meeting the ACA essential health benefits criteria, the Centers of Medicare and Medicaid Services (CMS) identified prescription drug plan designs that may be discriminatory. CMS is particularly concerned about "adverse tiering, which occurs when a formulary benefit design assigns most of or all drugs in the same therapeutic class needed to treat a specific chronic, high-cost medical condition to a high cost-sharing tier."[31] CMS has also identified "refusal[al] to cover a single-tablet drug regimen . . . that is customarily prescribed and is effective" and "placing most or all drugs that treat a specific condition on the highest cost tiers") as potentially discriminatory practices.[32]

Section 1557 specifically references the enforcement mechanisms "provided for" and "available under" Title VI, Title IX, Section 504, and the Age Discrimination Act ("the Age Act"). Disparate impact claims are allowed under the civil rights statutes referenced by Section 1557.[33] As Section

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[26] 42 U.S.C. § 18116.

[27] Because "contracts of insurance" are not excluded in the statutory text of Section 504 [of the Rehabilitation Act] but in its regulations, there have been conflicting decisions about whether the regulations properly exclude it.

[28] 45 C.F.R. § 92.4 (defining federal financial assistance as including assistance that HHS "plays a role in providing or administering, including all tax credits under Title I of the ACA . . . .); 81 FR 31445 (May 18, 2016) (listing examples of covered entities, including "Qualifying health plan issuers receiving assistance through advance premium tax credits and cost-sharing reductions").

[29] 45 C.F.R. § 92.207(b)(2).

[30] 45 C.F.R. § 156.225(b).

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

[32] U.S. Dep't of Health & Human Servs., Centers for Medicare & Medicare Servs., Patient Protection and Affordable Care Act: HHS Notice of Benefit and Payment Parameters Rule, 80 Fed. Reg. 10750, 10822 (Feb. 27, 2015).

[33] Dep't. of Justice, Title VI Legal Manual (2001), http://www.justice.gov/crUabout/cor/coord/vimanual.php#B (stating that Title VI regulations "may validly prohibit practices having a disparate impact on protected groups, even if the actions or practices are not intentionally discriminatory")(citing Guardians Ass'n v. Civil Serv. Comm'n, 463 U.S. 582, 582 (1983) and Alexander v. Choate, 469 U.S. 287, 293 (1985)); Dep't of Justice, Title IX Legal Manual (2001), http://www.justice.gov/crUabout/cor/coord/ixlegal.php#2 (citing cases and stating "[i]n furtherance of [Congress'] broad delegation of authority [to implement Title IX's prohibition of sex discrimination], federal agencies

1557 incorporates the enforcement mechanisms in those statutes, it too must be interpreted to provide for complaints brought on behalf of an individual, a class, or by a third party.

B. The Rehabilitation Act

The ACA incorporates in its consumer protections, Section 504 of the Rehabilitation Act, which prohibits programs and services which receive federal funds from discriminating against persons with disabilities.

> No 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 or under any program or activity conducted by any Executive agency or by the United States Postal Service.[34]

Under regulations implementing Section 504, programs subject to the Rehabilitation Act may not "provide benefits or services in a manner that limits or has the effect of limiting the participation of qualified [persons with disabilities]."[35] The Supreme Court has specified that the relevant inquiry under the Rehabilitation Act for determining if discrimination has occurred is whether "meaningful access" has been provided to individuals with disabilities.[36] The meaningful access inquiry asks "whether those with disabilities are as a practical matter able to access benefits to which they are legally entitled."[37]

Persons living with HIV fall within the definition of "disabled" under regulations implementing the Rehabilitation Act, where disability is defined as:

> (i) A physical or mental impairment that substantially limits one or more of the major life activities of such individual;
> (ii) A record of such an impairment; or
> (iii) Being regarded as having such an impairment.[38]

Under long settled case law, asymptomatic people living with HIV may be considered disabled and protected under federal anti-discrimination laws.[39]

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have uniformly implemented Title IX in a manner that incorporates and applies the disparate impact theory of discrimination.").

[34] 29 U. S .C. § 794(a).

[35] 45 C.F.R. § 84.52(a)(iv).

