ADMINISTRATIVE COMPLAINT

Office of Civil Rights, U.S. Department of Health and Human Services
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Washington, D.C. 20201

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Atlanta, GA 30303-8909

RE: DISCRIMINATORY PHARMACY BENEFITS DESIGN IN HUMANA QUALIFIED HEALTH PLANS OFFERED IN GEORGIA

I. COMPLAINANTS

Center for Health Law and Policy Innovation
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The Center for Health Law and Policy Innovation (CHLPI) is an 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, government officials, and others to expand access to high-quality healthcare; to reduce health disparities; to develop community advocacy capacity; and to promote more equitable and effective healthcare.

AIDS Research Consortium of Atlanta
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AIDS Research Consortium of Atlanta (ARCA) is a 501(c)(3) research center whose mission is to improve the quality and length of life for persons with HIV and viral hepatitis, and prevent new infections, through research, education, and access to therapies and services. ARCA participates in the development of local and national policies that facilitate its mission.

II. DEFENDANT

Humana is headquartered in Louisville, Kentucky, reporting over $54 billion in revenue for 2014.[1]

III. PRELIMINARY STATEMENT

Under the ACA and related federal law and regulation, health insurers may not discriminate on the basis of disability. Section 1557 prohibits discriminatory health insurance practices, including marketing practices and plan benefit designs that discourage the enrollment of individuals with significant health needs, such as people living with HIV/AIDS.

Beginning during the 2016 open enrollment period, the Complainants embarked on a project to assess comprehensively the silver-level Qualified Health Plans (QHPs) offered in the Georgia Marketplace.[2] Of the 45 QHPs assessed, Humana's five QHPs stand out as requiring cost sharing that discourages people with HIV/AIDS from enrolling or staying on their plans.[3] All Single Tablet Regimens (STRs)—treatments that require only one daily pill and are highly effective at maintaining adherence and minimizing hospitalizations—are listed at the highest cost sharing tier. Most non-STR HIV/AIDS medications are also listed on the highest cost sharing tier as well. This discourages individuals with HIV/AIDS from enrolling in these plans and raises the chances of serious health consequences for enrollees who are unable to afford their portion of cost sharing.[4]

Proof that Humana's plan benefit design violates federal law and regulation is found in two ways. First, unlike Humana, plans available from other Marketplace insurers offer HIV/AIDS medications in a range of tiers and cost sharing structures. Second, costly medications for similar health conditions have lower tiered options that prevent beneficiaries from reaching their out-of-pocket maximums. Humana does

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[1] Humana Annual Report at 2, *available at* http://phx.corporate-ir.net/phoenix.zhtml?c=92913&p=irol-reportsannual

[2] *See* Center for Health Law & Policy Innovation, *2016 Plan Analysis for Qualified Health Plans: Georgia*, Harvard Law School at 13-68, (Dec. 2015), *available at* http://www.chlpi.org/plan-assessment/.

[3] The QHPs also do not cover all HIV/AIDS medications available. *See* National Institutes of Health, *HIV Treatment – FDA-Approved HIV Medicines* (Last updated 9/30/2013), *available at* http://aidsinfo.nih.gov/education-materials/fact-sheets/21/58/fda-approved-hiv-medicines# (List of medications used in HIV/AIDS treatment).

[4] Single Tablet Regimens (STRs) allow people with HIV and AIDS to take only a single pill per day. Patients who adhere to therapy are 40% less likely to be hospitalized. Antiretroviral therapy consisting of a single pill per day is associated with significantly better adherence and lower risk of hospitalization in patients with HIV compared to patients receiving three or more pills per day. Paul Sax & Juliana Meyers, *Adherence to Antiretroviral Treatment and Correlation with Risk of Hospitalization among Commercially Insured HIV Patients in the United States*, PLoS ONE (2012), http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0031591.

not offer lower tiered medications to HIV/AIDS beneficiaries. Thus, Humana's plans make cost sharing for HIV/AIDS medications so expensive that beneficiaries are discouraged from joining their plans in the first place, or forced to migrate to other insurers.

Enforcement is also warranted due to Humana's transparency problems. Humana uses such opaque methods of providing cost sharing payment information that beneficiaries are unable to determine their expected cost sharing until after they sign up for these discriminatory plans.

