AIDS LEGAL COUNCIL of CHICAGO

AIDS FOUNDATION OF CHICAGO

April 1, 2014

Andrew Boron
IDOI Director
Illinois Department of Insurance
320 West Washington
Springfield, IL 62767

Re: HIV/AIDS Discrimination by ACA Exchange Insurers

Dear Director Boron:

We are writing to assist the Illinois Department of Insurance (DOI) in preventing discrimination against people with HIV/AIDS by insurers on the State's health insurance exchange. We thank you for soliciting our assistance and for your continued interest in this critical healthcare issue.

I. Executive Summary

The Patient Protection and Affordable Care Act (ACA) prohibits insurers from discriminating on the basis of preexisting conditions. Nevertheless, several plans currently sold on the State's exchange discriminate against people with HIV/AIDS by targeting HIV drugs for unreasonably poor coverage. Insurers engage in such discrimination by designing benefits for HIV/AIDS drugs in a way that has no basis in the medical consensus for treating the condition.

The medical consensus for treating HIV/AIDS is amply demonstrated by the treatment guidelines developed by the United States Department of Health and Human Services (HHS).[1] In these guidelines, HHS recommends a list of "preferred regimens," along with a list of "alternative" regimens that are "preferred" under certain circumstances. Disregarding this consensus, insurers have designated such "preferred" treatments as being "non-preferred" or "specialty" drugs under their formularies. Similarly, access to such "preferred" treatments is hindered by unequal coverage for HIV drugs purchased through state-contracted pharmacy benefit managers and by the imposition of dangerous medical management techniques.

To solve this problem, the DOI should make clear to insurers that it will exclude plans from the exchange that discriminate in any of the following ways:

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[1] U.S. Dep't of Health and Human Servs., *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents* (last updated Feb. 12, 2013) (the "HHS Guidelines"); U.S. Dep't of Health & Human Servs., *Recommendation on Integrase Inhibitor Use in Antiretroviral Treatment-Naive HIV-Infected Individuals from the HHS Panel on Antiretroviral Guidelines for Adults and Adolescents* (Oct. 30, 2013) (update to HHS guidelines).

1. Providing unreasonably poor coverage for HIV drugs that doctors consider as “preferred” and “alternative” regimens by categorizing them in the “non-preferred” or “specialty” tiers of the insurers' formularies;

2. Failing to provide equal coverage for HIV drugs purchased through any state-contracted pharmacy benefits manager (PBM), such as those working with the Illinois AIDS Drugs Assistance Program (ADAP); and

3. Imposing dangerous medical management techniques, such as by requiring patients to take less effective drugs before moving on to regimens preferred by doctors (“step therapy”), or by requiring patients to obtain the insurer’s permission to refill prescriptions.

After explaining the standard of care for treating HIV/AIDS, this letter explains the legal framework for regulating discrimination and recommends actions that should be taken to comply with the ACA and Illinois law.

II. The Standard of Care for Treating HIV/AIDS

A. The Threat of Drug Resistant HIV

HIV is a virus that hijacks a critical part of the immune system, CD4+ T helper cells (“T cells”), which are a type of white blood cell. Normally, T cells function by scanning the body for viruses and triggering an appropriate immune response. However, once HIV has gained entry to a T cell, the virus uses an enzyme called reverse transcriptase to transform the virus’s RNA into DNA. The virus then incorporates its DNA into the host cell’s chromosome with an intergrase enzyme. Because HIV incorporates its DNA into a host cell’s chromosome, it is categorized as a retrovirus.

After becoming part of the T cell’s chromosome, the viral DNA reprograms the cell’s machinery, directing it to make raw material for use in new copies of the virus. This raw material is then assembled by the virus’s protease enzymes into independently functioning copies of the HIV virus. Once assembled, these copies of the virus leave the host cell to infect other T cells, repeating the process of commandeering cells and producing new copies.

After the patient’s T cell count falls below 200, the patient is diagnosed with AIDS (Acquired Immune Deficiency Syndrome). As more T cells fall to the virus, the immune system collapses, permitting opportunistic infections and cancers to decimate the body, ultimately leading to death.

Left untreated, HIV can replicate by the billions every day, and as it does so, it mutates rapidly. Indeed, HIV has the highest mutation rate of any virus due to its uniquely error-prone process of transforming RNA into DNA. Because it mutates so rapidly, HIV quickly adapts and becomes immune to drugs when treated with only one type of drug at a time or when treatment is interrupted, even briefly.

B. Medical Guidelines for the Treatment of HIV/AIDS

The great breakthrough in HIV treatment came in the mid-90s when researchers realized that fighting the virus requires using different types of HIV drugs at the same time.[2] Combination treatments box the virus into a corner, decreasing the amount of the virus in the body to undetectable levels and allowing the immune system to function more normally.[3] Based on this insight, doctors now combat the virus by prescribing a combination of the following types of antiviral drugs:[4]

Protease Inhibitors (PI) – PIs block the virus's protease enzymes, which would otherwise assist in producing new copies of the virus.

Nucleoside and Nucleotide Reverse Transcriptase Inhibitor (NNRTI) – NNRTIs attach to immature stands of viral DNA and prevent the addition of any further DNA components, thus blocking the virus from transcribing its RNA into DNA.

Non-nucleoside Reverse Transcriptase Inhibitor (NRTI) – NRTIs block the reverse transcriptase enzymes used by the virus to transform its RNA into DNA for incorporation into a host cell's chromosome.

Integrase Inhibitors (IIs) – IIs block the intergrase enzymes used by the virus to transfer its DNA into the host's chromosome.

Fusion Inhibitors (FIs) – FIs block the HIV virus from fusing with T cells, which is part of the process by which the virus enters healthy T cells.

Entry Inhibitors (EIs) – EIs block certain receptors on T cells that HIV uses to gain entry to healthy T cells.

