It May Be Here to Stay, But Is It Working? The Implementation of the Affordable Care Act Through an Analysis of Coverage of HIV Treatment and Prevention

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I. INTRODUCTION

On June 25, 2015, the Supreme Court upheld a crucial element of the Affordable Care Act (the “Act”), which provides for subsidies to defray the cost of health insurance for applicable individuals.1 This decision, coupled with the Court’s 2012 decision to uphold the individual mandate, led President Obama to declare that “the Affordable Care Act still stands, it is working, and it is here to stay.”2

Even the most vocal opponents of the Act likely agree that the Act both “stands” and is “here to stay,” but the question remains whether the Act is truly “working,” particularly for the most medically vulnerable.3 More specifically, opponents

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3 See infra Section IV
of the Act are concerned with whether the Department of Health and Human Services ("HHS") has implemented the Act in a manner that allows those individuals who suffer from life-long, incurable conditions to benefit from meaningful, quality and nondiscriminatory coverage.

This article answers this question by evaluating the implementation of the Act through the perspective of its effect on those with one such condition: HIV/AIDS. This incurable condition requires life-long medical management, adherence to which is necessary to avoid opportunistic infections and expensive hospitalizations. Further, the treatment of existing HIV cases benefits the public's health because treatment acts to prevent future infections, as do proven prophylactic regimens. In this way, meaningful coverage for HIV-positive individuals translates into more than just the improved health of those afflicted.

The Act is replete with safeguards to ensure that conditions like HIV do not spiral out of control and to prevent future cases from occurring. For example, the essential community provider requirement ensures that health insurance issuers include HIV care specialists in provider networks. The essential health benefits provision

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4 See infra Section II.A.
5 See infra Section II.B. Some individuals with HIV who are eligible for health care under the Act live in states where they are unable to receive the services they need. Jennifer Kates et al., Health Insurance Coverage for People with HIV under the Affordable Care Act: Experiences in Five States, KAISER FAM. FOUND. (Dec. 19, 2014), http://kff.org/report-section/health-insurance-coverage-for-people-with-hiv-issue-brief/.
6 See infra Section III. The Affordable Care Act changed the history of health care in America by providing access to many who would not otherwise be able to afford the plans and services offered. Rachel Garfield et al., New Estimates of Eligibility for ACA Coverage among the Uninsured, KAISER FAM. FOUND. (Jan. 22, 2016), http://kff.org/health-reform/issue-brief/new-estimates-of-eligibility-for-aca-coverage-among-the-uninsured/.
7 Affordable Care Act § 1551 (codified as amended at 42 U.S.C. § 300gg-91(b)(2) (2012)). See also infra Section III.C (defining the scope of the Act). This article uses the term "health insurance issuer" or "issuer" as defined in the Public Health Service Act: "[A]n 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 insurance." Id.
requires health insurance issuers to include HIV medications and preventive services in health insurance products. Thus, the Act, coupled with the Obama Administration’s commitment to HIV treatment and prevention, requires that HHS implement the law so that HIV-positive individuals benefit from continuous and meaningful coverage.

Unfortunately, HHS has failed to deliver on the safeguards of the Act, including the essential community provider requirement and the essential health benefits provision. Under HHS’s rulemaking, or lack thereof, health insurance issuers can, and do, unlawfully limit coverage for HIV-positive people in the individual and small-group markets. For example, under HHS’s regulations, health insurance issuers can limit the providers in their networks to exclude HIV care specialists, thus discouraging HIV-positive individuals from enrolling, and leaving them without health insurance coverage.

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8 See infra Part III.D (defining the scope of essential health benefits).
10 See infra Sections III-IV. Although the Affordable Care Act has been in force for years, there are serious concerns regarding whether HHS is able to fully execute it. See infra Section III.
11 See infra Section IV.A. There is a clear disparity between those the Affordable Care Act is designed to assist and those who are actually benefiting from it. See Vinita Andrapalli, “Healthcare for All”? The Gap Between Rhetoric and Reality in the Affordable Care Act, 61 UCLA L. REV. DISC. 58, 61-65 (2013), available at http://www.ulawlawreview.org/health-care-for-all-the-gap-between-rhetoric-and-reality-in-the-affordable-care-act/ (highlighting Affordable Care Act does not protect recent legal immigrants, legal nonimmigrants, and undocumented immigrants). 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 article. See Avi Dor, et al., The Effect of Private Insurance on the Health of Older, Working Age Adults: Evidence from the Health and Retirement Study, 41 HEALTH SERVS. RES. 759, 761 (2006) available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1713193/.
Thus, these regulations enable insurance plans to prohibit access to important resources. Additionally, health insurance issuers can levy exorbitant cost-sharing requirements even for the generic versions of HIV drugs through discriminatory drug tiering. Furthermore, health insurance issuers can choose not to cover drugs proven to reduce the risk of HIV infection. When implementation fails to provide coverage for those most in need, particularly for those whose treatment equals prevention, it is difficult to conclude that the Act is working as well as President Obama has assured.

To address these coverage shortfalls, HHS can reverse the course by revising its regulations to require issuers to include HIV care specialists in their plan networks, to prohibit discriminatory drug tiering, and to make HIV prophylaxes available without, or with limited, cost sharing.

This article begins with a brief overview of HIV treatment and prevention. It then turns to the features of the Affordable Care Act that enable HIV-positive

12 See infra Section IV.A (describing how insurance issuers can exclude essential community providers from their networks).
14 See infra Section V(discussing how HHS has not mandated coverage of HIV medications as preventive services). See, e.g., Heather Boerner, This Article Made an Insurance Company Cover AIDS Drugs, THE DAILY BEAST (May 18, 2015), http://www.thedailybeast.com/articles/2015/05/18/this-story-made-an-insurance-company-cover-aids-drugs.html (demonstrating how insurers are not required to cover preventive HIV medication).
15 See supra note 2 (discussing President Obama’s assurances that the ACA will work). Although President Obama was not referring to the Act’s success in regards to HIV care and treatment, this article argues that we cannot declare that the Act is “working” until those who are most medically vulnerable are assured meaningful coverage through effective implementation of the law. Infra Section V.
16 See infra Section IV(discussing steps HHS can take to ensure equitable coverage for HIV patients).
17 See infra Section II (discussing statistics, treatment, and prevention of HIV in the United States).
individuals to obtain meaningful health insurance coverage that can, in turn, prevent future HIV infections. Next, this article analyzes HHS’s rulemaking regarding essential community providers and essential health benefits, and examines the ways in which health insurances issuers exploit weaknesses in these rules to the detriment of HIV-positive individuals and those at risk. The next section proposes revised rules that will effectively implement the Act. The article concludes with a discussion of why ensuring meaningful coverage for HIV-positive individuals is the first step towards meaningful coverage for all individuals.

II. HIV

Since the first reported cases of HIV/AIDS in 1981, over half a million people have died of HIV/AIDS-related causes in the United States alone. An estimated 1.2 million people are now living with HIV in the United States. There are an estimated 47,000 new HIV infections each year, thus demonstrating a failure in the country’s attempts to control the disease. Further, the Centers for Disease Control and Prevention (“CDC”) estimates that about thirteen percent of people with HIV do not know that they have the virus.

18 See infra Section III (explaining the aim of the Affordable Care Act is to provide coverage for vulnerable patients).
19 See infra Section IV (discussing ways in which insurers continue to circumvent goal of expanded coverage for HIV patients).
20 See infra Section VI (describing ways in which HHS can ensure coverage for HIV patients).
A. Treatment of HIV

HIV is incurable.25 The virus is particularly damaging because it attacks the immune system, specifically the CD4 T-cell lymphocytes ("CD4 cells"), which normally enable the immune system to fight diseases.26 Although there is no cure for HIV, it is both preventable and treatable.27 Indeed, the two are linked: adherence to HIV drug therapy reduces the risk of transmission to others.28 In other words, an HIV-positive individual who adheres to her drug regimen is much less likely to transmit HIV to an HIV-negative partner.29 Anti-retroviral therapy ("ART") has revolutionized HIV treatment.30 ART is responsible for significant reductions in HIV-associated illness and death, and has transformed HIV from a death sentence to a chronic-like illness by allowing HIV-positive individuals to lead more normal, healthy lives.31 ART can enable HIV-positive individuals to achieve "viral suppression," meaning a low level of HIV in the individual's blood.32 An HIV-positive twenty-year-old who begins ART soon after

26 See CD4 Count, AIDS.GOV, https://www.aids.gov/hiv-aids-basics/just-diagnosed-with-hiv-aids/understand-your-test-results/cd4-count/ (last visited Feb. 10, 2016) (providing background on significance of CD4 Counts). The virus attacks the CD4 cells and uses these cells to copy the virus. Id.
27 Id.
29 See infra Part B (discussing the advancements and need of HIV prevention treatments).
30 See Deeks, supra note 28, at 1525 (explaining benefits of ART, including improving life quality, prolonging life, and reducing HIV transmission risk).
diagnosis and adheres to the regimen can expect to live into her early seventies, which is near the life expectancy of a twenty-year-old without HIV.33

There are drawbacks to an HIV drug regimen. 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.34 Nearly all HIV drugs are available in generic form.35 An HIV-positive individual has to take medication consistently, usually at least once a day, for the rest of his or her life.36 Failing to adhere to the ART regimen can result in a reduced CD4 cell count, an increased viral load, and potential drug resistance.37 Nevertheless, even if a person adheres to the ART drug regime, there could be other unintended health outcomes, such as kidney damage and inflammation.38

Additionally, HIV care is expensive.39 In a recent study, researchers estimate that the lifetime medical cost of HIV treatment for an individual infected with HIV at

33 See 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) (discussing health patterns of ART participants).
37 See id. at H-1-3, E-5 (describing management of care and definitions for treated patients).
38 See Deeks, supra note 28, at 1526-27 (discussing the durability and risks of ART treatment).
The average lifetime medical cost for a thirty-five-year-old who is not HIV-positive is $96,700. 40 The average lifetime medical cost for a thirty-five-year-old is $326,500. 40 Sixty percent of that cost is attributable to the ART regimen; fifteen percent to chronic disease medication, opportunistic illness treatment, and prophylaxis; and the remaining twenty-five percent of the cost relates to non-drug costs, such as hospitalization. 41 Moreover, these costs do not include non-medical costs, such as lost productivity. 42

In a recent Kaiser Family Foundation survey, HIV-positive individuals reported that HIV care specialists are "critical" to obtaining quality care for HIV patients. 43 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. 44 HIV specialists can provide counseling on behavioral risk factors, as well as diagnosis and treatment of other conditions, such as sexually transmitted infections or common co-morbidities. 45 An HIV-positive individual is expected to see an HIV care specialist twice a year. 46

40 Id. at 295. The average lifetime medical cost for a thirty-five-year-old who is not HIV-positive is $96,700. Id. at 293. For HIV-positive individuals, lifetime medical costs range from $267,100 to $435,200, depending upon level of care. Id. at 297 tbl. 2.
41 Id. at 295-98.
42 Id. at 299.
43 Jennifer Kates & Lindsey Dawson, Health Insurance Coverage for People with HIV Under the Affordable Care Act: Experiences in Five States, KAISER FAMILY FOUNDATION 6 (Dec. 2014), http://files.kff.org/attachment/issue-brief-health-insurance-coverage-for-people-with-hiv-under-the-affordable-care-act-experiences-in-five-states. Establishing relationships built on trust with their doctors is vital in order for HIV-positive individuals to be provided with the best comprehensive treatment. Id.
44 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 (2011), available at http://cid.oxfordjournals.org/content/53/11/1043.full.pdf+html (discussing caseload management and higher patient outcomes with access to HIV medical provider experts). 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 treatment and number of HIV-positive patients. Id.
45 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). "Persons who do not receive a diagnosis or care
Certain intangible factors also make HIV specialists a critical part of the HIV-positive individual’s treatment plan. The majority of HIV-positive individuals have reported experiencing discrimination in the health care system, thus highlighting the need for a trust relationship between an HIV-positive individual and her health care provider. Because of a shortage of HIV care specialists working in the United States, experts recommend that primary care physicians, who are not specialists but who treat HIV-positive individuals, consult with HIV care specialists to provide effective treatment to their patients via alternate means, such as through telemedicine. Whether the HIV care specialist treats an HIV-positive individual directly or is simply one part of his or her treatment plan, research has found that HIV-positive individuals “who trust their medical providers have better medication adherence rates and are more likely to accept treatment recommendations.”

also cannot benefit from some additional prevention activities designed to reduce HIV transmission, including screening and counseling for risk behaviors and diagnosis and treatment of sexually transmitted diseases.”

