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AIDS Does Not Discriminate and Neither Should Our Laws Strengthening Health Care Enforcement to Support People Living with HIV

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Discrimination in access to health care is an unfortunate fact of life for many HIV patients. To probe this issue and examine possible solutions, 16 thought leaders in national and state HIV advocacy and policy organizations participated in a roundtable in Washington, D.C. in August 2016. ViiV Healthcare, a global specialist HIV company delivering advanced treatment and care for people living with HIV, organized and sponsored the event. This report reflects the thoughts and opinions of the roundtable participants from the meeting and ongoing discussions based on subsequent political events.

Today's HIV Health Care Reality

Over the past three decades, the HIV epidemic in the United States has expanded to cross lines of age, gender, race/ethnicity, sexual orientation, gender identity and socio-economic circumstance.¹ In 2015, while the majority of HIV transmissions continued to occur in men who have sex with men, nearly one-fourth of new cases were in heterosexual Americans, two-thirds of whom were women.² The Centers for Disease Control and Prevention (CDC) estimates that roughly 1.1 million people in the U.S. are living with HIV.³ Since the beginning of the epidemic, nearly 675,000 people with AIDS in the U.S. have died, and even today, nearly 13,000 Americans with AIDS die each year.⁴ HIV does not discriminate.

The promising news is that strong advocacy and scientific research efforts have led to proven solutions for the control, and even the prevention, of HIV. Antiretroviral therapy (ART), including single tablet regimens (STRs) and delayed-release treatments, has allowed for near-normal life expectancy. Preventative medicine (PrEP) for people who are at substantial risk of HIV transmission, in combination with improved education, testing and health care access, is expected to prevent up to 185,000 new infections over the next five years.⁵ Treatment as prevention (TasP) has been shown to decrease community viral load and reduce the rate of new HIV infections.⁶

While HIV remains a serious public health risk affecting many different populations, it has nonetheless become a chronic and manageable disease when properly treated. Today, individuals living with HIV can now live healthy, productive lives – a stark contrast with the early years when a diagnosis often meant near-term death.

Patient access to HIV treatment innovations, however, remains a significant issue. People living with HIV are incurring far more than their fair share of the cost of lifesaving medications, and many are not able to access necessary drugs at all. HIV is a disease that does not discriminate, but certain features of the existing and proposed national health care systems are essentially doing just that.

**“These are not lifestyle drugs,
they are lifesaving drugs.”**

Scott Schoettes
Counsel & HIV Project Director, Lambda Legal

Existing ACA Nondiscrimination Legislation

The Patient Protection and Affordable Care Act (ACA) includes provisions – notably Sections 1311 and 1557 – aimed to protect people living with HIV and other chronic conditions from discrimination and to increase their coverage options. HIV advocates, including those with the 200-patient group strong I Am Essential Coalition,⁷ firmly agree that the ACA has provided critical coverage, access and patient protections that beneficiaries with chronic conditions such as HIV simply cannot afford to lose.

Actionable regulations are necessary to enforce the ACA for those living with HIV. It took years to establish regulations to implement Sections 1311 and 1557. HIV advocates contend they still lack the specificity necessary to assist in challenging discriminatory plan designs. Nevertheless, the law and its regulations need to be upheld and strongly enforced.

In 2016, the White House Office of National AIDS Policy (ONAP) updated the National HIV/AIDS Strategy, working with federal agencies to refine the domestic plan to combat the HIV/AIDS epidemic.⁸ The goals of the Updated Strategy are to:

- Reduce new HIV infections
- Increase access to care and improve health outcomes among people living with HIV
- Reduce HIV-related health disparities and health inequities
- Achieve a more coordinated national response.

It is deeply concerning that under the new administration, the status of the ACA, Medicaid and Medicare, and even ONAP and the National HIV/AIDS Strategy are uncertain. The administration's proposed budget cuts to HIV programming for prevention, research and continued treatment advances send an ominous message. New health care legislation and plans to implement it have the potential to take the country backwards in the fight against HIV/AIDS.

Research-backed solutions and important laws and programs to address the HIV public health crisis are in place, but inequity in access to care persists, and the continued existence and implementation of proven measures to address those inequities are now in jeopardy. Health and Human Services (HHS) and the administration must fortify the evidence-based policies currently in place and improve and enforce regulations to assist in implementation of those policies.