This multi-drug therapy is called highly active antiretroviral therapy (HAART), colloquially referred to as the anti-HIV "cocktail." HAART has proven remarkably successful in preventing deaths from HIV/AIDS, reducing them from **50,876** deaths in 1995 to **8,963** in 2001.[5]

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[2] AVERT, *History of HIV & AIDS in the U.S.* (retrieved Mar. 2, 2014) ("[After being introduced], it soon became obvious that HAART was going to be revolutionary in HIV treatment."); HHS Guidelines at D-1 ("Achieving viral suppression requires the use of ARV [i.e., HAART] regimens with at least two, and preferably three, active drugs from two or more drug classes.").

[3] HHS Guidelines at E-1 ("The primary goal of antiretroviral therapy (ART) [i.e., HAART] is to prevent HIV-associated morbidity and mortality. This goal is best accomplished by using effective ART to maximally inhibit HIV replication so that plasma HIV RNA levels (viral load) remain below that detectable by commercially available assays. Durable viral suppression improves immune function and quality of life, lowers the risk of both AIDS-defining and non-AIDS-defining complications, and prolongs life.").

[4] U.S. Institutes of Health, *Types of HIV/AIDS Antiretroviral Drugs* (last updated Sept. 23, 2013); AIDS.gov, *Overview of HIV Treatments* (last revised Aug. 7, 2009).

[5] Dennis H. Osmond, *Epidemiology of HIV/AIDS in the United States*, at Table 3 (Mar. 2003).

In addition to saving the lives of those with HIV, HAART enormously benefits the general public. By reducing the amount of virus in a body, HAART reduces the risk of transmission from infected individuals to their sexual partners by 92%.[6] Similarly, HAART prevents pregnant HIV+ woman from transmitting the virus to fetuses and newborns.[7] Thus, besides saving the lives of people with HIV, HAART is also necessary to preserve the health of the public at large.[8]

To obtain these benefits, HAART should begin immediately after the patient is diagnosed as HIV+[9] and must be taken daily without interruption.[10] Delaying treatment causes long-term damage to vital organs[11] and allows HIV to mutate extensively as it replicates throughout the body, risking the possibility that one of those mutations makes the virus drug resistant.[12] Because HIV adapts so quickly, even minor interruptions in the pill-taking regimen can result in drug resistance, resulting in increased viral replication, higher infection rates, and poorer functioning of the immune system.[13]

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[6] D. Donnell, et al., *Heterosexual HIV-1 Transmission After Initiation of Antiretroviral Therapy: A Prospective Cohort Analysis*, 375 The Lancet 2092, 2095 (Jun. 2010) ("ART use by HIV-1 infected participants was associated with a 92% reduction in risk of transmission"); *see also* HHS Guidelines A-1 ("[E]ffective treatment of HIV-infected individuals with ART is highly effective at preventing transmission to sexual partners.") & E-1 ("[H]igh plasma HIV RNA is a major risk factor for HIV transmission and use of effective ART can reduce viremia and transmission of HIV to sexual partners.").

[7] HHS Guidelines at I-20 ("In pregnant women, an additional goal of therapy is prevention of perinatal transmission of HIV, with a goal of maximal viral suppression to reduce the risk of transmission of HIV to the fetus and newborn . . . .").

[8] HHS Guidelines at E-4 ("The expanded use of ART to treat individuals with CD4 counts >500 cells/mm^3 has also demonstrated public health benefits. . . Because the risk of HIV transmission is associated with level of viremia, from a public health standpoint, this reduction in community viral load can potentially reduce new HIV infections at the community level.")

[9] HHS Guidelines at E-1 ("[I]ncreasingly there have been concerted efforts to both increase testing of at-risk patients and to link HIV-infected patients to medical care soon after HIV diagnosis.") & E-10 ("At any CD4 count, adherence to therapy is essential to achieve viral suppression and prevent emergence of drug-resistance mutations."); M.S. Cohen, *Prevention of HIV-1 infection with early antiretroviral therapy*, 365 N. Engl. J. Med. 493 (Aug. 11, 2011) (concluding that "[t]he early initiation of antiretroviral therapy reduced rates of sexual transmission of HIV-1 and clinical events, indicating both personal and public health benefits from such therapy").

[10] HHS Guidelines at i–ii ("Antiretroviral therapy (ART) is recommended for all HIV-infected individuals to reduce the risk of disease progression. . .," including patients with a CD4 cell count >500/mm. "The recommendation for initiation of ART in patients with early infection" is "'should be offered'. . . .").

[11] HHS Guidelines at E–1 ("[Delaying treatment causes] cardiovascular disease (CVD), kidney disease, liver disease, neurologic complications, and malignancies.").

[12] HHS Guidelines at H-4 ("Persistent HIV RNA levels >200 copies/mL often are associated with evidence of viral evolution and drug resistance mutation accumulation; this is particularly common when HIV RNA levels are >500 copies/mL.") (footnotes omitted), D-1 ("Maximal and durable suppression of plasma viremia delays or prevents the selection of drug-resistance mutations, preserves CD4 T-cell numbers, and confers substantial clinical benefits, all of which are important treatment goals."), & C-10 ("Transmission of drug-resistant HIV strains is well documented and associated with suboptimal virologic response to initial antiretroviral therapy (ART).").

[13] HHS Guidelines at H-1 ("Discontinuing or briefly interrupting therapy in a patient with viremia may lead to a rapid increase in HIV RNA and a decrease in CD4 cell count and increases the risk of clinical

Effective HAART treatment requires giving patients and doctors flexibility to find the regimen that works best for each individual patient through a process of trial and error.[14] Many HIV+ people have strains that are resistant to a particular HIV drug.[15] Even when initially effective, treatment may stop working due to viral mutations, and many types of HIV drugs may cause certain people to suffer toxic side effects,[16] so that the patient must be allowed to quickly obtain substitute drugs.[17]

Based on these considerations, doctors generally agree on the following:

- HAART should begin as early as possible after diagnosis, using the HIV regimens designated by HHS.[18]
- To ensure adherence, patients must be prescribed the most convenient regimen, which is usually a one-a-day pill that combines more than one class of HIV drugs.[19]
- Interruptions in HAART treatment must be avoided.[20]
- Doctors must be able to quickly switch drugs when the patient's HIV becomes resistant to the drug or the patient has side effects that keep him or her from adhering to a regimen.[21]

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progression."), D-2 ("Suboptimal adherence may result in reduced treatment response."), & I-5 ("[A] large randomized controlled trial of patients with chronic HIV infection found that treatment interruption was harmful in terms of increased risk of AIDS and non-AIDS events . . . .").