IV. 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.[5] 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 of the Rehabilitation Act of 1973 under any health program or activity, any part of which is receiving federal financial assistance, or any entity established under Title I of the ACA or its amendments.[6]

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.[7] Humana offers QHPs on the Georgia health insurance exchanges and is therefore subject to OCR jurisdiction.[8] 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.[9]

V. FACTUAL BACKGROUND

A. Recommended Treatment for HIV.

The Complainants' QHP assessment centered on twenty-four of the most commonly prescribed antiretroviral HIV drugs on the market. HIV is a chronic illness that can

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[5] 29 U.S.C. § 701.
[6] 42 U.S.C. § 18116.
[7] *See* Nondiscrimination in Health Programs and Activities, 81 FR 31376-01, 31439 (interpreting the newly promulgated 45 C.F.R. § 92.301).
[8] 45 C.F.R. § 92.2(a).
[9] *See* 42 U.S.C. § 18116.

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]

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.[11]

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.[12] The Guidelines are meant to be used broadly by providers who work with HIV-positive patients.[13] 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):[14]

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

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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/.

[12] *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.

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

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

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

[16] 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.

[17] 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.

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

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

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

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

5. raltegravir[22] + Truvada (tenofovir DF plus emtricitabine)
6. darunavir[23] + ritonavir[24] + 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.[25] Having an exceptions process to the formulary through which an 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,[26] because this coverage is not guaranteed,[27] 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,[28] 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.[29] Therefore, it is important for patients to have access through their insurance plans to STRs—which are pharmacologically distinct—as well as various

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[22] Raltegravir is an integrase inhibitor (INSTI) with a brand name product Isentress.
[23] Darunavir is a protease inhibitor (PI) with a brand name product Prezista.
[24] Ritonavir is a PI with a brand name product Norvir.
[25] 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.

[26] *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).
[27] *See id.*
[28] *See id.* at J-1.
[29] *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).

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.[30] 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,[31] it is critical that doctors are able to prescribe any STR for a patient.

B. Humana's Prescription Drug Benefit Design

Humana offers five silver-level QHPs in Georgia: Atlanta HMOx, Columbus HMOx, Macon HMOx, National POS—Open Access, and Savannah HMOx. These plans use the same formulary and cost-sharing structure. Humana places prescription drugs on five tiers:

Tier 1 – Preferred generic drugs
Tier 2 – Non-preferred generic drugs
Tier 3 – Preferred brand name drugs
Tier 4 – Non-preferred brand name drugs
Tier 5 – Specialty drugs

Humana places 16 out of 22 of its covered HIV/AIDS drugs in Tier 5, including all STRs. Humana charges 50% co-insurance (40% when filled at a preferred network pharmacy) for Tier 5 drugs after a deductible of up to $4,600. Humana requires prior authorization for these commonly used HIV/AIDS treatment regimens and limits enrollees to only a 30-day supply.

C. Georgia Marketplace Norms

The practice of placing most HIV/AIDS drugs, and all STRs, on the highest formulary tier is not a market norm. Other insurers vary tiering or place HIV drugs on more

[30] https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/11/what-to-start
[31] http://www.fda.gov/ForPatients/Illness/HIVAIDS/Treatment/ucm118915.htm

affordable tiers.[32] Many plans are available in Georgia with more balanced cost-sharing practices, in which individuals with HIV/AIDS can obtain their medications at lower costs.

Humana provides more affordable cost sharing for many medications that do not treat HIV/AIDS. This holds true even for similar medications. Looking at immune suppressants as an example, Humana places Azasan on tier 3, requiring a copayment of $50 per month. Azasan is used to treat active rheumatoid arthritis, is usually given on a daily basis, and may be continued long-term. The Average Wholesale Price (AWP) of Azasan is $1,644.54.[33] Considering that the median income in Georgia is $4,111.83/month, a copayment of $50/month for Azasan means that a Georgia resident only pays 1.2% of his monthly income for this medication.[34] Other Georgia QHPs, like Aetna, provide formularies where HIV/AIDS medications are treated like any other prescription drug—with lower tiering for preferred brands and federally recommended treatment regimens.[35]

Humana likewise places immune suppressants Imuran, Trexall, and Sandimmune on tier three with a $50 copayment. This limits the cost sharing to no more than 1.2% of the average Georgian income. Nuvigil, a daily sleep disorder therapy agent used to treat issues like narcolepsy, is similarly placed on tier 3 with a $50 copayment. The AWP of Nuvigil is $729.60, therefore bringing the amounts paid by a beneficiary to 1.2% of Georgia's median monthly income.

