

ENDING THE HIV EPIDEMIC IN THE UNITED STATES:

A ROADMAP FOR FEDERAL ACTION

**We can end the HIV
epidemic by 2025.**

A COMMUNITY-DRIVEN DOCUMENT
DRAFTED AND PUBLISHED BY



ACT NOW: END AIDS

to those who acted up and those who continue to act now

Table of Contents

Executive Summary	4
Preamble.....	17
Introduction	21
Modeling Public Health Goals for Ending the United States HIV Epidemic.....	24
<i>ACHIEVING THE 95/95/95 FRAMEWORK BY 2030</i>	25
<i>ACHIEVING THE 95/95/95 FRAMEWORK BY 2025</i>	26
<i>BENDING THE CURVE THROUGH SCALE-UP OF PREP</i>	27
<i>ADDRESSING HIV-RELATED HEALTH DISPARITIES</i>	28
<i>BRINGING EFFECTIVE HIV PREVENTION AND CARE TO SCALE TO MEET 95-95-95 GOALS</i>	29
Reducing Health Disparities	30
<i>GEOGRAPHIC DISPARITIES</i>	32
<i>POPULATION CHARACTERISTIC-BASED DISPARITIES</i>	35
Improving HIV Care and Treatment	40
<i>INCREASE ACCESS TO MEDICAID FOR ALL PEOPLE WITH HIV AND COMMUNITIES AT HIGHER RISK FOR HIV</i>	41
<i>PROTECT MEDICARE</i>	45
<i>PROTECT THE HEALTH CARE GAINS MADE UNDER THE AFFORDABLE CARE ACT</i>	46
<i>STRENGTHEN THE RYAN WHITE HIV/AIDS PROGRAM</i>	48
<i>PREVENT AN HIV WORKFORCE SHORTAGE</i>	52
<i>PROTECT THE 340B DRUG DISCOUNT PROGRAM</i>	54
<i>ELIMINATE VIRAL HEPATITIS AS A PUBLIC HEALTH CRISIS IN THE UNITED STATES</i>	54
<i>ELIMINATE TUBERCULOSIS AS AN EPIDEMIC</i>	58
<i>PROVIDE UNIVERSAL HEALTH CARE ACCESS</i>	61
Preventing New Transmissions	62
<i>INCREASE TESTING AND LINKAGE TO CARE</i>	62
<i>INCREASE THE USE OF BIOMEDICAL PREVENTION INTERVENTIONS</i>	65
<i>SCALE UP HARM REDUCTION & SUBSTANCE USE DISORDER TREATMENT SERVICES</i>	68
<i>ENSURE YOUNG PEOPLE HAVE ACCESS TO COMPREHENSIVE, AGE-APPROPRIATE, EVIDENCE-BASED SEXUAL HEALTH EDUCATION</i>	70
<i>IMPLEMENT A NATIONAL HARM REDUCTION STRATEGY</i>	72
<i>REDUCE THE SYNDemics OF SEXUALLY TRANSMITTED INFECTIONS</i>	79
Investing in Structural Interventions	82

<i>FOOD AS MEDICINE FOR PEOPLE LIVING WITH HIV</i>	83
<i>HOUSING IS HEALTHCARE AND PREVENTION</i>	83
<i>EMPLOYMENT</i>	84
Ending HIV Criminalization.....	87
Investing in Research.....	90
Conclusion.....	93
Appendix A: Organizations Signing on to the Roadmap at Launch	94
Appendix B: Legislative Recommendations.....	99
Appendix C: Regulatory Recommendations by Department/Agency	106
Appendix D: Hybrid Legislative and Regulatory Recommendations.....	121

Executive Summary

HIV continues to be a major public health crisis in the U.S. with almost 40,000 new cases each year, compounded by the syndemics of opioid use, viral hepatitis, sexually transmitted infections (STIs), and tuberculosis (TB). While the more than 1.2 million people living with HIV in the U.S. reside in every congressional district, State, and territory, new cases of HIV and HIV/AIDS-related deaths are increasingly concentrated in communities of color, among members of the LGBTQ community, and in the Southern states. While communities across the U.S. have already begun taking concrete steps to end their state and local HIV epidemics,¹ ending the HIV epidemic across the country will require increased Federal commitment and the concerted and coordinated efforts of community-based organizations, state and local governments, people living with and vulnerable to HIV, communities, clinicians, and service providers.

The United States now has the tools and ability to end the HIV epidemic at home. We must also urgently seek to eliminate or reduce the related syndemics of opioid use, viral hepatitis, STIs, and TB. The undersigned call on the U.S. government to officially declare that it is our goal to end the HIV epidemic in the United States by 2025 and enact legislative and regulatory changes to achieve this goal.