[14] HHS Guidelines at D-2 ("Regimens should be tailored for the individual patient to enhance adherence and thus improve long term treatment success. Individual regimen choice is based on such considerations as expected side effects, convenience, comorbidities, interactions with concomitant medications, and results of pretreatment genotypic drug-resistance testing.").

[15] HHS Guidelines at D-1 – D-2 ("Baseline resistance testing and patient characteristics should guide design of the specific regimen. When initial suppression is not achieved or is lost, rapidly changing to a new regimen with at least two active drugs is required. The increasing number of drugs and drug classes makes viral suppression below detection limits an appropriate goal in all patients. . . . Current studies suggest a 6%–16% prevalence of HIV drug resistance in ART-naive patients, and some studies suggest that the presence of transmitted drug-resistant viruses may lead to suboptimal virologic responses.") (citations and footnotes omitted).

[16] HHS Guidelinest at H-2 (listing potential causes of virologic failure).

[17] HHS Guidelines at H-4 ("Once virologic failure is confirmed, generally the regimen should be changed as soon as possible to avoid progressive accumulation of resistance mutations."), & D-1 ("When initial suppression is not achieved or is lost, rapidly changing to a new regimen with at least two active drugs is required.").

[18] HHS Guidelines at i ("Antiretroviral therapy (ART) is recommended for ***all*** HIV-infected individuals to reduce the risk of disease progression. . . .") (emphasis added).

[19] HHS Guidelines at D-2 ("Regimens should be tailored for the individual patient to enhance adherence and thus improve long term treatment success.").

[20] HHS Guidelines at H-1 ("Discontinuing or briefly interrupting therapy in a patient with viremia may lead to a rapid increase in HIV RNA and a decrease in CD4 cell count and increases the risk of clinical progression. Therefore, this strategy is not recommended . . . .").

C. HIV Regimens Recommended by HHS

To ensure that plans adequately cover treatments for HIV/AIDS, it is critical for the DOI to understand which drugs are required under the medical standard of care for treating HIV/AIDS. Below are HHS's "preferred" and "alternative" regimens for HIV+ individuals, listed by the trade name (on the left) and by generic name with abbreviations (on the right):

Preferred Regimens – **"**Regimens with optimal and durable efficacy, favorable tolerability and toxicity profile, and ease of use."[22]

Atripla (one-a-day pill)	efavirenz (EFV) / tenofovir disoproxil fumarate (TDF) / emtricitabine (FTC)
Stribild (one-a-day pill)	elvitegravir (EVG) / cobicistat (COBI) / tenofovir disoproxil fumarate (TDF) / emtricitabine (FTC[a])
Reyataz + **Norvir** + **Truvada**	atazanavir (ATV) / ritonavir (/r) + tenofovir disoproxil fumarate (TDF) / emtricitabine (FTC[a])
Prezista + **Norvir** + **Truvada**	darunavir (DRV) / ritonavir (/r) + tenofovir disoproxil fumarate (TDF) / emtricitabine (FTC[a])
Tivicay + **Truvada**	dolutegravir (DTG) + tenofovir disoproxil fumarate (TDF) / emtricitabine (FTC[a])
Tivicay + **Epzicom**	dolutegravir (DTG) + abacavir (ABC) / lamivudine (3TC[a])
Isentress + **Truvada**	raltegravir (RAL) + tenofovir disoproxil fumarate (TDF) / emtricitabine (FTC[a])

[21] HHS Guidelines at D-1 ("When initial suppression is not achieved or is lost, rapidly changing to a new regimen with at least two active drugs is required.").

[22] HSS Guidelines at F-4 & U.S. Dep't of Health & Human Servs., *Recommendation on Integrase Inhibitor Use in Antiretroviral Treatment-Naive HIV Infected Individuals from the HHS Panel on Antiretroviral Guidelines for Adults and Adolescents* (Oct. 30, 2013)); *see also* U.S. Dep't of Health & Human Servs., *What to Start: Selecting a First HIV Regimen* (last updated November 7, 2013) (listing all drugs included on this list under "What are the preferred regimens for people taking HIV medicines for the first time?").

Alternative Regimens – "Regimens that are effective and tolerable, but have potential disadvantages when compared with preferred regimens. *An alternative regimen may be the preferred regimen for some patients*."[23]

Sustiva + **Epzicom**	efavirenz (EFV) + abacavir (ABC) / lamivudine (3TC[a])
Complera (one-a-day pill)	rilpivirine (RPV) / tenofovir disoproxil fumarate (TDF) / emtricitabine (FTC[a])
Edurant + **Epzicom**	rilpivirine (RPV) + abacavir (ABC) / lamivudine (3TC[a])
Reyataz + **Norvir** + **Epzicom**	atazanavir (ATV) / ritonavir (/r) + abacavir (ABC) / lamivudine (3TC[a])
Prezista + **Norvir** + **Epzicom**	darunavir (DRV) / ritonavir (/r) + abacavir (ABC) / lamivudine (3TC[a])
Lexiva + **Norvir** + **Epzicom** or **Truvada**	fosamprenavir (FPV) / ritonavir(/r) + abacavir (ABC) / lamivudine (3TC[a]) or tenofovir disoproxil fumarate (TDF) / emtricitabine (FTC[a])
Kaletra + **Norvir** + **Epzicom** or **Truvada**	lopinavir (LPV) / ritonavir (/r) + abacavir (ABC) / lamivudine (3TC[a]) or tenofovir disoproxil fumarate (TDF) / emtricitabine (FTC[a])
Isentress + **Epzicom**	raltegravir (RAL) + abacavir (ABC) / lamivudine (3TC[a])

In summary, there are 14 pills in the preferred and alternative regimens. The preferred regimens contain 9 pills (Atripla, Epzicom, Isentress, Norvir, Prezista, Reyataz, Stribild, Tivicay, and Truvada). The alternative regimens include 11 pills, including 6 that are already in the preferred regimens (Epzicom, Isentress, Norvir, Prezista, Reyataz, and Truvada), and 5 pills that are solely in the alternative regimens (Complera, Edurant, Kaletra, Lexiva, and Sustiva).