Inequalities in Care

Strides have been made to improve access to care and treatment for people living with HIV. Under the ACA, private health insurance plans can no longer deny insurance because of pre-existing conditions.⁹

§ 1557 of the Affordable Care Act

“An individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.)...or Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving federal financial assistance, including credits, subsidies, or contracts of insurance...”

§ 1311 of the Affordable Care Act

Qualified Health Plans may “not employ marketing practices or benefit designs that have the effect of discouraging the enrollment in such plan by individuals with significant health needs.” 42 U.S.C. § 18031(c)(1)(a))

Plans also cannot drop people from coverage when they get sick, and there are no annual or lifetime limits on coverage.

Within the federal and state marketplaces, plans cannot charge a higher premium based on health status or gender. They must offer Essential Health Benefits (EHBs), including medications and services imperative to the health of people living with HIV, and they are also required to cover services from essential community providers, such as the Ryan White HIV/AIDS Program.⁹ Each year, this federal program makes HIV-related health services available to more than half a million people who lack sufficient health care coverage or resources to manage the disease.

However, patients continue to encounter barriers that limit physicians' ability to prescribe medicines to treat HIV and patients' ability to access and afford them. Some insurers impose high levels of cost sharing for necessary care and often refuse to cover key medications, including STRs. For some medications, pricing set by pharmaceutical companies also plays a role.

In 2016, the Center for Health Law and Policy Innovation of Harvard Law School (CHLPI) and the AIDS Research Consortium of Atlanta (ARCA) found that a Georgia-based insurer had placed 16 out of 22 of the most widely used HIV drugs in the highest cost-sharing tier, including every STR.¹⁰ This practice leads to the average plan enrollee in Georgia with HIV spending nearly 20 percent of his/her entire monthly income to fill a single HIV prescription. In comparison, enrollees with rheumatoid arthritis can maintain their similarly priced, four-medication regimen for less than two percent of their monthly income, on average.

In Wisconsin, CHLPI and the AIDS Resource Center of Wisconsin showed an insurer covers only four of the 16 HIV drugs that are a part of the six treatment regimens recommended in the HHS treatment guidelines.¹¹ This level of coverage leaves five of the six recommended HIV treatment regimens effectively off-limits to enrollees.

The current administration's promise to repeal and replace the ACA has potentially dire implications for people living with, or at risk of, HIV. Looking toward 2018 and beyond, any cost-cutting move to defund state Medicaid expansion programs initiated under the ACA will immediately impair access to care for patients with little or no income. Furthermore, while the replacement plan is being crafted, the administration may choose to relax the ACA's insurance rules in order to "stabilize" marketplaces.

Multiple versions of the bills to repeal the ACA make prognostication difficult, but one potential outcome is that older patients with HIV may suddenly be saddled with premiums or other costs that are more than three times as much as younger enrollees – exceeding the threshold set under the ACA. Some experts also expect to see erosion in the ACA's safeguards preventing health plans from excluding those who have pre-existing conditions and requiring EHB coverage, thereby shifting overall health insurance costs to those who require more comprehensive coverage. Any of these changes could make life significantly tougher for people with chronic illnesses, including HIV.

Even if the White House opts for a less-than-radical overhaul of the ACA, shortcomings in the current ACA regulations and the lack of patient protections for private plans are jeopardizing the well-being of too many Americans living with HIV, as well as those who are at higher risk for HIV. There is an urgent need to more equitably treat the entire, diverse population of people living with HIV and to prevent new infections. At the same time, there have been some important successes in battling discrimination at the state level in some states. Whatever turns health care reform may take under the current

administration, the architects of the ACA’s future should take stock of these milestones and allow them to serve as models for improvements across the country, so that people living with HIV receive the care they need and deserve.

