The Affordable Care Act's Unfulfilled Promises for People Living with HIV

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Abstract

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At long last, the Affordable Care Act has ended health insurance discrimination that targets people living with HIV. This concludes thirty-four years of discriminatory tactics that barred HIV-positive individuals from health plans at worst and provided meager coverage at best. The nondiscrimination requirements of the Act are unmistakable and aimed at insurance practices that would keep HIV-positive people from coverage. No longer can issuers exclude individuals on the basis of pre-existing conditions or impose dollar limits on coverage. No longer can issuers narrow their plan networks to exclude HIV care specialists. Gone are exorbitant out-of-pocket costs for vital HIV therapy. Gone are the holes in existing civil rights laws where insurance contacts could hide.

But real change can only come through meaningful implementation of the sweeping promises of the Act, which must be translated into concrete rules that bind issuers selling plans in the health insurance exchanges. Only then can we proclaim that HIV-specific insurance discrimination is a relic of the past and that health insurance reform is a success.

Regrettably, implementation of the Act has been anemic, irreconcilable, or non-existent. Health insurance issuers have easily exploited the agency's regulatory missteps to continue to exclude HIV care specialists from networks and impose the highest cost-sharing on drugs that treat HIV. Moreover, health insurance issuers can refuse to cover highly effective preventive drugs that reduce the number of new HIV infections in populations at risk. Lackluster implementation means that issuers have barely missed a

step in discriminating against HIV-positive individuals, almost as if health insurance reform never happened.

It is not too late. The Department of Health and Human Services can still make good on the Act's promises by overhauling agency regulations concerning HIV care specialists and essential prescription drugs. Most importantly, the agency can stop present and future HIV-specific discrimination by implementing the Act's nondiscrimination provision, the strongest nondiscrimination law that health insurance has ever seen. Health insurance reform will be judged by whether it helps those who need it most. Without action, that judgment will be harsh indeed.

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I. INTRODUCTION

In the thirty-four years since the Centers for Disease Control and Prevention (CDC) first reported on the mysterious condition that came to be known as HIV/AIDS,[1] the federal government's response has gone from silence[2] and outright hostility[3] to compassion and action.[4] Nowhere was action needed more than in health insurance, where HIV-positive individuals had been consistently discriminated against in plan enrollment and in the scope of coverage.

With an awareness of this shameful history, Congress passed the Affordable Care Act,[5] which is full of promise for ending insurance discrimination that targets HIV-positive individuals. Congress ended the discriminatory techniques that health insurance issuers[6] have historically used to exclude HIV-positive individuals from the insurance

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[1] Ronald O. Valdiserri, *Thirty Years of AIDS in America: A Story of Infinite Hope*. 23 AIDS EDUC & PREVENTION 479, 479 (2011).

[2] Allen White, *Reagan's AIDS Legacy/ Silence Equals Death*, S.F. GATE, June 8, 2004, http://www.sfgate.com/opinion/openforum/article/Reagan-s-AIDS-Legacy-Silence-equals-death-2751030.php.

[3] S. Poverty L. Ctr., *History of the Anti-Gay Movement Since 1977*, 117 INTELL. REP. (2005), *available at* http://www.splcenter.org/get-informed/intelligence-report/browse-all-issues/2005/spring/the-thirty-years-war (quoting President Reagan's press secretary, Pat Buchanan, describing AIDS as "nature's revenge on gay men.")

[4] WHITE HOUSE, NATIONAL HIV/AIDS STRATEGY FOR THE UNITED STATES (2010), *available at* http://www.whitehouse.gov/sites/default/files/uploads/NHAS.pdf (outlining the Obama Administration's strategy for HIV/AIDS prevention and treatment) [hereinafter, NATIONAL HIV/AIDS STRATEGY]. *See also* Eugene Robinson, *George W. Bush's Greatest Legacy – His Battle Against AIDS*, WASH. POST, July 26, 2012, http://www.washingtonpost.com/opinions/eugene-robinson-george-w-bushs-greatest-legacy--his-battle-against-aids/2012/07/26/gJQAumGKCX_story.html.

[5] Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) and the Health Care and Education Reconciliation Act, Pub. L. No. 111-152, 124 Stat. 1029 (2010) [together, the Affordable Care Act or the Act].

[6] This thesis uses the term "health insurance issuer" or "issuer" as defined in the Public Health Service Act: "an insurance company, insurance service, or insurance organization (including a health maintenance organization...) which is licensed to engage in the business of insurance in a state and which is subject to state law which regulates

market or to limit their coverage through discriminatory benefit design.[7] The Act requires plans to include HIV care specialists in networks and cover essential health benefits, including prescription drugs and preventive services.[8] Indeed, as the Obama Administration wrote in the same year as the passage of the Affordable Care Act: "unless we take bold actions … we anticipate a new era of rising infections and even greater challenges serving people living with HIV."[9]

The way in which health insurance reform helps HIV-positive individuals can act as a sentinel for whether health reform is working, by asking: are those who have historically been denied insurance and discriminated against in coverage now protected?

The answer is no. This is a travesty for HIV-positive individuals and a bad omen for health reform. The Department of Health and Human Services (HHS) has failed to effectively implement the Affordable Care Act, despite such promise. The result has so weakened the force of the Act that, even in the first years of implementation, health insurance issuers can, and will, continue to discriminate against HIV-positive people in the individual and small-group markets.[10] Under the agency's regulations, health insurance issuers can use narrow networks to exclude HIV care specialists, thus discouraging HIV-positive individuals from enrolling, and issuers can levy exorbitant

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insurance." Affordable Care Act, Pub. L. No. 111-148, § 1551, 124 Stat. 264 (2010) (codified as amended at 42 U.S.C. § 300gg-91(b)(2) (2012)).

[7] *See infra* Part III.

[8] *See id*.

[9] NATIONAL HIV/AIDS STRATEGY, *supra* note 4, at 1.

[10] Although many HIV-positive individuals obtain health insurance coverage through Medicaid, Medicare, or employer-sponsored plans, these forms of coverage are outside the scope of this thesis.

cost-sharing requirements, even for the generic versions of HIV drugs. Health insurance issuers can choose not to cover drugs proven to reduce the risk of HIV infection.[11]

HIV is an expensive condition to treat, and HIV-positive individuals are dependent on medication and specialty providers. But near-sighted arguments against meaningful reform ignore the Act's unmistakable nondiscrimination requirements, and the very nature of HIV, which is better controlled when those affected are retained in care, and when prophylaxes are accessible to those at risk.[12]

Health reform that fails HIV-positive individuals has simply failed. But HHS can start now to fulfill the Act's promises, by revising its regulations to require issuers to include HIV care specialists in their plan networks, prohibit discriminatory drug tiering, and make HIV prophylaxes available without, or with limited, cost sharing.[13] The Affordable Care Act made big promises to people living with HIV and people at risk. It is time to fulfill them.

This thesis is divided into several parts. Part II describes HIV, a long-term condition that is treatable and preventable, and highlights the struggles in preventing new cases of HIV, despite the widespread use of drug therapy that is proven effective in preventing its spread. Part III outlines the history of health insurance in the United States, focusing on the ways in which the federal government's hands-off approach to insurance regulation has allowed issuers to avoid covering the most expensive conditions, despite the obvious long-term advantages. This Part highlights the historical discrimination against HIV-positive individuals in insurance, and shows how the Affordable Care Act

[11] *See infra* Part IV.
[12] *See infra* Part II.
[13] *See infra* Part V.

banned these practices. Part IV discusses the ways in which HHS has failed to enforce the Act by promulgating weak rules that allow condition-specific discrimination to continue. Finally, Part V argues for an overhaul of the agency's regulations to target the discriminatory practices that keep HIV-positive individuals from accessing care that is not only vital to their health, but also necessary to prevent new cases, and meaningful implementation of the Act's broad nondiscrimination provision.

II. HIV

An estimated 1.2 million people are living with HIV in the United States.[14] There are about 50,000 new HIV infections each year,[15] demonstrating a failure in the country's attempts to control the disease, despite universal screening, the efficacy of treatment as prevention, and the availability of pre- and post-exposure prophylaxes. This Part begins with the features of HIV and who it most affects; it then discusses how the prevention of future cases largely depends on the treatment of those currently infected. Next, this Part considers the linked concepts of treatment and prevention, and the factors contributing to the failures of both. This Part concludes with a discussion of the Obama Administration's National HIV/AIDS Strategy, which makes HIV treatment and prevention national priorities.

A. The Pathology of HIV/AIDS

[14] Heather Bradley et al., *Vital Signs: HIV Diagnosis, Care, and Treatment Among Persons Living with HIV—United States, 2011*. 63 MORBIDITY & MORTALITY WEEKLY REP. 1113, 1113 (2014).
[15] CDC, *Diagnoses of HIV Infection in the United States and Dependent Areas, 2012*, 24 HIV SURVEILLANCE REP. Tab.1a (2014). More than a quarter of new HIV infections are among people ages 13-24. *HIV/AIDS: Basic Statistics*, CDC, http://www.cdc.gov/hiv/basics/statistics.html (last visited Apr. 15, 2015).

HIV is incurable.[16] Infection occurs through human-to-human contact by means of bodily fluids including blood, vaginal secretions, and semen.[17] Men who have sex with men and injection drug users are at greatest risk.[18] HIV in the United States has a transmission rate of about five, meaning that, for every 100 HIV-positive people living in the United States, there will be five new HIV infections every year.[19]

HIV targets a person's immune system, specifically his CD4 T-cell lymphocytes (CD4 cells), which normally allow his immune system to fight disease.[20] Experts

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[16] *HIV/AIDS: About HIV/AIDS*, CDC, http://www.cdc.gov/hiv/basics/whatishiv.html (last visited Apr. 8, 2015).
[17] *Id.*
[18] *HIV/AIDS: HIV Transmission Risk*, CDC, http://www.cdc.gov/hiv/policies/law/risk.html (last visited Apr. 8, 2015).
[19] David M. Holtgrave, *Is the Elimination of HIV Infection Within Reach in the United States? Lessons from an Epidemiologic Transmission Model*,125 PUBLIC HEALTH REP. 372, 373 (2010). This rate is based on the assumption that 21% of HIV-positive people do not know they are infected. *Id.* at 374. The transmission rate is a variation of a basic reproductive rate. *Id.* at 373. The basic reproductive rate is an estimate of how many new infections will occur in an entirely susceptible population when one person is infectious. J.M. Heffernan et al., *Perspectives on the Basic Reproductive Ratio*, 2 J. ROYAL SOC'Y INTERFACE 281, 281-82 (2005). The reproductive rate is indicative of how dangerous a disease is to a population, that is, whether the disease will become an epidemic. If the reproductive rate is above 1, this means that there will be at least one new case of the disease in the population (and the higher the reproductive rate, the more new infections there will be, and the greater likelihood of the disease reaching epidemic levels). *Id.* The transmission rate is an annualized reproductive rate, meaning that it is only the reproductive rate for one year. Holtgrave, *supra*, at 373.
[20] *CD4 Count*, AIDS.GOV, https://www.aids.gov/hiv-aids-basics/just-diagnosed-with-hiv-aids/understand-your-test-results/cd4-count/ (last visited Apr. 8, 2015). The virus attacks the CD4 cells and uses these cells to copy the virus. *Id.*

consider the number of CD4 cells[21] and the viral load, or presence of HIV in a person's blood, as important indicators of immune health.[22]

There are three stages of HIV infection: acute infection, clinical latency, and AIDS, although not everyone who has HIV will progress to AIDS.[23] A person with HIV infection is most infectious in the first stage, and may not know that he is infected because symptoms of early HIV infection often resemble influenza or another common, treatable illness.[24] In the second stage, also known as asymptomatic or chronic HIV infection, a person may have no symptoms at all, and this stage lasts for an average of ten years for a person who is not in treatment.[25] The final stage, AIDS, is defined as a CD4 cell count of less than 200 cells/mm,[3] or when a person presents opportunistic illnesses[26] that affect the brain, respiratory system or other organs.[27]

B. The Demographics

Since the first reported cases of the disease that would come to be known as HIV/AIDS, over half a million people have died of HIV/AIDS-related causes in the

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[21] U.S. DEP'T OF HEALTH AND HUMAN SVCS., GUIDELINES FOR THE USE OF ANTIRETROVIRAL AGENTS IN HIV-1-INFECTED ADULTS AND ADOLESCENTS C-6 (2014), *available at* http://aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf [hereinafter, HHS GUIDELINES].

[22] *Viral Load,* AIDS.GOV, https://aids.gov/hiv-aids-basics/just-diagnosed-with-hiv-aids/understand-your-test-results/viral-load/ (last visited Apr. 12, 2015).

[23] *Stages of HIV Infection,* AIDS.GOV, https://www.aids.gov/hiv-aids-basics/just-diagnosed-with-hiv-aids/hiv-in-your-body/stages-of-hiv/ (last visited Apr. 12, 2015).

[24] *Id.* A person in the last stages of HIV is also more infectious than in the middle stage, but not as infectious as in the first stage. T. Déirdre Hollingsworth et al., *HIV-1 Transmission, by Stage of Infection*, 198 J. INFECTIOUS DISEASES 689, 690 (2008).

[25] *Stages of HIV Infection*, *supra* note 23.

[26] *Id*. A normal CD4 range is between 500-1,600 cells/mm.[3] *Id.*

[27] *HIV/AIDS: Opportunistic Infections*, CDC, http://www.cdc.gov/hiv/basics/livingwithhiv/opportunisticinfections.html (last visited Apr. 12, 2015).

United States alone.[28] An estimated 291.5 people per 100,000 have been diagnosed with HIV,[29] but HIV has reached generalized epidemic proportions in urban impoverished areas, where the CDC estimate that 2,070 people per 100,000 have been diagnosed.[30] HIV disproportionately burdens African-Americans and men who have sex with men: 41% of HIV-positive people are African-American, and 63% of HIV-positive people are men of all races who have sex with men.[31] Further, forty-four percent of HIV-positive non-elderly adults were living in poverty in 2009,[32] more than double the national rate.[33] More than half of all HIV-positive individuals are homeless or lack stable housing.[34]

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[28] Valdiserri, *supra* note 1, at 479.

[29] CDC, *Diagnoses of HIV Infection in the United States, 2013,* 25 HIV SURVEILLANCE REP. 9 (2015).

[30] Paul Denning & Elizabeth DiNenno, *Communities in Crisis: Is There A Generalized HIV Epidemic in Impoverished Urban Areas of the United States?* CDC poster, *available at* http://www.cdc.gov/hiv/risk/other/poverty.html (last visited April 9, 2015). A generalized HIV epidemic is defined as an HIV rate exceeding one percent of the population. *Id.* In this study, the researchers found that, of the 9,078 study enrollees that met the analysis criteria below, 188 were HIV-positive, or 2.1% of the population. *Id.* The analysis criteria were: individuals between the ages of 18 and 50 years old who had at least one opposite-gender partner in the past year and lived in one of 23 cities with a poverty area, defined as a Census tract where 20% or more of the residents had incomes below the U.S. poverty level. *Id.*

[31] Bradley et al., *supra* note 14, at 1115. In the United States, men represent seventy-seven percent of HIV cases. *Id*. This is in contrast to sub-Saharan Africa, where women represent fifty-eight percent of HIV cases. Joint United Nations Programme on HIV/AIDS, *Fact Sheet: Global Statistics*, http://www.unaids.org/en/resources/campaigns/2014/2014gapreport/factsheet (last visited April 8, 2015).

[32] Jennifer Kates et al., *Assessing the Impact of the Affordable Care Act on Health Insurance Coverage of People with HIV*, KAISER FAMILY FOUND. 6 (2014) [hereinafter, Kates et al., *Assessing the Impact*].

[33] Carmen DeNavas-Walt, *Income, Poverty, and Health Insurance Coverage in the United States: 2009*, U.S. Census Bureau 1, fig.5 (2010). It should be noted that the U.S. Census figure is slightly more than 100% FPL in 2009 ($11,161 per year as compared to $10,830 per year). *Id.* at 55. Also, the U.S. Census figure does not exclude HIV-positive non-elderly adults.

[34] The North American Housing & HIV/AIDS Research Summit, Breaking the Link Between Homelessness and HIV (2011), *available at* http://www.pshp.ca/documents/fact-sheets/2011-NAHC-Housing-HIV.pdf.

Data on health insurance before the Affordable Care Act show that the majority of HIV-positive, non-elderly adults in care were enrolled in Medicaid, which provides health coverage to low-income, eligible adults.[35] Approximately one-third had private insurance, and 6% were enrolled in Medicare.[36] Seventeen percent were uninsured.[37] After the Affordable Care Act, the Kaiser Family Foundation estimated that 96% of the 70,000 HIV-positive uninsured would be eligible for Medicaid or for subsidies to purchase a plan on an exchange.[38] Because not all states expanded Medicaid, only about 27,000 additional HIV-positive people are newly eligible for Medicaid.[39] About 15,000 HIV-positive individuals in care live in states that did not expand Medicaid and are not eligible for subsidies.[40]

C. Essential Elements of HIV Treatment and Prevention

HIV is both preventable and treatable, and indeed, the two are linked: adherence to HIV drug therapy reduces the risk of transmission to others.[41] However, a startling number of HIV-positive people are not in care, and many do not know that they are infected. New HIV infections continue without abatement. Recognition of these shortcomings, and that HIV can be better controlled if HIV-positive people are engaged

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[35] Jennifer Kates, *Medicaid and HIV: A National Analysis*, KAISER FAMILY FOUND. 3-4 (2011) [hereinafter, Kates, *Medicaid and HIV*].
[36] Kates et al., *Assessing the Impact*, *supra* note 32, at 6.
[37] *Id.*
[38] *Id.* at 7.
[39] *Id.* at tbl.3. About 43% of the HIV-positive population lives in a state that did not expand Medicaid. *Id. See also* Jonathan Capehart, *States Not Expanding Medicaid Hobble the Fight Against HIV/AIDS*, WASH. POST, Oct. 6, 2014, http://www.washingtonpost.com/blogs/post-partisan/wp/2014/10/06/states-not-expanding-medicaid-hobble-the-fight-against-hivaids/.
[40] Kates et al., *Assessing the Impact*, *supra* note 32, at Fig.5. For a discussion of health insurance under the Affordable Care Act, *see* Part III.B.
[41] Steven G. Deeks et al., *The End of AIDS: HIV Infection as a Chronic Disease*, 382 LANCET 1525, 1525 (2013).

in care, has motivated national health policy, in the form of the Obama Administration's National HIV/AIDS Strategy.