Id. See also TB & HIV Coinfection, CDC.GOV (July 12, 2012), http://www.cdc.gov/tb/topic/tbhivcoinfection/default.htm (explaining different kinds of treatments for HIV infected individuals who contract TB). See also Deeks, supra note 28, at 1526 (discussing the likelihood of HIV-infected individuals with treatment developing other disorders). Common co-morbidities include tuberculosis and hepatitis C. Id.

46 NATIONAL HIV/AIDS STRATEGY (2010), supra note 9, at 21 (explaining expected goals for increasing access to care and living health outcomes for HIV infected individuals). See Gallant et al., supra note 44, at 1046 (describing regular visits to an HIV provider as every three to six months).


48 Id. at 9-10 (discussing a national campaign to address the stigma of HIV in the LGBT community). Those surveyed reported one or more types of discrimination: “[B]eing 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.

49 Gallant, supra note 44, at 1046 (discussing how telemedicine encourages ongoing relationship between patient and provider).

50 Gallant, supra note 44, at 1046. This is with use of a co-management model that has proven effective especially when established at the time of an individual’s initial diagnosis. Id. See also
Despite the achievements of ART, experts have recognized that a dismal continuum of care is associated with HIV treatment. The continuum of care for HIV indicates a steep drop-off between the total number of HIV-positive individuals and the number of HIV-positive individuals that have reached certain milestones, such as linkage to care, receipt of ART, or have attained viral suppression. Less than half of all HIV-positive individuals in the United States are engaged in care, and only about thirty percent of HIV-positive individuals are virally suppressed.

B. Prevention of HIV

Treatment is a highly effective means of preventing HIV transmission, thus giving rise to the common mantra, "treatment as prevention," among HIV experts. When used consistently, ART is ninety-six percent effective in preventing the transmission of HIV to an HIV-negative partner. Early ART acts as a "double benefit" by improving the health of the HIV-positive individual and "by lowering their viral load, reducing the risk they will transmit HIV to others."
Additionally, 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.\textsuperscript{57} Further, early screening has been associated with a reduced risk in progression to AIDS, AIDS-related complications, and death.\textsuperscript{58} The United States Preventive Services Task Force ("Task Force") recommends that everyone aged fifteen to sixty-five be screened for HIV, as well as pregnant women, and those at increased risk of contracting the disease, such as injection drug users of any age.\textsuperscript{59}

There are also pharmacological interventions that reduce the risk of infection before exposure, known as pre-exposure prophylaxis ("PrEP"), and after exposure, known as post-exposure prophylaxis ("PEP").\textsuperscript{60} PrEP is a combination pill containing two anti-retroviral drugs and is recommended for individuals who are at high risk of HIV infection.\textsuperscript{61} In a randomized clinical trial, researchers found that PrEP resulted in a ninety-two percent reduction of the risk of acquiring HIV in those who took the drug consistently.\textsuperscript{62} Truvada, which was approved by the Food and Drug Administration ("FDA") for use as PrEP, costs approximately $1,000 to $1,300 a month, not including

\begin{itemize}
\item http://www.nih.gov/news/health/may2015/niaid-27.htm (proving significantly greater health benefits of starting antiretroviral therapy early to HIV-infected people).
\item See NATIONAL HIV/AIDS STRATEGY (2010), supra note 9, at 7 (calling for more involvement and education on HIV).
\item See supra note 34, at 52 (providing the benefits of early intervention).
\item See id. at 53 (providing clinical considerations and individuals at risk).
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\item HIV/AIDS: Pre-Exposure Prophylaxis (PrEP), supra note 60 (discussing PrEP resources, guidelines, and clinical trials).
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\item 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) (illustrating a multinational study evaluating the safety and efficiency of FTC-TDF). Study subjects were men and transgender women who have sex with men. Id. at 2587.
doctor visits and lab work. In addition, individuals who believe that they were exposed to HIV have the option of taking PEP, which has been scientifically proven to reduce the likelihood of HIV infection. Similar to PrEP, PEP is anti-retroviral therapy that is used after exposure to prevent HIV infection. PEP is eighty percent effective in averting HIV infection. However, PEP is expensive, and can cost between $600 and $1,000 for a twenty-eight day supply, not including other associated medical costs.

C. Insurance Coverage of HIV

Data on health insurance prior to the enactment of the Act show that the majority of HIV-positive, non-elderly adults receiving HIV treatment were enrolled in

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64 See NATIONAL HIV/AIDS STRATEGY (2020), supra note 9, at 16-17 (discussing ways to reduce HIV transmission). See also 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, 1-2 (2005), available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5402a1.htm (discussing PEP’s use after exposure). Like PrEP, PEP is antiretroviral therapy, but rather than being used before infection, it is used after exposure to prevent it. Id.

65 Smith, supra note 64, at 1-2 (discussing the use of PEP after exposure).

66 Raphael J. Landovitz & Judith S. Currier, Postexposure Prophylaxis for HIV Exposure, 361 NEW ENG. J. MED. 1768, 1773-74 (2009). Non-occupational PEP was shown to be effective in observational studies of exposed health care workers. Id. at 1768.

67 See Post-Exposure Prophylaxis, supra note 60 (discussing PEP availability and payment assistance). As with PrEP, manufacturer assistance programs may help with costs. Id.
Medicaid, which provides health coverage to low-income eligible adults. Approximately one-third had private insurance, and six percent were enrolled in Medicare. Seventeen percent were uninsured. The Kaiser Family Foundation estimated that passage of the Affordable Care Act would enable ninety-six percent of the 70,000 HIV-positive uninsured to be eligible for Medicaid or for subsidies to purchase a health insurance plan on an exchange. Because not all states expanded Medicaid under the Act, only about 27,000 additional HIV-positive people are newly eligible for Medicaid. About 15,000 HIV-positive individuals receiving care live in states that did not expand Medicaid and are not eligible for subsidies.

The Ryan White Comprehensive AIDS Resources Emergency Act of 1990 ("Ryan White Act") provides supplemental coverage for HIV-positive individuals who are underinsured and full coverage for HIV-positive individuals who are uninsured.

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70 Kates, supra note 69, at 1 (analyzing key provisions of the ACA and their effects on individuals with HIV).
71 Id. at 6.
73 Kates, supra note 69, at 8 (highlighting that the ACA may benefit individuals living with HIV).
The Ryan White Act enables recipients to either purchase or maintain health insurance by providing federal funds to pay premiums, deductibles, copayments, and coinsurance.\textsuperscript{75} Individuals who receive care at Ryan White-funded facilities are more likely to receive support services associated with better health outcomes, and almost two-thirds of patients who are HIV-positive are virally suppressed.\textsuperscript{76} In addition, the AIDS Drug Assistance Program ("ADAP") provides funding to states and territories to subsidize HIV-related prescription drugs.\textsuperscript{77} The Ryan White Act also provides funding for state or private groups that perform primary medical care for HIV-positive women, infants, children, and youth.\textsuperscript{78} In 2013, over 200,000 people received assistance through ADAP.\textsuperscript{79}

\textbf{III. THE AFFORDABLE CARE ACT'S PROMISE OF MEANINGFUL COVERAGE}

Historically, insurance discrimination against individuals with chronic conditions such as HIV was largely tolerated because of a lack of federal regulation of

\textsuperscript{75} See Neeraj Sood et al., \textit{HIV Care Providers Emphasize the Importance of the Ryan White Program for Access to and Quality of Care}, 33 No. 3 \textit{HEALTH AFF.} 394, 394 (2014) (addressing whether the Ryan White HIV/AIDS Program is still relevant).


\textsuperscript{79} Kaiser Family Foundation, \textit{AIDS Drug Assistance Programs}, supra note 77. Each state or territory determines individual ADAP eligibility, such as an individual's finances, health status, and insurance status. \textit{Id. See also} U.S. Dep't of Health & Human Servs., \textit{Part B- Grants to States & Territories}, HRSA.GOV, http://hab.hrsa.gov/abouthab/partbstates.html (last visited Apr. 11, 2016) (describing the eligibility requirements for ADAP).
health insurance and inadequate nondiscrimination laws.\textsuperscript{80} Prior to the passage of the Act, the absence of uniform health insurance law allowed private health insurance issuers to operate according to market principles, thus incentivizing the exclusion of those who were the most expensive to insure.\textsuperscript{81} For instance, a health insurance issuer could impose lifetime limits on the amount of coverage for HIV, even if there was no actuarial basis for the limits.\textsuperscript{82} Additionally, existing nondiscrimination laws, to the extent they reached health insurance at all, did not prohibit some of the most effective ways of keeping out the most medically vulnerable Americans, including those with HIV.\textsuperscript{83}

All of this changed with the passage of the Affordable Care Act.\textsuperscript{84} The Affordable Care Act attempted to reverse the exclusion of, or limited coverage for,
individuals with complex, life-long health conditions. The Act guarantees access to specialty providers and essential drugs through the insurance products sold in the health insurance exchanges. The Act also amends several other laws that touch on health care, including the Public Health Service Act and the Social Security Act, which demonstrates Congress's strong intent to realign health insurance law. As a result, the Act changed health care in four major ways: the individual mandate, the expansion of Medicaid, the creation of health care exchanges, and substantive health insurance reform.

A. The Individual Mandate and Medicaid Expansion

The central feature of the Affordable Care Act is the requirement of compulsory health insurance, known as the individual mandate. The Affordable Care

http://www.publichealthreports.org/issueopen.cfm?articleID=2586 (explaining Affordable Care Act implementation symbolic of fundamental government interest to provide universal health care).


See 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, 13 (2011) [hereinafter Rosenbaum, Realigning the Social Order] (demonstrating sweeping reforms intended to realign health insurance law).