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[32] *See* Center for Health Law & Policy Innovation, *2016 Plan Analysis for Qualified Health Plans: Georgia*, HARVARD LAW SCHOOL (Dec. 2015), *available at* http://www.chlpi.org/plan-assessment/.

[33] The Average Wholesale Price (AWP) is the average price at which drugs are purchased at the wholesale level. The pricing data is based on data obtained from manufacturers, distributors, and other suppliers and is often the only reliable method of obtaining actual market prices due to the widespread use of confidentiality clauses in prescription drug contracts. Published AWPs are generally higher than actual market prices for drugs. In comparison, "Big 4" pricing is the price that manufacturers "must sell brand-name drugs . . . to the VA, Department of Defense, Public Health Service, and Coast Guard." These prices are set at the Federal Ceiling Price, which is equal to or lower than the price given to any of the drug manufacturer's nonfederal purchasers. Dawn Gencarelli, *One Pill, Many Prices: Variation in Prescription Drug Prices in Selected Government Programs*, NATIONAL HEALTH POLICY FORUM, Aug. 29, 2005, *available at* http://www.nhpf.org/library/issue-briefs/IB807_DrugPricing_08-29-05.pdf.

[34] The median household income in Georgia was $49,342 between 2010 and 2014. In families with one earner, the median income was $41,214. This included a per capita income of $25,427 with 18.3% of Georgia residents in poverty. *QuickFacts, Georgia*, U.S. CENSUS BUREAU, *available at* https://www.census.gov/quickfacts/table/PST045215/13 (last visited Mar. 28, 2016); *Census Bureau Median Family Income by Family Size*, U.S. DEP'T OF JUSTICE, *available at* https://www.justice.gov/ust/eo/bapcpa/20130501/bci_data/median_income_table.htm (last visited Mar. 28, 2016). *See also* Center for Health Law & Policy Innovation, *2016 Plan Analysis for Qualified Health Plans: Georgia*, HARVARD LAW SCHOOL at 2-3, (Dec. 2015), *available at* http://www.chlpi.org/plan-assessment/.

[35] *See* Center for Health Law & Policy Innovation, *2016 Plan Analysis for Qualified Health Plans: Georgia*, HARVARD LAW SCHOOL at 13-68, (Dec. 2015), *available at* http://www.chlpi.org/plan-assessment/.

VI. LEGAL STANDARDS

A. ACA Anti-discrimination Protections

1. Section 1557 Protections

Section 1557 is the civil rights provision of the ACA. Section 1557 prohibits discrimination on the ground of race, color, national origin, sex, age, or disability under "any health program or activity, any part of which is receiving Federal financial assistance . . . or under any program or activity that is administered by an Executive agency or any entity established under [Title I of ACA]."[36] Section 1557 prohibits discrimination not only in federally funded health programs, but also in new ACA-authorized entities like the Exchanges.

Section 1557 cross-references Section 504 of the Rehabilitation Act, which prohibits disability discrimination in federally funded programs.[37] Section 1557 also references Title VI, prohibiting discrimination based on race, color, or national origin; Title IX, prohibiting sex discrimination; and the Age Discrimination Act of 1975. Thus, Section 1557 is firmly grounded in existing civil rights laws. Although Section 1557 does not define prohibited discrimination, it adopts the language of the Rehabilitation Act regarding disability discrimination, providing that an individual or entity shall not be "excluded from participation in, be denied the benefits of, or be subject to discrimination under" any health program or activity.[38]

Section 1557 applies to "any health program or activities, any part of which is receiving Federal financial assistance."[39] Federal financial assistance is expansively designed to include "credits, subsidies or contracts of insurance."[40] As such, Section 1557's inclusion of "credits" and "subsidies" shows that its antidiscrimination provision covers private insurance companies who receive any federal tax credits or subsidies under the ACA.