III. The DOI Must Prohibit Discrimination in How Insurers Design Their Benefits

Under Illinois law, the DOI must decide if plans satisfy the federal requirements for sale on the State's exchange, including the requirement that plans not discriminate against any

[23] HSS Guidelines at F-4 (emphasis added).

health conditions such as HIV/AIDS. This gatekeeping role was explicitly assigned to the DOI in the Illinois State Partnership Exchange Blueprint Application, which designates the DOI as the "Appropriate Authority to Perform and Oversee Certification of QHPs [qualified health plans]" under ACA § 1311: "The Illinois Department of Insurance (DOI) has this authority [to perform and oversee certification of QHPs] under the broad powers granted to the Director under 215 ILCS 5/401."[24] Thus, the DOI must act in conformity with ACA § 1311, which provides that a State "may not make available any health plan that is not a qualified health plan."[25] To be a "qualified health plan," a plan must provide "essential health benefits."[26] However, a plan does *not* provide "essential health benefits" if it discriminates against a "disability" or "health condition" such as HIV/AIDS in any way specified under 45 C.F.R. § 156.125.[27]

Under 45 C.F.R. § 156.125, an insurer is prohibited from discriminating in "its benefit design, or the implementation of its benefit design," such as the design or implementation of a drug formulary, pharmacy networks, or medical management techniques:

> (a) An issuer does not provide EHB [i.e., Essential Health Benefits] 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*.
>
> (b) An issuer providing EHB must comply with the requirements of § 156.200(e) of this subchapter; and
>
> (c) Nothing in this section shall be construed to prevent an issuer from appropriately utilizing reasonable medical management techniques.[28]

In turn, 45 C.F.R. § 156.200(e) provides as follows:

> (e) **Non-discrimination**. A QHP [Qualified Health Plan] issuer must not, with respect to its QHP, discriminate on the basis of race, color, national origin, *disability*, age, sex, gender identity or sexual orientation.[29]

Thus, to carry out its duties under Illinois law and the ACA, the DOI must prohibit discriminatory plans from being sold on the State's exchange. This task is explicitly assigned to the DOI in the "Blueprint Application" that Illinois submitted to the federal government to obtain funding grants for the State's exchange:

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[24] Illinois State Partnership Exchange Blueprint Application, at p. 1.

[25] ACA § 1311(d)(2)(b)(i).

[26] ACA § 1301(a)(1)(B).

[27] 45 C.F.R. § 156.125.

[28] *Id.* (emphasis added).

[29] 45 C.F.R. § 156.200(e) (emphasis added).

> For benefit design and marketing, DOI and DPH regulators *will check to ensure that issuers do not discriminate based on . . . disability* . . . . Non-discrimination will be evaluated during the assessment of service area, network adequacy, essential health benefits, and marketing. Complaints will be evaluated to further ensure that discrimination is not occurring in plans in the marketplace.[30]

IV. The DOI Must Enforce the HHS Regulations to End Discrimination in the Design of Formularies, Pharmacy Networks, and Medical Management Techniques

According to HHS, states must take the lead in enforcing 45 C.F.R. § 156.125: "[e]nforcement of [this regulation] . . . *first looks to states*"; only after a state has failed to prohibit discrimination does the HHS Secretary step in to enforce the regulation.[31] Accordingly, the DOI has a free hand to enforce the regulation based on the normal principles of legal interpretation.

As explained below, the DOI should exclude from the State's exchange any plan that discriminates against a health condition such as HIV/AIDS by providing poor coverage for HHS's preferred and alternative regimens. Under HHS regulations, insurers can use reasonable medical management techniques, but a technique is unreasonable—and thus must be prohibited—unless (1) it reduces unnecessary healthcare spending; and (2) it is comparable to, and is applied no more stringently than, the techniques applied to treatments for other conditions.

A. HIV/AIDS is a "Disability" or "Health Condition," and Thus is a Forbidden Criterion for Discrimination

Under 45 C.F.R. § 156.125, the forbidden criteria for discrimination are "an individual's age, expected length of life, *present or predicted disability*, degree of medical dependency, quality of life, or *other health conditions*."[32] "Disability" and similar terms such as "handicapped" are typically defined or interpreted to mean, at the very least, a physical or mental impairment that substantially limits one or more of the major life activities of such individual.[33]

To enforce this standard, the DOI should prohibit insurers from discriminating on the basis of whether an enrollee has HIV/AIDS. When applying this standard, courts—including the United States Supreme Court—have held that terms like "disability" and "handicap" include HIV/AIDS, even when a person with HIV is in the asymptomatic phase of the illness.[34] Even if there were any doubt as to whether HIV/AIDS was a "disability," it would obviously qualify under

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[30] Illinois State Partnership Exchange Blueprint Application, at pp. 9–10 (emphasis added).

[31] Fed. Register Vol. 78, No. 37 at 12846 (Feb. 25, 2013) (emphasis added).

[32] 45 C.F.R. § 156.125 (emphasis added).

[33] *Bragdon v. Abbott*, 524 U.S. 624, 630 (1998) ("disability"); *Chalk v. United States Dist. Ct.*, 840 F.2d 701, 704–09 (9th Cir. 1988) ("handicap").