1. Effective Treatment is Available, But Does Not Reach Many

For a person infected with HIV, the advent of anti-retroviral therapy, or ART, has revolutionized HIV treatment.[42] ART is responsible for significant reductions in HIV-associated illness and death, and transformed HIV from a death sentence to a chronic-like illness, allowing HIV-positive individuals to lead normal, healthy lives.[43] An HIV-positive 20 year-old who begins ART soon after diagnosis and adheres to the regimen can expect to live into their early 70s, near the life expectancy of a 20 year-old without HIV.[44]

ART prevents HIV from multiplying in an infected person's body, thus impeding damage to their immune system that the virus would do if left alone.[45] Experts recommend that an HIV-positive person take combined ART, defined as three or more anti-retroviral drugs from two or more different drug classes.[46] The CDC recommends that all HIV-positive patients receive ART, particularly individuals with a CD4 cell count between 350-500 cells/mm.[3] [47] Nearly all HIV drugs are available in generic form.[48]

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[42] *Id.*
[43] *Id.*
[44] Hasina Samji et al., *Closing the Gap: Increases in Life Expectancy among Treated HIV-Positive Individuals in the United States and Canada*, 8 PLOS ONE 1, 5 (2013).
[45] Deeks, *supra* note 41, at 1526.
[46] Virginia A. Moyer, U.S. Preventive Services Task Force, *Screening for HIV: U.S. Preventive Services Task Force Recommendation Statement*, 159 ANN. INTERNAL MED. 51, 53-4 (2013). Combination ART is available in a single-dose pill. *Overview of HIV Treatment,* AIDS.GOV, https://www.aids.gov/hiv-aids-basics/just-diagnosed-with-hiv-aids/treatment-options/overview-of-hiv-treatments/ (last visited Apr. 12, 2015).
[47] HHS GUIDELINES, *supra* note 21, at E-3.

There are drawbacks. An HIV-positive individual has to take medication consistently, usually at least once a day,[49] for the rest of their life. Some medications cannot be taken together,[50] should not be taken by individuals just starting drug therapy,[51] or must be taken with food.[52] Failing to adhere to the ART regimen can result in a reduced CD4 cell count, an increased viral load,[53] and potential drug resistance.[54] But even if a person adheres to the drug regime, there could be other outcomes, including kidney damage, inflammation and the redistribution of body fat.[55] HIV-positive individuals on ART have an increased risk of heart attack, as compared to HIV-negative adults.[56] Some experts question whether HIV accelerates the aging process, perhaps due to inflammation associated with the use of ART.[57] Further, the health effects of an ART regime for certain populations are still unknown.[58]

Next, HIV care is expensive. In a recent study, researchers estimate that the lifetime medical cost of HIV treatment for an individual infected with HIV at age 35 is

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[48] *HIV Treatment: FDA-Approved HIV Medicines*, AIDSINFO, *avavailable at* http://aidsinfo.nih.gov/education-materials/fact-sheets/21/58/fda-approved-hiv-medicines (last visited Apr. 29, 2015).
[49] *See* HHS GUIDELINES, *supra* note 21, at F-1-5 (discussing ART regimens for HIV-positive individuals beginning treatment).
[50] *Id.* at Tab.10.
[51] *Id.* at Tab.9.
[52] *Id.* at Tab.8 (outlining advantages and disadvantages of medications recommended as initial ART).
[53] *Id.* at H-1-3.
[54] *Id.* at E-5.
[55] Deeks et al., *supra* note 41, at 1526-27.
[56] *Id.* at 1526.
[57] *Id.* at 1528-29.
[58] *Id.* at 1529. The authors discuss the use of ART by pregnant women to prevent perinatal transmission, and find that "future research will need to assess whether to exposure to these drugs affects health even as they prevent infection."

$326,500.[59] Sixty percent of that cost is attributable to the ART regimen, 15% for chronic disease medication, opportunistic illness treatment and prophylaxis, and the remaining 25% for non-drug costs, such as hospitalization.[60] This figure does not include non-medical costs, such as lost productivity.[61]

An HIV-positive individual is expected to see an HIV care specialist twice a year.[62] HIV specialists may be trained as infectious disease specialists, or may be primary care physicians who have HIV-positive patient experience and who complete continuing medical education specifically concerning HIV.[63] HIV specialists can provide counseling on behavioral risk factors and diagnosis and treatment of other conditions, such as sexually transmitted infections,[64] and common co-morbidities, such as tuberculosis[65] and

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[59] Bruce R. Schackman et al., *The Lifetime Medical Cost Savings from Preventing HIV in the United States*, 53 MED. CARE 293, 295 (2015). The average lifetime medical cost for a 35-year-old who is not HIV-positive is $96,700. *Id.* at 297. For HIV-positive individuals, lifetime medical costs range from $267,100 to $435,200, depending upon level of care. *Id.* at Tab.2.

[60] *Id.* at 294-97.

[61] *Id.* at 299.

[62] NATIONAL HIV/AIDS STRATEGY, *supra* note 4, at 21. *See also* Joel E. Gallant et al., *Essential Components of Effective HIV Care: A Policy Paper of the HIV Medicine Association of the Infectious Diseases Society of America and the Ryan White Medical Providers Coalition*, 53 CLINICAL INFECTIOUS DISEASES 1043, 1046 (describing regular visits to an HIV provider as every 3 to 6 months).

[63] Gallant et al., *supra* note 63, at 1045. The authors note that HIV providers are not recognized as a specialty board designation, but some HIV medical groups have recommended guidelines for identifying HIV providers, such as the number of continuing medical education hours in HIV and number of HIV-positive patients. *Id.*

[64] H. Irene Hall, et al., *Differences in Human Immunodeficiency Virus Care and Treatment Among Subpopulations in the United States*, 173 J. AM. MED. ASS'N 1337, 1338 (2013).

[65] *TB & HIV Coinfection*, CDC, http://www.cdc.gov/tb/topic/TBHIV coinfection/default.htm (last visited April 14, 2015).

hepatitis C.[66] In a recent Kaiser Family Foundation survey, HIV-positive individuals reported that HIV care specialists are "critical" to obtaining quality care.[67]

Intangibles also make HIV specialists critical. HIV-positive individuals "who trust their medical providers have better medication adherence rates and are more likely to accept treatment recommendations."[68] A trust relationship between an HIV-positive individual and their HIV care specialist is crucial because the majority of HIV-positive individuals have reported discrimination in their interactions with the health care system.[69] Unfortunately, there are not enough clinicians who are HIV specialists, and so primary care physicians may need to consult with HIV specialists to provide effective treatment to their patients via alternate means, such as through telemedicine.[70]

Social factors may act as barriers to effective HIV treatment. Many HIV-positive individuals struggle with substance abuse and mental illness.[71] HIV-positive individuals are at increased risk of homelessness, and are less likely to adhere to treatment if homeless.[72] In addition, poverty, unemployment and lack of transportation may make it

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[66] Deeks et al., *supra* note 41, at 1526.
[67] Jennifer Kates & Lindsey Dawson, *Health Insurance Coverage for People with HIV Under the Affordable Care Act: Experiences in Five States* 6 (KAISER FAMILY FOUND. 2014).
[68] Gallant et al., *supra* note 63, at 1046. *See also* Kates & Dawson, *supra* note 67, at 6 (reporting that, for HIV-positive individuals, "a relationship with their doctor is important to build a level of trust.")
[69] LAMBDA LEGAL, WHEN HEALTH CARE ISN'T CARING: LAMBDA LEGAL'S SURVEY OF DISCRIMINATION AGAINST LGBT PEOPLE AND PEOPLE WITH HIV 9-10 (2010). Those surveyed reported one or more types of discrimination: "being refused needed care; health care professionals refusing to touch them or using excessive precautions; health care professionals using harsh or abusive language; being blamed for their health status; or health care professionals being physically rough or abusive." *Id.*
[70] Gallant et al., *supra* note 63, at 1046.
[71] NATIONAL HIV/AIDS STRATEGY, *supra* note 4, at 22.
[72] The North American Housing & HIV/AIDS Research Summit, Breaking the Link Between Homelessness and HIV (2011), *available at* http://www.pshp.ca/documents

difficult for HIV-positive individuals to maintain treatment and regularly visit a clinician.[73] Those without insurance, or with insufficient insurance, simply may not be able to engage in care if they cannot afford the doctor's visits or the drug therapy.[74]

In sum, ART is now widely available and effective, and HIV specialists can ensure treatment options that will enable HIV-positive individuals to lead healthy, normal lives.[75] However, there are high medical costs associated with HIV,[76] HIV specialists are in short supply,[77] and drug adherence can be complicated by medical and social factors.[78] For some or all of these reasons, less than half of all HIV-positive individuals in the United States are engaged in care, and only about 30% of HIV-positive individuals are virally suppressed.[79]

2. Prevention is Possible, But New Infections Persist

Treatment is a highly effective means of preventing HIV transmission, giving rise to the common mantra "treatment as prevention" among HIV experts.[80] When used consistently, ART is 96% effective in preventing the transmission of HIV to an HIV-

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/fact-sheets/2011-NAHC-Housing-HIV.pdf.

[73] NATIONAL HIV/AIDS STRATEGY, *supra* note 4, at 22.

[74] Edward M. Gardner et al., *The Spectrum of Engagement in HIV Care and its Relevance to Test-and-Treat Strategies for Prevention of HIV Infection*, 52 CLINICAL INFECTIOUS DISEASES 797 (2011) (noting the need for more data on the role that insurance plays in engagement in HIV care).

[75] Deeks et al., *supra* note 41, at 1525.

[76] Schackman et al., *supra* note 59, at 295.

[77] Gallant et al., *supra* note 63, at 1046.

[78] *See, e.g.,* NATIONAL HIV/AIDS STRATEGY, *supra* note 4, at 22.

[79] Bradley et al., *supra* note 14, at Tab.1.

[80] Lancet, Editorial, *Treatment as Prevention—It Works*, 377 LANCET 1719, 1719 (2011). *See also Treatment is Prevention*, AVERT.ORG, http://www.avert.org/hiv-treatment-as-prevention.htm (last visited Apr. 14, 2015) (discussing benefits of treatment in preventing new HIV infection).

negative partner.[81] According to one study, the use of ART prevented approximately 13,500 new HIV infections from 1996 to 2009.[82] In addition, condoms are also effective in preventing HIV transmission during sex.[83] Likewise, injection drug users reduce their risk when they do not share needles.[84]

HIV screening can prevent new infection, because people who are unaware of their HIV status may continue to engage in risky behaviors that allow the virus to spread.[85] The U.S. Preventive Services Task Force recommends that everyone ages 15 to 65 be screened for HIV, as well pregnant woman and younger and older people with increased risk factors.[86]

There are also pharmacological interventions that reduce the risk of infection before exposure (pre-exposure prophylaxis, or PrEP),[87] or after exposure (post-exposure prophylaxis, or PEP).[88] First, PrEP is a combination pill containing two anti-retroviral drugs, tenofovir disoproxil fumarate and emtricitabine (TDF/FTC), that prevents HIV

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[81] Myron S. Cohen et al., *Prevention of HIV-1 Infection with Early Antiretroviral Therapy*. 295 N ENG. J. MED. 499, 499 (2011).
[82] Dana P. Goldman et al., *Early HIV Treatment In The United States Prevented Nearly 13,500 Infections Per Year During 1996-2009*, 33 HEALTH AFFAIRS 362, 364-65 (2014).
[83] *Lower Your Sexual Risk of HIV*, AIDS.GOV, https://www.aids.gov/hiv-aids-basics/prevention/reduce-your-risk/sexual-risk-factors/ (last visited Apr. 14, 2015).
[84] *Substance Abuse/Use*, AIDS.GOV, https://www.aids.gov/hiv-aids-basics/prevention/reduce-your-risk/substance-abuse-use/ (last visited Apr. 14, 2015).
[85] NATIONAL HIV/AIDS STRATEGY, *supra* note 4, at 7.
[86] Moyer, supra note 46, at 53.
[87] *HIV/AIDS: Pre-Exposure Prophylaxis (PrEP)*, CDC, http://www.cdc.gov/hiv/prevention/research/prep/ (last visited Apr.14, 2015).
[88] *Post-Exposure Prophylaxis*, AIDS.GOV, https://www.aids.gov/hiv-aids-basics/prevention/reduce-your-risk/post-exposure-prophylaxis/ (last visited Apr. 14, 2015).

transmission.[89] PrEP must be taken every day and requires HIV testing every three months.[90]

In a randomized clinical trial, researchers found that PrEP resulted in a 92% reduction in the risk of acquiring HIV in those who took the drug consistently.[91] In a study of heterosexual couples in which one partner was HIV-negative and the other partner was HIV-positive in Kenya and Uganda,[92] the use of TDF/FTC reduced the risk of HIV infection by 90% for those who took the drug consistently.[93] In each of these studies, there was a strong correlation between efficacy and risk reduction; in other words, if individuals do not take PrEP regularly, the protective benefit drops substantially.[94]

In 2012, the U.S. Food and Drug Administration approved once-daily, orally-administered Truvada, the brand name of TDF/FTC, for individuals at high risk of HIV infection.[95] Truvada costs about $1,000 to $1,300 a month, not including doctor visits and

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[89] *HIV/AIDS: Pre-Exposure Prophylaxis (PrEP)*, CDC, *supra* note 87.
[90] *Id.*
[91] Robert M. Grant et al., *Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men*, 363 N. ENG. J. MED. 2587, 2596-97 (2010). Study subjects were men and transgender women who have sex with men. *Id.* at 2587.
[92] Jared Baeten et al., *Antiretroviral Prophylaxis for HIV Prevention in Heterosexual Men and Women*, 367 N. ENG. J. MED. 399, 400 (2012).
[93] *Id.* at 405. Studies conducted abroad have tested the efficacy of TDF alone. *See id.* at 400. Although TDF is sold in the United States under the trade name Viread, the FDA has not approved its use as PrEP. U.S. PUBLIC HEALTH SERVICE, CLINICAL GUIDELINES, PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES – 2014 9 (CDC, 2014) [hereinafter PREP GUIDELINES].
[94] Grant et al., *supra* note 91, at 2,594 (44% protective benefit); Beaten et al., *supra* note 92, at 407 (75% protective benefit).
[95] Press Release, U.S. Food & Drug Administration, FDA Approves First Drug for Reducing the Risk of Sexually Acquired HIV Infection (July 16, 2012), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm312210.htm.

lab work,[96] although Truvada's manufacturer, Gilead Sciences, Inc., offers payment assistance.[97] In May 2014, the U.S. Public Health Service published guidelines for the use of PrEP for high-risk individuals.[98]

In addition, individuals who believe that they were exposed to HIV have the option of taking PEP, a "scientifically proven biomedical … approach" to reduce the likelihood of HIV infection.[99] Like PrEP, PEP is anti-retroviral therapy, but rather than being used before infection, it is used after exposure to prevent it.[100] Originally recommended for exposure to HIV infection in health care settings, PEP is now used to prevent HIV infection within 72 hours after sexual or drug-use exposure.[101] PEP consists of a 28-day prescription of two anti-retroviral drugs,[102] and requires three HIV tests in the six months after exposure.[103]

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[96] Erin Allday, *Health Providers Slowly Embrace Drug Truvada to Prevent HIV*, S.F. GATE, June 3, 2014, http://www.sfgate.com/health/article/Health-providers-slowly-embrace-drug-Truvada-to-5526316.php.

[97] *Paying for Truvada*, TRUVADA.COM, http://www.truvada.com/truvada-patient-assistance (last visited Apr. 15, 2015). Gilead offers reduced-cost Truvada to people without insurance who make less than $58,000 a year. Heather Boerner, *Even After Obamacare, It's Still Way Too Hard to Get HIV Meds*, THE DAILY BEAST (Feb. 8, 2015), http://www.thedailybeast.com/articles/2015/02/08/even-after-obamacare-it-s-still-way-too-hard-to-get-hiv-meds.html.

[98] PREP GUIDELINES, *supra* note 93, at Tab.1.

[99] NATIONAL HIV/AIDS STRATEGY, *supra* note 4, at 16-17.

[100] Dawn K. Smith et al., *Antiretroviral Postexposure Prophylaxis After Sexual, Injection-Drug Use, or Other Nonoccupational Exposure to HIV in the United States: Recommendations from the U.S. Department of Health and Human Services*, 54 MORBIDITY & MORTALITY WEEKLY REP. 1 (2005), *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5402a1.htm [hereinafter PEP GUIDELINES].

[101] *Id.*

[102] *Id*. In 2013 guidelines, the U.S. Public Health Service recommended that providers treat occupational HIV exposure with a combination of three or more anti-retrovirals. David T. Kuhar et al., *Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV & Recommendations for Postexposure*

PEP is 80% effective in averting HIV infection, based on observational data.[104] PEP is more effective when a person takes it as soon as possible after exposure.[105] However, PEP is expensive; it can cost between $600 and $1,000 for the 28-day supply, not including other associated medical costs.[106] As with PrEP, manufacturer assistance programs may help with costs.[107]

Despite universal HIV screening, the fact that drug therapy is effective for preventing new HIV incidence, and the availability of pre- and post-exposure prophylaxes, there were an estimated 48,000 new cases of HIV in 2012,[108] a figure that has remained stable for more than a decade.[109] Further, the CDC estimates that about 14% of people with HIV do not know that they have the virus.[110]

3. The National HIV/AIDS Strategy

It is undisputed that the United States has the tools to effectively treat HIV and reduce the number of new HIV infections, yet most HIV-positive people are not in care and people continue to be newly infected at steady rates. In its National HIV/AIDS Strategy, the Obama Administration sought to level out the so-called continuum of care

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Prophylaxis, 34 INFECTIOUS CONTROL HOSPITAL EPIDEMIOLOGY 875 (2013). The guidelines for non-occupational exposure have not been updated.

[103] PEP GUIDELINES, *supra* note 100. The individual will be tested about a month after exposure, then three months after exposure, then again six months after exposure. *Id.*

[104] Raphael J. Landovitz & Judith S. Currier, *Postexposure Prophylaxis for HIV Exposure*, 361 N. ENG. J. MED. 1768, 1773-74 (2009). There were no clinical trials of non-occupational PEP because it was shown to be effective in observational studies of exposed health care workers. *Id.* at 1768.

[105] *Id.* at 1770.

[106] *Id.* at 1773.

[107] *Post-Exposure Prophylaxis*, AIDS.GOV, *supra* note 88.

[108] *Diagnoses of HIV Infection in the United States and Dependent Areas*, 24 HIV SURVEILLANCE REPORT Tab.1a (2014).

[109] Gardner et al., *supra* note 74, at 794.

[110] *HIV/AIDS: Basic Statistics*, CDC, http://www.cdc.gov/hiv/basics/statistics.html (last accessed Apr. 15, 2015).

for HIV-positive individuals[111] and to lower the number of new infections each year.[112]

To increase and improve HIV treatment, the National HIV/AIDS Strategy identified three steps:

> 1. Establish a seamless system to immediately link people to continuous and coordinated quality care when they are diagnosed with HIV.
> 2. Take deliberate steps to increase the number and diversity of available providers of clinical care and related services for people living with HIV.
> 3. Support people living with HIV with co-occurring health conditions and those who have challenges meeting their basic needs, such as housing.[113]

The Administration anticipated that, if these steps were implemented, by 2015, more people would be linked to care within three months of an HIV diagnosis, more would be in continuous care, and more would have permanent housing.[114] The National HIV/AIDS Strategy also identified three steps to prevent new HIV infection:

> 1. Intensify HIV prevention efforts in communities where HIV is most heavily concentrated.
> 2. Expand targeted efforts to prevent HIV infection using a combination of effective, evidence-based approaches.
> 3. Educate all Americans about the threat of HIV and how to prevent it.[115]

With these steps, the Administration hoped, by 2015, to reduce new infections by 25%, reduce the HIV transmission rate, and increase the number of HIV-positive individuals who know their status.[116]

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[111] The continuum or cascade of care refers to the steep drop off between the total number of HIV-infected individuals and the number of HIV-infected individuals that have reached certain milestones (*e.g.,* are linked to care; receive ART; and have an undetectable viral load). *See* Gardner et al., *supra* note 74, at Fig.2.
[112] NATIONAL HIV/AIDS STRATEGY, *supra* note 4, at 5.
[113] *Id.* at 23.
[114] *Id*. The Administration expressly targeted those HIV-positive individuals who are clients of the Ryan White program, discussed in Part III.A, for improvements in continuous care and housing. *See also id.* at 23-9 (detailing specific actions to achieve these goals).
[115] *Id. at* 7-8.