Id. at 11-16. The Affordable Care Act also contains a broad guarantee of nondiscrimination of health care insurance coverage based on race, sex, disability, and other criteria in health programs and contracts of insurance. See Affordable Care Act § 1557, 42 U.S.C. § 18116 (2012). Although this is an important civil rights provision that could provide protections for HIV-positive individuals and others with disabilities, HHS only recently issued a proposed regulation implementing this provision. See Nondiscrimination in Health Programs and Activities, 80 Fed. Reg. 54,172 (Sept. 8, 2015) (to be codified at 42 C.F.R. pt. 92) (prohibiting discrimination on basis of race, color, national origin, sex, age, or disability); Sara Rosenbaum, Section 1557 of the ACA and Non-Discrimination: The HHS Request for Information, HEALTH REFORM GPS (Aug. 12, 2013), http://www.healthreformgps.org/wp-content/uploads/Rosenbaum-1557-PDF1.pdf [hereinafter Rosenbaum, Section 1557] (explaining implementation of Section 1557 of Affordable Care Act).

I.R.C. § 5000A(f) (2012). See also Rosenbaum, Law & the Public's Health, supra note 84, at 130-31 (explaining the benefits of the individual mandate).
Act requires individuals to maintain "minimum essential coverage" or be subject to a "shared responsibility payment."90 In other words, if an individual does not maintain minimum essential coverage, she must pay a tax.91 The requirement that almost everyone maintain health coverage, known as the individual mandate, is necessary for the creation of "the type of robust risk pool on which fundamental health insurance reform can be built."92 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.93 In exchange, the Act provides for subsidies so that people can afford to purchase plans in the health insurance exchanges.94

The Supreme Court rendered unenforceable the second major feature of the Act, which is the extension of Medicaid to all low-income, non-elderly people who are

90 I.R.C. § 5000A(a)-(b) (2012) (defining minimum essential coverage requirement and tax consequences of failure to maintain standard of coverage).
91 See id. § 5000A(b) (explaining shared responsibility payment). See also id. § 5000A(c) (describing the amount of the tax). 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. Id. § 5000A(e). The requirement does not apply to people with religious exemptions, people not lawfully present in the United States, and people in prison. Id. § 5000A(d).
92 Rosenbaum, Realigning the Social Order, supra note 87, at 12 (explaining benefits of individual mandate in health insurance reform).
94 See Affordable Care Act § 1401, 26 U.S.C. § 36B (2012) (imposing tax credit process for individuals covered under qualified health plans). Individuals may receive subsidies if they have incomes between 100-400 percent of the federal poverty level and are not otherwise eligible for Medicaid or benefits through an employer-sponsored health plan. Id.; Affordable Care Act § 1331(d), 42 U.S.C. § 18031 (2012). See also King v. Burwell, 135 S. Ct. 2480, 2489-97 (2015) (identifying tax credits as crucial to Affordable Care Act and analyzing process of their establishment). In June 2015, the Supreme Court held that premium subsidies are available to individuals purchasing health insurance plans in both the state-based and federally-facilitated health insurance exchanges. Id. See also Rosenbaum, Realigning the Social Order, supra note 87, at 12 (discussing subsidies available to taxpayers within 100 and 400 percent of federal poverty level).
legally present in the United States. The expansion of Medicaid would have given millions of eligible individuals access to affordable health care. Despite the Court’s ruling, twenty-eight states and the District of Columbia have complied with the Act and expanded Medicaid.

B. Health Insurance Exchanges

The Act also creates Health Benefit Exchanges ("Exchanges"). Exchanges act as portals in each state for the purchase of health plans by individuals and small groups. A state agency or nonprofit entity established by the state runs the state’s Exchange. 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 that state. As of the date of this publication, thirteen states and the District of Columbia have elected to establish state Exchanges.

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97 See Current Status of State Medicaid Expansion, KAISER FAMILY FOUNDATION, http://kff.org/health-reform/slide/current-status-of-the-medicaid-expansion-decision/ (last visited Apr. 19, 2016) (showing state responses to Medicaid expansion option). The number has increased to thirty-two states, including D.C. Id.
98 Affordable Care Act § 18031(b) (codifying the requirement to create an Exchange in each state).
100 Affordable Care Act § 18031(d)(1) (stating an Exchange is a government agency or nonprofit established by a State).
101 Affordable Care Act § 18041(c) (stating the Secretary will establish and operate an Exchange within the state and implement requirements).
102 See State Health Insurance Marketplace Types, 2016, KAISER FAMILY FOUNDATION, http://kff.org/health-reform/state-indicator/state-health-insurance-marketplace-types/ (last visited Apr. 13, 2016) (showing the state by state status of each Exchange). Three states have "federally-supported" Exchanges and seven have "state-partnership" Exchanges. Id. The remaining twenty-seven states have federally-facilitated Exchanges. Id.
Only "qualified health plans" can be sold in the Exchanges.\textsuperscript{103} The Secretary of HHS establishes criteria for the certification of health plans as qualified health plans.\textsuperscript{104} The criteria requires that issuers must "meet marketing requirements and not employ marketing practices or benefit designs that have the effect of discouraging the enrollment in such plans by individuals with significant health needs."\textsuperscript{105}

C. Essential Community Providers

The Act also serves to end a more subtle form of discrimination that results when HIV-positive individuals are discouraged from enrolling in health insurance plans due to the exclusion of certain providers from a plan's network.\textsuperscript{106} Under the Act, qualified health plans must ensure a sufficient choice of providers and include essential community providers within their plan networks.\textsuperscript{107} 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

\textsuperscript{103} See Affordable Care Act § 18031(d)(2)(B) (discussing limitations on the Exchanges).
\textsuperscript{104} See \textit{id.} § 18031(c)(1) (stating the Secretary is responsible for determining qualified health plans).
\textsuperscript{105} \textit{Id.} § 18031(c)(1)(A).
\textsuperscript{106} See Rosenbaum, \textit{Section 1557}, supra note 88 (discussing the efforts taken to end discrimination in health care under the Affordable Care Act).
\textsuperscript{107} See Affordable Care Act § 18031(c)(1)(B)-(C) (stating providers serve predominately low-income, medically-underserved individuals).
\textsuperscript{108} \textit{Id.}
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, which includes HIV care specialists who receive funding through the Ryan White program.109

D. Essential Health Benefits

Qualified health plans must also include "essential health benefits" with limited cost-sharing, and are rated based on their actuarial values.110 The Act sets out the actuarial levels of coverage for essential health benefits packages, and identifies each level with a medal.111 The extent of coverage varies depending on the medal level.112 Additionally, plans sold "off the exchange" in the private health insurance market must include essential health benefits.113 However, the essential health benefits provision does not apply to self-insured, employer-sponsored plans or large group, fully-insured employer plans.114

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111 See id. § 18022(d) (stating the medal levels are platinum, gold, silver, and bronze).

112 See id. § 18022(d)(1)(B). 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 seventy percent of the full actuarial value of the benefits provided under the plan. Id.

113 Affordable Care Act tit. I, § 2727 (codified as amended at 42 U.S.C. § 300gg-6(a) (2012)) (discussing plans sold in the private health insurance market). "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 this title." Affordable Care Act tit. I, § 1304, (codified as amended at 42 U.S.C. § 18024(b)(2) (2012) (defining small employer as one with 100 employees or less).

114 Affordable Care Act tit. I, § 2727 (codified as amended at 42 U.S.C. § 300gg-6 (2012)). See also, ESSENTIAL HEALTH BENEFITS: BALANCING COVERAGE AND COST 19 (Cheryl Ulmer, et al.)
Essential health benefits include ten general categories of items and services, which include the following:

(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; and
(J) Pediatric services, including oral and vision care.\textsuperscript{115}

The Affordable Care Act does not define any of the categories, and because this is a new law, there is little to no legislative history or case law to aid the interpretation.\textsuperscript{116} However, the scope of essential health benefits must be “equal to the scope of benefits provided under a typical employer plan, as determined by the Secretary.”\textsuperscript{117}

The essential health benefits requirement also promises nondiscrimination.\textsuperscript{118} In defining the categories of essential health benefits, 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

\textsuperscript{115} Affordable Care Act tit. I, § 1302 (codified as amended at 42 U.S.C. § 18022(b)(1) (2012)).
\textsuperscript{116} See 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] (explaining it is not necessary to define the essential benefits under the health benefits statute).
\textsuperscript{117} Affordable Care Act tit. I, § 1302 (codified as amended at 42 U.S.C. § 18022(b)(2) (2012)). 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 the essential health benefits should be modified or updated. Id. § 1302 (codified as amended at 42 U.S.C. § 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. § 1302 (codified as amended at 42 U.S.C. § 18022(d)(3)).
\textsuperscript{118} Rosenbaum, Section 1557, supra note 88 (explaining the nondiscriminatory position of the essential health benefits plan).
expected length of life.” HHS must “take into account the health care needs of diverse segments of the population,” including people with disabilities, and “ensure that health benefits established as essential [are] not . . . subject to denial” on the basis of the individual’s “present or predicted disability, degree of medical dependency, or quality of life.” In other words, the Secretary’s requirements for the essential health benefits package must safeguard against discriminatory practices.

E. Other Insurance Market Reforms

The Affordable Care Act introduced important market reforms, particularly with respect to the content and design of health insurance plans. For instance, the Act requires all issuers to cover “preventive health services” without cost-sharing. Preventive health services include certain recommendations of the Task Force, certain immunizations, and certain preventive care and screening for women and children.

\[\text{Reference numbers and citations}\]

119 Affordable Care Act, § 1302 (codified as amended at 42 U.S.C. § 18022(b)(4)(B)).
120 Id. § 1302 (codified as amended at 42 U.S.C. § 18022(b)(4)(C)-(D)).
121 Rosenbaum, Section 1557, supra note 88 (explaining the shielding against discrimination in essential health benefits plans). However, the Affordable Care 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, § 1562 (codified as amended at 42 U.S.C. § 18120(d)(2) (2012)). The Affordable Care Act does not define utilization management techniques. Rosenbaum, Crossing the Rubicon, supra note 116, at 555-56 (describing the limits of discretion of the Health and Human Service secretary). At this point, it is unclear how HHS will reconcile its nondiscrimination mandate with this exclusion for utilization management. Id.
122 Rosenbaum, Law & the Public’s Health, supra note 84, at 131 (explaining the relationship between Americans and health care system).
123 Affordable Care Act, § 2713 (codified as amended at 42 U.S.C. § 300gg-13) (amending § 2701 of the Public Health Services Act). A benefit with an “A” rating is one in which “there is high certainty that the net benefit is substantial.” Grade Definitions, U.S. PREVENTIVE SERVICES TASK FORCE, http://www.uspreventiveservicestaskforce.org/Page/Name/grade-definitions-after-july-2012 (last updated Oct. 2014). 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.” Id.
124 Affordable Care Act, § 2713 (codified as amended at 42 U.S.C. § 300gg-13); USPSTF A and B Recommendations, U.S. PREVENTIVE SERVICES TASK FORCE, http://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations/ (last updated Feb. 2016). Some specific examples of recommendations allocated specifically to women include screening tests for breast cancer, breastfeeding counseling, and a whole host of other preventative care issues that are predominantly issues for only women. See USPSTF A and
The Act also bans discriminatory tactics that kept many people from becoming insured before the Act’s passage. For example, an issuer must accept every individual that applies for coverage, and cannot deny or refuse to renew coverage because of a pre-existing condition. In addition, an issuer cannot set premiums in a discriminatory manner, nor can it set lifetime or annual monetary limits on coverage. Furthermore, an issuer cannot rescind a plan except where the enrollee has committed fraud or misrepresented material facts and, it cannot impose excessive waiting periods (more than ninety days) before coverage begins. The Act also prohibits discrimination on the basis of health status and disability in determining rules of eligibility and establishing premiums.