In addition to Section 1557, Section 1311 of the ACA also prohibits the employment of "marketing practices or benefit designs that have the effect of discouraging enrollment in such plan by individuals with significant health needs."[41] CMS thus interprets the ACA's antidiscrimination provisions to apply specifically to instances where issuers place "most or all drugs that treat a specific condition on the highest cost tiers." [42]

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[36] 42 U.S.C. § 18116.
[37] 29 U.S.C. § 794(a).
[38] 42 U.S.C. § 12132 (2006).
[39] 42 U.S.C. § 12132 (2006).
[40] *Id*.
[41] ACA § 1311(c)(1)(A); 42 USC § 18031(c)(1)(A).
[42] *See* Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016, 80 FR 10750-01, 10823 (Feb. 27, 2015). *See also* CMS, 2017 Letter to Issuers in the Federally-facilitated Marketplaces (Feb. 29, 2016) *available at*

Although OCR need not make out even a prima facie case of disparate impact under either the ACA or the Rehabilitation Act to justify administrative enforcement of these regulations,[43] the principles discerned from disparate impact jurisprudence provide a useful backdrop against which the discrimination alleged here can be viewed.[44] 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."[45] 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."[46] Interpreting this standard further, the Ninth Circuit has concluded that the question is whether the required services have been provided "in an effective manner."[47] 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.[48]

2. The Rehabilitation Act

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https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2017-Letter-to-Issuers-2-29-16.pdf ("if an issuer places most or all drugs that treat a specific condition on the highest cost formulary tiers, that plan design might effectively discriminate against, or discourage enrollment by, individuals who have those conditions.")

[43] "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 Hous. & 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 against Humana by undertaking the investigation necessary to discern why it 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.

[44] 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).

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

[46] *Id*. at 300.

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

[48] *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).

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."[49] Under 45 C.F.R. § 84.52(a)(iv), which implemented Section 504, programs that are 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."[50]

People living with HIV are considered "disabled" under the Rehabilitation Act, with disability 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.[51]

Individuals with HIV are *de jure* disabled and therefore protected under federal anti-discrimination laws.[52]

VII. DISCUSSION

A. Humana's Adverse Tiering of HIV/AIDS Medications Departs from the Market Norm

1. Humana Places Federally Recommended HIV/AIDS Medications on the Highest Cost Sharing Tier

Humana places nearly all HIV/AIDS drugs on specialty tiers, noted as tier 5. This includes all STRs, which are the most effective form of HIV/AIDS medication because of their higher levels of patient adherence and lower rates of hospitalization. These four STRs include Atripla, Complera, Stribild, and Triumeq.

All of the HIV/AIDS medication regimens recommended by the National Institutes of Health (NIH) are classified as tier 5 under Humana's formularies. Obtaining NIH recommended treatment is therefore cost-prohibitive under Humana's QHPs.
The vast majority of QHPs on Georgia's Insurance Exchange have lower rates of cost sharing than Humana. None of the plans offered by Aetna, Blue Cross Blue Shield,

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[49] 29 U.S.C. § 794(a).
[50] 45 C.F.R. § 84.52(a)(iv).
[51] 45 C.F.R. § 84.52(j).
[52] *Bragdon v. Abbott*, 524 U.S. 624, 633 (1998); *Know the Rights that Protect Individuals with HIV and AIDS*, U.S. DEP'T OF HEALTH & HUMAN SERVS., *available at* http://www.hhs.gov/sites/default/files/ocr/civilrights/resources/factsheets/hivaids.pdf (last visited April 10, 2016) (HHS has established that individuals with HIV/AIDS are protected under the Rehabilitation Act and the Americans with Disabilities Act (ADA)).

Harken Health, Ambetter, or United Healthcare require the same levels of co-payments/co-insurance or even place HIV/AIDS drugs in specialty tiers.

Humana's QHPs are outliers in the Georgia health insurance marketplace. They stand out from the market-norm insurers both in terms of their enormous cost-sharing obligations and their unreasonable lack of low cost HIV/AIDS medication alternatives. A brief look at Humana's competition in the insurance marketplace shines light on Humana's unfair treatment of those with HIV/AIDS.

Aetna:
Provides coverage for all STRs and places them in tiers 2 or 3. These tiers have retail copayments ranging from $40/month to $80/month. No HIV/AIDS medications covered by Aetna require any amount of co-insurance because they are all in tier 3 or below, and all tier 1 HIV/AIDS medications are available for as little as $5/month. [53]

Ambetter
Provides coverage for all STRs and places all but two covered HIV/AIDS medications on tiers 1 or 2. These tiers require copayments between $10/month and $50/month. Atripla is the only STR that Ambetter places in tier 3, and consequently requires a 20% coinsurance payment.[54]

Blue Cross Blue Shield
Covers one STR—Atripla—but requires only a 10% co-insurance, thereby minimizing the possibility of a beneficiary reaching her out-of-pocket maximum for this medication alone.[55]