[34] *E.g.*, *Bragdon*, 524 U.S. at 630–647 (1998) (ADA); *Doe v. County of Centre, Pa.*, 242 F.3d 437, 447 (3d Cir. 2001) (Rehabilitation Act); *Chalk v. United States Dist. Ct.*, 840 F.2d 701, 704–09 (9th Cir. 1988) (Rehabilitation Act).

the broader category of "other health conditions."[35] Thus, the HHS regulation clearly prohibits discrimination on the basis of whether an enrollee has HIV/AIDS.

B. Insurers Must Be Prohibited from Discriminating Against People with HIV/AIDS in How They Design Their Formularies and Pharmacy Networks

The DOI must prohibit insurers from discriminating against people with HIV/AIDS in how they design their formularies and pharmacy networks. Because it has been left undefined, "discrimination" should be interpreted according to its meaning in similar civil rights provisions.[36] "Discrimination" is typically interpreted to mean any form of "differential treatment" on the basis of a forbidden criterion, such as "disability."[37] Moreover, "discrimination" is usually interpreted to include not only intentional discrimination, but also unintentional discrimination, such as when an otherwise neutral rule actually or predictably results in discrimination or has a discriminatory effect: as noted by the United States Supreme Court, a rule against discrimination "would ring hollow" if it "could not rectify the harms resulting from action that discriminated *by effect* as by design."[38]

Additionally, the DOI's interpretation of "discrimination" should accord with the fundamental policy goal of the Affordable Care Act, which is to ensure that all Americans have access to affordable health insurance regardless of background or preexisting conditions. This policy has been aptly summarized by President Obama:

> Once states set up these health insurance marketplaces, known as exchanges, insurance companies will no longer be able to discriminate against any American with a preexisting health condition. They won't be able to charge you more just because you're a woman. They won't be able to bill you into bankruptcy. If you're sick, you'll finally have the same chance to get quality, affordable health care as everyone else.[39]

1. Discrimination in Formulary Design

To enforce the regulation, the DOI should interpret "discrimination" to include instances where carriers fail to cover a condition in accordance with the medical standard of care for treating that condition. Such discrimination is particularly clear in situations where insurers

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[35] 45 C.F.R. § 156.125(a).

[36] *Fitzgerald v. Barnstable Sch. Comm.*, 555 U.S. 246, 258–59 (2009) (holding that analogous language in similar civil rights laws should be interpreted consistently).

[37] *See Jackson v. Birmingham Bd. of Educ.*, 544 U.S. 167, 174 (2005) (quotes omitted); *Rene v. MGM Grand Hotel, Inc.*, 305 F.3d 1061, 1067 (9th Cir. 2002).

[38] *Alexander v. Choate*, 469 U.S. 287, 297–299 (1985) (emphasis added); *see also Hill v. Community of Damien of Molokai*, 911 P.2d 861, 872–74 (N.M. 1996) (explaining standard and holding that, if restrictive covenant could be enforced to exclude people with HIV/AIDS, then it would violate the federal Fair Housing Act due to its disparate impact on people with HIV/AIDS).

[39] President Barack Obama, *Remarks by the President on Supreme Court Ruling on the Affordable Care Act* (Jun. 28, 2012).

designate HHS's "preferred regimens" for treating HIV/AIDS as being "non-preferred" or "specialty" regimens.

As a preliminary point, insurers' poor coverage for HIV drugs disproportionately burdens a discrete class of individuals, people with HIV/AIDS. It is a fundamental principle of civil rights law that discrimination on the basis of something "closely correlated" with a protected class is discrimination against the protected class itself.[40] Here, using HIV drugs is "closely correlated" with HIV/AIDS: people affected by the condition must take the drugs to stay alive and generally do so as much as possible after being diagnosed with HIV, but very few people risk the potentially toxic side effects of HIV drugs unless they have or are at risk for HIV/AIDS.

In HHS's own words, the guidelines on the treatment of HIV/AIDS are designed to "[p]rovide guidance to HIV care practitioners on the optimal use of antiretroviral (ARV) agents for the treatment of HIV infection in adults and adolescents in the United States."[41] "These guidelines generally represent the state of knowledge regarding the use of ARV agents."[42] Thus, the HHS guidelines reflect "the state of knowledge" on the "optimal use" of HIV drugs.

Insurers disregard this medical consensus when they designate HHS's "preferred" and "alternative" regimens for treating HIV as "non-preferred" or "specialty" drugs on their formularies. Disregarding the medical consensus in this manner should be treated as *prima facie* proof of discrimination, because no reasonable insurer would completely disregard medical knowledge when making decisions over whether to designate drugs for conditions *other than HIV/AIDS* as "preferred," "non-preferred," or "specialty" on their formularies.[43] Unless an insurer admits that it has disregarded medical knowledge when deciding how to cover *all* drugs on its formulary, the insurer should not be permitted to cover HIV drugs in a way that disregards the medical consensus. Thus, if HHS has designated a treatment as a "preferred regimen," insurers should not be permitted to turn that recommendation on its head, listing the same treatment on its formulary as being a "non-preferred" or "specialty" drug.

No reasonable insurer would ever completely disregard medical knowledge when designing a formulary because this clearly violates the formulary design guidelines agreed on by many major health industry groups, the Principles of a Sound Drug Formulary System ("the Principles").[44] Insurers cannot ignore the medical consensus on HIV treatment because, under the Principles, formulary decisions must be "based on the strength of scientific evidence and

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[40] *See Lawrence v. Texas*, 539 U.S. 558, 583 (2003) (O'Connor, J., concurring) (holding that law against same-sex sodomy targeted "conduct that is closely correlated with being homosexual").

[41] HHS Guidelines at A-2.

[42] HHS Guidelines at A-1.

[43] *See* Principles of a Sound Drug Formulary System, at 2 (Oct. 2000) (stating in document endorsed by major pharmaceutical, medical, and insurance industry groups that "[f]ormulary system decisions" must be "based on *scientific* and economic considerations that achieve *appropriate*, *safe* and cost effective drug therapy") (emphasis added).