Further, the Obama Administration found that "what has been missing and what is needed at this time is an enhanced focus on coordinating our efforts across Federal agencies, across all levels of government, with external partners, and throughout the health care system."[117] The National HIV/AIDS Strategy called for additional coordination and collaboration among the many agencies that fund HIV services, and state, local and tribal governments; and the development of monitoring systems to determine whether the United States is achieving its goals of improved treatment and prevention.[118]

III. THE AFFORDABLE CARE ACT'S PROMISE FOR PEOPLE LIVING WITH HIV

Historically, health insurance issuers have discriminated against HIV-positive individuals because of the cost of treating this complex, life-long health condition.[119] Discrimination was largely tolerated because of a lack of federal regulation of health insurance and inadequate nondiscrimination laws.[120] The Affordable Care Act promised

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[116] *Id.* at 8. *See also id.* at 8-20 (detailing specific actions to achieve these goals) and Exec. Order No. 13,649 (2013) (announcing the HIV Care Continuum Initiative, which aims to "accelerat{e} efforts to increase HIV testing, services, and treatment along the continuum").
[117] *Id.* at 39.
[118] *Id.* at 39-43.
[119] Sara Rosenbaum, *Insurance Discrimination on the Basis of Health Status: An Overview of Discrimination Practices, Federal Law, and Federal Reform Options*, 37 J L MED & ETHICS 102, 106-107 (2009) (discussing the means used by health insurance issuers to discriminate on the basis of health status, including HIV, in order to shield against risk) [hereinafter, Rosenbaum, *Insurance Discrimination*].
[120] Theodore Ruger, *Of Icebergs and Glaciers: The Submerged Constitution of American Healthcare*, 75 L. & CONTEMP. PROBS. 215, 232-34 (2012) (discussing the "jurisdictional holes" in health insurance and health care law because of Congress' reluctance to regulate).

to end discrimination against HIV-positive individuals,[121] with provisions that specifically guarantee access to HIV care providers and essential drugs through the insurance products sold in the newly-created health insurance exchanges.[122]

This Part briefly walks through the federal authority to regulate health insurance in the United States and the many missed opportunities to do so.[123] It shows how health insurance issuers have taken advantage of these lapses to discriminate against people who are expensive to insure, including HIV-positive individuals, and the limitations of federal nondiscrimination laws. It then discusses the Ryan White Comprehensive AIDS Resources Emergency Act (the Ryan White program),[124] which acts as a safety net for HIV-positive individuals left out of the insurance market. This Part concludes with the

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[121] Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1311, 124 Stat. 160 (2010) (codified as amended at 42 U.S.C. § 18116 (2012)).
(a)(2012) (prohibiting discrimination on the basis of disability in insurance contracts).

[122] Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1302, 124 Stat. 163 (2010) (codified as amended at 42 U.S.C. § 18022(b)(1)(F) (2012)) (including, as an essential health benefit, prescription drugs) and Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1311(b), 124 Stat. 173 (2010) (codified as amended at 42 U.S.C. § 18031(c)(2) (2012)) (requiring that qualified health plans include essential community providers, where available, including Ryan White providers). For a discussion of the health insurance exchanges, *see infra* Part III.B.

[123] This Part is concerned with health insurance reform, as opposed to health care reform, specifically the requirements as to what a health insurance issuer must do to comply with insurance law. It is not concerned with the regulation of health care, such as the quality of treatment.

[124] The Ryan White Comprehensive AIDS Resources Emergency Act of 1990, Pub. L. 101-38, 104 Stat. 576. The Act has been reauthorized four times, most recently in 2009. Ryan White HIV/AIDS Extension Act of 2009, Pub. L. 111-87, 123 Stat. 2885. *Legislation*, HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA), http://hab.hrsa.gov/abouthab/legislation.html (last visited Apr. 16, 2015). The Act was scheduled for reauthorization in 2013, and Congress is currently funding it through annual appropriations. Rebecca Adams, *Ryan White Reauthorization Can Wait, Some HIV/AIDS Advocates Say*, CQ HEALTHBEAT NEWS, Mar. 11, 2014, http://www.theaidsinstitute.org/sites/default/files/attachments/Ryan%20White%20Reauthorization%20Can%20Wait.pdf.

Affordable Care Act, the broadest piece of legislation to date, and the tremendous promise it represents for people with HIV.[125]

A. BEFORE THE AFFORDABLE CARE ACT

Before the Affordable Care Act, the absence of uniform health insurance law allowed private health insurance issuers to operate according to market principles rather than "social solidarity," thus incentivizing the exclusion of those who were the most expensive to insure.[126] Nondiscrimination law, where it reached health insurance at all, did not prohibit some of the most effective ways of keeping out the most vulnerable Americans, including those with HIV.[127]

1. Inadequate Federal Regulation of Health Insurance

Although the U.S. Constitution grants Congress the authority to regulate health insurance through the commerce clause[128] and Congress' power to "lay and collect taxes, to… provide for the … general Welfare,"[129] Congress has been historically reluctant to regulate.[130]

A good example of this reluctance is Congress' response to the Supreme Court's decision in *United States v. South-Eastern Underwriter's Association*, in which the Court confirmed that Congress has the power to regulate health insurance as interstate

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[125] Sara Rosenbaum, *Law & the Public's Health*, 126 PUB. HEALTH REP. 130 (2011) [hereinafter, Rosenbaum, *Law & the Public's Health*].
[126] Rosenbaum, *Insurance Discrimination*, *supra* note 119, at 103-104.
[127] *See generally id.* at 105-113 (discussing common techniques to discriminate in health insurance, and federal nondiscrimination laws that apply to health insurance).
[128] U.S. CONST. art. 1, § 8, cl. 3.
[129] *Id.* § 8, cl. 1.
[130] Ruger, *supra* note 120, at 232.

commerce.[131] Congress, just a year later, gave this power to the states by passing the McCarran-Ferguson Act, in which Congress declared that "the continued regulation and taxation by the several States of the business of insurance is in the public interest, and that silence on the part of the Congress shall not be construed to impose any barrier to the regulation or taxation of such business by the several States."[132]

Likewise, federal laws aimed at social welfare that were enacted in the first half of the twentieth century dodged the issue of whether, and how, to implement federal rules about health insurance.[133] For example, the Social Security Act of 1935, a major piece of social welfare legislation, did not include any substantive regulation of health insurance, thanks in part to opposition from health care providers, who saw compulsory or even voluntary health insurance as an intrusion on the medical profession.[134] Further, Medicare and Medicaid, which were passed in the 1960s, reach only selected markets: individuals over 65 and the disabled,[135] and low-income adults without minor children.[136]

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[131] 322 U.S. 533, 533-62 (1944). The Court held that health insurance is thus subject to federal anti-trust law. *Id.* at 561-62.

[132] McCarran-Ferguson Act, Pub. L. 79-15, 59 Stat. 33 (1945) (codified at 15 U.S.C. § 1011 et seq). *See also* Baird Webel & Carolyn Cobb, Cong. Research Serv., RL31982, Insurance Regulation: History, Background, and Recent Congressional Oversight 8-9 (2005) (discussing the political backlash from *South-Eastern Underwriter's Association* and the history of the passage of McCarran-Ferguson).

[133] *See generally* PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 266-89 (1982).

[134] *Id.* at 265-69.

[135] *What is Medicare?* MEDICARE.GOV, http://www.medicare.gov/sign-up-change-plans/decide-how-to-get-medicare/whats-medicare/what-is-medicare.html (last visited Apr. 16, 2015). People under 65 with end-stage renal disease are also eligible for Medicare. *Id.*

[136] Kates, *Medicaid and HIV*, *supra* note 35, at 3-4.

Commercial insurance companies, beginning with Blue Cross and Blue Shield,[137] as well as employer-sponsored health insurance,[138] became the primary sources of health insurance for Americans. Because of the government's hands-off approach, commercial insurance companies, rather than the federal government, essentially wrote the rules that would govern the world of health insurance.[139]

To the extent that government regulation existed, it was enacted at the state level.[140] A notable exception is federal pre-emption of some employer-sponsored insurance by the Employee Retirement Income Security Act (ERISA).[141] State laws governing insurance may be pre-empted by ERISA even where there is no relevant federal law, resulting in no law at all.[142]

2. The Freedom to Discriminate

Because of the lack of federal regulation, a private health insurance issuer did not have to operate according to the federal government's idea of social good, but could run their business like a business, according to market principles.[143] In other words, if an

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[137] STARR, *supra* note 133, at 295-310.
[138] David Blumenthal, *Employer-Sponsored Health Insurance in the United States – Origins and Implication*s. 355 NEW ENG. J. MED. 82, 82-3 (2006). The majority of non-elderly Americans have employer-sponsored health insurance. Julie Sonier et al., *State Level Trends in Enployer-Sponsored Health Insurance: A State-by-State Analysis*, *Key Findings* (2013), *available at*: http://www.rwjf.org/en/library/research/2013/04/state-level-trends-in-employer-sponsored-health-insurance.html?cq_ck=1365787641906. The enormous breadth and importance of employer-sponsored insurance is outside the scope of this thesis.
[139] STARR, *supra* note 133, at 331-34.
[140] Webel & Cobb, Cong. Research Serv., *supra* note 132, at 1-2.
[141] Peter Jacobson, *The Role of ERISA Preemption in Health Reform: Opportunities & Limits*, LEGAL SOLUTIONS IN HEALTH REFORM 5 (2009), *available at* https://www.law.georgetown.edu/oneillinstitute/research/legal-solutions-in-healthreform/Papers/ERISA.pdf.
[142] This is known as the "ERISA vacuum." *Id.*
[143] Rosenbaum, *Insurance Discrimination, supra* note 119, at 103-104.

issuer did not have to enroll a person with an expensive, life-long, complex health condition like HIV, it would not, since people without such health conditions are a much safer risk.[144]

Health insurance issuers had several tools at their disposal. First, an issuer could exclude HIV-positive individuals from enrollment in a plan based on a pre-existing condition exclusion,[145] and deny coverage if the condition existed before the date of the application.[146] Thus, a person who is HIV-positive when he applies could be denied.[147] If an HIV-positive person were enrolled in a plan, more discriminatory practices followed. The issuer was free to charge a higher premium for enrollees with higher medical costs.[148] Unaffordable premiums could keep sicker Americans, which may include people with HIV, from entering the health care market at all, thus decreasing the issuer's outlay.[149] An issuer could decide, during a plan year, that a plan enrollee is too expensive to treat, and simply cancel their coverage.[150] This could mean that an HIV-positive person is left without insurance coverage after an unexpected hospitalization during the year. Health insurance issuers also routinely denied coverage for certain treatments or

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[144] *Id.* at 104-108 (explaining the concepts of risk-pooling, actuarial fairness, and risk-shielding, all used to discriminate in health insurance).
[145] Mark Bolin, *The Affordable Care Act and People Living with HIV/AIDS: A Roadmap to Better Health Outcomes*, 23 ANN HEALTH L 32, 40-1 (2014).
[146] Ashley N. Southerland, *Stigmatized Silence: The Exclusion of HIV and AIDS Sufferers from the "Obamacare" Legal Landscape*, 20 CORNELL J. L. & PUB. POL'Y 834, 844 (2011).
[147] *Id.*
[148] Rosenbaum, *Insurance Discrimination*, *supra* note 119, at 106-107.
[149] *Id.* at 105-106.
[150] *Id.* at 106.

services to HIV-positive individuals, such as organ transplants, based only on the person's HIV status.[151]

Health insurance issuers could decide not to provide any of the benefits that a person with a specific condition would need to make the insurance plan worth the money.[152] For instance, a health insurance issuer could impose lifetime limits on the amount of coverage for HIV, even if the limits were not actuarially sound.[153] A plan with dollar limits on coverage may cover ART and other medical costs for only a few years before the lifetime limit is reached.[154]

Health insurance issuers could discourage HIV-positive individuals from enrolling in their plans by narrowing their plan networks and excluding HIV care specialists, or using tiered networks by which the enrollee was charged more to visit HIV care specialists than other providers.[155] In addition, the plan could charge high-out-of-pocket costs if an enrollee visited a care provider who was not in the plan's network.[156]

Health insurance issuers could increase the costs to the enrollee by charging more for drugs depending on the tier in which the drugs are placed.[157] Tiering is a common

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[151] Bolin, *supra* note 145, at 46.
[152] Rosenbaum, *Insurance Discrimination*, *supra* note 119, at 107.
[153] Doe v. Mutual of Omaha Insur. Co., 179 F.3d 557, 558 (7th Cir. 1999).
[154] In *Doe v. Mutual of Omaha*, one of the plans at issue instituted a lifetime coverage limits of $25,000 for AIDS and AIDS-related conditions. 179 F.3d at 558. As discussed above, HIV has an estimated lifetime medical cost of more than $300,000. Schackman et al., *supra* note 59, at 295.
[155] Rosenbaum, *Insurance Discrimination*, *supra* note 119, at 107.
[156] Jay Hancock, *'Narrow Networks' Trigger Push-Back from State Officials* (Nov. 25, 2013) KAISER HEALTH NEWS, http://kaiserhealthnews.org/news/states-balk-at-narrow-networks/.
[157] Bolin, *supra* note 145, at 46. Coinsurance is a specified percentage that the enrollee must pay, in addition to any deductible, while copayment is usually a set dollar amount. *Copayment & Coinsurance in Drug Plans*, Centers for Medicare & Medicaid Services,

feature of health plans and is often used to steer enrollees and providers towards certain drugs on the basis of price.[158] Typically, generic drugs and "preferred brand" drugs, so-called because the issuer has analyzed the side effects and other aspects and determined that the drug is superior to its competitors,[159] are likely to be in the lowest tiers.[160] But, issuers can also use "adverse tiering" to discourage people with expensive conditions from enrolling, or re-enrolling[161] in a plan, where drugs to cover a certain condition are all included in the same cost tier.[162]

3. Nondiscrimination Laws Fall Short

Federal and state nondiscrimination laws often did not reach far enough in protecting HIV-positive individuals from health insurance discrimination.[163] As discussed below, the Americans with Disabilities Act (ADA),[164] the Rehabilitation Act of 1973,[165]

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http://www.medicare.gov/part-d/costs/copayment-coinsurance/drug-plan-copayments.html#1437 (last visited Apr. 16, 2015).

[158] Douglas B. Jacobs & Benjamin D. Sommers, *Using Drugs to Discriminate – Adverse Selection in the Insurance Marketplace*, 372 NEW ENG. J. MED. 339, 400 (2015).

[159] Thomas S. Rector et al., *Effect of Tiered Prescription Copayments on the Use of Preferred Brand Medications*, 41 MED. CARE 398, 398-99 (2003).

[160] Jacobs & Sommers, *supra* note 158, at 400. Thus, if a participant's provider prescribed her a non-preferred brand drug that was included in Tier 3, she would have the incentive to seek out a preferred brand alternative in Tier 1. In a study of tiering of preferred brand and non-preferred brand drugs, where non-preferred brands had higher copayments, researchers found an increase in the use of preferred brand drugs. Rector et al., *supra* note 159, at 403.

[161] It is often impossible for an individual to know, in advance of filling the prescription or receiving a bill, how much the drug will cost. Jacobs & Sommers, *supra* note 158, at 401. Thus, drug tiering may cause that individual to decide not to re-enroll in the plan.

[162] *Id.* at 400. It should be noted that drug tiering based on condition has gained prominence after the passage of the Affordable Care Act, because now issuers are limited in the ways in which they may exclude HIV-positive individuals, as discussed in Part III.B. *See* Bolin, *supra* note 145, at 46.

[163] Rosenbaum, *Insurance Discrimination*, *supra* note 119, at 106.

[164] 42 U.S.C. § 12101 et seq. (1990). The ADA was amended in 2008. *See* Pub. L. 110-325.

[165] 29 U.S.C. § 794 (2012).

and the Health Insurance Portability and Accountability Act (HIPAA)[166] may prevent certain types of discrimination, but often do apply to the ways in which health insurance issuers actually discriminate against HIV-positive individuals. A state insurance law may provide strong nondiscrimination provisions, but they are necessarily limited to that jurisdiction.

One purpose of the ADA is "to provide a clear and comprehensive national mandate for the elimination of discrimination against individuals with disabilities," including within hospitals and private medical offices.[167] The ADA prohibits discrimination against individuals on the basis of disability "in the full and equal enjoyment of the goods, services, facilities, privileges, advantages or accommodations of any place of public accommodation."[168] The ADA applies to employer-sponsored health plans, public issuers, and state regulated private issuers.[169] The Supreme Court has held that an HIV-positive person has a qualifying disability under the ADA.[170]

Thus, in general, a health care provider will not be able to refuse treatment to an HIV-positive person,[171] but the law does not stop a health insurance issuer from limiting the plan's coverage specifically for HIV-related services and treatment.[172] In *Doe v. Mutual of Omaha*, discussed above, the Seventh Circuit concluded that the issuer did not discriminate against the enrollee on the basis of his disability in violation of the ADA

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[166] Pub. L. No. 104-191, 110 Stat. 1936 (codified at 42 U.S.C. § 300gg and 29 U.S.C § 1181 et seq. and 42 USC § 1320d et seq.).
[167] 42 U.S.C. §§ 12101(b)(1), 12132 & 12181(7)(F) (2012).
[168] 42 U.S.C. § 12182(a) (2012).
[169] Rosenbaum, *Insurance Discrimination*, *supra* note 119, at 109.
[170] Bragdon v. Abbott, 524 U.S. 624, 641 (1998).
[171] *Id.*
[172] Rosenbaum, *Insurance Discrimination*, *supra* note 119, at 107.

because it offered plans to, and enrolled, HIV-positive individuals,[173] even though the coverage limits would render the product all but worthless for an HIV-positive enrollee after only a few years.[174] The Seventh Circuit held that the ADA does not require an issuer to change its insurance product to make the plan "equally valuable" for HIV-positive individuals as for HIV-negative individuals.[175] Under this reasoning, health insurance issuers act in compliance with the ADA if, for example, they exclude all HIV care specialists from their plan networks or charge high rates for ART, as long they offer plans to HIV-positive individuals.

Another civil rights law, the Rehabilitation Act of 1973, bans discrimination in programs or activities that receive federal financial assistance, including health programs and services,[176] but does not require that such programs treat people with disabilities equal to those without disabilities; rather, like the ADA, it is "limited to access to coverage as well as to methods of administration that result in segregated and isolated treatment of persons with disabilities."[177]

HIPAA, enacted in 1996, bans pre-existing condition exclusions and discrimination based on health status,[178] and is thus significant as a federal inroad into the

[173] 179 F.3d at 559 (finding that "Mutual of Omaha does not refuse to sell insurance policies to such persons—it was happy to sell health insurance policies to the two plaintiffs").
[174] Rosenbaum, *Insurance Discrimination*, *supra* note 119, at 107.
[175] *Id*. at 563. *See also* McGann v. H. & H. Music Co., 946 F.2d 401, 407-408 (5th. Cir. 1991) (in a pre-ADA decision, upholding AIDS-specific lifetime treatment limits of $5,000 and $10,000).
[176] 29 U.S.C. § 794(a) (2012).
[177] Rosenbaum, *Insurance Discrimination*, *supra* note 119, at 109.
[178] *Id.* at 109-110.

content of insurance plans.[179] However, HIPAA prohibits pre-existing condition exclusions only where the applicant had "creditable coverage" prior to applying for new coverage.[180] Further, the prohibition against discrimination based on health status applies only to certain employer-sponsored plans and group health insurance.[181] Thus, HIPAA is of only limited usefulness to HIV-positive individuals seeking insurance for the first time in the private market.