Harken Health
Places three STRs on tier 2 with a $40/month copayment, one STR on tier 3 with a $225/month copayment, and one STR on tier 4 with a $500/month copayment. 19 out of 22 HIV/AIDS drugs offered by Harken Health are on tiers 1 or 2 with a $10/month or $40/month copayment.[56]

United Healthcare
Covers all STRs and places them on tiers 2 or 3, requiring a $40/month or $80/month copayment. All but two of United Healthcare's HIV/AIDS drugs are on tier 3 or less.[57]

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[53] Center for Health Law & Policy Innovation, *2016 Plan Analysis for Qualified Health Plans: Georgia*, HARVARD LAW SCHOOL, at 13-68 (Dec. 2015), *available at* http://www.chlpi.org/plan-assessment/.
[54] *Id.* at 84-97.
[55] *Id.* at 98-115.
[56] *Id.* at 125-31.
[57] *Id.* at 161-69.

Although there are few generics available for HIV/AIDS drugs, these law-abiding insurers deal with the same lack of generics and still provide insurance plans where beneficiaries with HIV/AIDS are treated fairly.

Whereas a Humana beneficiary with HIV/AIDS will pay more than $700 each month for her medication, those covered by the aforementioned insurers will likely pay *less than $500 each year* in prescription drug co-payments. As such, Humana does more than just evade the market norm—it ignores it entirely.

2. Humana's Plans are Unaffordable for Individuals with HIV/AIDS in Georgia

Georgia families with one earner have a median income of $41,214 and a per capita income of $25,427. [58] With 18.3% of Georgia residents in poverty, Humana's plans are completely unaffordable for most Georgians with HIV/AIDS.[59] Exacerbating this lack of meaningful access to life-saving medications is the fact that 23% of those with HIV/AIDS are below the poverty threshold.[60] As illustrated by Table 1, a median wage earner with HIV/AIDS in Georgia would have to spend between 17.0% and 20.8% of his income on medications each month on commonly prescribed STRs. This is a conservative figure because Big 4 pricing is used and it is assumed that the median income in Georgia is $49,342—the median household income—instead of the per capita or single wage earner median incomes.

Table 1

Medication	Big 4 Price for HIV/AIDS Medication	% Median Income (Humana)
Atripla	$1399.47	17.0%
Complera	$1421.53	17.3%
Stribild	$1528.59	18.6%
Tivicay+Truvada	$1712.43	20.8%
Triumeq	$1520.93	18.5%

This cost sharing amount is not limited to STRs. In fact, under Humana's plans it remains the same for virtually all of the HIV/AIDS drugs that are federally recommended.

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[58] *Census Bureau Median Family Income by Family Size*, U.S. DEP'T OF JUSTICE, *available at* https://www.justice.gov/ust/eo/bapcpa/20130501/bci_data/median_income_table.htm (last visited Mar. 28, 2016).

[59] *See QuickFacts, Georgia*, U.S. CENSUS BUREAU, *available at* https://www.census.gov/quickfacts/table/PST045215/13 (last visited Mar. 28, 2016).

[60] Paul Denning and Elizabeth DiNenno, *Communities in Crisis: Is There a Generalized HIV Epidemic in Impoverished Urban Areas of the United States?*, CTRS. FOR DISEASE CONTROL AND PREVENTION, June 23, 2015, http://www.cdc.gov/hiv/group/poverty.html.

Humana's out-of-pocket maximums do little to make medications more affordable for individuals with HIV/AIDS. Although cost sharing for medications is no longer required once the out-of-pocket maximum is reached, even beneficiaries with lower out-of-pocket maximums are required to pay significant cost sharing before their limit is reached. Using Big 4 pricing as a conservative benchmark, this means Humana beneficiaries pay between $699 and $856 each month for many of the more commonly prescribed HIV/AIDS medications. With a median monthly income of only $4,111.83, the cost sharing is high enough that many individuals with HIV/AIDS are unable to afford even one month of their prescription medication.

Humana's adverse tiering is in direct violation of Section 1557 of the ACA. Whereas Humana requires individuals with HIV/AIDS to provide cost sharing at rates of more than $800/month, the majority of insurers—like Aetna, Ambetter, Harkness Health, Blue Cross Blue Shield, and United Healthcare—have plans that provide cost sharing as low as $5/month for HIV/AIDS medications and as low as $40/month for STRs. Consequently, individuals with HIV/AIDS have to spend between 17% to 30% of the median monthly income in Georgia to receive their medications.[61]

Humana's tiering decisions are not the market norm. None of Humana's QHPs provide a way for a beneficiary with HIV/AIDS from paying a penny less than their out-of-pocket maximum. This denies "meaningful access" to individuals with HIV/AIDS because Humana's tiering decisions are unreasonable in comparison to other Georgia health insurers.