As the essential community provider requirement, essential health benefits package, and market reforms demonstrate, the Act includes numerous provisions that

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\(^{125}\) Rosenbaum, Realigning the Social Order, supra note 92, at 13-14. The market reform’s primary responsibility was to halt all discriminatory practices against those who needed insurance the most. \(\text{Id.}^{126}\) Secondly, the market reform addressed these issues by requiring more transparent processes to verify coverage was extended to all. \(\text{Id.}^{127}\) Lastly, the market reform ensured the quality of clinical research by requiring coverage to routine health care costs incurred by participants as a result of these clinical studies. \(\text{Id.}^{128}\) at 15.

\(^{126}\) Affordable Care Act, § 1101 (codified as amended at 42 U.S.C. § 18001). A “pre-existing condition exclusion” is described as “a limitation or exclusion of benefits relating to a condition based on the fact that the condition was present before the date of enrollment for such coverage, whether or not any medical advice, diagnosis, care, or treatment was recommended or received before such date.” \(\text{Id.}^{129}\)

\(^{127}\) Affordable Care Act, § 1101 (codified as amended in 42 U.S.C. § 300gg-11). However, an insurer can restrict enrollment to special or open enrollment periods. \(\text{Id.}^{130}\) § 2702 (codified as amended in 42 U.S.C. § 300gg-1). An insurer may vary its rates with respect to coverage or plan involvement for the following exceptions: whether the plan covers an individual or a family; age; tobacco use; and rating area. \(\text{Id.}^{131}\) § 1101 (codified as amended in 42 U.S.C. § 300gg-11).


\(^{129}\) Affordable Care Act, § 2705 (codified as amended in 42 U.S.C. § 300gg-4).
aim to remedy the inequities in insurance coverage experienced by individuals with complex, lifelong health conditions, such as HIV.\(^\text{130}\) The only remaining question is whether HHS, the agency charged with implementing much of health insurance reform, has implemented the Affordable Care Act such that these inequities are remedied in practice.\(^\text{131}\)

**IV. HHS HAS NOT MEANINGFULLY IMPLEMENTED THE ACT’S REFORMS, AS ILLUSTRATED BY THE TREATMENT OF HIV-POSITIVE INDIVIDUALS**

HHS has failed to require meaningful, not just accessible or affordable, coverage for individuals with complex health conditions, such as HIV. 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. For example, health insurance issuers can exclude essential community providers from plan networks and charge exorbitant prices for medication, despite unambiguous statutory prohibitions against such plan networks and benefit designs.\(^\text{132}\) Discriminatory practices specifically targeting or impacting HIV-

\(^\text{130}\) *Id.* (stating provisions set out to protect individual patients and beneficiaries of the Affordable Care Act).


positive individuals have continued in the health insurance Exchanges since issuers began to sell plans in the Exchanges in 2014.133

A. Rulemaking that Excludes Essential Community Providers

As discussed above, HIV-positive individuals often rely upon HIV care specialists for treatment because these providers are familiar with the complex nature of the condition and can provide low-cost care to those who would otherwise not be able to afford it.134 Thus, to ensure access to Ryan White providers, the Act requires issuers to include essential community providers, where available, in plan networks.135 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 an issuer of a qualified health plan (“QHP”) sold in the federally-facilitated and state-based Exchanges:

[M]ust 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 Shortage Areas within the QHP’s service area, in accordance with the Exchange’s network adequacy standards.136

As numerous commenters argued, the Act plainly states that plans shall “include within health insurance plan networks those essential community providers, where

133 Affordable Care Act § 1311 (codified as amended at 42 U.S.C. § 18031(b)(1) (2012)).
134 See supra note 76 and accompanying text (highlighting utility of Ryan White Programs in expanding and enhancing treatment options for HIV patients).
135 Affordable Care Act, § 1311 (codified as amended at 42 U.S.C. § 18031(c)(1)(C) (2012)). This article uses the terms “Ryan White provider” and “HIV care specialist” interchangeably, because HIV care specialists receive funding through the Ryan White program. See supra notes 80-83 (summarizing history of insurance coverage for HIV patients).
136 Essential Community Providers, 45 C.F.R § 156.235 (2016) (emphasis added) (requiring QHP to contract with at least one ECP provider).
available, that serve predominately low-income, medically-underserved individuals."¹³⁷

Thus, the Act does not give plans the discretion to include only a "sufficient number" of essential community providers, and thereby potentially exclude some available Ryan White providers.¹³⁸

If Congress intended to limit the number of essential community providers in a plan network, it would have provided this discretion in the law.¹³⁹ Indeed, Congress permitted this discretion concerning network adequacy in the subsection of the Act immediately preceding the subsection concerning essential community providers.¹⁴⁰ In that provision, Congress did not require plans to include all providers, but instead required merely "a sufficient choice of providers."¹⁴¹ Accordingly, by leaving out the word "sufficient" from the provision requiring that essential community providers be provided in plan networks, it is clear that Congress intended no such limitation.¹⁴²

The only plausible limitation on the requirement that essential community providers be included in plan networks is that the essential community providers must


¹³⁸ Cf. 42 U.S.C. § 18031(c)(1)(B); Letter from Roger Schwartz to Centers for Medicare and Medicaid services, supra note 137, at 2 (recognizing the critical role of health centers by making the statutory requirement "shall").


¹⁴¹ Id. (discussing criteria for the certification of health plans as qualified health plan).

be “available.” However, an analysis of other uses of the phrase “where available” within the Act demonstrate that “where available” connotes existence or presence, not sufficiency or distribution. For 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.” The usual reading of this phrase is that agencies should use common quality measures, if they exist, rather than selecting only some measures and leaving out the rest. Further, HHS itself uses the word “available” to refer to essential community providers that exist in a plan’s service area.

In the preamble to the 2013 regulation, HHS argued that the term “where available,” as used in the provision requiring that essential community providers be

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144 Affordable Care Act tit. III, §§ 3011, 3502(b)(3) (codified as amended at 42 U.S.C. § 399HH(b)(2)(A) (2012); 42 U.S.C. § 256a-1(b)(3) (2012)); tit. VI § 6703(a)(1)(C) (codified as amended at 42 U.S.C. § 1397m); tit. X, § 10501(1)(2). The term “where available” is used in five other places in the Affordable Care Act. In discussing the development of national quality standards, it provides that coordination among departmental agencies shall include steps to minimize duplication of efforts and utilize common quality measures, “where available.” See Affordable Care Act § 3011 (codified at 42 U.S.C. § 399HH(b)(2)(A) (2012)). When providing grants for community health teams, it describes 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.” Affordable Care Act § 3502(b)(3) (codified at 42 U.S.C. § 256a-1(b)(3)(2012)). It further provides 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.” Affordable Care Act § 6703(a)(1)(C) (codified at 42 U.S.C. § 1397m (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.” Affordable Care Act § 10501(1)(2) (codified at 42 U.S.C. § 293m(2012)).
145 Affordable Care Act § 3011 (codified at 42 U.S.C. § 399HH(b)(2)(A) (2012)).
included in plan networks, justifies, in part, its insertion of a sufficiency limitation. HHS stated:

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.147

However, the HHS regulation uses both the term “a sufficient number” and “where available,” which suggests that HHS itself does not find the terms equivalent.148 This argument is further flawed because the Act does not indicate that plans will include a “subset” of essential community providers: all essential community providers, by the terms of the Act, serve predominately low-income and medically underserved populations, not just a subset.149 HHS’s argument that the Act allows plans to include only a subset of essential community providers is undermined by its own definition of essential community providers, which provides that “essential community provider[s] [are] provider[s] that serve[] predominantly low-income, medically underserved individuals.”150

Although HHS developed more specific requirements for issuers selling plans in the federally-facilitated Exchanges, these rules fall short of the Act’s requirement that all essential community providers, including Ryan White providers, be included in plan networks.151 For plan year 2016, health plans sold through the federally-facilitated

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148 See 45 C.F.R. § 156.235 (2014) (stating both terms used in regulation discussing QHP’s use of community providers).
149 Affordable Care Act § 1311 (codified as amended at 42 U.S.C. § 18031(c)(1)(C) (2012)) (explaining there is no mention of a subset within the Affordable Care Act).
150 45 C.F.R. § 156.235(c) (2014) (emphasis added) (discussing the definition of community provider and how QHP issuer enrolls and terminates coverage).
151 See id. HHS set out its rules for issuers selling plans in the federally-facilitated Exchanges through letters to issuers and in its regulations. Id.
Exchanges will be found to have a sufficient number and geographic distribution of essential community providers if the plan network includes at least thirty percent of available essential community providers in the plan’s service area.\textsuperscript{152} This includes all available Indian health care providers and at least one essential community provider in each HHS “[Essential community provider] category,” including Ryan White providers.\textsuperscript{153} 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.\textsuperscript{154} The regulations do not require that a plan include all essential community providers in the plan’s network, as the Act requires.

To make matters worse, HHS does not even hold issuers to the woefully low standards that the regulations provide. Where an issuer chooses not to comply with the thirty percent threshold and minimum provider participation requirement, it may instead 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 explain how the network will be strengthened for the next plan.

\hspace{1cm}\textsuperscript{152} See 2016 Letter to Issuers, \textit{infra} note 146, at 25 (examining the requirements for the general ECP enforcement standard). The minimum percentage of thirty percent is set forth in the 2016 Letter to Issuers. \textit{Id.}

\hspace{1cm}\textsuperscript{153} 45 C.F.R. § 156.236 (2014). The Act defines essential community providers as those providers 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.” Affordable Care Act § 1311 (c)(1)(C). Providers described under section 1927(c)(1)(D)(i)(IV) of the Social Security Act are also expressly included. \textit{Id.}

These providers have been found to benefit from nominal drug pricing under Medicaid but do not participate in the low-cost drug purchasing program under section 340B of the Public Health Service Act. 42 U.S.C. § 1396r-8(c)(1)(D)(i)(IV) (2012).

\hspace{1cm}\textsuperscript{154} 45 C.F.R. § 156.235 (2014). 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). \textit{Id.} (providing an additional explanation of HHS’s alternate standard).
For example, "if available . . . Ryan White HIV/AIDS Program provider(s) . . . are missing from the network(s), the [QHP] Application must explain how its target populations will be served." However, Congress determined that essential community providers, not other providers, should serve target populations.

What is the end result of the agency's inconsistent rulemaking? First, because HHS does not require issuers to offer contracts to all Ryan White providers, there is no real essential community provider requirement in state-based Exchanges, despite the clear mandate of the Act. Instead, issuers in state-based Exchanges have the option of limiting the number of Ryan White providers, as long as they cover a "broad range," and "sufficient number" of providers, and the "geographic distribution . . . ensures reasonable and timely access" to those individuals who rely upon them. Since the regulation does not define the terms "broad range," "sufficient number," "geographic distribution," "reasonable and timely access," states are free to establish their own rules.