State Initiatives: What “Good” Looks Like

Several regulatory solutions to address limitations in the health care system can be found in successful and ongoing state actions. Consider, for example:

Discrimination Complaints Filed Against Insurers in Eight States – Alabama, Georgia, Illinois, Louisiana, Pennsylvania, Tennessee, Texas and Wisconsin

CHLPI recently launched a grassroots initiative to enforce health care rights guaranteed by the ACA for people living with HIV and other chronic conditions.¹² CHLPI worked with seven state partners: AIDS Alabama, ARCA, AIDS Foundation of Chicago, CrescentCare (formerly the NO/AIDS Task Force) in Louisiana, Nashville CARES, AIDS Resource Center of Wisconsin and AIDS Law Project of Pennsylvania. Together, they filed formal administrative complaints with the HHS Office for Civil Rights (OCR), asking OCR to implement the new antidiscrimination regulations in state health insurance marketplaces. CHLPI anticipates that its OCR complaints will help define and set the standard for how these new civil rights protections are applied in health insurance markets.

“When an insurer requires chronically ill patients to pay a disproportionate share of the cost of medication, it violates federal law.” Robert Greenwald, Faculty Director, Center for Health Law and Policy Innovation & Clinical Professor of Law, Harvard Law School

Florida Requires Insurance Plans to Limit Patient Cost Sharing for HIV Drugs

In June 2015, as a result of a complaint issued by The AIDS Institute and the National Health Law Program with the HHS OCR, the Florida Office of Insurance Regulation announced limits to patient cost sharing of HIV medications to reasonable co-pays.¹³ Florida’s insurance regulator also warned insurers that Florida would be reviewing 2016 Qualified Health Plans (QHPs) for possible discriminatory practices in prescription coverage. In a memo sent to insurers preparing to file their 2016 marketplace plans, the state regulator said it would deem plans discriminatory if the tiered formulary of HIV medications was not at least as favorable as the state’s benchmark plan. Florida’s benchmark plan, based on the ACA guidance to issuers, limits patient co-pays to \$40, \$70 or \$150 per 30-day supply, depending on the medication. One injectable medication has a co-pay limit of \$200. These limits have continued into 2017 and plans are being held accountable. Florida has also devised an adverse tiering tool, which allows patients to filter and select plans based on medication coverage. At the federal level, this tool is being considered for rollout nationwide.

California Passes Bill Reducing Out-Of-Pocket Expenses for Prescription Drugs

California’s hard won AB 339 bill, passed in October 2015, aims to help individuals with serious and chronic conditions pay for their prescription medications.¹⁴ AB 339 was adopted thanks to the efforts of strong state consumer coalitions. These organizations partnered with groups such as Project Inform, which has deep expertise in HIV and hepatitis C. They also engaged provider and legal groups in their advocacy. According to AB 339, all medically necessary drugs, including non-formulary drugs, must be covered by insurance. Cost sharing can’t exceed \$250 per drug, per 30-day supply in most coverage tiers. Formularies cannot be abused in a way that discourages enrollment of individuals with specific health conditions, such as placing all or most drugs to treat a condition on the highest formulary cost

Roundtable Participants Included:

- Nic Carlisle, JD, Southern AIDS Coalition
- Sean Dickson, National Alliance of State and Territorial AIDS Directors (NASTAD)
- Anne Donnelly, Project Inform
- Ramon Gardenhire, AIDS Foundation of Chicago
- Robert Greenwald, Harvard Law School
- Julia Hidalgo, MSW, MPH, ScD, Positive Outcomes, Inc.
- Kathie Hiers, AIDS Alabama
- Ernest Hopkins, San Francisco AIDS Foundation (SFAF)
- Brian Hujdich, HealthHIV
- Joseph Interrante, Nashville CARES
- Holly Kilness Packett, American Academy of HIV Medicine
- Matthew Rose, NMAC
- Carl Schmid II, The AIDS Institute
- Scott Schoettes, Lambda Legal
- Tyler TerMeer, Cascade AIDS Project
- Andrea Weddle, HIV Medicine Association

This report reflects participants' own opinions, offered during the roundtable and ongoing discussions, and not necessarily the opinions of the organizations they represent. It also does not reflect everything discussed or all views expressed during the roundtable.

tiers. Plans must also cover STRs for the treatment of HIV, unless they can demonstrate that a multi-tablet regimen is clinically equivalent or more effective and likely to improve adherence.