[36] *See Choate*, 469 U.S. at 287.

[37] *Henrietta D. v. Bloomberg*, 331 F.2d 261, 273 (2003).

[38] 45 C.F.R. § 84.3(j). *See also* 29 C.F.R. § 1630.2(g). The Rehabilitation Act specifically incorporated the definition of "disability" as defined in the Americans with Disabilities Act. (29 U.S.C. § 705(9)(B) (2012).

[39] *E.g.*, *Bragdon v. Abbott*, 524 U.S. 624, 633 (1998).

VI. DISCUSSION

A. Recommended Treatment for HIV

HIV is a chronic illness that can be treated but not cured. Individuals need to remain on treatment and take antiretroviral drugs every day for the rest of their lives in order to maintain the benefits of treatment.[40] Strict adherence to Antiretroviral Therapy (ART)[41] can stop the progression of HIV and prevent its transmission to others.[42] One multi-country study has found, for instance, that early initiation of ART resulted in a 96% reduction in HIV transmission.[43] 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).[44]

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.[45] Accordingly, STRs are preferred because of the ease of taking only one pill per day and the important benefits of greater treatment adherence.[46] Because different STRs include different drug combinations,[47] 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.[48] The Guidelines are meant to be

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[40] *See About HIV/AIDS*, CENTERS FOR DISEASE CONTROL AND PREVENTION (last updated Dec. 6, 2015), http://www.cdc.gov/hiv/basics/whatishiv.html.
[41] 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).
[42] *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).
[43] Myron S. Cohen et al., *Prevention of HIV-1 Infection with Early Antiretroviral Therapy*, 365 N. ENGL. J. MED. 493 (2001).
[44] *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).
[45] *See Guidelines*, supra note 11, at K-5.
[46] *See id.* at K1-K2.
[47] *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.
[48] *See generally Guidelines*, *supra* note 11.

used broadly by providers who work with HIV-positive patients.[49] 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):[50]

1. dolutegravir[51] + (abacavir + lamivudine)[52] = Triumeq (STR).
2. dolutegravir + Truvada (tenofovir DF plus emtricitabine)[53,54]
3. elvitegravir[55] + cobicistat[56] + tenofovir alafenamide[57] + emtricitrabine = Genvoya (STR)
4. elvitegravir + cobicistat +(tenofovir DF + emtricitrabine) = Stribild (STR)
5. raltegravir[58] + Truvada (tenofovir DF plus emtricitabine)
6. darunavir[59] + ritonavir[60] + 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.[61] 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

[49] *See id.* at A-1
[50] *See id.* at F-3.
[51] Dolutegravir is an integrase inhibitor (INSTI) with a brand name product Tivicay.
[52] 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.
[53] 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.
[54] In certain cases where emtricitabine is part of the combination drug, lamivudine can be substituted.
[55] Elvitegravir is an integrase inhibitor (INSTI) with a brand name product Vitekta.
[56] Cobicistat is a pharmacokinetic enhancers with a brand name of Tybost.
[57] Tenofovir alafenamide is a prodrug of the NRTI tenofovir.
[58] Raltegravir is an integrase inhibitor (INSTI) with a brand name product Isentress.
[59] Darunavir is a protease inhibitor (PI) with a brand name product Prezista.
[60] Ritonavir is a PI with a brand name product Norvir.
[61] 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.

process,[62] because this coverage is not guaranteed,[63] 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,[64] 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.[65] 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.[66] An individual who is currently on Isentress and becomes resistant must be able to switch to Tivicay, necessitating that both medications be covered by his or her insurer, despite being in the same class.

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

1. Triumeq
2. Tivicay + Truvada
3. Genvoya[67]
4. Stribild
5. Isentress + Truvada
6. Prezista + Norvir + Truvada

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

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[62] *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).
[63] *See Guidelines*, supra note 11.
[64] *See id.* at J-1.
[65] *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).
[66] *See Tivicay*, POSITIVELY AWARE, http://www.positivelyaware.com/tivicay (last visited Apr. 20, 2016).
[67] Genvoya was not FDA approved during the open enrollment for the 2016 QHPs. Therefore, it was not included on formularies at the time of our assessment. It has since been added.