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155 Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016, 80 Fed. Reg. 10,750, 10,834 (2015). 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 was not reached; and plans for how the current design of the network will provide adequate care to enrollees. See 2016 Letter to Issuers, supra note 146, at 28 (explaining the criteria used for narrative justification in issuer’s application for QHP certification).

156 2016 Letter to Issuers, supra note 146, at 28 (illustrating example of QHP requirement).


concerning what constitutes a plan network that will pass muster under HHS's regulations. States are equally permitted to forgo any rulemaking, as long as the Exchange is satisfied that there are a "sufficient number and geographic distribution" to provide access to "a broad range of . . . providers."\(^{159}\) In other words, states can evaluate each plan's network on an ad hoc basis because HHS neither imposes discrete requirements on the Exchange, nor mandates that states make their own requirements.

Second, HIV patients will fare little better in federally-facilitated Exchanges. A plan must offer a contract to only one Ryan White provider in the plan's service area and offer contracts to at least thirty percent of available essential community providers in the plan's service area.\(^{160}\) Further, a plan need not meet this low bar if it can explain why it has not included any Ryan White providers in its plan network.\(^{161}\)

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. HIV-positive individuals are discouraged from enrolling in plans that do not cover Ryan White providers, which is an implicit form of discrimination that the Act was supposed to remedy. Rather than explicitly excluding HIV-positive individuals based on their health status, issuers can simply craft plan networks that do not include those providers who are essential to HIV care. Such a permissive interpretation contravenes the federal government's broader goals of

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\(^{159}\) 45 C.F.R. § 156.235 (2014) (establishing QHP issuer requirements).

\(^{160}\) See id. The minimum percentage of thirty percent is set forth in the 2016 Letter to Issuers. 2016 Letter to Issuers, supra note 146, at 25-26. This is in contrast to all Indian health providers, to whom issuers must offer contracts. Id. at 25.

\(^{161}\) See Transparency in Coverage, 45 C.F.R. 156.220 (2015) (discussing the low standard set by HHS regarding the Ryan White provider). See also 2016 Letter to Issuers, supra note 146, at 28 (setting out requirements for the narrative justification).
increasing the number of HIV-positive individuals who are retained in care by excluding the very providers who are essential to that care.\textsuperscript{162}

B. Rulemaking that Allows Adverse Drug Tiering

As discussed above, the essential health benefits package also takes aim at discriminatory benefit design by requiring certain plans, including those sold in the Exchanges, to cover prescription drugs and nine other essential health benefits categories.\textsuperscript{163} However, HHS has deferred to the states regarding what constitutes essential health benefits, and has determined not to enforce the prohibition on discriminatory benefit design, thus allowing issuers to use adverse drug tiering to discourage enrollment by HIV-positive individuals.

Pursuant to the Act, in defining the ten core essential health benefits, the Secretary must not “design benefits in ways that discriminate against individuals because of their age, disability, or expected length of life.”\textsuperscript{164} This is no simple task, in part because the Act does not provide any guidance as to how to define the categories, and HHS is without the benefit of legislative history on the matter.\textsuperscript{165} Further, the Act contains a “paradoxical statutory juxtaposition” because the Act requires that the essential health benefits package be “equal to the scope of benefits provided under a typical employer plan, as determined by the Secretary,” but the design of those benefits

\textsuperscript{162} See NATIONAL HIV/AIDS STRATEGY (2020), supra note 9, at 23 (discussing the various evidence-based approaches that can be implemented to prevent HIV infections).

\textsuperscript{163} See supra notes 110-115, and accompanying text (discussing the specific categories under the essential health benefits).

\textsuperscript{164} See Affordable Care Act tit. I, § 1302 (codified as amended at 42 U.S.C. § 18022(b)(4) (2012)).

\textsuperscript{165} See Rosenbaum, Crossing the Rubicon, supra note 116, at 556 (explaining the lack of legislative history and how essential health benefits should be interpreted).
must not discriminate against individuals, which does not take into account that a
“typical employer plan” might well discriminate against individuals.166

To aid in the design of these benefits, HHS called upon the Institute of
Medicine (“IOM”) for advice in how to interpret the Act’s requirement that the essential
health benefits package be both “typical” and nondiscriminatory.167 A committee within
IOM researched what benefits were offered under employer plans.168 Although by no
means a fulsome survey of typical employer plans, the committee found that “it appears
the typical employer plan will have to be expanded to accommodate the [ten] categories
of care.”169 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 expand to include the
ten essential health benefits.170 It reasoned that any package had to consider cost to be
feasible; thus, “the cost of the initial [essential health benefits (“EHBs”) ] package . . .
should be compared to a premium target, defined by the committee as what small
employers would have paid on average in 2014.”171

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166 Id. at 556. See also Affordable Care Act tit. I, § 1302 (codified as amended at 42 U.S.C. §
18022(b)(2) (2012)).
167 See IOM REPORT, supra note 114, at 13 (describing the process of determining essential health
benefits).
168 Id. at 61-62. The Affordable Care Act required the U.S. Department of Labor to conduct a
survey to determine what benefits were included in a typical employer plan. See Affordable Care
found this survey lacking, and stated that the survey “did not fully reflect whether plans actually
offer a specific benefit.” IOM REPORT, supra note 114, at 61-62.
169 Id. IOM conducted its research in part by surveying three issuers of employer plans about the
covered items and services that could be considered “habilitative.” Id. 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.” Id. at 62.
170 See id. at 90 (summarizing findings of the committee).
171 Id. at 1-2.
If HHS did not entirely ignore the committee's recommendations, it diverged in a surprising way.\(^{172}\) In its 2013 regulation, rather than defining the essential health benefit package and tying it to the costs of a typical small employer plan, HHS allowed states to choose an existing employer plan in the state as a benchmark plan to "reflect[] both the scope of services and limits offered by a typical employer plan in that state."\(^{173}\) The regulation then required that the essential health benefits package be "substantially equal" to the benefits in the benchmark plan, including coverage benefits, limitations on coverage, and prescription drug benefits.\(^{174}\)

As to prescription drug benefits, the 2013 regulations contain minimal requirements that only relate to drug formularies.\(^{175}\) Specifically, a plan must include either one drug in every United States Pharmacopeia category and class, or the same number of prescription drugs in each category and class as the benchmark plan.\(^{176}\) 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."\(^{177}\) The plan

\(^{172}\) See Nicholas Bagley & Helen Levy, *Essential Health Benefits & the Affordable Care Act: Law & Process*, 39 J. Health Pol. Pol'y & Law 441, 446-67 (2014) (explaining the new regulation that was implemented).

\(^{173}\) State selection of benchmark, 45 C.F.R. § 156.100 (2015) (describing how states identify a single EHB-benchmark plan); Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation, 78 Fed. Reg. at 12,840. The benchmark plan could be any of the following: (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. 45 C.F.R. § 156.100(a). If the state does not select a benchmark, the default benchmark is the largest small-group plan in the state. *Id.* § 156.100(d).

\(^{174}\) *Id.* § 156.115(a)(1).

\(^{175}\) *Id.* § 156.122.

\(^{176}\) *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). *Id.*

\(^{177}\) 45 C.F.R. § 156.280(d).
must also provide its drug formulary to the Exchange, the state, or the Office of Personnel Management. \textsuperscript{178}

As to the nondiscrimination provision regarding essential health benefits, the 2013 regulations generally track the language of the Act that prohibits plan design that discriminates on the basis of age, disability or expected length of life:

\begin{quote}
\text{[A]n 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.} \textsuperscript{179}
\end{quote}

An issuer must also comply with § 156.200(e) of the regulations, which prohibits discrimination in qualified health plans on the basis of race, color, national origin, disability, age, sex, gender identity, or sexual orientation. \textsuperscript{180} Although the regulation’s mandate is clear, HHS does not define the term “discriminate.” \textsuperscript{181}

Under the 2013 regulations, HHS let the states decide what benefits are essential, rather than the federal government. \textsuperscript{182} Other regulations lead to further variation among state plans, such as benefit substitution (allowing issuers to substitute benefits from one category with benefits from another) and state-mandated benefit requirements (requiring that state benefit requirements be incorporated into the state’s

\textsuperscript{178} Id.
\textsuperscript{179} Id. § 156.125(a); Affordable Care Act, tit. I, § 1302 (codified as amended at 42 U.S.C. § 18022(b)(4)(B)(2012). “In defining the essential health benefits ... the Secretary 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.” \textit{Id}. \textsuperscript{180} See 45 C.F.R. § 156.125(b) (2016) (stating that an issuer providing EHB must comply with given requirements).
\textsuperscript{181} See Rosenbaum et al., \textit{Crossing the Rubicon}, supra note 116, at 558 (discussing the meaning of “discriminate” and discussing generally medical necessity definitions).
package).\textsuperscript{183} If the plan covers the greater of one drug in every USP category or class, or the same number of drugs in each category or class as the benchmark; complies with state coverage mandates; and provides benefits consistent with the state’s benchmark plan, then the plan will satisfy HHS’s regulations.\textsuperscript{184} Despite ostensibly prohibiting discrimination in benefit design, HHS has failed to explain how the same prohibition might apply to benefit coverage.\textsuperscript{185} For instance, HHS has provided no clarification as to whether the regulation bans “macro” level discrimination, such as refusing to cover any medications that treat a specific condition, or whether the regulation bans case-specific discrimination, such as refusing to cover a medication for a particular enrollee.\textsuperscript{186}

Issuers wasted no time in exploiting the weaknesses in the 2013 regulations to discriminate against HIV-positive individuals, by, for example, placing ART within the plan’s highest cost tiers.\textsuperscript{187} For example, Coventry Health Care offered a silver plan sold in the Exchange that included six drug tiers.\textsuperscript{188} Under the plan, all HIV drugs were included in the highest tier, and required prior authorization, quantity limits and forty percent coinsurance after a $1,000 prescription deductible.\textsuperscript{189} One study found that

\textsuperscript{183} See 45 C.F.R. § 156.115 (2016) (describing provision of EHB). Note that benefit substitution is not permitted for prescription drugs. See id.; 45 C.F.R. § 155.170 (2016) (describing additional required benefits). See also GIOVANELLI ET AL., supra note 182, at 3-6 (discussing benefit substitutions, habilitative services, and state mandated benefits of Affordable Care Act).

\textsuperscript{184} See GIOVANELLI ET AL., supra note 182, at 6 (discussing implementation of mandated services).

\textsuperscript{185} See Rosenbaum et al., Crossing the Rubicon, supra note 116, at 560 (discussing two types of coverage determinations and under what circumstances each applies).

\textsuperscript{186} Id.

\textsuperscript{187} See NHeLP and The AIDS Institute Complaint to HHS Re HIV/AIDS Discrimination by Florida Insurers (May 29, 2014) [hereinafter, NHeLP complaint], available at http://www.healthlaw.org/publications/browse-all-publications/HHS-HIV-Complaint#.Vz40YNcb4iE (arguing that the placement of ART drug in a high cost tier is discrimination).

\textsuperscript{188} See id. at 8 (outlining Coventry’s six drug tiers).