The Call to Action: End Discriminatory Practices

While state efforts have made advances in increasing patient access to health care, more must be done at state and federal levels to improve overall public health. The policy roundtable in Washington on August 30, 2016 served this purpose with a two-fold focus. First, to fully analyze and vet the new nondiscrimination regulations; second, to explore ways to enhance patient protections and to make them sustainable. During the roundtable and in subsequent conversations, participants identified the need to strengthen current health care rules, add new protections to the law and ultimately to enforce protections to ensure a civil rights framework that is meaningful and impactful.

The HIV community leaders called upon HHS and the administration to do the following:

- **Strengthen existing regulations** by providing concrete examples and clear guidance as to which practices will be considered discriminatory
- **Establish new regulations and/or sub-regulations** to guide insurers away from discriminatory benefit design
- **Enforce current law/regulations** and take swift action on complaints

Strengthen Existing Regulations

The ACA was signed into law in March 2010 – and regulations implementing Section 1557 were not finalized and effective until July 2016.⁹ It's been a long road, and while the new regulations governing nondiscrimination are a starting point, enhancements are needed. A more expansive interpretation of the protections embodied in Sections 1557 and 1311 should not be viewed as merely a means of stabilizing the exchanges as they are constituted today.¹⁵ Rather, enforcement of more robust nondiscrimination protections should be seen as a way to create better functioning marketplaces and the correct balance between personal and governmental responsibility. Whatever shape the current administration's plans for the future of the ACA may eventually assume, HIV advocates insist that nondiscrimination provisions must be preserved and strengthened in the following ways.

Define health care discrimination. Section 1557 incorporates the nondiscrimination principles found in Section 504 of the Rehabilitation Act, which applies the Americans with Disabilities Act (ADA) definition of disability.⁹ Under the ADA standard, HIV is essentially a categorical disability, so all people living with HIV are covered by Section 1557, as the major life activity of “immune function” is substantially impaired for all of them. However, the Rehabilitation Act and ADA were drafted as public accommodation and employment discrimination statutes, not to address discrimination specific to health insurance and health care. Currently, regulations under Sections 1557 and 1311 provide no specific guidance as to what constitutes discrimination in health plan design and coverage. HHS must mandate specific benefits and policies to ensure equal access to care, addressing potential discriminatory practices related to transparency, coverage and cost.

Provide examples of discriminatory plan design and access barriers. Without specific HIV-related examples, health plans do not have clear instruction for how to develop products and procedures that comply with nondiscrimination requirements. Practices that cause concern include, but are not limited to:

- Placing medications on high cost-sharing tiers to dissuade enrollment and/or to push significant costs on to those who do enroll
- Requiring chronically ill patients to pay a disproportionate share of the cost of medication through co-insurance or co-pays
- Failing to cover many/most commonly prescribed HIV regimens, including STRs and PrEP
- Narrowing provider networks, and even excluding entire categories of providers from networks
- Requiring—and sometimes repeatedly requiring—prior authorization or step therapy, which forces members to try one or more “prerequisite therapy” medication(s) first
- Employing excessive utilization management, or evaluation, not tied to efficacy or safety
- Failing to allow providers to easily follow HHS treatment guidelines.

Increase oversight for Pharmacy and Therapeutics (P&T) committees. The experts also recommend that the Centers for Medicare & Medicaid Services (CMS) place requirements on Pharmacy and Therapeutics (P&T) committees at hospitals and insurance plans. P&T committees that manage drug formularies should include providers, follow guidelines and be subject to monitoring.

Establish New Regulations

The thought leaders in HIV advocacy and policy also recommend establishing several new provisions through regulations and/or sub-regulations at the federal level to guide insurers. These include:

Require plans to report prior authorization data. While health plans may see prior authorization as an effective tool to cut costs or ensure appropriate treatment, physicians experience prior authorization as a manual, time-consuming process that questions their clinical judgment and takes valuable resources away from patient care.¹⁶ Even more troubling are the treatment delays and negative patient health outcomes prior authorizations often cause. Federal regulations should require insurers to provide information regarding how often prior authorization is required and how often appeals are approved or denied. That way, diverse stakeholders can determine how prior authorizations impact all parties across the continuum of care.

Enact limits to cost sharing. The advocates also called upon CMS to introduce federal monthly out-of-pocket limits for patients, with the same maximum spend, and state limits on co-pays. At present,

certain insurers who offer reasonable cost sharing are being forced to leave the marketplaces, unable to compete with insurers utilizing potentially discriminatory plan designs.¹² This leaves patients at the mercy of insurers overcharging for lifesaving medications, and it destabilizes the marketplaces by reducing the number of insurers offering plans, thus stifling competition.