Highly effective antiretroviral therapy, taken as treatment or prevention, provides the means to end our HIV epidemic, even without a vaccine or cure, by dramatically reducing new HIV cases, ending AIDS deaths, and eliminating disparities in access to quality HIV prevention and treatment. We now know that for people living with HIV, retention in HIV treatment that suppresses viral load to an undetectable level both sustains optimal individual health and eliminates the risk of sexual transmission of the virus. Successful HIV prevention for HIV-negative individuals is available through a combination of sexual health education, routine HIV screening, wide access to both pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) for those who need it, syringe access and other harm reduction services, and comprehensive insurance coverage of these interventions as essential preventive health care services.

U.S. innovation and leadership on HIV have laid the foundation for decisive action to end the epidemic. Numerous federal government departments, agencies, and programs are involved in the domestic HIV/AIDS response; together they provide disease surveillance, prevention, care, support services, and research. The Centers for Disease Control and Prevention (CDC) leads U.S. surveillance and prevention activities, which are carried out in conjunction with state and local health departments and community-based organizations (CBOs).

Federal health care programs including Medicaid, Medicare, the Ryan White HIV/AIDS Program, and the Veterans Administration provide care, treatment, and supportive services. The Housing Opportunities for Persons with AIDS (HOPWA) program, as well as other safety net services through the Department of Housing and Urban Development (HUD), provides essential access to affordable housing for low-income people living with, affected by, or

vulnerable to HIV. The Social Security Administration's income programs for those who are disabled — Supplemental Security Income (SSI) and Social Security Disability Insurance (SSDI) — are important sources of support and financial stability. The passage of the Patient Protection and Affordable Care Act (ACA) in March 2010 provided new opportunities for expanding health care access, prevention, and

The United States now has the tools and ability to end the HIV epidemic at home. We must also urgently seek to eliminate or reduce the related syndemics of opioid use, viral hepatitis, STIs, and TB. The undersigned call on the U.S. government to officially declare that it is our goal to end the HIV epidemic in the United States by 2025 and enact legislative and regulatory changes to achieve this goal.

¹ Ending the Epidemic plans have been announced in eight states (and DC), two counties, and two cities and are being developed in an additional seven states, one county, and nine cities. More information can be found at <https://www.nastad.org/resource/ending-hiv-epidemic-jurisdiction-plans>.

treatment services for millions of people in the U.S., including many people living with or vulnerable to HIV.

Programs outside the Department of Health and Human Services also play key roles in this work. The Department of Justice Civil Rights Division, the Bureau of Prisons, the Department of Education, the Department of Labor, the Department of Transportation, the Department of Defense, the Department of Agriculture, and others have crucial roles to play in ending new HIV transmissions in the U.S. and supporting the health of people living with HIV.

We can change the trajectory of the U.S. HIV epidemic by setting and meeting the ambitious but achievable goal of reaching a 95/95/95 framework for HIV care (95% of people living with HIV are aware of their HIV status, 95% of diagnosed individuals are retained in care, and 95% of individuals on antiretroviral therapy virally suppressed), significantly increasing access to combination prevention for people who are HIV negative, and taking concrete action to ensure that no population or region is left behind. But we must bring all available treatment and prevention tools to scale now to have the necessary impact on the epidemic. Failure to act swiftly at the required scale and across all affected communities and populations will result in more HIV transmissions, more HIV-related morbidity and mortality, continued health inequities, and increased health care costs.

Through the joint effort of community, all levels of government, and industry, we can harness the progress made over the last three decades to achieve a once unthinkable goal. Experience and research show us that a focus on the following pillars of work will provide the guidance, framework, and direction needed to drastically reduce new HIV cases, improve the length and quality of the lives of people living with HIV, effectively address the related opioid, viral hepatitis, STI, and TB syndemics, and in doing so dramatically reduce overall costs in lives and health care dollars.

Pillar 1: Commit to end the U.S. HIV epidemic and eliminate HIV health disparities

To end the U.S. HIV epidemic, we must use all the powerful tools available, hold ourselves accountable for results, and ensure that no person or community is left behind.