\textsuperscript{189} See id. at 3, 8 (discussing insurance coverage or lack thereof for generic and brand name antiretrovirals).
HIV-positive individuals who were enrolled in adverse tiering plans paid more than three times—or $3,277—more per year than enrollees in plans that did not engage in adverse tiering. Further, half of the adverse tiering plans, as opposed to nineteen percent of plans without adverse tiering, required a prescription deductible.

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 offered silver-level qualified health plans sold in Florida that used adverse tiering to discriminate against HIV-positive enrollees and discouraged enrollment by HIV-positive individuals. Although all of the issuers identified in the complaint eventually agreed to reduce the costs of ART in plans sold in Florida, the agreements were reached with the state insurance commission, not HHS.

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191 Id. (comparing cost of drugs and differences in deductibles between plans with and without adverse tiering).
Adverse tiering discourages enrollment by HIV-positive individuals, and, even worse, deprives HIV-positive individuals of access to drugs that are essential to survival because these drugs continue to be prohibitively expensive under the drug tiers. The true function of drug tiering—to restrict the use of expensive drugs where an alternative 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 the plan’s highest cost tier. Thus, because adverse tiering constitutes a discriminatory benefit design, it violates the Act by discriminating against HIV-positive individuals because of their disability and because it discourages enrollment by HIV-positive individuals. Yet, 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, which began six months after NHeLP filed its complaint against the Florida issuers, HHS referred to the existence of “benefit designs that [it] believe[d] would discourage enrollment by individuals based on . . . health conditions, in effect making those plans . . . state regulators). On a positive note, Aetna, one issuer implicated in the NHeLP complaint, recently agreed to include all ART in the generic brand tier in its plans sold nationwide. Press Release, National Health Law Program, Aetna Agrees to Make HIV Medications More Affordable After Complaint (Mar. 27, 2015), available at 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 $5 to $100, after deductibles. Id. The change became effective on June 1, 2015. Id.

194 See infra Section IV.B (explaining that placing essential HIV medicines in the highest tier makes them overly expensive).

195 See Jacobs & Sommers, supra note 13, at 400 (discussing how adverse tiering’s function is deterrence whereas traditional tiering encourages generic drug use).


discriminatory.” The agency specifically referenced the practice of adverse tiering in its proposed rule, stating, “[S]uch plan designs effectively discriminate against, or discourage enrollment by, individuals who have those chronic conditions.” Although HHS addressed the practice of adverse tiering, even going so far as to imply that a plan design that uses adverse tiering would be discriminatory, it nevertheless declined to propose a regulation that prohibited adverse tiering, even while acknowledging the nondiscrimination provisions in the Act.

In response to the proposed rule, one commenter urged HHS to declare that adverse tiering is not discriminatory. 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.

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198 See Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016, Proposed rule, 79 Fed. Reg. 70,673, 70,722 (proposed Nov. 26, 2014) (reaffirming that 45 C.F.R. § 156.125 as it stands provides a blanket prohibition against discrimination).

199 79 Fed. Reg. 70,723.

200 See id. (lacking any express guidance on adverse tiering and its potentially discriminating impact).

201 Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016, Final Rule 80 Fed. Reg. at 10,823 (2015). It should be noted that many other commenters urged HHS to find adverse tiering discriminatory. See, e.g., HIV HEALTH CARE ACCES WORKING GROUP COMMENTS ON NOTICE OF PAYMENT AND BENEFIT PARAMETERS FOR 2016 1 (Dec. 22, 2014), available at https://www.regulations.gov/#!documentDetail;D=CMS-2014-0152-0144 (urging HHS to adopt national approach to include coverage for people living with chronic conditions).

HHS explained its decision not to regulate by claiming that a determination of discrimination “is often dependent on specific facts and circumstances.” HHS again acknowledged that practices such as adverse drug tiering “contain indications that they are discriminatory, and therefore further investigation by the enforcing entity may be required.”

If adverse tiering were merely theoretical, then HHS’s cautious approach might 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 ART—including generics—in the plan’s highest cost tiers, which singles out HIV-positive individuals for discriminatory treatment. In other words, HHS already had the “facts and circumstances” to find that adverse tiering is a per se discriminatory benefit design, and therefore should have stated so in the preamble and regulated accordingly.

Further, HHS’s revised rules concerning an issuer’s list of approved drugs (“drug formularies”) did not go far enough to level the playing field for HIV-

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203 Id.
204 Id. HHS went on to state, “We strongly caution issuers that the examples cited [in the proposed rule, including adverse drug tiering] appear discriminatory in their application when looking at the totality of the circumstances, and they may therefore be prohibited.” Id.
205 See Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016, Final Rule, 80 Fed. Reg. at 10,823 (stating that having specialty tier is not discriminatory on its face). Circumstances where drug tiering is done for a true purpose such that HHS would not want to declare it *per se* discriminatory would arise when a health plan is able to justify its design through a non-discriminatory reason. Id. Unfortunately, the process is still not efficient and simple, as it requires copious amount of time from the initiation of a complaint to completion of the investigatory process of the State or HHS in order to conclusively determine whether an act of discrimination exists. Id.
206 NHelP complaint, *supra* note 187, at 7-10 (discussing apparent discriminatory treatment of HIV-positive individuals in Florida QHP marketplace).
individuals. 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. Under the revised rules, 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

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.

At first glance, the rule seems to prohibit issuers from using adverse tiering for ART because this practice discourages enrollment by HIV-positive individuals, and because ART is an instrumental part of HIV treatment. There are two main limitations with this argument. First, HHS stated in its preamble that adverse tiering is not per se discriminatory, so it likely did not intend to ban adverse tiering. In addition, even if the regulation banned adverse tiering, it does not prohibit an issuer from engaging in the practice; rather, it bans the P&T committee from establishing an adverse tiering formulary. If the P&T committee’s actions were discovered, the

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208 Id. It should be noted that HHS promulgated additional rules concerning processes to get access to drugs not otherwise covered by the plan. See 45 C.F.R. § 156.122(c) (2015) (outlining process for request for exception granting enrollee coverage to non-covered prescription medication). Although outside the scope of this article, a streamlined exceptions process will benefit HIV-positive enrollees, if a medically-indicated ART is not provided on the plan’s formulary. See id. (granting exception would provide coverage to non-formulary drugs).


211 See supra Part II.A (describing possible HIV treatment and prevention).

212 Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016, Final Rule, 80 Fed. Reg. at 10,823.
committee would be in violation of the regulation and would, presumably, be replaced; however, the issuer itself would not be in violation of the regulation.213

HHS's deference to the states in regards to the design of the essential health benefits package has resulted in the continuation of discriminatory practices.214 Issuers are thus able to discourage HIV-positive individuals from enrolling in health plans offered by the insurer.215 If the individual does enroll in a plan, she may discover that the cost of her life-saving medications, even those available in generic form, are so expensive that she cannot afford to fill the prescription.216 The Act's intent to eliminate such discriminatory practices, whether explicit or implicit, has not been satisfied because of HHS's weak or nonexistent rulemaking.

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."217 To date, the only regulation that HHS has enacted in this category requires that plans include preventive health services described in the coverage of preventive health services regulation.218 Section 147.130 of HHS's regulations implements § 2713 of the Public Health Services Act, which requires that Task Force

213 See id. 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 also 45 C.F.R. § 156.125 (2016).


215 See id. (discussing the practice of issuers deferring HIV-positive individuals from enrolling in health plans).

216 See id. (discussing the high expense of essential prescriptions to insured HIV-positive individuals).


screening recommendations, immunizations, and certain screenings and care specific to children’s and women’s health be provided without cost sharing. 219 In response to comments concerning preventive health services that incorporate prescription drugs, and the extent to which they were covered by the essential health benefits package, HHS explained that:

[P]reventive 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 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. 220

Under HHS’s reasoning, it is clear that issuers must cover the preventive services required under § 2713, and issuers can also cover preventive service drugs under any of the ten essential health benefit categories. 221 However, HHS does not answer the question of what the essential health benefits category “preventive and wellness services and chronic disease management” covers beyond the preventive services required under § 2713 of the Public Health Services Act. First, all plans must cover preventive services under § 2713 of the Public Health Services Act, so it would be

219 Affordable Care Act, 42 U.S.C. § 300gg-13 (2012) (amending § 2713 of the Public Health Services Act). This regulation has proven to be highly controversial for reasons unrelated to this article because of the inclusion of contraceptives as a preventive health service. Id. See also Burwell v. Hobby Lobby Stores, Inc., 134 S. Ct. 2751, 2762 (2014) (holding the contraceptive mandate can be objected to by closely held corporations on religious grounds). See also Timothy Jost, Implementing Health Reform: The Supreme Court Rules on Contraception Coverage (Updated), HEALTH AFFAIRS BLOG (Jul. 1 2014), http://healthaffairs.org/blog/2014/06/30/implementing-health-reform-the-supreme-court-rules-on-contraception-coverage/ (discussing regulation’s implementation of section 2713 of the Public Health Services Act).

220 Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016, 80 Fed. Reg. 10,822 (February 27, 2016) (to be codified at 45 C.F.R. in scattered sections).

duplicative if the same benefits were encompassed under the essential health benefits provision.\textsuperscript{222} Furthermore, if Congress intended for this category to only include the preventive services under § 2713 of the Public Health Services Act, then surely it would not have used a term that encompasses more than just “preventive services,” but also includes “wellness services” and “chronic disease management.”\textsuperscript{223}

To date, the agency has not expanded the reach of this benefit, and has deferred to the states for the application of the benchmark’s version beyond that required by Public Health Services Act § 2713 and 45 C.F.R. § 147.130. In effect, some issuers do not cover essential preventive services drugs, such as PrEP and PEP, which are highly effective in preventing HIV infection, if they are not covered under the particular state’s mandate.\textsuperscript{224} The agency is thus missing an opportunity to easily and effectively reduce HIV incidence by categorizing PrEP and PEP as essential health benefits under “preventive and wellness services” or as preventive services under § 2713 of the Public Health Services Act.\textsuperscript{225}

\textsuperscript{222} \textit{See} Potter v. United States, 155 U.S. 438, 446 (1894) (holding statutory language “cannot be regarded as mere surplusage; it means something”).

\textsuperscript{223} \textit{See} Russello v. United States, 464 U.S. 16, 23 (1983) (determining scope of “preventive and wellness services and chronic disease management” category under the Act). 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. \textit{Id. See also} 42 U.S.C. § 300gg-13 (2012) (discussing mandated coverage of preventative health coverage).

\textsuperscript{224} \textit{See} Boerner, \textit{This Article Made an Insurance Company Cover AIDS Drugs}, \textit{supra} note 14 (discussing one insurance company’s efforts not to cover Truvada); \textit{infra} note 275 (analyzing problem of deferring states to apply preventive services under the Public Health Services Act). There are dangers at stake when states do not mandate essential preventive drugs. \textit{See id.}

\textsuperscript{225} \textit{See} Bolin, \textit{supra} note 81, at 57-58 (discussing effect of Agency categorizing PrEP/PEP as preventive services under Public Health Services Act). \textit{See also} NATIONAL HIV/AIDS STRATEGY (2010), \textit{supra} note 9, at 15 (discussing the reduction of HIV incidence as one goal of President Obama’s National HIV/AIDS Strategy).
V. COVERAGE UNDER THE AFFORDABLE CARE ACT WILL ONLY BE MEANINGFUL IF THE AGENCY ACTS THROUGH BINDING RULEMAKING

To ensure meaningful coverage under the Act, HHS must promulgate regulations that specifically address the ways in which issuers discriminate against HIV-positive individuals or otherwise impose obstacles to HIV treatment and prevention.226 Regulations that target the discriminatory practices previously discussed would make health care meaningful for HIV-positive individuals and those at greatest risk, as well as aid in retaining HIV-positive individuals in care and reduce the number of new HIV infections.