[44] *Id.* at 1 (endorsed by Academy of Managed Care Pharmacy, Alliance of Community Health Plans, the American Medical Association, the American Society of Health-System Pharmacists, the Department of Veterans Affairs, the National Business Coalition on Health, and the U.S. Pharmacopeia).

standards of practice," including "peer-reviewed medical literature" such as "randomized clinical trials (especially drug comparison studies), pharmacoeconomic studies, and outcomes research data."[45] According to the Principles, formularies should consider drugs as "preferred" if they promote adherence, as is the case with one-a-day pills: "[formulary designers should] [a]ssess[] the likely impact of a drug product on patient compliance when compared to alternative products."[46] Similarly, a formulary should not force patients to take less effective drugs or drugs with worse side effects, so that it is clearly unreasonable to designate HHS's preferred and alternative regimens as "non-preferred" and "specialty" drugs: "[formulary designers should] [c]ompar[e] the efficacy as well as the type and frequency of side effects . . . among alternative drug products."[47]

While the Principles allow insurers to incentivize enrollees to choose less expensive drugs, they are permitted to do so only among *equally effective* drugs: "[formulary designers should] bas[e] formulary system decisions on cost factors only after the safety, efficacy and therapeutic need have been established."[48] Indeed, according to the Principles, formulary decisions "that may interfere with the delivery of medically necessary care are unacceptable."[49]

Even if an insurer adequately covered only one of the three single-pill regimens, that would still be insufficient, because there are significant problems that many patients have with each of the one-a-day pills. For example, a recent study concluded that "[o]ne-fifth of all individuals commencing Atripla will need to switch therapy, often for adverse events," the commonest of which is toxicity to the patient's central nervous system.[50] As for Complera, it was introduced in 2012, and initial studies suggest that it may be less toxic than Atripla, though studies also suggest that Complera is less effective in people with high viral loads and may also be more prone to drug resistance.[51] Stribild also poses problems for many patients who

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[45] *Id.* at 2.

[46] *Id.*

[47] *Id.*

[48] *Id.*

[49] *Id.*

[50] Andrew Scourfield, *Discontinuation of Atripla as first-line therapy in HIV-1 infected individuals*, 26 AIDS 1399 (Jul. 2012); K.A. Lyseng-Williamson & L.J. Scott, *Emtricitabine/rilpivirine/tenofovir disoproxil fumarate single-tablet regimen: a guide to its use in HIV-1 infection*, 32 Clin. Drug. Investig. 715 (Oct. 2012) ("[Complera was] generally better tolerated than efavirenz plus emtricitabine/tenofovir disoproxil fumarate [i.e., Atripla]).")

[51] Test Positive Aware Network, *Complera* (retrieved Feb. 27, 2014) ("The advantages and disadvantages of Complera vs. Atripla are discussed elsewhere (see Edurant [which is a component drug in Complera]).."); Test Positive Aware Network, *Edurant* (retrieved Feb. 27, 2014) ("The combination of Edurant plus two NRTIs was shown to be better tolerated than Atripla in two large clinical trials. Overall results were similar, but Atripla was somewhat more effective in people with viral loads above 100,000, and there was more virologic failure and resistance, including cross-resistance to Intelence, in people who took Edurant. Current guidelines list Edurant-based regimens as 'alternatives' to the preferred regimens.").

experience severe liver damage or buildup of lactic acids in the bloodstream while taking the medication.[52]

Thus, insurers discriminate against people with HIV/AIDS by designating "preferred" and "alternative" HIV regimens as "non-preferred" or "specialty" drugs. As noted above, using the "preferred" and "alternative" regimens is closely correlated with the status of having HIV/AIDS, so that discriminating against these regimens is essentially the same thing as discriminating against people with HIV/AIDS. Because of this close correlation, designating "preferred" and "alternative" regimens as "non-preferred" or "specialty" should be considered as intentional discrimination that is illegal under 45 C.F.R. § 156.125. But even if these designations were considered as facially-neutral rules, they would have a clear disparate impact and thus would discriminate unintentionally in violation of 45 C.F.R. § 156.125. Either way, the insurers' poor coverage for "preferred" and "alternative" regimens is essentially the same thing as an illegal coverage cap for healthcare costs related to HIV/AIDS. Accordingly, the term "discrimination" under 45 C.F.R. § 156.125 should be interpreted to include instances where insurers designate HHS's "preferred" and "alternative" regimens as being "non-preferred" or "specialty" treatments.

2. Discrimination in Pharmacy Networks

The DOI should also prohibit insurers from discriminating against people with HIV/AIDS by refusing to provide equal coverage for HIV drugs purchased through state-contracted pharmacy benefits managers (PBM), such as the one working with the Illinois AIDS Drugs Assistance Program (ADAP). ADAP is administered by the Illinois Department of Public Health and provides assistance for out-of-pocket costs of state residents who satisfy the program's financial requirements.

To administer benefits, ADAP has a dispensing contract with a PBM, CVS Caremark. As ADAP's PBM, CVS Caremark enters into contracts with a network of pharmacies from which ADAP beneficiaries can buy their drugs. Though some insurers on the State's exchange also use CVS Caremark as their PBM, others use different PBMs (such as Medco Health Solutions) that have their own networks of pharmacies. Thus, ADAP beneficiaries are effectively shut out from enrolling in plans that do not use CVS Caremark as their PBM.

To end this discrimination, the DOI should require each plan to have an exception to its normal network rules for people who receive benefits from State programs like ADAP. Under this exception, plans would have to treat as in-network a pharmacy through which State drug dispensary programs provide their benefits. These programs' beneficiaries should not be penalized by their insurers for using pharmacies in the network of the State-contracted PBM, so that there would also be no additional out-of-network charges imposed on ADAP beneficiaries.

[52] Gilead Sciences, Inc., *Stribild FDA label* at 5.1 (Oct. 2013) ("Treatment with STRIBILD should be suspended in any patient who develops clinical or laboratory findings suggestive of lactic acidosis [buildup of lactic acids in the bloodstream] or pronounced hepatotoxicity [liver damage] . . . .").