State insurance laws may expressly prohibit discrimination against HIV-positive individuals,[182] or ban practices that target HIV-positive individuals. For example, California banned health insurance issuers from denying coverage for organ transplants to HIV-positive individuals based solely on their HIV status.[183] However, such laws are by no means uniform, or present in every state.[184] Further, most states do not prohibit discrimination in health insurance on the basis of race, national origin, or religion, classifications that are considered "inherently suspect" in Supreme Court jurisprudence.[185]

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[179] Sara Rosenbaum, *Realigning the Social Order: The Patient Protection and Affordable Care Act and the U.S. Health Insurance System*, 7 J. HEALTH & BIOMEDICAL L. 1, 10 (2011) [hereinafter, Rosenbaum, *Realigning the Social Order*].
[180] Rosenbaum, *Insurance Discrimination*, *supra* note 119, at 110.
[181] *Id.*
[182] See, e.g., FL. STAT. § 627.429(5)(b)(2014) (prohibiting discrimination against HIV-positive individuals).
[183] CAL. HEALTH & SAFETY CODE § 1347.17. In the same year that California passed this law, an administrative law judge ruled that Arizona's Medicaid program could not deny a liver transplant to an HIV-positive woman based only on her HIV status. *Arizona Health Care Cost Containment System Must Cover Transplant for HIV-Positive Woman*, Oct. 31, 2005, THE BODY, http://www.thebody.com/content/art24538.html.
[184] Ronen Avraham et al., *Understanding Insurance Anti-Discrimination Laws*, 12-017, PUB. L. & ECON. RES. PAPER SERIES 1, 32-46 (2013).
[185] Frontiero v. Richardson, 411 U.S. 677, 682 (1973) (discussing suspect classifications) and Avraham et al., *supra* note 184, at 46.

4. The Ryan White Program's Role As Payer of Last Resort

The Ryan White program[186] fills the gaps left by the insurance industry's systematic exclusion of HIV-positive individuals. The Ryan White program is known as the "payer of last resort" because it provides supplemental coverage for HIV-positive individuals who are underinsured, or provides coverage for HIV-positive individuals who are uninsured.[187] One important feature is the provision of federal funds to pay premiums, deductibles, copayments, and coinsurance to enable recipients to purchase or maintain health insurance.[188]

In addition, the AIDS Drugs Assistance Program provides funding to states and territories to subsidize HIV-related prescription drugs.[189] In 2013, over 200,000 people received assistance through ADAP.[190] Each state or territory determines ADAP eligibility, considering an individual's finances, health status, and insurance status.[191] The Ryan White program also provides grants to public and nonprofit organizations for efforts to "develop, enhance, or expand access to primary health care services for HIV positive, or at risk, in underserved or rural communities,"[192] and funding for state or

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[186] The Ryan White Comprehensive AIDS Resources Emergency Act of 1990, *supra* note 124.
[187] Neeraj Sood et al., *HIV Care Providers Emphasize the Importance of the Ryan White Program for Access to and Quality of Care*, 33 HEALTH AFF. 394, 394 (2014).
[188] Lindsey Dawson & Jennifer Kates, *The Ryan White Program and Insurance Purchasing in the ACA Era: An Early Look at Five States*, KAISER FAMILY FOUND. 2 (2015).
[189] *AIDS Drug Assistance Programs (ADAPs): What are ADAPs?*, KAISER FAMILY FOUND., http://kff.org/hivaids/fact-sheet/aids-drug-assistance-programs/ (last visited April 16, 2015).
[190] *Id*.
[191] *Part B- Grants to States & Territories*, HRSA, http://hab.hrsa.gov/abouthab/partbstates.html (last visited Apr. 16, 2015).
[192] *Part C*, HRSA, http://hab.hrsa.gov/abouthab/partc.html (last visited Apr. 16, 2015).

private groups that perform primary medical care for HIV-positive women, infants, children and youth.[193]

B. THE AFFORDABLE CARE ACT

It is no exaggeration to say that the Affordable Care Act is a "watershed" of health reform in the United States.[194] The Act amends several other laws that touch on health care, including the Public Health Service Act and the Social Security Act, showing just how deeply Congress was prepared to realign health insurance law.[195] The Act changed health care in four major ways: the individual mandate; the expansion of Medicaid; substantive health insurance reform; and the creation of health care exchanges.[196] Further, the Act explicitly tackled the discriminatory practices that targeted individuals with expensive health conditions through broad nondiscrimination provisions.[197]

The Obama Administration recognized the Act's promise specifically for HIV-positive people. As the Administration explained,

> HIV exists within a health care system where different groups have varying access to services – and achieve varying health outcomes. The *Affordable Care Act* represents the broadest Federal effort, to date, to address health inequities.[198]

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[193] *Part D- Services for Women, Infants, Children, Youth & Their Families*, HRSA, http://hab.hrsa.gov/abouthab/partd.html (last visited Apr. 16, 2015).
[194] Rosenbaum, *Law & the Public's Health*, *supra* note 125, at 130.
[195] Rosenbaum, *Realigning the Social Order*, *supra* note 179, at 13.
[196] *Id.* at 11-16.
[197] *See, e.g.,* Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1557, 124 Stat. 260 (2010) (to be codified as amended at 42 U.S.C. § 18116 (2012)) (prohibiting discrimination on the basis of race, sex, disability and other factors in health programs and in contracts of insurance). *See also* Kevin Sack, *For Many, Health Care Relief Begins Today* (N.Y. TIMES, Sept. 22, 2010), http://www.nytimes.com/2010/09/23/health/policy/23careintro.html (describing the implications of the Act for people with pre-existing conditions).
[198] NATIONAL HIV/AIDS STRATEGY, *supra* note 4, at 31.

1. The Individual Mandate and Medicaid Expansion

The central feature of the Act is the requirement of compulsory health insurance, known as the individual mandate.[199] Specifically, individuals must maintain "minimum essential coverage" or be subject to a "shared responsibility payment."[200] If an applicable individual[201] does not maintain minimum essential coverage, they must pay a tax.[202] The IRS will not impose the tax on people who cannot afford coverage, taxpayers with income below the filing threshold, and members of Indian tribes.[203]

The requirement that almost everyone maintain health coverage is necessary for the creation of "the type of robust risk pool on which fundamental health insurance reform can be built."[204] Thus, the Act requires almost everyone to participate in the health insurance market so that health insurance issuers will have, as customers, a mix of healthier individuals who require less health care (and who might not otherwise buy health insurance unless required) and those with costly health conditions who have no choice but to utilize health care.[205] In exchange, the Act provides for subsidies[206] so that people can afford to purchase plans in the health insurance exchanges.[207]

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[199] 26 U.S.C. § 5000A (2012). *See also* Rosenbaum, *Law & the Public's Health*, *supra* note 125, at 130-31.
[200] 26 U.S.C. §§ 5000A(a)-(b) (2012).
[201] *Id.* § 5000A(d). The requirement does not apply to: people with religious exemptions, people not lawfully present in the United States, and people in prison. *Id.*
[202] *Id.* § 5000A(b). *See also id.* § 5000A(c) (describing the amount of the tax).
[203] *Id.* § 5000A(e).
[204] Rosenbaum, *Realigning the Social Order*, *supra* note 179, at 12.
[205] *Id*. at 25-6. My description is an over-simplification of a much more nuanced subject. For a thorough analysis, *see* Neera Tanden & Topher Spiro, *The Case for the Individual Mandate in Health Reform*, CTR. FOR AM. PROGRESS (2012).
[206] Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1401(a), 124 Stat. 213 (2010) (codified as amended at 26 U.S.C. § 36B (2012)). Individuals may receive subsidies if

The Supreme Court upheld the individual mandate, finding it to be a lawful exercise of Congress' power to tax.[208] The Court distinguished the tax from a penalty, finding that the individual mandate does not "attach{} negative legal consequences to not buying health insurance, beyond requiring a payment to the IRS."[209]

The Supreme Court rendered unenforceable the second major feature of the Act: the extension of Medicaid to all low-income, non-elderly people who are legally present in the United States.[210] Despite this, twenty-eight states and the District of Columbia have complied with the Act and expanded Medicaid.[211]

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they have incomes between 100-400% of the Federal Poverty Level and are not otherwise eligible for Medicaid or benefits through an employer-sponsored health plan. *Id. See also* Rosenbaum, *Realigning the Social Order*, *supra* note 179, at 12.

[207] Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1311(b), 124 Stat. 173 (2010) (codified as amended at 42 U.S.C. § 18031(b) (2012)). In March 2015, the Supreme Court heard argument in *King v. Burwell*, on the issue of whether premium subsidies are available to individuals purchasing health insurance plans in the federally-facilitated health insurance exchanges, which are discussed below in Part III.B.2. 759 F.3d 358 (4th Cir. 2014). *See also King v. Burwell*, SCOTUSBLOG, http://www.scotusblog.com/case-files/cases/king-v-burwell/ (last visited Apr. 18, 2015). The Court's decision will have major implications for health insurance reform, beyond the scope of this thesis. *See The Health Care Supreme Court Case: Who Would Be Affected?* N.Y. TIMES, Mar. 12, 2015, http://www.nytimes.com/interactive/2015/03/03/us/potential-impact-of-the-supreme-courts-decision-on-health-care-subsidies.html.

[208] 132 S. Ct. at 2594-2600.

[209] *Id.* at 2597. The Court acknowledged that the Act itself refers to the shared responsibility payment as a penalty, but held that this "does not determine whether the payment may be viewed as an exercise of Congress' taxing power." *Id.* at 2594.

[210] *Id.* at 2601-2607. Although Medicaid is significant for any discussion of health care coverage for HIV-positive individuals, this thesis focuses on health insurance reform in the private insurance market.

[211] *Current Status of State Medicaid Expansion*, KAISER FAMILY FOUND., http://kff.org/health-reform/slide/current-status-of-the-medicaid-expansion-decision/

2. Health Insurance Exchanges

The Act also creates "American Health Benefit Exchanges."[212] Exchanges act as portals for the purchase of health plans by individuals, and small groups, in each state. A state agency or nonprofit entity established by the state runs the state's exchange.[213] If a state does not elect to establish an exchange, or is unable to establish an exchange, then HHS will establish and operate a federally-facilitated exchange in the state.[214] Thirteen states and the District of Columbia have elected to establish state exchanges.[215]

Only qualified health plans can be sold in the exchanges.[216] The Secretary of HHS establishes criteria for the certification of health plans as qualified health plans.[217] Through these criteria, issuers must "meet marketing requirements, and not employ marketing practices or benefit designs that have the effect of discouraging the enrollment in such plan by individuals with significant health needs."[218]

3. Essential Community Providers

The Act also serves to end a more subtle form of discrimination that has discouraged HIV-positive individuals from enrolling in health insurance plans: excluding

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[212] Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1311, 124 Stat. 173 (2010) (codified as amended at 42 U.S.C. § 18031(b) (2012)).
[213] *Id.* § 18031(d).
[214] Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1321, 124 Stat. 186 (2010) (codified as amended at 42 U.S.C. § 18041(c) (2012)).
[215] *State Health Insurance Marketplace Types, 2015*, KAISER FAMILY FOUND., http://kff.org/health-reform/state-indicator/state-health-insurance-marketplace-types/. Three states have "federally-supported" exchanges and seven have "state-partnership" exchanges. The remaining twenty-seven states have federally-facilitated exchanges. *Id.*
[216] Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1311, 124 Stat. 173 (2010) (codified as amended at 42 U.S.C. § 18031(d)(2)(B) (2012)).
[217] *Id.* § 18031(c)(1).
[218] *Id.* § 18031(c)(1)(A).

HIV care specialists from a plan's network.[219] Under the Act, qualified health plans must ensure a sufficient choice of providers[220] and include essential community providers within their plan networks.[221] Specifically, a plan shall:

> (B) ensure a sufficient choice of providers (in a manner consistent with applicable network adequacy provisions under section 2702(c) of the Public Health Service Act), and provide information to enrollees and prospective enrollees on the availability of in-network and out-of-network providers; {and}
>
> (C) include within health insurance plan networks those essential community providers, where available, that serve predominately low-income, medically-underserved individuals, such as health care providers defined in section 340B(a)(4) of the Public Health Service Act and providers described in section 1927(c)(1)(D)(i)(IV) of the Social Security Act as set forth by section 221 of Public Law 111–8, except that nothing in this subparagraph shall be construed to require any health plan to provide coverage for any specific medical procedure…[222]

Essential community providers are those providers who are eligible to participate in the low cost drug-purchasing program defined in section 340B(a)(4) of the Public Health Service Act,[223] which includes HIV care specialists that receive funding through the Ryan White program.[224]

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[219] Sara Rosenbaum, *Section 1557 of the ACA and Non-Discrimination: The HHS Request for Information*, HEALTH REFORM GPS 4 (2013) [hereinafter, Rosenbaum, *Section 1557*].
[220] Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1311, 124 Stat. 173 (2010) (codified as amended at 42 U.S.C. § 18031(c)(1)(B) (2012)).
[221] *Id.* § 18031(c)(1)(C).
[222] *Id.* at §§ 18031(c)(1)(B)-(C).
[223] 42 U.S.C. § 256b (2012).
[224] Sara Rosenbaum, *Essential Community Providers*, HEALTH REFORM GPS 3 n.8 (2011) The inclusion of essential community providers within plan networks had its origins in President Clinton's Health Security Act of 1993. *Id.* at 1.

4. Essential Health Benefits

Qualified health plans must also include "essential health benefits" with limited cost-sharing[225] and are rated based on their actuarial values.[226] The Act sets out the actuarial levels of coverage for essential health benefits packages, identifying each level with a medal (platinum, gold, silver and bronze).[227] The extent of coverage will thus vary depending on the medal level.[228]

Unlike the essential community provider provision, which is required only for qualified health plans sold on exchanges, plans sold "off" the exchange (*i.e.*, in the private health insurance market) also must include essential health benefits.[229] Essential health benefits apply to the public program expansion (Medicaid Benchmark and Benchmark-equivalent "Alternative Benchmark Plans"),[230] and state-run Basic Health Plans.[231] The essential health benefits provision does not apply to self-insured employer-

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[225] Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1301, 124 Stat. 162 (2010) (codified as amended at 42 U.S.C. § 18021(a)(1)(B) (2012)).
[226] Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1302, 124 Stat. 163 (2010) (codified as amended at 42 U.S.C. § 18022(a) (2012)).
[227] *Id.* § 18022(d).
[228] For example, a plan in the silver level must provide a level of coverage that is designed to provide benefits that are actuarially equivalent to 70 percent of the full actuarial value of the benefits provided under the plan. *Id.* § 18022(d)(1)(B).
[229] Affordable Care Act, Pub. L. No. 111-148, tit. I, § 2727, 124 Stat. 161 (2010) (codified as amended at 42 U.S.C. 42 U.S.C. § 300gg-6(a) (2012)) ("A health insurance issuer that offers health insurance coverage in the individual or small group market shall ensure that such coverage includes the essential health benefits package under section 1302(a)" of the Act) and Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1304, 124 Stat. 170 (2010) (codified as amended at 42 U.S.C. § 18024(b)(2) (2012) (defining small employer as one with 100 employees or less)).
[230] Section 1937 of the Social Security Act (codified at 42 U.S.C. § 1396u-7 (2012)).
[231] Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1331, 124 Stat. 199 (2010) (codified as amended at 42 U.S.C. 42 U.S.C. § 18051 (2012)). This provision allows states to establish "basic health programs" for low-income individuals who are not eligible for Medicaid because their income is between 133-200% FPL, and "whose income fluctuates above and below Medicaid" and the Children's Health Insurance Plan.

sponsored plans or large group fully-insured employer plans.[232] The Act also limits annual out-of-pocket costs for essential health benefits provided within the plan's network.[233]

Essential health benefits are "at least the following general categories and the items and services covered within the categories."[234] The ten categories are:

> (A) Ambulatory patient services.
> (B) Emergency services.
> (C) Hospitalization.
> (D) Maternity and newborn care.
> (E) Mental health and substance abuse disorder services, including behavioral health treatment.
> (F) Prescription drugs.
> (G) Rehabilitative and habilitative services and devices.
> (H) Laboratory services.
> (I) Preventive and wellness services and chronic disease management.
> (J) Pediatric services, including oral and vision care.[235]

The Act does not define any of the categories, and a lack of legislative history does not help in the interpretation.[236] However, the scope of essential health benefits must be "equal to the scope of benefits provided under a typical employer plan, as determined by

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The state could also choose to cover legal resident immigrants who are not eligible for Medicaid. *Basic Health Program*, MEDICAID.GOV, http://www.medicaid.gov/basic-health-program/basic-health-program.html (last visited Apr. 26, 2015).

[232] Affordable Care Act, Pub. L. No. 111-148, tit. I, § 2727, 124 Stat. 161 (2010) (codified as amended at 42 U.S.C. § 300gg-6 (2012)). *See also* INSTITUTE OF MEDICINE, ESSENTIAL HEALTH BENEFITS: BALANCING COVERAGE AND COST 19 (Cheryl Ulmer et al eds. 2012) [hereinafter, IOM REPORT].

[233] Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1302, 124 Stat. 163 (2010) (codified as amended at 42 U.S.C. § 18022(c) (2012)).

[234] *Id.* § 18022(b)(1) (2012)).