3. Humana's Adverse Tiering Discourages Individuals with HIV/AIDS from Enrolling and Staying in its QHPs

To invoke its administrative enforcement authority, OCR need not prove the intent that underlies the plan benefit design here. Nonetheless, it is difficult to escape the common sense conclusion that Humana prioritizes its own financial incentives above the needs of chronically ill health care consumers by categorically placing federally recommended HIV/AIDS medications on its highest cost sharing tier. Not only do Humana members pay more cost sharing expenses than other insurers, but this design discourages individuals with HIV/AIDS from enrolling and staying on its insurance plans.

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[61] HHS is concerned about affordability and access for drugs included in accepted treatment guidelines. For plan years beginning on or after January 1, 2017, health plans must use a pharmacy and therapeutics (P& T) committee to "[e]nsure the issuer's formulary drug list: (1) Covers a range of drugs across a broad distribution of therapeutic categories and classes and recommended drug treatment regimens that treat all disease states, and does not discourage enrollment by any group of enrollees; and (2) Provides appropriate access to drugs that are included in broadly accepted treatment guidelines and that are indicative of general best practices at the time." 45 C.F.R. § 156.122.

The AWPs of STRs used to treat HIV/AIDS range from $1707.26 to $3244.76/month, with Big 4 pricing—a more accurate measure of the price paid by insurers for medications—between $818.61 and $1528.59/month. A Humana beneficiary in Georgia would therefore be expected to pay approximately 20% of Georgia's median income towards cost-sharing each month until his out-of-pocket maximum was reached.

HIV/AIDS beneficiaries enrolled in Humana's plans will *inevitably* reach their out-of-pocket maximum. Given this level of cost-sharing, any fiscally-rational beneficiary would therefore switch plans. This is the very definition of discouraging enrollment of chronically ill members.

Adverse tiering by Humana therefore constitutes discrimination under Section 1311(c)(1)(A) of the ACA as implemented by 45 C.F.R. § 156.225(b). This regulation requires that insurers "not employ marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs in QHPs."[62]

B. Humana Places HIV/AIDS Medications in Higher Tiers than Similarly Expensive Non-HIV/AIDS Drugs

Humana's formularies single out HIV/AIDS drugs for adverse tiering. While Humana places nearly all HIV/AIDS medication on its highest cost sharing tier, it places similar drugs for other health conditions on lower tiers, or provides at least a handful of alternative, lower cost medications in each category. Humana's plan benefit design discriminates against those living with HIV/AIDS.

Immune suppressants and wakefulness drugs offer a telling comparison of how Humana tiers HIV/AIDS medications compared to other prescription drugs. In these non-HIV/AIDS cases, Humana places similarly expensive drugs on lower cost sharing tiers. This allows beneficiaries to pay 1.2% of Georgia's median income for Azasan, Imuran, Sandimmune, or Trexall—drugs prescribed to treat rheumatoid arthritis that all have similar costs to HIV/AIDS medications. Similarly, a Humana beneficiary must pay 1.2% of Georgia's median income for Nuvigil, a drug used to treat excessive sleepiness caused by sleep apnea, narcolepsy, or shift work sleep disorder. Despite price similarities, a Humana beneficiary with HIV/AIDS will have to pay approximately 20% of Georgia's median income on his prescription drugs. No federally recommended lower cost medications are available to a Humana beneficiary with HIV/AIDS.

Table 2

Medication	**Wholesale Price**	**% Median Income**
Imuran	$329.79	1.2%

[62] 45 C.F.R. § 156.225(b).

Trexall	$1,313.09 (AWP)	1.2%
Azasan	$1,644.54 (AWP)	1.2%
Nuvigil	$357.58	1.2%

Similar to most of the HIV/AIDS medications, these immune suppressant and wakefulness drugs do not have generic equivalents. A side-by-side comparison of a beneficiary's expected contributions shows the stark disparities between how Humana treats HIV/AIDS medications compared to similar medications.