B. UPMC Discriminates Against People Living with HIV in its Plan Design

UPMC has discriminated against people living with HIV by creating a benefits plan that discourages enrollment by offering HIV medications at cost-prohibitive levels. UPMC offers 12 different silver-level QHP plans that all utilize the same formulary on Pennsylvania's Marketplace. At the time of the assessment, during open enrollment when individuals are selecting plans, none of UPMC's QHPs provided coverage for Tivicay, a component in one of the regimens recommended by the *Guidelines* for first-line treatment. UPMC's QHPs now cover Tivicay in a formulary updated on August 1, 2016. UPMC engages in adverse tiering in all of its plans, placing all but one of the medications for treatment-naïve patients on tiers requiring high co-insurance. These plans are far more cost-prohibitive than other silver-level QHPs.[68]

Table 1

Drug	Big 4 Price[69]	UPMC Cost Sharing	Monthly Cost to Insured	Percentage of Income
Truvada and Isentress	$893.82 + $750.40	50% + 50%	$822.11	18.6%
Truvada and Tivicay	$893.82 + $818.61	50% + 50%	$856.22	19.3%
Stribild	$1,528.59	50%	$764.30	17.3%
Truvada, Prezista, and Norvir	$893.82 + $700.64 + $35.90	50% + 50% + $45	$842.23	19%
Triumeq	$2,174.09	50%	$1,087.05	24.6%
Genvoya	$1,528.52	50%	$764.26	17.3%

The cost sharing imposed by UPMC is a burden on the average Pennsylvania consumer. The median household income for Pennsylvania is $53,115, although the per capita income is much lower at $28,912. As illustrated by Table 1 above, a median wage earner living with HIV in Pennsylvania would have to spend between 15% and 24% of his or her monthly income on the commonly prescribed HIV medications while enrolled in UPMC plans.

UPMC's practice of adverse tiering makes HIV care unaffordable to the average Pennsylvanian and discourages people living with HIV from enrolling in its plans, in violation of the ACA. Along with the unlawful discrimination, these plans place the structure of the ACA at risk. By

[68] See *Supra* 16 (discussing Aetna's copays of $40 or $75 per month).

[69] Prices paid by insurers (or by their intermediaries – pharmacy benefit managers) to pharmaceutical companies for medications are not publicly available. Several indexes exist that provide information about drug prices. Two such indexes that are widely used are the Average Wholesale Price (AWP) and the Big 4 Price. AWP is considered an inflated cost estimate. The Big 4 Price is the amount paid by four government agencies – the Department of Veterans Affairs, the Department of Defense, the Public Health Service, and the U.S. Coast Guard – and includes large, negotiated discounts. For this reason, it is considered a very low estimate of the price paid by private insurance companies. In this analysis, we use the Big 4 pricing index to conservatively estimate costs for private insurers. The actual prices paid by insurers and passed on to consumers are likely to be even higher than the estimates presented here.

discouraging enrollment by people living with HIV, UPMC causes clustering of individuals with HIV/AIDS into other insurers' plans, creating financial pressure on those that provide affordable coverage. Without legal intervention, the increased costs from clustering will lead them to raise premiums or alter their benefit designs in ways similar to UPMC. If Section 1557 is not enforced against UPMC, the practice of discouraging enrollment through plan design will lead to a "race to the bottom," where savvy insurers will require individuals with HIV/AIDS to pay increasingly more for their medications.

VII. RELIEF REQUESTED

Complainants requests that OCR:

1. Review HIV prescription drug benefit designs of QHPs offered by UPMC;
2. Take all necessary steps to remedy the unlawful conduct of UPMC, including a corrective action plan and targeted outreach and enrollment of people living with HIV and AIDS;
3. Engage in ongoing monitoring to ensure that insurers do not revert to these discriminatory practices; and
4. Seek civil monetary penalties for continued non-compliance with civil rights protections.

People with HIV have a right to enroll in health insurance plans that do not discriminate against them because of their disability. The Center for Health Law and Policy Innovation at Harvard Law School and the AIDS Law Project of Pennsylvania are available to provide any assistance necessary.

Respectfully submitted,

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