[235] *Id.*

[236] Sara Rosenbaum et al., *Crossing the Rubicon: The Impact of the Affordable Care Act on the Content of Insurance Coverage for Persons with Disabilities*, 25 NOTRE DAME J. L. ETHICS & PUB. POL'Y 527, 556 (2011) [hereinafter, Rosenbaum et al., *Crossing the Rubicon*].

the Secretary."[237] The Act requires the Department of Labor to conduct a survey to determine what is provided under a typical employer health plan.[238]

The essential health benefits requirement promises nondiscrimination.[239] In defining the categories, HHS shall "not make coverage decisions, determine reimbursement rates, establish incentive programs, or design benefits in ways that discriminate against individuals because of their age, disability, or expected length of life."[240] HHS must "take into account the health care needs of diverse segments of the population" including people with disabilities,[241] and "ensure that health benefits established as essential not be subject to denial" on the basis of the individual's "present or predicted disability, degree of medical dependency, or quality of life."[242] In other words, the Secretary's requirements for the essential health benefits package must safeguard against discriminatory practices.[243]

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[237] Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1302, 124 Stat. 163 (2010) (codified as amended at 42 U.S.C. § 18022(b)(2) (2012)).
[238] *Id.* § 18022(b)(2). In addition, the essential health benefit categories are not intended to remain static: HHS must periodically review the essential health benefits provision and report to Congress on its functioning, including whether individuals are facing difficulties in accessing care because of coverage or cost, and whether EHB needs to be modified or updated due to medical evidence or scientific advancement. HHS must update the essential health benefits accordingly. *Id.* §§ 18022(b)(4)(G)-(H). States may require that additional items and services be covered, on top of the essential health benefits, but the state must assume the cost of these additional benefits. *Id.* § 18022(d)(3).
[239] Rosenbaum, *Section 1557, supra* note 219, at 4.
[240] Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1302, 124 Stat. 163 (2010) (codified as amended at 42 U.S.C. § 18022(b)(4)(B) (2012)).
[241] *Id.* § 18022(b)(4)(C).
[242] *Id.* § 18022(b)(4)(D).
[243] Rosenbaum, *Section 1557*, *supra* note 219, at 4. However, the Act provides that health insurance issuers may not be prohibited "from carrying out utilization management techniques that are commonly used as of the date of enactment of the Act." Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1562, 124 Stat. 264 (2010) (codified as amended at 42 U.S.C. § 18120(d)(2) (2012)). The Act does not define utilization management techniques. At this point, it is unclear how HHS will reconcile its nondiscrimination

One further element of the essential health benefits package deserves note. Section 1302(b)(1)(I) of the Act includes "preventive and wellness services and chronic disease management."[244]

5. Market Reforms and Section 1557

The Act also introduces important market reforms, delving into the content and design of health insurance plans.[245] For instance, the Act requires all issuers to cover, without cost-sharing, preventive health services, defined as: recommendations by the U.S. Preventive Health Services Task Force that receive an A or B rating; certain immunizations; certain preventive care and screening for children; and certain preventive care and screening for women.[246] The Act also bans discriminatory tactics that kept many people from becoming insured.[247] Now, an issuer cannot deny coverage because of a pre-existing condition.[248] An insurer cannot set premiums in a discriminatory manner.[249] An

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mandate with this exclusion for utilization management. Rosenbaum et al., *Crossing the Rubicon*, *supra* note 236, at 555-56.

[244] Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1302, 124 Stat. 163 (2010) (codified as amended at 42 U.S.C. § 18022(b)(1)(I) (2012)).

[245] Rosenbaum, *Law & the Public's Health*, *supra* note 125, at 131.

[246] Affordable Care Act, Pub. L. No. 111-148, §1001, 124 Stat. 130 (2010) (codified as amended at 42 U.S.C. § 300gg-13) (amending § 2713 of the Public Health Services Act). A benefit with an "A" is one in which "there is high certainty that the net benefit is substantial." A benefit with a "B" rating is one in which "there is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial." *Grade Definitions*, U.S. PREVENTIVE SVCS. TASK FORCE, *available at* http://www.uspreventiveservicestaskforce.org/Page/Name/grade-definitions#grade-definitions-after-july-2012 (last visited February 27, 2015).

[247] Rosenbaum, *Realigning the Social Order*, *supra* note 179, at 13-4.

[248] Affordable Care Act, Pub. L. No. 111-148, tit. I, §1201, 124 Stat. 154 (2010) (codified as amended at 42 U.S.C. § 300gg-3) (amending § 2704 of the Public Health Services Act).

[249] *Id.* § 300gg. There are some exceptions: whether the plan covers an individual or a family; age; tobacco use; and rating area. *Id.*

insurer cannot set lifetime or annual monetary limits on coverage.[250] An insurer must accept every individual that applies for coverage, and renew their coverage.[251] An insurer cannot rescind a plan except where the enrollee has committed fraud or misrepresented material facts.[252] An insurer cannot impose excessive waiting periods (more than 90 days) before coverage begins.[253] The Act also prohibits discrimination on the basis of health status and disability in determining rules of eligibility and establishing premiums.[254]

Even more broadly, section 1557 of the Act includes an expansive nondiscrimination provision.[255] Specifically:

> Except as otherwise provided for in this title (or an amendment made by this title), an individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.), the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.), or section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title (or amendments). The enforcement mechanisms provided for and

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[250] Affordable Care Act, Pub. L. No. 111-148, tit. I, §1001, 124 Stat. 130 (2010) (codified as amended at 42 U.S.C. § 300gg-11) (amending § 2711 of the Public Health Services Act).
[251] Affordable Care Act, Pub. L. No. 111-148, tit. I, §1201, 124 Stat. 154 (2010) (codified as amended at 42 U.S.C. §§ 300gg-1-2) (amending §§ 2702-2703 of the Public Health Services Act). An insurer can restrict enrollment to special or open enrollment periods.
[252] Affordable Care Act, Pub. L. No. 111-148, tit. I, §1001, 124 Stat. 130 (2010) (codified as amended at 42 U.S.C. § 300gg-12) (amending § 2712 of the Public Health Services Act).
[253] Affordable Care Act, Pub. L. No. 111-148, tit. I, §1201, 124 Stat. 154 (2010) (codified as amended at 42 U.S.C. § 300gg-7) (amending § 2708 of the Public Health Services Act).
[254] *Id.* § 300gg-4.
[255] Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1311, 124 Stat. 160 (2010) (codified as amended at 42 U.S.C. § 18116 (2012)).

> available under such title VI, title IX, section 504, or such Age Discrimination Act shall apply for purposes of violations of this subsection.[256]

HHS called section 1557 of the Act "the first broad based Federal civil rights statute incorporating the grounds prohibited by four distinct civil rights statutes," specifically, Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments Act of 1972, the Age Discrimination Act of 1972, and section 504 of the Rehabilitation Act of 1973.[257] The Act specifically applies to any program or activity that receives federal funding, including "credits, subsidies, or contracts of insurance," or any program or activity that is administered by a federal agency.[258] Because the Act provides federal subsidies to individuals purchasing plans in the state-based and federally-facilitated exchanges, there can be no doubt that section 1557 applies to plans sold in the health insurance exchanges.[259]

In sum, as the essential community provider requirement, essential health benefits package, market reforms, and section 1557 demonstrate, the Affordable Care Act made tremendous promises to HIV-positive individuals. The only question is whether the agency tasked with implementing the law would be willing to fulfill them.

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[256] *Id.* § 18116(a). The following subsection specifies that all rights and remedies available under the listed civil rights laws remain available, as well as any state laws that provide additional protections on the bases described in subsection (a). *Id.* § 18116(b).
[257] Request for Information Regarding Nondiscrimination in Certain Health Programs or Activities, 78 Fed. Reg. 46,558, 46,558 (Aug. 1, 2013).
[258] Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1311, 124 Stat. 160 (2010) (codified as amended at 42 U.S.C. § 18116 (2012)).
[259] Rosenbaum, *Section 1557*, *supra* note 219, at 4. Even if the Supreme Court determines that subsidies are available in federally-facilitated exchanges, *supra* note 206, the federally-facilitated exchanges are "administered by an Executive Agency" and thus fall within the section 1557.

IV. TO THE DETRIMENT OF PEOPLE LIVING WITH HIV, HHS HAS NOT EFFECTIVELY IMPLEMENTED THE ACT.

HHS, the agency charged with implementing much of health insurance reform and its nondiscrimination provisions, has reneged on many of the promises that the Act held for HIV-positive individuals. Under HHS's supervision, health insurance issuers can exclude HIV care specialists from plan networks and charge exorbitant prices for ARTs, despite unambiguous statutory prohibitions against such plan networks and benefit designs. Discriminatory practices specifically targeting or impacting HIV-positive individuals have thrived in the health insurance exchanges since 2014, the year in which issuers began to sell plans in the exchanges.[260]

With such promise, what went wrong? First, the agency has issued a series of regulations that are either so weak as to be ineffective, or are plainly inconsistent with the provisions of the Act. Despite well-publicized discrimination, the agency refuses to address condition-specific discrimination in its rules, thus allowing discrimination to continue. Further, the agency has not issued a regulation implementing section 1557 of Act, even though it requested comment on this regulation almost two years ago[261] and complaints brought under the section are already making their way through the courts.[262]

This Part considers HIV-specific discrimination in health insurance that has emerged, or persisted, as a result of the agency's rulemaking efforts to date. This Part begins with an overview of HHS's rulemaking concerning the essential community

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[260] Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1311, 124 Stat. 173 (2010) (codified as amended at 42 U.S.C. § 18031(b)(1) (2012)).
[261] Request for Information Regarding Nondiscrimination in Certain Health Programs or Activities, 78 Fed. Reg. 46,558, 46,558 (Aug. 1, 2013).
[262] *See* Rumble v. Fairview Health Svcs., 2015 U.S. Dist. LEXIS 31591 (Mar. 16, 2015), discussed *infra* Part IV.D.

provider requirement and the essential health benefits package, detailing how the rules have allowed health insurance issuers to exclude HIV care specialists from plan networks and place all ART in the plan's highest cost tiers. Next, the Part turns to how HIV prophylaxes may be left out of drug formularies despite their efficacy in reducing HIV infection rates. The Part concludes with a discussion of the stalled implementation of section 1557 of the Act.

A. Rulemaking that Excludes Essential Community Providers

As discussed above, the essential community provider requirement is one of several provisions of the Act specifically aimed at prohibiting discrimination that has traditionally targeted HIV-positive individuals.[263] The Act requires issuers to include essential community providers, where available, in plan networks, including Ryan White providers.[264]

Although HHS has issued regulations purporting to implement the essential community provider requirement, these regulations are inconsistent with the plain language of the Act. HHS's regulations, which are effective for plans sold in coverage year 2016, require that a plan sold in the federally-facilitated and state-based exchanges

> must include in its provider network a sufficient number and geographic distribution of essential community providers (ECPs), where available, to ensure reasonable and timely access to a broad range of such providers for low-income individuals or individuals residing in Health Professional

[263] *See infra* Part III.B.3.

[264] Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1311, 124 Stat. 173 (2010) (codified as amended at 42 U.S.C. § 18031(c)(1)(C) (2012)). This thesis uses the terms "Ryan White provider" and "HIV care specialist" interchangeably, because HIV care specialists receive funding through the Ryan White program. *See infra* Part III.A.4.

> Shortage Areas within the QHP's service area, in accordance with the Exchange's network adequacy standards.[265]

As numerous commenters argued,[266] the Act plainly states that plans *shall* "include within health insurance plan networks those essential community providers, where available, that serve predominately low-income, medically-underserved individuals…"[267] Thus, the Act does not give plans the discretion to exclude available essential community providers, including Ryan White providers.[268]

If Congress intended that the number of essential community providers in a plan network could be limited in this way, it would have provided this discretion in the law.[269] Indeed, Congress permitted this discretion concerning network adequacy generally in the subsection directly above, in which Congress does not require plans to include all providers, merely "a sufficient choice of providers."[270] By leaving out the word "sufficient" from the provision concerning essential community providers, it is clear that Congress intended no such limitation when it came to the inclusion of essential community providers in plan networks.[271]

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[265] Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016, Final rule, 80 Fed. Reg. 10,750, 10,837 (Feb. 27, 2015) (to be codified 19 C.F.R. § 156.235(a)(1)).
[266] *See, e.g.,* National Association of Community Health Centers, Comments on 79 Fed. Reg. 70,674 4 (Dec. 22, 2014).
[267] Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1311, 124 Stat. 173 (2010) (codified as amended at 42 U.S.C. § 18031(c)(1)(C) (2012)).
[268] *Cf. id.*
[269] Russello v. United States, 464 U. S. 16, 23 (1983); *see also* Brown v. Gardner, 513 U.S. 115, 120 (1994) (striking down a regulation that imposed a fault requirement where the statute was devoid of language concerning fault).
[270] Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1311, 124 Stat. 173 (2010) (codified as amended at 42 U.S.C. § 18031(c)(1)(B) (2012)).
[271] *See* King v. St. Vincent's Hosp., 502 U.S. 215, 220 (1991) (statute must be read as a whole).

The only plausible limitation is that essential community providers must be "available," but as other uses of the term within the Act demonstrate, "where available" connotes existence or presence, not sufficiency or distribution.[272] To take one example, as to the development of national quality standards, the Act provides that coordination among Departmental agencies shall include steps to minimize duplication of efforts and utilization of common quality measures, "where available."[273] The usual reading of this provision is that agencies should use common quality measures if they exist, not to select only some of measures and leave out the rest. Further, HHS itself uses the word "available" to refer to essential community providers that exist in a plan's service area.[274]

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[272] The term "where available" is used in five other places in the Act. *See* section 3011 of the Affordable Care Act [42 U.S.C. § 399HH(b)(2)(A) (2012)] (concerning the development of national quality standards, and providing that coordination among Departmental agencies shall include steps to minimize duplication of efforts and utilization of common quality measures, "where available"); Section 3502(b)(3) of the Affordable Care Act [42 U.S.C. § 256a-1(b)(3)] (providing grants for community health teams, describing eligible entities as those that "submit a plan for incorporating prevention initiatives and patient education and care management resources into the delivery of health care that is integrated with community based prevention and treatment resources, where available"); Sections 2041(b)(4) & (c)(1) of the Affordable Care Act [42 U.S.C. § 1397 et seq.] (providing that long-term care facilities receiving grants under the Act "shall, where available, participate in activities conducted by the State" and adopt standards for the exchange of clinical data, "including, where available, standards for messaging and nomenclature"); Section 749B(d)(4) of the Affordable Care Act [42 U.S.C. § 293k et seq. (2012)] (recipients of rural physician training grants may use those funds for "residency placement assistance, where available, to assist all students in obtaining clinical training experience").

[273] Affordable Care Act, Pub. L. No. 111-148, tit. III, § 3011, 124 Stat. 378 (2010) (codified as amended at 42 U.S.C. § 399HH(b)(2)(A)).

[274] *See* Letter from Center for Consumer Information and Insurance Oversight (CCIIO), Centers for Medicare & Medicaid Services (CMS), to Issuers in the Federally-facilitated Marketplaces 25 (Feb. 20, 2015), http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2016_Letter_to_Issuers_2_20_2015.pdf [hereinafter 2016 Letter to Issuers] (explaining that "the number and types of ECPs *available* vary significantly by location").

In the preamble to the 2013 regulation, HHS argued that the term "where available" justifies, in part, its insertion of a sufficiency limitation:

> The statute refers to "those essential community providers, where available," and "that serve predominantly low-income and medically-underserved," which suggests a requirement that QHP issuers contract with a subset of essential community providers.[275]

But HHS's own regulation uses both the term "a sufficient number" and "where available," indicating that HHS itself does not find the terms equivalent.[276] Further, HHS is wrong that the Act intends for plans to include a "subset" of essential community providers because all essential community providers, by the terms of the Act, serve predominately low-income and medically underserved populations, not just a subset.[277] This justification is undermined by HHS's own definition of essential community providers: "essential community providers *are* providers that serve predominantly low-income, medically underserved individuals…"[278]

Although HHS developed more specific requirements for issuers selling plans in the federally-facilitated exchanges, through letters to issuers and ultimately codified within the regulation, these rules fall short of the Act's requirement that all essential community providers, including Ryan White providers, are included in plan networks. For plan year 2016, plans sold in the federally-facilitated exchanges have a sufficient number and geographic distribution of essential community providers if the plan network includes at least 30% of available essential community providers in the plan's service area, includes all available Indian health care providers, and at least one essential

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[275] 76 Fed. Reg. at 41,899.
[276] 80 Fed. Reg. at 10,873 (to be codified 19 C.F.R. § 156.235(a)).
[277] Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1311, 124 Stat. 173 (2010) (codified as amended at 42 U.S.C. § 18031(c)(1)(C) (2012)).
[278] 80 Fed. Reg. at 10,874 (to be codified 45 C.F.R. § 156.235(c)) (emphasis added).

community provider in each "ECP category," developed by HHS, including Ryan White providers.[279] Multiple essential community providers at a single location count as a single essential community provider for both the minimum percentage requirement and the satisfaction of the participation standard.[280]

These requirements are less than the Act requires, because a plan need not include all essential community providers in the plan's network. To make matters worse, HHS will not hold issuers even to these woefully low standards: an issuer may not comply with the 30% threshold and minimum provider participation requirement and instead may provide a "narrative justification describing how the plan's provider network provides an adequate level of service for low-income and medically underserved enrollees," as currently designed and how the network will be strengthened for the next plan year.[281] The narrative justification must also include: the number of contracts offered to essential community providers for plan years beginning in 2016; the number of additional contracts the issuer expects to offer to essential community providers; the names of essential community providers to which the issuer has offered contracts in good faith, but an agreement has not been reached; and plans for how the current design of the network will provide adequate care to enrollees.[282] For example, "if available … Ryan White HIV/AIDS Program provider(s) … are missing from the network(s), the {Qualified

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[279] *Id.* (to be codified 45 C.F.R. § 156.235(a)(2)). The minimum percentage of 30% is set forth in the 2016 Letter to Issuers. *See supra* note 274, at 25-6.
[280] 80 Fed. Reg. at 10,874 (to be codified 45 C.F.R. § 156.235(a)(2)(i)). Integrated issuers, whose plan "provides a majority of covered professional services through physicians employed by the issuer or through a single contracted medical group" may comply with an alternate standard, described in 45 C.F.R. § 156.235(b). *Id.* (to be codified at 45 C.F.R. § 156.235(a)(5)). For additional explanation of HHS's alternate standard, *see* 80 Fed. Reg. 10,836 (preamble to 45 C.F.R. § 156.235(b)).
[281] *Id*. (to be codified at 45 C.F.R. § 156.235(a)(3)).
[282] 2016 Letter to Issuers, *supra* note 274, at 28.

Health Plan} Application must explain how its target populations will be served."[283] Importantly, this should not be a concern for federal officials tasked with certifying health insurance plans in the federally-facilitated exchanges, because Congress determined that essential community providers, not other providers, should serve these populations.

What is the end result of the agency's inconsistent rulemaking? First, in state-based exchanges, there is no real essential community provider requirement, because HHS has declined to implement the Act and require issuers to offer contracts to all Ryan White providers in the plan's service area.[284] Instead, issuers in state-based exchanges have the option of limiting the number of Ryan White providers, as long as the providers constitute a "broad range," the number is "sufficient" and the "geographic distribution … ensures reasonable and timely access" to those individuals who rely upon them. But since the regulation leaves undefined the terms "broad range of providers," "sufficient number," "geographic distribution" and "reasonable and timely access" or "a broad range" of providers, forcing issuers and the state-based exchanges to guess as to whether a plan satisfies this amorphous standard. States are thus free to establish their own rules concerning what constitutes sufficiency.[285] States are equally permitted to forgo any rulemaking, as long as the exchange is satisfied that there are a "sufficient number and

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[283] *Id.*

[284] Further, HHS refused HHS refused to extend its minimum percentage standard to plans sold in state-run exchanges, although the agency "urge{d}" state-based exchanges to adopt the 30% threshold established for plans sold in the federally-facilitated exchanges. 80 Fed. Reg. at 10,837.

[285] Sally McCarty and Max Ferris, *ACA Implications for State Network Adequacy Standards*, STATE HEALTH REFORM ASSISTANCE NETWORK 9 (2013).

geographic distribution" to provide access to "a broad range of …. providers."[286] In other words, HHS neither imposes discrete requirements on the exchange nor requires the states to make its own requirements; exchanges could decide to evaluate each plan's network on an ad hoc basis.