C. Insurers Must Be Prohibited from Using Unreasonable Medical Management Techniques

Under HHS's anti-discrimination regulation, insurers are permitted to "appropriately utiliz[e] reasonable medical management techniques."[53] Though the anti-discrimination regulation does not define this phrase, it appears to be a term of art addressed by other HHS regulations. Based on such usage, the phrase should be interpreted as meaning techniques that (1) reduce unnecessary healthcare spending and (2) are comparable to, but applied no more stringently than, the medical management techniques applied to drugs for other conditions.

1. Reducing Unnecessary Healthcare Spending

HHS has previously used the phrase "reasonable medical management" in a regulation on the ACA's coverage for preventive services. Based on this usage, a "reasonable medical management technique" must refer to some sort of means for reducing unnecessary healthcare spending:

> **Reasonable medical management**. Nothing prevents a plan or issuer from using reasonable medical management techniques *to determine the frequency, method, treatment, or setting* for an item or service described in paragraph (a)(1) of this section [listing items insurers must cover] to the extent not specified in the recommendation or guideline.[54]

Though not a definition, this provision suggests that a "reasonable medical management technique" simply affects the "frequency, method, treatment, or setting" for an item or service, but without actually removing access to the item or service. Thus, "reasonable medical management" must result in a reduction of unnecessary healthcare spending.

To enforce this requirement, the DOI should prohibit insurers from requiring that enrollees use less effective HIV drugs before moving on to more effective drugs (i.e., "step therapy"), because such a requirement does not reduce unnecessary healthcare spending. As noted above, the standard of care for treating HIV/AIDS is to begin HAART therapy as soon as possible after diagnosis using a preferred regimen or, if necessary, an alternative regimen. If a patient fails to begin these regimens immediately, that gives the virus an opportunity to replicate rapidly and develop drug resistance. For similar reasons, patients should be prescribed the most convenient drugs as soon as possible after diagnosis, because even minor mistakes in adherence give HIV the opportunity to become drug resistant.

Similarly, the DOI should prohibit insurers from requiring an enrollee to get their pre-authorization for every refill of HIV drugs after the insurer has already approved the initial filling of the prescription and in the absence of any change to the enrollee's other prescriptions. HIV/AIDS is a chronic disease – until a cure is developed, virtually no one with HIV will stop

[53] 45 C.F.R. § 156.125.

[54] 45 C.F.R. § 147.130(a)(4) (emphasis added).

having HIV. Thus, there is no reasonable purpose for requiring pre-authorization for every refill, because the drugs never stop being medically necessary, so that these redundant pre-authorizations do nothing to reduce unnecessary healthcare costs. Moreover, redundant pre-authorizations are dangerous because drugs may be held up by late or incomplete paperwork or by the insurer's own delay, resulting in an interruption that increases the risk of the virus becoming drug resistant to the patient's regimen.

2. Comparability and Equality in Application

HHS has previously used the phrases "medical management standards" and "medical management techniques" in a regulation for the Mental Health Parity and Addiction Equity Act ("Parity Act").[55] These references suggest that, for "medical management techniques" to be "reasonable" and "appropriately utilize[d]," they must be comparable to, but applied no more stringently than, the techniques applied to drugs for other conditions.

The Parity Act is a statute that mandates coverage for mental health and substance abuse treatment in tax-deductible group health insurance plans.[56] Given that the statute deals with health insurance, the term's meaning in this context should closely approximate the meaning of the same term in the ACA.

Under the Parity Act regulation, insurers may not impose "medical management standards" to a covered "classification" of benefits for mental health or substance use disorders *unless* the following is true:

> [U]nder the terms of the plan (or health insurance coverage) as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying the [medical management standards] to mental health or substance use disorder benefits in the classification *are comparable to, and are applied no more stringently than*, the processes, strategies, evidentiary standards, or other factors used in applying the [medical management standards] with respect to medical/surgical benefits in the classification.[57]

In the regulation, HHS also applied this rule to a hypothetical factual situation where it referred to "medical management techniques" as including "pre-authorization," a practice where insurers refuse to provide certain benefits unless approved beforehand.[58] Under the hypothetical facts, HHS stated that the plan adequately covered the mandated treatment insofar as the applicable pre-authorization standards were "comparable to, and applied no more stringently than," the pre-authorization standards applied to other types of treatment.

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[55] *See* 45 C.F.R. § 146.136(c)(2)(i) & (c)(4)(iii), Example 8.

[56] *See* Pub. Law 110-343, Title V, Subtitle B, *codified at* Act 42 U.S.C. 300gg-1–5, 11–23, & 91–92.

[57] 45 C.F.R. § 146.136(c)(4)(ii)(A) (defining "medical management standards" as a "nonquantitative treatment limitation"); 45 C.F.R. § 146.136(c)(2)(i) (emphasis added) (rule for "nonquantitative treatment limitations"); *see also id.* (c)(4)(iii), Example 8.

[58] 45 C.F.R. § 146.136(c)(4)(iii), Example 8.

Similarly, here, insurers should not be permitted to use measures like redundant pre-authorizations and step therapy for HIV drugs unless such measures are comparable to and applied no more stringently than measures applied to drugs for other conditions. Moreover, the burden should be on insurers to prove that their measures satisfy this standard and to produce a summary of the medical management techniques for *all* drugs on its formulary. Insurers must bear this evidentiary burden because otherwise the DOI would have no way to compare the measures for a given type of drugs with the measures imposed on other types of drugs.

V. Findings from the Investigation of Insurer Discrimination

The AIDS Foundation of Chicago (AFC) has investigated the total out-of-pocket costs under several plans sold on the State's exchange for HHS's preferred regimens.[59] This investigation revealed that several insurers selling plans on the exchange discriminated against people with HIV/AIDS in how they designed their formularies.