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 ART on the same cost tiers. Third, HHS should promulgate additional rulemaking to implement the preventive services benefit to include HIV prophylaxes.227

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

HHS must propose rules that mandate the inclusion of HIV specialists in all health plans sold in Exchanges. HIV care specialists are essential to retaining patients in care and improving drug adherence in order to improve health outcomes for HIV-positive individuals by, for example, increasing the number of HIV-positive individuals

226 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 comments).
227 Bolin, supra note 81, at 57-8 (discussing effect of targeting the discriminating practices against HIV-positive individuals and those at greatest risk).
whose HIV disease is virally suppressed. The Act requires the inclusion of Ryan White providers in plan networks sold in Exchanges, and HHS should take action to make this mandate a guarantee. To this end, HHS should revise its essential community provider 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 provide HIV-positive enrollees access to out-of-network Ryan White providers.

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, the agency has failed to implement the Act’s requirement that available Ryan White providers be included in plan networks. Even more egregious, HHS has declined to apply any concrete rules for state-based Exchanges, which could result in the exclusion of all Ryan White providers from their plan networks.

HHS should revise its essential community provider regulation to require that all issuers offer contracts to all Ryan White providers, just as other HHS regulations require issuers to offer contracts to all Indian health care providers in federally-facilitated Exchanges. An “any willing Ryan White provider” requirement would give issuers certainty and predictability about what networks will satisfy the essential

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228 NATIONAL HIV/AIDS STRATEGY (2020), supra note 9, at 21 (discussing when HHS mandates the inclusion of HIV specialists in all health plans, it advances care for HIV-positive individuals).
229 See 45 C.F.R. § 156.235.
230 Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016, Final Rule, 80 Fed. Reg. 10,837 (discussing proposed changes to strengthen ECP standards).
community provider requirement for certification as a qualified health plan. As discussed above, Congress required plans to include available essential community providers in their networks, and so this should be the end of the matter.\textsuperscript{232}

Further, the “any willing Ryan White provider” requirement must apply to issuers that offer plans in both the state-based and federally-facilitated Exchanges because the Act requires the Secretary to establish criteria that apply to all qualified health plans, and does not contemplate different standards between plans offered in the state-based and federally-facilitated Exchanges.\textsuperscript{233} 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.\textsuperscript{234} Any fear that HHS cannot regulate the state-based Exchanges is unfounded. The Act

\textsuperscript{232}See supra note 135 and accompanying text. See also 45 C.F.R. § 156.235 (explaining the requirements of issuers to offer contracts to community providers). The only portion of the provision that is ambiguous is whether issuers need to only offer contracts to all essential community providers, or whether issuers are required to contract with all essential community providers. \textit{Id.} 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. \textit{Id.} There may be practical and legal difficulties in 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. \textit{Id.} Further, this is consistent with HHS’s current interpretation in federally-facilitated Exchanges. See 2016 Letter to Issuers, supra note 146, at 27-28 (laying out elements required for an issuer application for QHP certification). See also \textit{Chevron}, U.S.A., Inc. v. Natural Res. Def. Council, 467 U.S. 837, 843 (1984) (requiring court to defer to agency’s reasonable interpretation of statute unless Congress expressed clear intent); \textit{Brown v. Gardner}, 513 U.S. at 120 (striking down an agency’s regulation as unlawful under the first step of \textit{Chevron}).

\textsuperscript{233}See 42 U.S.C. § 1803(c)(1) (2012) (discussing Secretary’s duties with qualified health plans). However, section 1311(c)(1) of the Affordable Care Act does not differentiate between state-run and federally-facilitated Exchanges. \textit{Id.}

\textsuperscript{234}See \textit{Letter from Chief Lynn Malerba, Mohegan Tribe Chairwoman, Tribal Self-Governance Advisory Committee to Centers for Medicare and Medicaid Services, Comment letter on CMS-9944-P; Notice of Benefits and Payment Parameters for 2016, 15 (Dec. 22, 2014), available at http://www.regulations.gov/contentStreamer?documentId=CMS-2014-0152-0227&attachmentNumber=1&disposition=attachment&contentType=pdf (explaining preference that federal Indian health care provider requirements apply to state-run Exchanges for overall consistency). In response to this and other comments from various stakeholders, CMS urged state-based Exchanges to apply the same standard when examining adequacy of ECPs, including the requirement that issuers offer contracts to all IHCPs in the plan’s service area. See Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016, 80 Fed. Reg. 10,837. The basis behind this proposal was the existence of tribal members in states with both state-run Exchanges and federally-facilitated Exchanges. \textit{Id.}
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. Indeed, the provision governing qualified health plans expressly provides that the Secretary of HHS will engage in rulemaking: "The Secretary shall, by regulation, establish criteria for the certification of health plans as qualified health plans." Although an agency may look to an outside entity, including a state, "for advice and policy recommendations," the agency must make the final decision itself.

HHS should simplify its regulations to eliminate sufficiency standards and minimum percentages, and clarify that issuers must offer contracts to all Ryan White 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. This will also ensure consistency in implementation because Exchanges will be applying the same standards across the country.

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

In addition, HHS should require that issuers follow a process to enable HIV-positive individuals to access their HIV care specialist, even if that provider is not within

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235 See United States Telecommunications Ass'n v. F.C.C., 359 F.3d 554, 566 (D.C. Cir. 2004) (holding that federal agency officials need affirmative evidence of authority to delegate their decision-making authority). See also Bagley & Levy, supra note 172, at 450 (clarifying the Secretary's role when making decisions regarding essential benefit plans).


237 See United States Telecommunications Ass'n, 359 F.3d at 568 (outlining the reach of agency delegation capabilities).

238 See 45 C.F.R. § 156.235 (discussing statutory and regulatory standards that issuers are required to follow).

239 Id.
the plan's network. In establishing a process for enrollees to access an out-of-network Ryan White provider, HHS can begin with suggestions from experts in the field. For instance, the National Association of Insurance Commissioners ("NAIC") has issued a network adequacy model rule that can serve as a starting point for HHS to develop its own process.

The NAIC Model Rule, issued in November 2015, requires issuers to establish a process to "assure that, under certain circumstances, a covered person obtains a covered benefit at an in-network level of benefits, including an in-network level of cost-sharing, from a non-participating provider or shall make other arrangements acceptable to the [state insurance] commissioner." These circumstances include situations where the health insurance issuer has a sufficient network, but does not have the type of provider available to provide the covered benefit to the enrollee; or it cannot provide the benefit without unreasonable travel or delay; or the issuer has an insufficient number or type of providers to provide the benefit without unreasonable travel or delay.

The NAIC Model Rule requires that issuers establish and inform enrollees of a process to request access to a non-participating provider to obtain a covered benefit. 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 participating provider with the required specialty, or cannot provide reasonable access to an in-network

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241 See HEALTH BENEFIT PLAN NETWORK ACCESS AND ADEQUACY MODEL ACT § 5 (Nat’l Ass’n Ins. Comm’rs 2015) [hereinafter NAIC MODEL RULE].
242 See id. § 5(C).
243 id. § 5(C)(1).
244 Id. § 5(C)(3). This requirement is defined as "including counting the person’s cost-sharing towards the maximum out-of-pocket limit applicable to services obtained from participating providers under the health benefit plan." Id.
specialist “without unreasonable travel or delay,” then the issuer must specify a process for an enrollee to access a non-network provider.\(^{245}\) If the enrollee followed the issuer’s process to obtain a covered benefit from an out-of-network provider, then the enrollee would be able to see an out-of-network provider and receive care for the same cost as if the provider were within the network.\(^{246}\)

The NAIC Model Rule suffers from some deficiencies. First, it does not establish restrictions on the process to obtain access to an out-of-network provider.\(^{247}\) For example, issuers could institute a process that involves multiple levels of review, which would discourage enrollees from attempting to access an out-of-network provider.\(^{248}\) In addition, the NAIC Model Rule allows issuers to avoid establishing a process entirely if the plan makes “other arrangements acceptable to the commissioner,” without explaining what arrangements may be acceptable.\(^{249}\) The NAIC Model Rule does not define “unreasonable travel or delay,” leaving significant discretion to the issuer to define these terms.\(^{250}\) Although the NAIC specifies that whether the issuer’s network is sufficient can include reference to, for example, “geographic accessibility of providers” and “geographic variation and population dispersion,” the NAIC Model Rule does not provide firm rules as to what reasonable travel or delay means.\(^{251}\) This discretion can result in the disadvantage of enrollees who are attempting to access out-

\(^{245}\) Id. § 5(C)(2)(a)-(b). The NAIC Model Rule also specifies that this process cannot be used a substitute for establishing a sufficient provider network, or used as a means for enrollees to “circumvent the use of covered benefits” available through the network. NAIC MODEL RULE § 5(C)(6).

\(^{246}\) Id. § 5(C)(3). This requirement is defined as “including counting the person’s cost-sharing towards the maximum out-of-pocket limit applicable to services obtained from participating providers under the health benefit plan.” Id.

\(^{247}\) See id. § 5(C)(1)-(2).

\(^{248}\) Id. § 5(C)(4). “The process . . . shall ensure that requests to obtain a covered benefit from a non-participating provider are addressed in a timely fashion appropriate to the covered person’s condition.” Id.

\(^{249}\) Id. § 5(C)(1).

\(^{250}\) See NAIC MODEL RULE § 5(A), (C).