Table 3

Medication	**Tier**	**Condition**	**Expected Monthly Contribution**
Atripla	5	HIV/AIDS	$550
Complera	5	HIV/AIDS	$550
Stribild	5	HIV/AIDS	$550
Tivicay+Truvada	5	HIV/AIDS	$550
Triumeq	5	HIV/AIDS	$550
Imuran	3	Rheumatoid Arthritis	$50
Trexall	3	Rheumatoid Arthritis	$50
Azasan	3	Rheumatoid Arthritis	$50
Azasan	3	Rheumatoid Arthritis	$50
Nuvigil	3	Sleep Disorders	$50

As shown, Humana provides significantly more affordable levels of cost sharing for categories of expensive drugs other than HIV/AIDS medications. Similar trends exist in the areas of diabetes medications, biologics, and others.

The prohibitively high levels of cost sharing discourage any reasonable individual with HIV/AIDS from enrolling in Humana's QHPs. This is in clear violation of Sections 1557 and 1311(c)(1)(A) of the ACA.

Moreover, given these comparisons, it is fair for OCR to conclude that disabled individuals living with HIV/AIDS are denied "meaningful access" to Humana's Georgia QHPs, as that term is used in *Choate. Choate*, 469 U.S. at 301. An overall review of the Georgia QHP marketplace shows that designing a formulary that does not so strongly disfavor disabled enrollees living with HIV/AIDS is entirely reasonable. Left undeterred, it cannot be said that Humana's QHPs are providing meaningful insurance "in an effective manner,"[63] nor can it be said that such individuals are provided the same opportunities to benefit from the insurance that are available to other similarly situated individuals.[64]

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

[64] *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).

C. Humana's Adverse Tiering Lacks Transparency

Humana denies meaningful access to individuals with HIV/AIDS through its lack of transparency. 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 requirements.[65] 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."[66] Nevertheless, the facts recounted in this Complaint were only obtained after an arduous information gathering process during which Humana erected significant roadblocks. Information on HIV/AIDS drugs was not readily discernible from Web sources and telephone representatives requested account information as an initial threshold to proceeding with the call. Where cost-sharing involves co-insurance, individuals with HIV/AIDS do not know how much they will actually be paying for their medications until after they have already paid their premiums and are at the pharmacy counter. Furthermore, Humana's website does not provide a comprehensive list of Silver-level marketplace plans. Insurance shoppers are therefore unable to compare Silver-level plans without investing a great deal of time looking up different plans individually. Humana's transparency failings warrant administrative enforcement by OCR.

D. Humana's Adverse Tiering Generates Alarming Policy Concerns

By discouraging those with HIV/AIDS from enrolling in its QHPs, Humana causes clustering of individuals with HIV/AIDS in a smaller number of plans and insurers. This creates financial disincentives for insurers that are currently abiding by ACA anti-discrimination mandates. Ultimately, without legal intervention the higher costs inflicted on law-abiding insurers through clustering will lead them to raise premiums or alter their benefit designs in ways similar to Humana. Therefore, if Section 1557 is not enforced against Humana, it will lead to a "race to the bottom," where savvy insurers will require individuals with HIV/AIDS to pay increasingly more for their medications.

By providing plans to HIV/AIDS beneficiaries that mandate the highest levels of cost sharing, Humana beneficiaries are subject to a *de facto* denial of meaningful access to HIV/AIDS medications. No reasonable HIV/AIDS drug consumer would choose to enroll or stay on Humana's QHPs. Considering that the median monthly income in Georgia is $4,111.83, cost sharing between 17-30% of this value is impractical for most Georgia residents. As such, beneficiaries on Humana's plans are more likely to stop taking HIV/AIDS medications, thereby increasing the chances of transmission and raising the expenses incurred by the state. Moreover, Humana's prescription drug benefit design is entirely unreasonable as illustrated by the Georgia market norm.

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[65] *See* 42 U.S.C. § 300gg-15; 45 C.F.R. § 156.122(d)(1).
[66] 45 C.F.R. § 156.122(d)(1)(i).

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

VIII. RELIEF REQUESTED

The Complainants Policy request that OCR:

1. Investigate transparency issues, drug plan tiering, cost sharing structures, prior authorization requirements, and supply limits for the HIV/AIDS prescription drug benefits in QHPs offered by Humana;

2. Take all necessary steps to remedy Humana's unlawful conduct, including a corrective action plan and targeted outreach and enrollment of people living with HIV and AIDS;

3. Seek civil monetary penalties and decertification of the above-named QHPs, for continued non-compliance with federal civil rights protections.