One particularly egregious example of discriminatory benefit design comes from Coventry Health and Life Insurance Company and Coventry Health Care of Illinois (collectively, "Coventry"). On Coventry's formulary, all drugs in the preferred regimens were listed as tier 4 "specialty preferred" drugs or tier 5 "specialty non-preferred" drugs, the tiers of Coventry's formulary with the worst coverage.[60] Because all of these drugs are at Coventry's highest tiers, an enrollee prescribed with one of the preferred regimens would at best have to pay the full out-of-pocket costs until he or she exhausted the plan's deductible.[61] Even after exhausting the deductible, monthly out-of-pocket costs for preferred regimens ranged from $686.13 to $1,124.38.[62]

Another egregious example comes from Humana Health Plan, Inc. and Humana Insurance Company (collectively, "Humana"). Humana's formulary listed all drugs in the preferred regimens as tier 5 "specialty" drugs, the least covered category.[63] Thus, Humana's plans provided no coverage until the enrollee fully paid the deductible.[64] After exhausting the deductible, the monthly out-of-pocket costs for preferred regimens ranged from $721.24 to $1,542.76.[65]

Similarly troubling was the coverage provided by Health Alliance Medical Plans, Inc. ("Health Alliance"). Health Alliance's formulary had six tiers, from tier 1 (most preferred) to tier 6 (least preferred), and listed at least four of the drugs in the preferred regimens as being in tier 5 for "non-preferred specialty" drugs and the rest falling under tier 3 for "non-preferred brand

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[59] *See* AIDS Foundation of Chicago, *Cost of HIV Medications in the Illinois Health Insurance Marketplace* (Mar. 13, 2014).

[60] *Id.* at 6.

[61] *Id.*

[62] *Id.*

[63] *Id.* at 9–10.

[64] *Id.* at 9.

[65] *Id.* at 10.

drugs."[66] Included in the tier 5 listing were the two one-a-day pills in the list of preferred regimens (Atripla and Stribild).[67] Thus, in many of Health Alliance's plans, HIV+ enrollees had to pay the full cost of the drugs out-of-pocket until meeting the deductible, or otherwise had to pay out-of-pocket costs as high as $400 a month.[68]

One final example of discrimination comes from Aetna Life Insurance Company, Inc. ("Aetna"). Aetna provided inadequate coverage for the two one-a-day pills listed as preferred regimens, because it did not cover Stribild at all, so that out of pocket costs were $2,810.96 per month, and covered Atripla only as a "non-preferred drug[]."[69] Even for covered drugs, monthly out-of-pocket costs for preferred regimens ranged from $634.63 to $1,542.76.[70]

The discrimination by these insurers is apparent. With such high out-of-pocket costs, HIV+ individuals bear a severe financial burden unless they receive the protection the ACA promises. Moreover, even middle-income individuals with HIV may not be able to afford their HAART drugs or could risk months in which they have to skip treatment as they save up for their out-of-pocket costs. Such delays and interruptions needlessly increase the risks of drug resistance, immune system deterioration, and higher infection rates.

In contrast, other plans on the exchange showed that insurers could provide adequate coverage for people with HIV/AIDS. For example, plans provided by Blue Cross Blue Shield of Illinois ("BCBS") listed all preferred regimen drugs as being "preferred" treatments under its formulary.[71] Similarly, good coverage was generally provided by Land of Lincoln Mutual Health Insurance Company, Inc. ("Land of Lincoln"), which had a formulary that listed nearly all preferred regimen drugs as being "preferred."[72] However, Land of Lincoln did not cover Tivicay, a "preferred regimen" drug that the DOI should also require insurers to cover.[73]

During its investigation, the AFC also discovered that many insurers did not list their specialty formularies online, and that there was no simple way to compare different plans' coverage of various drugs. Indeed, it took an AFC staff member a full week of work to do the research on HIV/AIDS drugs that would need to be done by a person with HIV/AIDS who wants to compare coverage of different drugs under various plans. To solve this problem, we propose requiring insurers to list their specialty formularies online. We also encourage the DOI to create a website that allows users to look up which plans cover their prescribed drugs and make a side-by-side comparison of coverage for these plans, including actual prices that the user would pay at the pharmacy, similar to the website for Medicare Part D.

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[66] *Id.* at 7–8.

[67] *Id.* at 8.

[68] *Id.*

[69] *Id.* at 4.

[70] *Id.*

[71] *Id.* at 5.

[72] *Id.* at 11.

[73] *Id.*

VI. Conclusion

The DOI is the State's designated gatekeeper for deciding which plans are sold on the exchange. In this role, the DOI must exclude from the exchange any plans that discriminate against people with HIV/AIDS as a result of the insurer's design of formularies, pharmacy networks, or medical management techniques. Insurers cannot be allowed to provide unreasonably poor coverage for "preferred" and "alternative" HIV regimens by categorizing them in the "non-preferred" or "specialty" tiers of their formularies. Insurers also should be required to provide equal coverage for HIV drugs purchased through state-contracted PBMs. Finally, insurers should not be permitted to impose dangerous procedural burdens on patients, such as step therapy and redundant pre-authorizations. Thus, we recommend that the DOI make clear to insurers that it will exclude plans from the exchange that discriminate against people with HIV/AIDS in the ways described above, and we further recommend that the DOI actually exclude such plans if insurers fail to comply.

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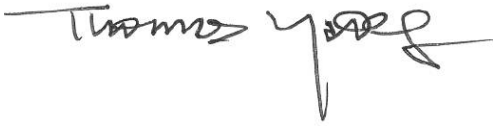
Again, we thank you for soliciting our input and for your continued interest in addressing discrimination by health insurers against people with HIV/AIDS. Should you have any questions or wish to discuss these matters, please feel free to contact either the AFC or ALCC. At the AFC, please feel free to call 312-334-0921 to reach John Peller, the AFC's Interim President/CEO. As for the ALCC, please call 312-427-8990 to reach the ALCC's new Executive Director, Tom Yates, or its Senior Attorney, Ruth Edwards.

Sincerely,



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