\(^{251}\) See id. § 5(B).
of-network providers because the issuer may define "unreasonable travel or delay" narrowly so that an HIV care specialist located hours from the enrollee's home would not be considered unreasonable.\textsuperscript{252} Further, even without these limitations, the NAIC Model Rule is not binding on the states and, by extension, on the Exchanges.\textsuperscript{253} Even if states adopted the rule, each state could modify it, thus reducing consistency across the Exchanges.\textsuperscript{254}

Although the NAIC Model Rule needs improvement, HHS could use it as a starting point for a process to provide HIV-positive individuals access to Ryan White providers. One advantage to the NAIC Model Rule is the use of specific criteria for determining whether an enrollee should be given access to an out-of-network provider as if the provider were in-network.\textsuperscript{255} This could be applied and weighted to account for the importance of an HIV-positive individual's relationship with her care provider to the quality and continuity of care.\textsuperscript{256} For example, HHS's regulation could provide that an issuer will cover services 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; (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 is not reasonably accessible to that enrollee. "Reasonably accessible" may be defined by geographic distance (e.g., no more than two

\textsuperscript{252} See id. § 5(C).
\textsuperscript{253} See id.
\textsuperscript{254} Id.
\textsuperscript{255} Id. § 5(C)(2).
\textsuperscript{256} Gallant et al., supra note 44, at 1046 (describing the need for HIV experts in HIV care for patients). See also Kates & Dawson, Health Insurance Coverage for People with HIV, supra note 43, at 6 (describing HIV participant wanting to have physicians that are experts with HIV care).
miles from the enrollee's home in an urban area, or fifteen miles in rural areas) and could account for the enrollee's means of transportation.\footnote{See Memorandum 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), available at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/HPMSMEMORetailHIAccess.pdf (stating similar standard concerning geographic distance applies to Medicare Part D plans concerning pharmacy access). Under this rule, if an enrollee demonstrates 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 (3) of the rule.}

If the regulations specify a process that requires issuers to allow access to out-of-network providers under certain circumstances, then it is likely to increase retention in care. For example, if HHS does not adopt the recommendation concerning “any willing Ryan White provider” described above, then this alternative proposal will ensure enrollees access to a Ryan White provider when such access is excluded under their plans. Further, an HIV-positive individual who has a pre-existing relationship with an out-of-network Ryan White provider will have access to her provider if she can verify the relationship. This process, as outlined in regulation, will also benefit those enrollees whose plan includes Ryan White providers, but those providers are not reasonably accessible. This element of the process is essential for HIV-positive individuals because a plan may include a Ryan White provider, but one that is not within reasonable access to the enrollee, while another Ryan White provider is geographically closer to the enrollee, but is not in-network.

Finally, this process, as outlined in regulation, will not be a great burden on issuers because, in general, an HIV-positive person is expected to consult with her HIV care specialist only twice a year.\footnote{NATIONAL HIV/AIDS STRATEGY (2010), supra note 9, at 21. An HIV-positive individual is considered to be in “continuous care” if she has routine HIV medical care at least twice a year, with each visit at least three months apart. Id.} 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 care specialist.259

B. HHS Must Regulate to Prohibit Discriminatory Drug Tiering

Congress made it clear that HHS could not “design benefits in ways that discriminate against individuals because of their age, disability, or expected length of life” when defining the essential health benefits categories.260 HHS’s preamble to its final essential health benefits provision suggests that adverse tiering is discriminatory, but HHS does not prohibit it in a rule. HHS should remedy this error by revising its prescription drug rules to declare adverse tiering to be per se discriminatory.261

HHS should promulgate rulemaking, rather than merely discuss drug tiering in a preamble.262 Although courts consider a preamble to a rule “informative,” it is not binding.263 Thus, HHS should revise its regulations by instituting a rebuttable presumption that adverse HIV drug tiering, defined as a tiering structure that places all drugs to treat HIV on the same tier, is per se discriminatory.264 A rebuttable

259 Gallant et al., supra note 44, at 1046. When an HIV expert is not available in person, it is recommended that an HIV-positive individual see a primary care physician with an HIV expert “serving as an ongoing consultant via teleconference or telemedicine.” Id.

260 Affordable Care Act tit. I, § 1302 (codified as amended at 42 U.S.C. § 18022(b)(4)(B) (2012)). Congress defined how health benefit categories cannot be segregated. Id.

261 Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016, 80 Fed. Reg. 10,823 (asserting that adverse tiering is discriminatory, but it is not prohibited). See also supra Part IV.B (describing adverse tiering as discriminatory in nature).


264 Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016, 80 Fed. Reg. 10,813-23. In the preamble, HHS discusses placing drugs to treat one condition on a “high” cost tier. Id. 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. Id. 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 193 (discussing Aetna’s agreement to place
presumption would thereby place the burden on issuers to explain why such drug tiering is not discriminatory, and also remove the burden from the Exchanges to investigate each suspect drug tiering structure. Of course, the Exchange will need to judge the merits of the issuer’s explanation, but a rebuttable presumption could discourage issuers from implementing suspect drug tiers.

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 ART 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 also consider the costs that can be avoided in the long term. By ensuring that their HIV-positive enrollees have access to ART, the issuers may avoid the costs of hospitalizations and the treatment of opportunistic infections in the future. Health care cost savings are one goal outlined by HHS in its implementation of the Affordable Care Act.

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265 Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016, 80 Fed. Reg. at 10,813-22. Under the preamble, the Exchange, upon receiving a complaint, will be required to “request justification” for suspect drug tiering. Id.


267 Strategic Goal 1: Strengthen Health Care, HHS.GOV, http://www.hhs.gov/about/strategic-plan/strategic-goal-1/ (last accessed Apr. 19, 2016) (discussing one of major goals of the Affordable Care Act).
C. HIV Prophylaxes Available without, or with Limited, Cost Sharing

HIV prophylaxes must be covered as a “preventive service” to be effective in reducing new HIV incidence.\textsuperscript{268} As discussed above, the Act requires that preventive health services defined under § 2713 of the Public Health Services Act be available without cost sharing, and HHS has incorporated the requirements of § 2713 into the essential health benefits package through 45 C.F.R. § 156.115(a)(4).\textsuperscript{269} Preventive health services include recommendations of the Task Force that receive an A or B rating.\textsuperscript{270} PrEP and PEP are preventive health services worthy of such a recommendation: there is a wealth of research concerning the benefits of PrEP and PEP, as previously discussed.\textsuperscript{271} If PrEP and PEP were classified as preventive health services under the Public Health Service Act, as amended by the Affordable Care Act, then issuers would have to make them available without cost sharing.\textsuperscript{272} Inclusion as preventive health services under the Public Health Services Act would also mean that PrEP and PEP are

\textsuperscript{268} Affordable Care Act tit. I, § 1302 (codified as amended at 42 U.S.C. § 18022(b)(1)(I) (2012)) (suggesting coverage for preventive and wellness services and chronic disease management). See also Bolin, supra note 81, at 58 (arguing that health insurance issuers should be required to cover PrEP).

\textsuperscript{269} See Exchange Establishment Standards and Other Related Standards under the Affordable Care Act, 78 Fed. Reg. 12,867 (codified at 45 C.F.R. § 156.115(a)(4)) (defining preventative health care and its costs).

\textsuperscript{270} See Affordable Care Act §1001 (codified as amended at 42 U.S.C. § 300gg-13(a)(1d)(2010)) (amending § 2713 of the Public Health Services Act). An “A” rating means that the Task Force recommends it, and that “there is high certainty that the net benefit is substantial.” Id. A “B” rating indicates that the Task Force recommends it, 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.” Id. See also Grade Definitions, U.S. PREVENTIVE SERVS. TASK FORCE, http://www.uspreventiveservicestaskforce.org/Page/Name/grade-definitions#grade-definitions-after-july-2012 (last updated Feb. 2013) (setting guidelines for A and B ratings of preventative health services).

\textsuperscript{271} See supra Part II.B (providing task force and PEP and PrEP benefits under Affordable Care Act).

effectively eliminated from the issuer's drug tiering structure because the Act requires that preventive health services be offered at no cost sharing.

Currently, 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. The Task Force may be reluctant to recommend preventive drugs such as PrEP and PEP, as it is a "reputedly conservative body," and the FDA only approved PrEP three years ago. Therefore, there could 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.

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. As discussed above, HHS should not limit this category to drugs and screening required under § 2713 because this is both duplicative and contrary to the wording of the Act provision concerning essential health benefits.

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273 See U.S. Preventive Servs. Task Force, USPSTF A & B Recommendations, U.S. PREVENTIVE SERVS. TASK FORCE (Feb. 2016) (listing the USPSTF A and B recommendations by topic, grade, and description). See also CAHILL, supra note 272, at 29 (stating both aspirin and tamoxifen were approved for preventative purposes).

274 CAHILL, supra note 272, at 29 (explaining the Task Force rating system based on science and not cost).

275 See Smith, supra note 64, at 4 (discussing CDC recommendations to increase PEP availability and usage). See also supra note 54 (discussing the best measures in place for preventing the spread of HIV).

276 See supra note 222 (discussing duplicative coverage).
As previously discussed, issuers are prohibited from discriminating in the design of the essential health benefits package on the basis of certain factors, including disability. Because HIV is a disability recognized under the Americans with Disabilities Act, and PrEP and PEP are prescribed to individuals who have not been diagnosed with HIV, the exclusion of coverage of these preventive services drugs could not be classified as discrimination on the basis of disability. However, an enrollee could argue that the issuer refused to cover PrEP because of sexual orientation. PrEP is recommended not just for men who have sex with men, but also for certain "heterosexually active" men and women, and injection drug users. Thus, an issuer could argue that the micro-level decision to refuse to cover PrEP or PEP for a particular enrollee is discriminatory.

However, the Act also requires the Secretary to ensure that qualified health plans are not designed to "have the effect of discouraging the enrollment in . . . plan[s]
by individuals with significant health needs."\textsuperscript{282} 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 interpreted more broadly to include injection drug users, who are at high-risk of HIV, and individuals who are regularly exposed to HIV because of an HIV-positive partner. These individuals have a significant health interest in preventing HIV, and are at highest risk. In sum, HHS must consider the long-term advantages of keeping people HIV-negative and include PrEP and PEP as preventive services under the essential health benefits provision.

VI. CONCLUSION

More than five years after the passage of the Affordable Care Act, and after two major Supreme Court cases upholding the Act, HHS has not succeeded in making health coverage meaningful, accessible, and affordable. There is no better lens through which to view these shortfalls than through the Act's treatment of HIV, where treatment equals cost savings to the health system and also prevention of future cases. Many of the Act's provisions seem to have been written with HIV in mind: Ryan White providers may not be left out of plan networks and prescription drugs and preventive services must be covered with limited cost-sharing. The Act can be considered a success only when these provisions are implemented so that HIV-positive individuals have access to HIV care specialists and affordable ART, and HIV-negative individuals have access to no- or low-cost preventive medications.

The Act has not been successfully implemented because health insurance issuers can exclude HIV care specialists from provider networks and render HIV

\textsuperscript{282} Affordable Care Act tit. I, § 1311 (codified as amended at 42 U.S.C. § 18031(c)(1)(A) (2012)) (discussing minimum criteria for Secretary to certify health plans as qualified health plans).
medications and prophylactics prohibitively expensive. The ways in which HHS has failed HIV-positive individuals—whose care and treatment translates into fewer new cases of HIV—is an unfortunate indication of the ways in which HHS has failed to make coverage meaningful.

This article has outlined some of the ways in which HHS can remedy these deficiencies to benefit people living with HIV and as those who are at risk of contracting the disease, but it also serves as a starting point for ensuring meaningful coverage for other life-long, expensive and complex conditions. For example, the “any willing provider” requirement and regulatory process to access an out-of-network provider could be easily applied to all essential community providers, given the importance of a relationship with a provider to drug adherence in other conditions, such as diabetes, hypertension, and heart disease. Similarly, HHS could prevent issuers from engaging in adverse tiering for other conditions by prohibiting such tiering for other condition-specific medication.

Rulemaking under the Affordable Care Act has not yet reached its full potential, thus disadvantaging HIV-positive individuals and others suffering from life-long, expensive, and complex health conditions. HHS must regulate to ensure meaningful coverage for HIV-positive individuals in plan networks and essential health benefit design, and let improved HIV treatment and prevention prove that health insurance reform has accomplished its goals.