In federally-facilitated exchanges, HIV care specialists (and their patients) will fare little better. A plan must offer a contract to only one Ryan White provider in the plan's service area and offer contracts to at least 30% of available essential community providers in the plan's service area. This minimum percentage need not include any particular number of additional Ryan White providers beyond just one.[287] Indeed, a plan need not meet this low bar, if it can explain to the exchange's satisfaction why it has included *no* Ryan White providers in its plan network.[288]

HHS's erroneous interpretation of the essential community provider requirement allows issuers to exclude Ryan White providers from their plan networks, in contravention of the Act. Plans that exclude Ryan White providers discourage HIV-positive individuals from enrolling in plans, an implicit form of discrimination that the Act intended to remedy. Further, HHS's permissive interpretation contravenes the federal government's broader goals of increasing the number of HIV-positive individuals who are retained in care[289] by excluding the very providers who are essential to that care.

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[286] 80 Fed. Reg. at 10,873 (to be codified 19 C.F.R. § 156.235(a)(1)).
[287] This is in contrast to all Indian health providers, to whom issuers must offer contracts. *Id.* (to be codified 45 C.F.R. § 156.235(a)(2)).
[288] *Id.* at 10,874 (to be codified 45 C.F.R. § 156.235(a)(3)). *See also* 2016 Letter to Issuers, *supra* note 274, at 28 (setting out requirements for the narrative justification).
[289] NATIONAL HIV/AIDS STRATEGY, *supra* note 4, at 23.

B. Rulemaking that Allows Adverse Tiering

As discussed above, the essential health benefits package also takes aim at discriminatory benefit design by requiring that issuers include prescription drug benefits, along with nine other essential health benefits, in certain plans, including those sold in the exchanges.[290] In defining these ten core categories, the Secretary must not "design benefits in ways that discriminate against individuals because of their age, disability, or expected length of life."[291]

This is no simple task, in part because the Act does not provide any guidance as to what the agency should included in the definitions of each of the categories, and the agency is without the benefit of legislative history on the matter.[292] Further, the Act contains a "paradoxical statutory juxtaposition"[293] because the essential health benefit package must be both "equal to the scope of benefits provided under a typical employer plan, as determined by the Secretary"[294] but the design of those benefits must not discriminate against individuals.[295]

HHS called upon the Institute of Medicine (IOM) for advice.[296] A committee within the IOM researched what benefits were offered under employer plans, in part by surveying three issuers of employers plans about the covered items and services that

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[290] *See infra* Part III.B.4.
[291] Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1302, 124 Stat. 163 (2010) (codified as amended at 42 U.S.C. § 18022(b)(4) (2012)).
[292] Sara Rosenbaum et al., *Crossing the Rubicon*, *supra* note 236, at 556.
[293] *Id.* at 557.
[294] Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1302, 124 Stat. 163 (2010) (codified as amended at 42 U.S.C. § 18022(b)(2) (2012)).
[295] *Id.* § 18022(b)(4) (2012)).
[296] IOM REPORT, *supra* note 232, at 13.

could be characterized as "habilitative" (one of the essential health benefits).[297] The committee found that "habilitation was not covered by two of the three issuers reporting, with the third including habilitation in most plans but with coverage criteria determined by state mandates."[298] Although by no means a fulsome survey of typical employer plans, the committee found, "it appears the typical employer plan will have to be expanded to accommodate the 10 categories of care."[299] In other words, although the typical employer plan could act as a framework, it would have to be supplemented to include all of the essential health benefits.

The committee recommended that the essential health benefits package include the scope and design of a typical small employer plan, but be expanded to include the ten essential health benefits.[300] The committee reasoned that any package had to consider cost to be feasible; thus, "the cost of the initial EHB package … should be compared to a premium target, defined by the committee as what small employers would have paid, on average, in 2014."[301]

If HHS did not entirely ignore the committee's recommendations, it diverged in a surprising way.[302] In its 2013 regulation, rather than defining the essential health benefit package and then tying it to the costs of a typical small employer plan, HHS allowed

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[297] *Id.* at 61-2. The Act required the U.S. Department of Labor to conduct a survey to determine what benefits were included in a typical employer plan. Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1302, 124 Stat. 163 (2010) (codified as amended at 42 U.S.C. § 18022(b)(2) (2012)). The IOM committee found this survey lacking, stating that the survey "does not fully reflect whether plans actually offer a specific benefit." IOM REPORT, *supra* note 232, at 61-2.
[298] *Id.* at 62.
[299] *Id.*
[300] *Id. at* 90.
[301] *Id.* at 1-2 (summarizing findings).
[302] Nicholas Bagley & Helen Levy, *Essential Health Benefits & the Affordable Care Act: Law & Process*, 39 J. HEALTH POL. POL'Y & LAW 441, 446-67 (2014).

states to choose an existing employer plan in the state as a benchmark plan[303] "reflecting both the scope of services and limits offered by a typical employer plan in that state."[304] The essential health benefits package must be "substantially equal" to the benefits in the benchmark plan, including coverage benefits, limitations on coverage, and prescription drug benefits that meet the definition of 45 C.F.R. § 156.122.[305]

As Bagley and Levy describe at length, this approach shocked many, not least because it was originally announced in a bulletin, rather than through notice-and-comment rulemaking.[306] Several members of Congress expressed dismay at this approach. In a letter to Secretary of HHS Kathleen Sebelius, Representative Henry Waxman and others stated, "When creating the EHB package, we intended this to be a federal decision. We had not anticipated your decision to delegate the definition of the EHB package to states."[307]

As to prescription drug benefits, the 2013 regulations contained minimal requirements, relating only to drug formularies.[308] Specifically, to provide essential

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[303] Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation, Final rule, 78 Fed. Reg. 12,834, 12,866 (Feb. 25, 2013) (codified at 45 C.F.R. § 156.100).
[304] *Id.* at 12,840. The benchmark plan could be: (1) the largest plan by enrollment in any of the three largest small group insurance products in the state's small group market; (2) any of the largest three state employee health benefit plans by enrollment; (3) any of the largest three national Federal Employees Health Benefits Program plan options that are open to Federal employees; or (4) the largest insured commercial non-Medicaid HMO operating in the state. If the state does not select a benchmark, the default benchmark is the largest small-group plan in the state. *Id.* at 12,866 (codified at 45 C.F.R. § 156.100).
[305] *Id.* at 12,867 (codified at 45 C.F.R. § 156.115(a)(1)).
[306] Bagley & Levy, *supra* note 302, at 446-47.
[307] Letter from Rep. Henry Waxman, Ranking Member, Committee on Energy and Commerce, et al. to Sec. Kathleen Sebelius (Feb. 6, 2012), *available at* http://democrats.energycommerce.house.gov/sites/default/files/documents/Sebelius-PPACA-Essential-Health-Benefits-2012-2-6.pdf.
[308] 78 Fed. Reg. at 12,867 (codified at 45 C.F.R. § 156.122 (2013)).

health benefits, a plan must include one drug in every U.S. Pharmacopeia category and class or the same number of prescription drugs in each category and class as the benchmark plan.[309] Further, the plan must have "procedures in place that allow an enrollee to request and gain access to clinically appropriate drugs not covered by the health plan."[310] The plan must also provide its drug formulary to the exchange, the state, or the Office of Personnel Management (OPM).[311]

As to the essential health benefits' nondiscrimination provision, the 2013 regulations generally tracked the language of the Act:

> an issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions.[312]

An issuer must comply with section 156.200(e), which prohibits discrimination with respect to qualified health plans on the basis of race, color, national origin, disability, age, sex, gender identity or sexual orientation.[313] HHS does not define the term "discriminate."[314]

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[309] *Id.* A plan need not cover drugs approved by the U.S. Food and Drug Administration as abortion services, described in 45 C.F.R. § 156.280(d). *See id.* at 12,867 (codified at §156.122(b) (2013)).
[310] *Id*.
[311] *Id*.
[312] *Id.* at 12,867 (codified at 45 C.F.R. § 156.125(a) (2013)). *Cf.* Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1302, 124 Stat. 163 (2010) (codified as amended at 42 U.S.C. § 18022(b)(4)(B)) ("In defining the essential health benefits … the Secretary shall … (B) not make coverage decisions, determine reimbursement rates, establish incentive programs, or design benefits in ways that discriminate against individuals because of their age, disability, or expected length of life").
[313] 78 Fed. Reg. at 12,867 (codified at 45 C.F.R. § 156.125(b)).
[314] Rosenbaum et al., *Crossing the Rubicon*, *supra* note 236, at 558.

Thus, under the 2013 regulations, HHS let the states decide what benefits were "essential" rather than the federal government.[315] Other rules, such as benefit substitution (allowing issuers to substitute benefits from one category with benefits from another)[316] and state-mandated benefit requirements (requiring that state benefit requirements be incorporated into the state's package)[317] led to further variation among state plans.[318] As applied to the prescription drug benefit, so long as the plan was covering the greater of one drug in every USP category, or the same number of drugs in each category or class as the benchmark, complying with state coverage mandates, providing benefits consistent with the state's benchmark plan, the plan complied with HHS's regulations. Despite ostensibly prohibiting discrimination in benefit design, HHS made no attempt to explain how this prohibition might apply when it came to coverage.[319] For instance, whether the regulation banned "macro" level discrimination, such as refusing to cover ART at all, or whether the regulation banned case-specific discrimination, such as refusing to cover ART for a particular enrollee.[320]

Issuers wasted no time in exploiting the weaknesses in the 2013 regulations to discriminate against HIV-positive individuals. Issuers instituted adverse tiering within plans, in which ARTs were all placed in the plan's highest cost tiers.[321] For example,

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[315] Justin Giovanelli et al., *Implementing the Affordable Care Act: Revisiting the ACA's Essential Health Benefits Requirements* 2-3, COMMONWEALTH FUND (2014).
[316] 78 Fed. Reg. at 12,867 (codified at 45 C.F.R. § 156.115). Note that benefit substitution is not permitted for prescription drugs. *Id.*
[317] *Id.* at 12,865 (codified at 45 C.F.R. § 155.170).
[318] Giovanelli et al., *supra* note 315, at 3-6.
[319] Rosenbaum et al., *Crossing the Rubicon*, *supra* note 236, at 560.
[320] *Id*.
[321] The AIDS Institute and the National Health Law Program, Admin. Compl. 3 (2014), *available at* http://www.healthlaw.org/publications/browse-all-publications/HHS-HIV-Complaint#.VOs9NVPF8kU [hereinafter, NHeLP complaint].

Coventry Health Care offered a silver plan sold in the exchange that included six drug tiers.[322] *All* HIV drugs were included in the highest tier, and required prior authorization, quantity limits, and 40% coinsurance after a $1,000 prescription deductible.[323] One study found that HIV-positive individuals enrolled in adverse tiering plans paid more than three times that of enrollees in plans that did not engage in adverse tiering, or $3,277 more per year.[324] Further, fifty percent of the adverse tiering plans required a prescription deductible, while only 19% of the plans without adverse tiering had a prescription deductible.[325]

In May 2014, the AIDS Institute and the National Health Law Program (NHeLP) filed a complaint with HHS's Office for Civil Rights, alleging that four health insurance issuers in Florida, Coventry Health Care, Cigna, Humana and Preferred Medical, offered silver-level qualified health plans sold in Florida used adverse tiering to discriminate against HIV-positive enrollees and discourage enrollment by HIV-positive individuals.[326] Although all of the issuers implicated in the complaint eventually agreed to reduce the costs of ARTs in plans sold in Florida, the agreements were reached with the state insurance commission, not HHS.[327]

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[322] *Id.* at 8.
[323] *Id.*
[324] Jacobs & Sommers, *supra* note 158, at 401.
[325] *Id.*
[326] NHeLP complaint, *supra* note 321, at 3-7.
[327] *See, e.g.,* Florida Office of Insurance Regulation, Consent Order, Case No. 162232-14-CO (2014). In Fall 2014, Coventry Health Care, Cigna and Preferred Medical agreed to reduce costs of ARTs for plans sold in the exchange; Coventry agreed to cap the amount of coinsurance for four common ARTs at $200 for plans sold in 2015, and to move generic HIV drugs to a lower tier. Nicholas Nehamas, *Second Florida Insurer Strikes Deal with State Over HIV Drugs*, MIAMI HERALD, Nov. 21, 2014 (5:12 pm), http://www.miamiherald.com/news/local/community/miami-dade/article4051858.html. Humana and Preferred Medical entered into similar voluntary agreements with Florida

Adverse tiering discourages enrollment by HIV-positive individuals, or at worst, to require HIV-positive individuals to forgo drugs that are essential to survival[328] because they are prohibitively expensive. The true function of drug tiering – to restrict the use of expensive drugs where a generic or preferred drug is available – is not served by adverse tiering, where issuers place both generics and non-preferred medication that treat the same condition on its plan's highest cost tier.[329] Thus, because adverse tiering constitutes a discriminatory benefit design, it violates section 1302(b)(4)(B) of the Act by discriminating against HIV-positive individuals because of their disability,[330] and section 1311(c)(1)(A) of the Act because it discourages enrollment by HIV-positive individuals.[331] Adverse tiering also foils the Obama Administration's efforts to retain more HIV-positive individuals in care, because if HIV-positive people cannot afford the essential drugs, they will not enroll in plans and thus fall out of the continuum of care.[332] But HHS's 2013 regulation does not prohibit adverse drug tiering; it does not even require that ARTs be included in drug formularies unless the drugs are included in the benchmark plan.

In the next round of rulemaking concerning essential health benefits – begun six months after NHeLP's complaint against the Florida issuers – HHS referred to the

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regulators in December 2014 and January 2015, respectively. Jodie Tillman, *Humana Agrees to Cut Costs of HIV Drugs for Florida Patients*, TAMPA BAY TIMES, Dec. 19, 2014 (9:57 a.m), http://www.tampabay.com/news/health/humana-agrees-to-cut-costs-of-hiv-drugs-for-florida-patients/2210831.

[328] *See infra* Part II.C.

[329] Jacobs & Sommers, *supra* note 158, at 400.

[330] Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1302, 124 Stat. 163 (2010) (codified as amended at 42 U.S.C. § 18022(b)(4)(B) (2012)).

[331] Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1311, 124 Stat. 173 (2010) (codified as amended at 42 U.S.C. § 18031(c)(1)(A) (2012)).

[332] NATIONAL HIV/AIDS STRATEGY, *supra* note 4, at 23.

existence of "benefit designs that we believe would discourage enrollment by individuals based on … health conditions, in effect making those plans discriminatory."[333] The agency specifically referenced the practice of adverse tiering and stated: "such plan designs effectively discriminate against, or discourage enrollment by, individuals who have those chronic conditions."[334] Nevertheless, HHS did not propose a regulation to prohibit adverse tiering, even while acknowledging the nondiscrimination provisions in the Act.[335]

In response to the proposed rule, one commenter urged HHS to draw the opposite conclusion as the obvious one, and declare that adverse tiering is not discriminatory.[336] HHS responded,

> The examples {including adverse drug tiering} provided in the proposed rule are potentially discriminatory if there is no appropriate non-discriminatory reason for the noted practice. Having a specialty tier is not on its face discriminatory; however, placing most or all drugs for a certain condition on a high cost tier without regard to the actual cost the issuer pays for the drug may often be discriminatory in application when looking at the totality of the circumstances, and therefore prohibited. When CMS or the State requests a justification for such a practice, issuers should be able to identify an appropriate non-discriminatory reason that supports the benefit design, including their formulary design.[337]

HHS explained its decision not to regulate this way:

> We are not prohibiting certain practices in regulatory text at this time. Several factors must be taken into consideration during benefit design, and a discrimination determination is often dependent on specific facts and

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[333] Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016, Proposed rule, 79 Fed. Reg. 70,674, 70,722 (Nov. 26, 2014).
[334] *Id.* at 70,723. For a description of adverse tiering, *see* Part VI.B.
[335] *Id.*
[336] 80 Fed. Reg. at 10,823. It should be noted that many other commenters argued that HHS should find adverse tiering discriminatory. *See, e.g.,* HIV Care Access Working Group, Comments on 79 Fed. Reg. 70,674 (Dec. 22, 2014), *available at* http://www.regulations.gov.
[337] 80 Fed. Reg. at 10,823.

> circumstances. However, the examples identified in the proposed rule {including adverse drug tiering} contain indications that they are discriminatory, and therefore further investigation by the enforcing entity may be required. We strongly caution that the examples cited appear discriminatory in their application when looking at the totality of the circumstances, and may therefore be prohibited.[338]

If adverse tiering were merely theoretical, then HHS's cautious approach may be justified on the grounds that the agency should not declare a practice discriminatory without determining its effect in practice. However, there was concrete evidence that issuers were placing all ARTs, even generics, in the plan's highest cost tiers, singling out HIV for this discriminatory treatment.[339] In other words, HHS already had the "facts and circumstances" to find that adverse tiering is a per se discriminatory benefit design.[340]

Further, HHS's revised rules concerning drug formularies did not go far enough in leveling the playing field for HIV-individuals with respect to the price of ARTs.[341] HHS expanded its drug formulary rules from the 2013 regulations by requiring that plans use a pharmacy and therapeutics (P&T) committee to establish and manage the plan's drug formulary. The P&T committee must ensure that the drug formulary

> (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 groups of enrollees; and

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[338] *Id.*
[339] NHeLP complaint, *supra* note 321.
[340] 80 Fed. Reg. at 10,823.
[341] It should be noted that HHS promulgated additional rules concerning processes to get access to drugs not otherwise covered by the plan. *See* 80 Fed. Reg. at 10,872 (to be codified at 45 C.F.R. § 156.122(c)). Although outside the scope of this thesis, a streamlined exceptions process will benefit HIV-positive enrollees, if a medically-indicated ART is not provided on the plan's formulary.

> (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.[342]

At first glance, the rule seems to prohibit issuers from using adverse tiering for ARTs because adverse tiering discourages enrollment by HIV-positive individuals, and because ARTs are an instrumental part of HIV treatment.[343]

There are two main limitations with this argument. First, HHS stated in its preamble that adverse tiering is not per se discriminatory,[344] so it likely did not promulgate a regulation that banned adverse tiering. In addition, even if the regulation prohibits adverse tiering, the subject of the rule is the P&T committee, not the plan itself. In other words, if the P&T committee established an adverse tiering formulary, the committee would be violating the regulation and would, presumably, be replaced, but the issuer itself is not in violation of the regulation.[345]

On a positive note, Aetna, one issuer implicated in the NHeLP complaint, recently agreed to include all ARTs in the generic brand tier in its plans sold nationwide, this decision comes not because HHS has banned adverse drug tiering, but through voluntary agreement.[346] HHS's decision to defer to the states regarding what constitutes essential

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[342] 80 Fed. Reg. at 10,871 (to be codified at 45 C.F.R. § 156.122(a)(3)(iii)).
[343] *See infra* Part II.C.1.
[344] 80 Fed. Reg. at 10,823.
[345] This is in contrast to the essential health benefits nondiscrimination regulation, which provides that an issuer does not provide essential health benefits if it uses a benefit design that discriminates on the basis of disability. *See* 78 Fed. Reg. at 12,867 (codified at 45 C.F.R. § 156.125(a) (2013)).
[346] National Health Law Program, *Aetna Agrees to Make HIV Medications More Affordable After Complaint*, Press Release (Mar. 27, 2015), http://www.healthlaw.org/news/press-releases/342-aetna-agrees-to-make-hiv-medications-more-affordable-after-complaint. The change will result in a decrease of the average copayment for these drugs from $1,000 (when the drugs were included in the specialty tier) to between $5 to $100, after deductibles. The change will be effective June 1, 2015. *Id.*

health benefits, as well as its decision not to enforce the prohibition on discriminatory benefit design, has permitted issuers to use adverse tiering to discourage enrollment by HIV-positive individuals.