Enforce Current Law/Regulations

It is clear that issues with health plan transparency, coverage and cost persist, resulting in barriers to care and potential discrimination for people living with HIV. Thus far, the HHS has demonstrated little capacity to uphold the antidiscrimination provisions of the ACA and may lack some tools and resources necessary to do so.

Advocates recommend strategies to extend and enforce Sections 1557 and 1311:

Address complaints to health plans and policies allegedly using discriminatory practices. Participants in the roundtable discussion encouraged wider use of tools, such as complaint letters, to challenge health plan policies that discriminate against individuals living with HIV. They also called on HHS to actively review these complaints — something it has not done in the past. The alternative would be costly and time-consuming litigation to establish legal precedents.

Implement HHS Notice of Benefit and Payment Parameters and CMS Letters to Issuers. The HHS Notice of Benefit and Payment Parameters and CMS Letters still need to be fully executed.⁹ These letters address transparency issues and strongly caution insurers to avoid discouraging enrollment of people with chronic conditions. The letters require that:

- All formulary drug lists must be up-to-date
- and accurately list all covered drugs. P&T committees must meet quarterly and make an effort to review new drugs within 90 days and make a decision within 180 days of a drug being on the market (or provide a justification if they miss this deadline)
- Formulary links must be accessible to the general public through a clearly identified link or tab on the plan website
- Plans are discouraged from mid-year formulary changes, while recognizing that changes related to availability may be necessary.

*“We have seen HHS address
no complaint
thus far.”*

*Holly Kilness Packett
Director of Public Policy
American Academy of HIV Medicine*

Engage with state health insurance regulators on nondiscrimination regulation enforcement.

Commissioners, legislators, health departments and others at the state level do not necessarily have the experience or resources to review their state health plans through an HIV-treatment lens. In the states where progress has been made, patients and third parties have actively engaged with authorities around issues and complaints. CMS/OCR and advocates must continue working with regulators, providing them with education and tools to competently review and improve their respective state plans.

Enforce and track the Essential Community Providers (ECP) provision. The ECP provision requires plans to:

- Include each type of ECP in their network or justify otherwise
- Highlight the ECPs in their plan on the provider network list
- Show the geographic distribution of the providers in their networks, and account for accessibility by beneficiaries in the coverage area.

CMS has not been able to report what plans have which ECPs, as these data have not been collected. Maintaining and successfully implementing ECPs is essential for ensuring the care and treatment of people living with HIV.

Implement proven monitoring and oversight processes. The success of the health care marketplaces depends on HHS (CMS/OCR) establishing effective approaches for identifying and addressing potentially discriminatory practices.⁹ Such practices include unreasonably excluding large numbers of treatments and subjecting them to prior authorization or exceedingly high cost sharing. There also must be consequences, such as warning letters for first-time offenders. Continued allegations of discrimination should lead to litigation.

Now Is the Time to Make Antidiscrimination Health Law Meaningful for Americans Impacted by HIV and AIDS

Today HIV is a manageable chronic disease, but it still remains a serious public health risk, touching every corner of the U.S.³ HIV does not discriminate, and neither should the health care system in the way it treats those living with this disease.

As a nation, our health care system is at a critical crossroads of uncertainty and opportunity. Failure to strengthen and improve public programs could have grave long-term consequences, not just for those living with HIV, but for all of public health in the U.S.

The nondiscrimination and patient protections roundtable took an important step by prioritizing measures that would improve the lives of patients and strengthen the enforcement of rules on which those changes rest. The shared objective at the meeting was to ensure people living with HIV have access to high-quality, affordable care and a strong safety net. The need for cross-stakeholder collaboration to dismantle known barriers to care and prevent new ones from emerging in a political climate demonstrated to be increasingly hostile to regulatory controls can't be overstated. The core aspirations of participants in the roundtable have broad support in government circles and across American civil society: namely, to bring relief to people suffering with chronic health conditions.

The next step is embracing the ideas of key national and state HIV thought leaders to turn these ideals into action.

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