C. Insufficient Rulemaking Concerning Preventive and Wellness Services and Chronic Disease Management

Another conspicuous absence in HHS's rulemaking on essential health benefits concerns the provision of "preventive and wellness services and chronic disease management."[347] To date, the only rulemaking that HHS has engaged in concerning this essential health benefit category is to require that plans include "preventive health services described in {45 C.F.R.} § 147.130."[348] Section 147.130 of HHS's regulations implements section 2713 of the Public Health Services Act, as amended, which requires that Task Force screening recommendations, immunizations, and certain screenings and care specific to children and women's health be provided without cost sharing.[349] In response to comments concerning preventive health services that are also prescription drugs, and the extent to which they were covered by the essential health benefits package, HHS explained that "preventive service drugs"

> are required to be covered as part of EHB. Non-grandfathered group health plans and health insurance coverage must provide benefits for preventive health services, including preventive service drugs, without

[347] Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1302, 124 Stat. 163 (2010) (codified as amended at 42 U.S.C. § 18022(b)(1)(I) (2012)).
[348] 78 Fed. Reg. at 12,867 (codified at 45 C.F.R. § 156.115(a)(4)).
[349] Affordable Care Act, Pub. L. No. 111-148, §1001, 124 Stat. 130 (2010) (codified as amended at 42 U.S.C. § 300gg-13) (amending § 2713 of the Public Health Services Act). This regulation has proven to be highly controversial, for reasons unrelated to this thesis, because of the inclusion of contraceptives as a preventive health service. *See* Burwell v. Hobby Lobby Stores, Inc., 134 S. Ct. 2751 (2014). *See also* Timothy Jost, *Implementing Health Reform: the Supreme Court Rules on Contraception Coverage (Updated)*, Health Affairs Blog, http://healthaffairs.org/blog/2014/06/30/implementing-health-reform-the-supreme-court-rules-on-contraception-coverage/ (last visited Apr. 29, 2015).

> cost sharing, consistent with the requirements of section 2713. Similarly, the rules set forth under § 156.122 are specific to coverage of drugs under the prescription drug EHB category. Issuers could cover drugs administered as part of another service (such as during an inpatient hospitalization or a physician service) under the EHB category that covers that service, in addition to covering the drug under the prescription drug EHB category. We believe this clarification reflects the current practice of issuers.[350]

Thus, issuers must cover the preventive services required under section 2713, but can also cover preventive service drugs under the prescription drug category or another essential health benefit category. What is left unexplained is what constitutes "preventive and wellness services and chronic disease management" *beyond* the preventive services required under section 2713. The term used in the essential health benefits provision is broader than "preventive," and thus is intended to cover more.[351] Further, if the term is defined only as those services required under section 2713, it would be rendered as "mere surplusage" since all plans must cover preventive services under section 2713.[352]

To date, the agency has not expanded the reach of this benefit, deferring to the states for the application of the benchmark's version beyond that required by section 2713 and 45 C.F.R. §147.130. In effect, issuers may not cover essential preventive services drugs, such as PrEP and PEP, which are highly effective in preventing HIV infection,[353] because they are not currently covered under section 2713, without a state

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[350] 80 Fed. Reg. at 10,822.
[351] *See* Russello v. United States, 464 U.S. 16, 23 (1983) Thus, if Congress intended for "preventive health services," as that term is defined in section 2713, to be covered by the essential health benefits package, it would have used the identical phrase.
[352] *See* Potter v. United States, 155 U.S. 438, 446 (1894) (statutory language "cannot be regarded as mere surplusage; it means something").
[353] *See infra* Part II.C.2.

mandate. This thwarts one of the National HIV/AIDS Strategy's primary goals: to reduce HIV incidence.[354]

D. No Rulemaking to Implement Section 1557

Contributing to the continued discrimination against HIV-positive individuals is HHS's lack of rulemaking implement section 1557 of the Act, the Act's broad nondiscrimination provision.[355] In August 2013, HHS published a request for information regarding the implementation of section 1557 of the Act.[356] In its notice, after discussing the civil rights laws that are incorporated into the provision, HHS remarked that, since these laws were enacted, there have been major changes in the demographic makeup of the country, the health care system and technology in general.[357] Calling the issues in implementing section 1557 "significant," the agency requested comment on three categories of information: examples of current forms of discrimination in health programs and activities; access to health programs and activities; and approaches to enforcement and compliance.[358] Comments were due by September 30, 2013.[359]

HHS received 160 comments in response, including examples and the effects of discrimination on various grounds in the provision of health care.[360] NHeLP noted examples of discrimination against people with disabilities in health insurance, including coverage limits on durable medical equipment, and noted that barriers to health care

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[354] NATIONAL HIV/AIDS STRATEGY, *supra* note 4, at 18.
[355] Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1311, 124 Stat. 160 (2010) (codified as amended at 42 U.S.C. § 18116 (2012)).
[356] 78 Fed. Reg. at 46,558.
[357] *Id*.
[358] *Id.* at 46,559-46,560.
[359] *Id.* at 46,558.
[360] Requests for Information: Nondiscrimination in Certain Health Programs or Activities, *available at* http://www.regulations.gov/#!docketBrowser;rpp=100;so=DESC;sb=docId;po=0;dct=PS;D=HHS-OCR-2013-0007 (last accessed Apr. 21, 2015).

access are likely in health insurance exchanges.[361] A coalition of advocacy groups remarked on the use of adverse tiering, including the use of specialty tiers, as "inherently discriminatory … based on disease state, treatment modality, and ability to pay."[362] The HIV Health Care Access Working Group informed HHS of discriminatory practices in benefit design against people living with HIV, including plan networks that exclude HIV care specialists, and high-cost sharing for essential drugs.[363] Further, the group noted that HIV-positive individuals are more likely to experience adverse coverage decisions, thus "it is essential that HHS monitor the amount and types of adverse coverage decisions to ensure that people living with HIV are not systematically denied coverage."[364]

Nevertheless, HHS has yet to issue proposed regulations as to the implementation of section 1557 of the Act. However, the Office of Civil Rights with HHS reports that it has been "accepting and investigating" complaints of violations of this provision,[365] and litigation to enforce the provision has already begun to make its way through the courts. In *Rumble*, the U.S. District Court for Minnesota recently denied a hospital's motion to dismiss a cause of action under section 1557 of the Act, finding that this section provides a remedy for individuals who allege discrimination on the basis of gender identity by a

[361] NHeLP, Comments on 78 Fed. Reg. 76,558 12 (Sept. 30, 2013), *available at* http://www.regulations.gov.
[362] AIDS United et al., Comments on 78 Fed. Reg. 76,558 2 (Sept. 30, 2013), *available at* http://www.regulations.gov.
[363] HIV Health Care Access Working Group, Comments on 78 Fed. Reg. 76,558 2-3 (Sept. 30, 2013), *available at* http://www.regulations.gov.
[364] *Id.* at 4.
[365] *Section 1557 of the Patient Protection and Affordable Care Act*, HHS, http://www.hhs.gov/ocr/civilrights/understanding/section1557/ (last accessed Apr. 21, 2015).

hospital.[366] The court held that the hospital was included under the provision because it is an organization that has a health program or activity receiving federal assistance, specifically Medicare and Medicaid.[367]

That the agency is pursuing section 1557 causes of action is encouraging, but it is not enough. The possibility looms of an adverse substantive decision in *Rumble* or in other litigation. Thus, HHS must go further to protect HIV-individuals from discrimination, by remedying lacunas in the regulatory framework.

V. HHS MUST FULFILL THE PROMISE OF THE ACT THROUGH BINDING RULEMAKING.

To make the promise of the Affordable Care Act a reality, HHS must promulgate regulations[368] that specifically address the ways in which issuers discriminate against HIV-positive individuals, or otherwise impose obstacles to HIV treatment and prevention. Regulations that target the discriminatory practices discussed above would make health care both affordable and accessible to HIV-positive individuals and those at greatest risk, and achieve the Obama Administration's goals of retaining HIV-positive individuals in care and reducing the number of new HIV infections.[369]

This Part sets forth proposals for revised regulations to prohibit discrimination against HIV-positive individuals, consistent with the plain language of the Act, the

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[366] Rumble v. Fairview Health Svcs., 2015 U.S. Dist. LEXIS 31591 (Mar. 16, 2015). Discrimination on the basis of gender identity has been interpreted to violate Title IX of the title IX of the Education Amendments of 1972, one of the federal civil rights statutes incorporated in section 1557 of the Act. *Id.* at 25-6. The court was also guided by an opinion issued by HHS's Office of Civil Rights, interpreting section 1557 of the Act to reach discrimination on the basis of gender identity. *Id.* at 26-8.

[367] *Id.* at 35-38.

[368] *See* Administrative Procedure Act, 5 U.S.C. §§ 553(b)-(c) (2012) (requiring agencies to propose regulations, allow for comment, and issue final regulations after considering the comments).

[369] *See infra* Part II.C.3.

National HIV/AIDS Strategy, and the unique nature of HIV, in which the treatment of HIV-positive individuals translates into prevention of future cases.[370] First, HHS should require that all Ryan White providers in the plan's service area are included in plan networks and institute a uniform process to enable HIV-positive individuals to access their care providers. Second, HHS should prohibit issuers from including all ARTs on the same cost tiers. Third, HHS should promulgate additional rulemaking to implement the preventive services benefit to include HIV prophylaxes.[371] Finally, HHS should implement section 1557 of the Act, taking advantage of the application of federal civil rights laws to contracts of insurance as a powerful means to enable fair access to the exchanges for HIV-positive individuals.

A. Consistent with the Act, HHS Must Ensure Access to HIV Care Specialists.

HHS must propose rules mandating the inclusion of HIV specialists in all health plans sold in the exchanges. HIV care specialists are essential to retaining patients in care and improving drug adherence, to both improve health outcomes and level the continuum of care.[372] The Act requires the inclusion of Ryan White providers in plan networks sold in the exchanges, and HHS should take action to make this aspiration a guarantee. To this end, HHS should revise section 156.235 of its regulations to require that all issuers offer contracts to all Ryan White providers in the plan's service area, regardless of whether the issuer sells plans in state-based or federally-facilitated exchanges. HHS should also require issuers to follow a streamlined process to enable HIV-positive enrollees access to out-of-network Ryan White providers.

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[370] *See infra* Part III.
[371] Bolin, *supra* note 145, at 57-8.
[372] NATIONAL HIV/AIDS STRATEGY, *supra* note 4, at 21.

1. Any Willing Ryan White Provider

As discussed above, although HHS now requires that all plans sold in the federally-facilitated exchanges include at least one Ryan White provider and include a minimum percentage of essential community providers in plan networks,[373] the agency has failed to implement that Act's requirement that Ryan White providers, where available, be included in plan networks. Even more egregiously, HHS has declined to apply any concrete rules to state-based exchanges, which could exclude all Ryan White providers from their plan networks and stay within the bounds of HHS's rule.[374]

HHS should revise section § 156.235 of its regulations to require that all issuers offer contracts to all Ryan White providers, just as HHS requires issuers to offer contracts to all Indian health care providers in the federally-facilitated exchanges.[375] An "any willing Ryan White provider" requirement would give issuers certainty and predictability about what networks will satisfy the essential community provider requirement for certification as a qualified health plan. As discussed above, Congress has spoken directly to the issue of whether issuers must include all essential community providers in their network, and so should be "the end of the matter."[376]

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[373] 80 Fed. Reg. at 10,873 (to be codified 45 C.F.R. § 156.235).
[374] *Id.* at 10,832 (in response to a comment on the proposed rule, declining to apply the essential community provider requirement imposed on issuers in federally-facilitated exchanges to state exchanges).
[375] *Id.* at 10,873 (to be codified at 45 C.F.R. § 156.235(a)(2)(ii)(A)).
[376] Chevron, U.S.A., Inc. v. Natural Res. Def. Council, 467 U.S. 837, 843 (1984). *See also* Brown v. Gardner, 513 U.S. at 120 (striking down an agency's regulation as unlawful under the first step of *Chevron*). The only portion of the provision that is ambiguous is whether issuers need only offer contracts to all essential community providers, or whether issuers are required to contract with all essential community providers. Throughout the rulemaking process, commenters argued that issuers should be required to contract with essential community providers, as opposed to offer contracts in good faith. *See* 80 Fed. Reg. at 10,837. There may be practical and legal difficulties in

Further, this standard must apply to issuers that offer plans in both the state-based and federally-facilitated exchanges, because the Secretary is required to establish criteria that apply to all qualified health plans, and the Act does not contemplate differing standards for each.[377] As a practical matter, there is no reason why a plan sold in Wyoming's federally-facilitated exchange should include different federal standards than a plan sold in New York's state-based exchange.[378] Any fear that HHS cannot regulate the state-based exchanges is unfounded. The Act provides that the Secretary will decide the criteria for what constitutes a qualified health plan, and the agency cannot delegate that role to the states.[379] Although an agency may look to an outside entity, including a sovereign entity, "for advice and policy recommendations," the agency must make the final decision itself.[380]

Thus, HHS should revise its regulations to eliminate sufficiency standards and minimum percentages, and clarify that issuers must offer contracts to all Ryan White

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requiring issuers to contract with Ryan White providers, and a standard that simply requires issuers to offer contracts in good faith is consistent with the Act. Further, this is consistent with HHS's current interpretation in federally-facilitated exchanges. *See* 2016 Letter to Issuers, *supra* note 274, at 27-8.

[377] *See* section 1311(c)(1) of the Act, which does not differentiate between state-run and federally-facilitated exchanges. Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1311, 124 Stat. 173 (2010) (codified as amended at 42 U.S.C. § 18031(c)(1) (2012)),

[378] *See* Indian Health Service Tribal Self-Governance Advisory Committee, Comments on 79 Fed. Reg. 70,674 15 (Dec. 22, 2014), *available at* http://www.regulations.gov (stating a preference that the requirements concerning Indian health care providers apply to federally-facilitated exchanges also apply to state-run exchanges, because of the existence of tribal members in states with both state-run exchanges and federally-facilitated exchanges).

[379] United States Telecommunications Ass'n v. F.C.C., 359 F.3d 554, 566 (D.C. Cir. 2004) (holding that, while federal agency officials may subdelegate their decision-making authority to subordinates absent evidence of contrary congressional intent, they may not subdelegate to outside entities--private or sovereign—absent affirmative evidence of authority to do so"). *See also* Bagley & Levy, *supra* note 302, at 450.

[380] 359 F.3d at 567.

providers that are located in the plan's service area. Under a simplified rule, issuers wishing to sell plans in all health insurance exchanges would have the certainty of knowing that a plan that offers contracts to all Ryan White providers in the service area will satisfy the statutory and regulatory standard, and ensure consistency in implementation.[381]

2. Process to Access an Out-of-Network Ryan White Provider

In addition, HHS should require, through rulemaking, that issuers follow a process to enable HIV-positive individuals to access their HIV care specialist, even if that provider is not within the plan's network.[382] HHS should use a network adequacy draft model rule proposed by the National Association of Insurance Commissioners (NAIC)[383] as a basis for this process, with critical modifications.

The NAIC Draft Rule, proposed in November 2014, requires issuers to establish a process to "assure that a covered person obtains a covered benefit at an in-network level of benefits from a non-participating provider" under certain circumstances.[384] If the issuer's network is "sufficient," but does not have "a type of participating provider available that can provide the covered benefit," and the issuer "has an insufficient number

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[381] Although beyond the scope of this thesis, there is a compelling argument for requiring issuers to offer contracts to all essential community providers, not solely Ryan White providers. *See infra* Part IV.A.
[382] HIV Care Access Working Group, Comments on 79 Fed. Reg. 70,674 9 (Dec. 22, 2014), *available at* http://www.regulations.gov.
[383] Nat'l Ass'n of Insurance Commissioners, Health Benefit Plan Network Access and Adequacy Model Act, § 5 (Nov. 12, 2014) [hereinafter, NAIC Draft Rule]. The final rule is expected sometime in 2015. Robert Pear, *Obama Administration to Investigate Insurers for Bias Against Costly Conditions,* N.Y. TIMES, Dec. 22, 2014, http://www.nytimes.com/2014/12/23/us/politics/obama-administration-to-investigate-insurers-for-bias-against-costly-conditions.html?_r=0.
[384] NAIC Model Rule at § 5(C).

or type of participating provider available to provide the covered benefit,"[385] then the issuer must establish a process for an enrollee to access a non-network provider if the enrollee has "a condition or disease that requires specialized health care services or medical services," and the issuer's network does not include a provider in that specialty, or cannot provide reasonable access to an in-network specialist.[386]

The NAIC Draft Rule suffers from some deficiencies. First, the NAIC Draft Rule does not establish parameters for the process to obtain access to an out-of-network provider. Thus, issuers could institute a process that involves multiple levels of review, which would discourage enrollees from using it. In addition, the NAIC Draft Rule allows plans to avoid establishing a process entirely if the plan makes "other arrangements acceptable to the commissioner."[387] The NAIC Draft Rule's definition of a "sufficient" network is vague,[388] and "reasonable access" is undefined, leaving significant discretion to the plan to define this to the disadvantage of enrollees attempting to access out-of-network providers. Further, even without these limitations, the NAIC Draft Rule, if finalized, is not binding on the states, and by extension, on the exchanges. Even if states adopted the finalized rule, each state could modify it, thus reducing consistency across the exchanges.

However, HHS could use the NAIC Draft Rule as a starting point for a process to allow access to Ryan White providers. One advantage to the NAIC Draft Rule is the use of specific criteria for determining whether an enrollee should be given access to an out-

[385] *Id.* § 5(C)(1).
[386] *Id.* § 5(C)(2).
[387] *Id.* § 5(C)(1).
[388] *See id.* §§ 5(A)-(B).

of-network provider as if the provider were in-network.[389] HHS should eliminate the NAIC Draft Rule's first criterion because it is unduly vague and leaves too much to issuer discretion. However, the second criterion could be applied and weighted to account for the importance of an HIV-positive person's relationship with their care provider to the quality and continuity of care.[390]

For example, HHS's regulation could provide that an issuer will treat the services that an enrollee receives from an out-of-network Ryan White provider as if the services were provided by an in-network provider if: (1) the plan does not include Ryan White providers;[391] (2) the enrollee can demonstrate, using medical records, a pre-existing provider-patient relationship with a Ryan White provider who is not in-network, or (3) an in-network Ryan White provider(s) is not reasonably accessible to that enrollee. "Reasonably accessible" may be defined by geographic distance (*e.g.*, no more than two miles from the enrollee's home in an urban area, or fifteen miles in rural areas)[392] and could take into account the enrollee's means of transportation.[393]

If issuers were required to allow access to out-of-network providers if the enrollee satisfied any of these three requirements, it is likely to increase retention in care. For example, if HHS does not adopt the recommendation concerning "any willing Ryan

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[389] *Id.* § 5(C)(2).
[390] Gallant et al., *supra* note 63, at 1046 and Kates & Dawson, *supra* note 67, at 6.
[391] This criterion will only apply if HHS does not adopt the recommendation concerning "any willing Ryan White providers" described above.
[392] A similar standard is applied to Medicare Part D plans concerning access to pharmacies. *See* Letter from Cynthia Tudor, Ph.D., Director, Medicare Drug Benefit and C & D Data Group, to All Part D Sponsors (excluding PACE Organizations) 2 (Dec. 22, 2010), http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/HPMSMEMORetailHIAccess.pdf.
[393] For example, if an enrollee demonstrated that her only means of transportation is by public transit, and the Ryan White provider(s) in the plan's network is not accessible via public transit, the enrollee would satisfy prong (2) of the rule.

White provider" described above, the proposal outlined here will enable enrollees whose plans have excluded Ryan White providers access to a Ryan White provider. Further, an HIV-positive individual who has a pre-existing relationship with a Ryan White provider, but whose provider is not in-network, will have access to her provider if she can verify the relationship. This process would also benefit those enrollees whose plan area does not include Ryan White providers, or which includes Ryan White providers that are not reasonably accessible. This is essential because, although there is at least one Ryan White provider in every state, the number of providers is not proportional to the number of HIV-positive individuals.[394]

Finally, this process will not be a great burden on issuers, because in general, an HIV-positive person is expected to consult with their HIV doctor only twice a year.[395] Barring grave HIV-related health conditions at other points in the year, the enrollee could access other services from in-network providers if additional provider services are needed, ideally in consultation with the enrollee's HIV expert.[396]

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[394] Find Ryan White HIV/AIDS Medical Care Providers, HRSA, *available at* http://findhivcare.hrsa.gov (searching by state). For example, Delaware and Utah only have one Ryan White provider each in the state. Although Utah has a low rate of HIV diagnoses (forty-first in the country), Delaware ranks eleventh of the states in HIV diagnoses. *Nat'l Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention Atlas*, CDC, *available at* http://gis.cdc.gov/GRASP/NCHHSTPAtlas/main.html (last accessed Apr. 29, 2015) (searching for HIV diagnoses by state).

[395] An HIV-positive individual is considered to be in "continuous care" if they have routine HIV medical care at least twice a year, with each visit at least three months apart. NATIONAL HIV/AIDS STRATEGY, *supra* note 4, at 21.

[396] Gallant et al., *supra* note 63, at 1046 (where an HIV expert is not available, recommending that an HIV-positive individual could see a primary care physician with an HIV expert "serving as an ongoing consultant via teleconference or telemedicine").

B. HHS Must Regulate to Prohibit Discriminatory Drug Tiering.

Congress made it clear that, in defining the essential health benefits categories, HHS could not "design benefits in ways that discriminate against individuals because of their age, disability, or expected length of life."[397] Yet HHS's preamble, which suggests that adverse tiering is discriminatory without prohibiting it in a rule, has done just that. HHS should remedy this error by revising its prescription drug rules to declare adverse tiering to be per se discriminatory.

HHS should promulgate rulemaking, rather than discuss drug tiering in a preamble, as in the latest revision to the essential health benefits rules.[398] Although courts consider a preamble to a rule "informative," it is not binding.[399] Thus, HHS should revise its regulations, through section 146.122 of the Act.[400] HHS should institute a rebuttable presumption that adverse tiering, defined as a tiering structure that places all drugs to treat HIV on the same tier, is per se discriminatory, and put the burden on issuers to explain why such drug tiering is not discriminatory.[401] A rebuttable presumption would

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[397] Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1302, 124 Stat. 163 (2010) (codified as amended at 42 U.S.C. § 18022(b)(4)(B) (2012)).
[398] 80 Fed. Reg. at 10,813-22.
[399] Howmet Corp. v. E.P.A., 613 F.3d 544, 550 (D.C. Cir. 2010).
[400] Although outside the scope of this thesis, HHS could also consider other discriminatory practices that are used in prescription drug benefit designs, including issuing a uniform definition of "specialty drugs," requiring more transparency in the cost of drugs, limiting prior authorizations, and restricting the use of quantity limits.
[401] In the preamble, HHS discusses places drugs to treat one condition on a "high" cost tier. 80 Fed. Reg. at 10,823. However, because HHS does not define cost tiering, and because issuers could all use different tiering structures, under this proposal, the rule must be general enough to capture most discriminatory drug tiering, but there could be outliers for which the rule is not a perfect fit. For example, an issuer could place all HIV drugs on the lowest tier, and there is a rebuttable presumption that this is discriminatory, even though it clearly advantages HIV-positive enrollees. *See, e.g., supra* note 346 (discussing Aetna's agreement to place ARTs on its generic drug tier). On the other end of the spectrum, if an issuer attempted to circumvent the rule by, for example, using a

also take the burden from the exchange to investigate each suspect drug tiering structure.[402] Of course, the exchange will need to judge the merits of the issuer's explanation, but a rebuttable presumption may discourage issuers from using suspect drug tiers at all.

The strongest objection to any HIV-specific requirements concerning drug therapy will be based on cost. Issuers will likely argue that, if HHS requires issuers to offer ARTs on lower cost tiers, issuers will have to raise premiums and many people, not just HIV-positive individuals, will be priced out of the market. But issuers should consider the costs that can be avoided in the long term. By ensuring that their HIV-positive enrollees have access to ART, they may avoid paying for expensive hospitalizations and opportunistic infections in the future.[403]

HHS should also consider the savings to the government. HIV-positive individuals who do not purchase plans because the plans do not include their doctors or charge exorbitant rates for their HIV drugs may become more dependent on public programs such as Medicaid. Further, if HIV drugs are not available at low- or no-cost sharing, then the Ryan White program, as the federal payer of last resort, will have to foot the bill.

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structure with six tiers and placing all HIV drugs on the sixth (highest) and fifth (next-highest) tier, the issuer may be in technical compliance with the regulation, but the exchange could find that the practice is discriminatory under section 1302(b)(4)(B) of the Act (discriminatory benefit design).

[402] Under the preamble, the exchange, upon receiving a complaint, will be required to "request justification" for suspect drug tiering. *Id.*

[403] David Kashihara & Kelly Carper, *National Health Care Expenses in the U.S. Civilian Noninstitutionalized Population, 2009*, Statistical Brief #355, AGENCY FOR HEALTHCARE RESEARCH & QUALITY (2012) 1 (reporting that almost a third of all health care costs in 2009 were attributed to hospital inpatient stays).

C. HIV Prophylaxes Available without, or with Limited, Cost Sharing

For HIV prophylaxes to be effective in reducing new HIV incidence, they must be covered as a "preventive service."[404] As discussed above, the Act requires that preventive health services defined under 2713 be available without cost sharing, and HHS has incorporated the requirements of section 2713 into the essential health benefits package through 45 C.F.R. § 156.115(a)(4).[405]

If PrEP and PEP were classified as preventive health services under the Public Health Service Act, as amended by the Act, issuers must make them available without cost sharing.[406] Preventive health services include recommendations of the U.S. Preventive Health Services Task Force (Task Force) that receive an A or B rating.[407] Inclusion as preventive health services under the Public Health Service Act would also mean that PrEP and PEP are effectively eliminated from the issuer's drug tiering structure because they must be offered at no cost sharing. PrEP and PEP are preventive health services worthy of a recommendation by the U.S. Preventive Services Task Force.

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[404] Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1302, 124 Stat. 163 (2010) (codified as amended at 42 U.S.C. § 18022(b)(1)(I) (2012)). *See also* Bolin, *supra* note 145, at 58 (arguing that health insurance issuers should be required to cover PrEP).
[405] 78 Fed. Reg. at 12,867 (codified at 45 C.F.R. § 156.115(a)(4)).
[406] The Fenway Institute, *Pre-Exposure Prophylaxis for HIV Prevention: Moving Toward Implementation* 31 (FENWAY INSTITUTE, 2d ed. 2012).
[407] Affordable Care Act, Pub. L. No. 111-148, §1001, 124 Stat. 130 (2010) (codified as amended at 42 U.S.C. § 300gg-13(a)(1)) (amending § 2713 of the Public Health Services Act). An "A" rating means that it is recommended by the Task Force, and that "there is high certainty that the net benefit is substantial." A "B" rating indicates that it is recommended, and that "there is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial." U.S. Preventive Services Task Force, Grade Definitions (2013), http://www.uspreventiveservices taskforce.org/Page/Name/grade-definitions#grade-definitions-after-july-2012 (last accessed Apr. 30, 2015).

As discussed above, there is a wealth of research concerning the benefits of PrEP and PEP.[408]

However, there are only two preventive drug recommendations on the Task Force's list: aspirin to prevent certain conditions, and tamoxifen to prevent some forms of breast cancer; the majority of the recommendations are screening tests.[409] Thus, the Task Force may be reluctant to recommend preventive drugs, and so could be unwilling to recommend PrEP and PEP. The Task Force is a "reputedly conservative body" which suggests that it may not recommend PrEP because the FDA only approved it only three years ago.[410] Thus, there may be a significant delay before the Task Force adds PrEP to its recommended services. On the other hand, the CDC has been recommending PEP for ten years, and so there is no basis to argue that it is not a well-established preventive treatment.[411]

If the Task Force does not recommend PrEP and PEP, HHS should require issuers to include both prophylaxes as "preventive services" within the essential health benefits package. Including HIV prophylaxes within the essential health benefits provision will require limited cost sharing, thus allowing more individuals access to the drugs and reducing new HIV infection, two aims of the National HIV/AIDS Strategy.[412] As discussed above, HHS should not limit this category to drugs and screening required

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[408] *See infra* Part II.C.2.
[409] *USPSTF A & B Recommendations*, U.S. Preventive Services Task Force (2014), http://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations/ (last visited Apr. 30, 2015) and The Fenway Institute, *supra* note 406, at 31.
[410] The Fenway Institute, *supra* note 406, at 31.
[411] *See* PEP GUIDELINES, *supra* note 100.
[412] NATIONAL HIV/AIDS STRATEGY, *supra* note 4, at 7-8, 23.

under section 2713 because this is both duplicative and contrary to the wording in section 1302(b)(1)(I), which differs from section 2713.

Because individuals who are prescribed PrEP or PEP likely will not have HIV, in general, nothing about their health status would trigger provisions that prohibit discrimination on the basis of disability.[413] Although an enrollee could argue that the issuer refused to cover PrEP because of sexual orientation,[414] PrEP is recommended not just for men who have sex with men,[415] but certain "heterosexually active" men and women, and injection drug users.[416] Thus, an enrollee could argue that the micro-level decision to refuse to cover PrEP or PEP for a particular enrollee is not discriminatory.[417]

However, the Act requires the Secretary to ensure that qualified health plans are not designed to "have the effect of discouraging the enrollment in such plan by individuals with significant health needs."[418] HHS has not defined the term "significant health needs," but an individual who has been exposed to HIV and is seeking immediate intervention has a strong argument for satisfying this definition. The term could also be defined more broadly to consider injection drug users, who are at high-risk of HIV, and individuals who are regularly exposed to HIV because of an HIV-positive partner.

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[413] Matt Baume, *Does Hobby Lobby Have to Pay for my PrEP?*, Oct. 27, 2014, ADVOCATE, http://www.advocate.com/31-days-prep/2014/10/27/does-hobby-lobby-have-pay-my-prep.
[414] 45 C.F.R. § 156.200(e) (2013) (prohibiting an issuer of qualified health plans from discriminating on the basis of sexual orientation).
[415] Men who have sex with men may not identify as gay or bisexual. *See* Chandra Ford et al., *Black Sexuality, Social Construction, and Research Targeting 'the Down Low' (the 'DL')*. 17 ANN. EPIDEMIOLOGY 209, 209 (2007).
[416] PREP GUIDELINES, *supra* note 93, at 26-30.
[417] *See* Rosenbaum, *Crossing the Rubicon*, *supra* note 236, at 460 (discussing enrollee-specific discrimination).
[418] Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1311, 124 Stat. 173 (2010) (codified as amended at 42 U.S.C. § 18031(c)(1)(A) (2012)).

A recent article suggests that many plans already cover PrEP, despite its high cost, and that the trouble lies more with health care providers who are hesitant to prescribe it, or patients who are wary of asking for it.[419] While this may be the case now, the use of PrEP has increased in the past two years since the FDA approved it.[420] Thus, if more providers prescribe the drug, PrEP will become more expensive for issuers and they may attempt to exclude it, failing to consider the long-term advantages of keeping people HIV-negative.

D. Section 1557 of the Act Must Act as a Safeguard against Present and Future Discrimination.

Through section 1557 of the Act, Congress was forceful in its statement that no person, on the basis of disability, shall be excluded from participation in, denied the benefits of, or be subject to discrimination under, any health program or activity that is receiving federal financial assistance, including contracts of insurance.[421] HHS must act to implement this provision to safeguard against the continued discriminatory treatment of HIV-positive individuals in contracts of insurance, as its unique breadth demonstrates that it was intended to reach farther than the civil rights laws that came before it. Moreover, HHS's rulemaking on section 1557 would work in conjunction with the more specific nondiscrimination safeguards in the essential health benefits and essential community provider regulations.[422]

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[419] Allday, *supra* note 96.
[420] *Id.*
[421] Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1311, 124 Stat. 160 (2010) (codified as amended at 42 U.S.C. § 18116 (2012)).
[422] *See* Rosenbaum, *Section 1557*, *supra* note 219, at 3 (identifying section 1557 of the Act as "clearly meant to operate in addition to the ACA's fundamental reforms aimed at barring discrimination on the basis of gender, age, and disability").

HHS's regulation implementing section 1557 should specify that a plan would be deemed discriminatory where the plan limits or restricts HIV-related items or services more than items or services for other conditions. Thus, this rule would reach discrimination that has a disparate impact on HIV-positive individuals, because there need not be a demonstration of intent to discriminate: if the plan restricts HIV-related items and services where items and services for other conditions are not so restricted, it is discriminatory.[423] Thus HHS can take a page from mental health parity rules, which require that mental health or substance use disorder benefits, when offered by a plan, do not have more restrictive benefits than medical/surgical benefits.[424]

One challenge to such a regulation may be that section 504 of the Rehabilitation Act has been determined not to delve into the contents of insurance.[425] As discussed above, the Seventh Circuit in *Doe v. Mutual of Omaha* held that a plan that limited coverage for HIV-related services was not discriminatory because it enrolled HIV-positive individuals in plans.[426] Issuers may use the reasoning applied in *Doe v. Mutual of Omaha* to argue that a plan which places all ARTs on the highest cost tier does not discriminate against HIV-positive individuals because they are welcome to enroll in the

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[423] *See* Alexander v. Choate, 469 U.S. 287, 299 (1985) (where the Court "assume{s} without deciding" that section 504 of the Rehabilitation Act permits a disparate impact claim).
[424] Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008, Pub. L. 110-343 (2008) (amending 26 U.S.C. § 9812, 29 U.S.C. § 1185a, and 42 U.S.C. § 300gg-5) and 45 C.F.R. § 146.136(c)(2) (2011). *See also* Rosenbaum, *Insurance Discrimination, supra* note 119, at 111-12.
[425] Rosenbaum, *Insurance Discrimination, supra* note 119, at 108-09.
[426] 179 F.3d 557, 558 (7th Cir. 1999).

plan, they will just need to pay significantly more for their life-saving, generic ARTs than another enrollee pays for their live-saving, generic diabetes medication.[427]

One response to this argument is that a rule that prohibits restriction of items and services solely because they treat HIV does not impose requirements on the contents of the plan. Rather, the rule simply requires plans to offer HIV-related items and services equally as other condition-related items and services. Further, the Affordable Care Act bans the dollar limits in *Doe v. Mutual of Omaha*.[428]

But even if the proposed regulation reaches the content of insurance, section 1557 was intended to go beyond the limits of section 504 of the Rehabilitation Act and other federal civil rights laws. The court in *Rumble* reasoned that, when reading the Act as a whole, "it appears that Congress intended to create a new, health-specific, anti-discrimination cause of action that is subject to a singular standard, regardless of a plaintiff's protected class status."[429] To read the provision otherwise would lead to an "illogical result" because of the varying "enforcement mechanisms and standards that would apply" depending on if the party's claim was based on race, sex, age or disability.[430]

> However, the Court does not intend to imply that Congress meant to create a new anti-discrimination framework that is completely "unbound by the jurisprudence of the four referenced statutes." Nonetheless, given the

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[427] It should also be noted that the claim *Doe v. Mutual of Omaha* was brought under the ADA, not section 504 of the Rehabilitation Act. *Id.* at 558-59.
[428] Affordable Care Act, Pub. L. No. 111-148, tit. I, §1001, 124 Stat. 130 (2010) (codified as amended at 42 U.S.C. § 300gg-11) (amending § 2711 of the Public Health Services Act).
[429] 2015 U.S. Dist. Ct. LEXIS 31591 at 30 ("For instance, a plaintiff bringing a Section 1557 race discrimination claim could allege only disparate treatment, but plaintiffs bringing Section 1557 age, disability, or sex discrimination claims could allege disparate treatment or disparate impact") (citations omitted).
[430] *Id.*

> inconsistency that would result if the Court interpreted Section 1557 as Defendants do, the Court holds that Congress likely referenced the four civil rights statutes mainly in order to identify the "ground{s}" on which discrimination is prohibited — i.e., race, sex, age, and disability. Congress also likely intended that the same standard and burden of proof to apply to a Section 1557 plaintiff, regardless of the plaintiff's protected class status.[431]

Thus, if section 504 of the Rehabilitation Act was referenced only to identify the grounds on which a claim could be brought, then the agency has the opportunity to interpret section 1557 beyond the "standard and burden of proof" applied in section 504 claims.[432] Further, the agency may not be bound by prior interpretations of the reach of section 504 of the Rehabilitation Act, because section 1557 expressly references broader venues in which prohibited discrimination could occur, including "contracts of insurance."[433]

Some may argue that the proposed regulation would be duplicative if HHS relies upon the essential health benefit nondiscrimination provision and the essential community provider requirement to prohibit specific discriminatory practices against HIV-positive individuals.[434] But a general regulation prohibiting the restriction of HIV items and services will enable the agency to prohibit new forms of discrimination which may arise once HHS closes the door to these existing forms.

VI. CONCLUSION

The Affordable Care Act has made improved HIV treatment and prevention possible for the more than one million HIV-positive individuals in the United States and

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[431] *Id.* at 32-3 (citations omitted). The issue of what burden of proof to apply to the plaintiff in *Rumble* was left for another day, as the court only ruled on the defendant's motion to dismiss.
[432] *See id*. at 33.
[433] Affordable Care Act, Pub. L. No. 111-148, tit. I, § 1311, 124 Stat. 160 (2010) (codified as amended at 42 U.S.C. § 18116 (2012)).
[434] In other words, if HHS adopts the proposed regulations discussed in Parts V.A-C.

millions more who are at risk. Indeed, so many of the Affordable Care Act's provisions seem to have been written with HIV in mind: Ryan White providers may not be left out of plan networks; prescription drugs and preventive services must be covered with limited cost-sharing; and discrimination in contracts of insurance has been banished.

Yet the dream of managing and containing HIV through better health insurance coverage for all died on the agency's doorstep, the result of rulemaking that never reached the Act's full potential. HHS must end the ceaseless discrimination against HIV-positive individuals in plan networks and benefit design, and let improved HIV treatment and prevention prove that health insurance reform has accomplished its goals.