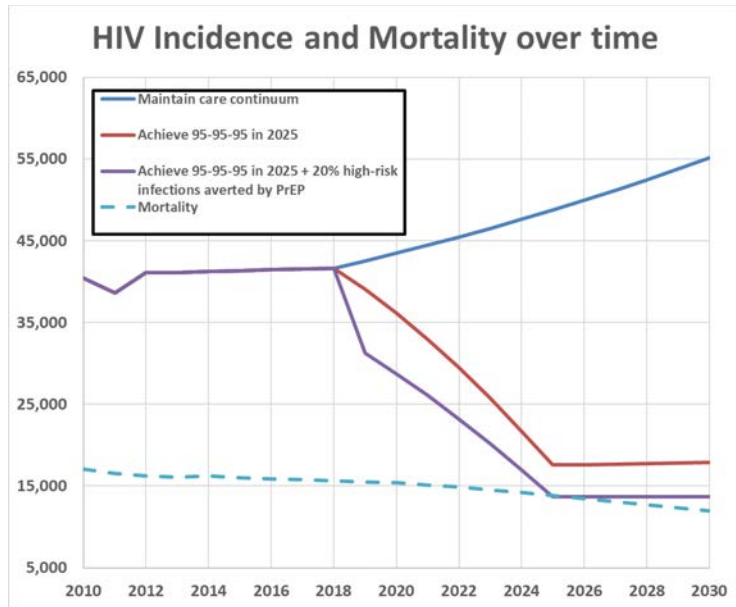
Set public health goals to end the U.S. HIV epidemic by 2025

Experience has demonstrated that time-bound public health goals drive progress, promote accountability, and unite stakeholders. To end the U.S. HIV epidemic, we must set and meet benchmarks, modernize our national HIV surveillance system, and develop a real-time dashboard of key metrics to track the epidemic, gauge our progress, and better prioritize resources.

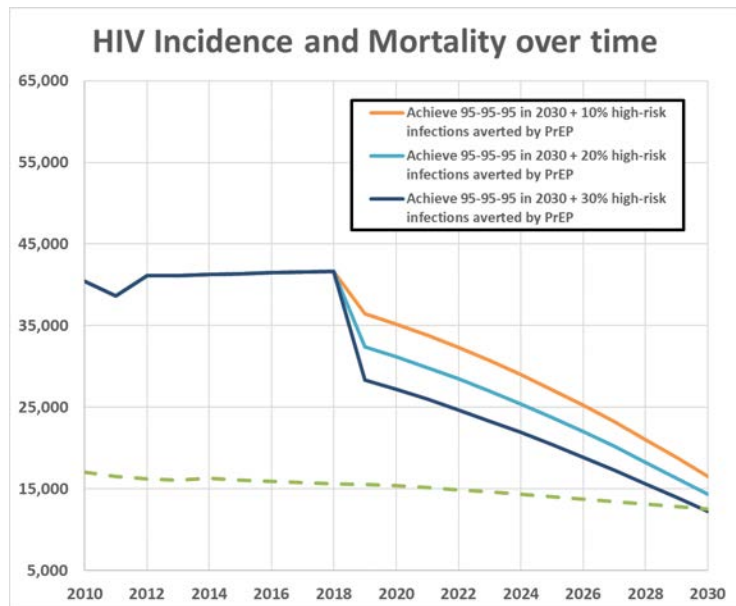
Mathematical modeling, detailed starting on page 7 of this Roadmap, indicates that achieving the 95/95/95 HIV care framework by the year 2025, coupled with PrEP scale-up, will have significant impacts on HIV incidence and prevalence in the U.S.

Compared with the scenario of simply continuing current efforts:

- Achieving the 95/95/95 care framework and 40% PrEP coverage by the year 2025 would have the greatest impact on HIV incidence and prevalence, reducing the number of new HIV cases occurring during the years 2019 to 2030 by approximately 353,000 persons.



- Achieving the 95/95/95 framework by the year 2030 would reduce the number of new HIV cases occurring during the years 2019 to 2030 by approximately 210,500 persons. Increasing uptake of PrEP to achieve 40% coverage of persons vulnerable to HIV would further amplify these gains, bringing the total of averted new HIV cases between now and 2030 to 292,500 persons.



Additional resources will be required to achieve these programmatic service delivery goals. Without such rapid scale-up, however, the U.S. HIV epidemic will continue to outrun the response, increasing the long-term need for HIV treatment and dramatically raising future costs. Indeed, public spending on accelerated scale-up will generate historic health benefits and savings sufficient to offset or exceed the required investments. Modeling indicates that achieving the 95/95/95 HIV care framework by 2025 would translate into a savings in public spending on HIV medical treatment costs from prevented new HIV cases of at **least \$57 billion** that could be better used between now and 2030 to fund the care and services needed to prevent new HIV cases, stop HIV-related deaths, and end HIV-related health disparities. Investment now would make history by ending the U.S. epidemic and still be considered cost-saving.

Recommendations for action:

1. Set concrete public health goals and benchmarks to end the U.S. HIV/AIDS epidemic by the year 2025, by dramatically reducing new cases, optimizing health for all persons with HIV, and ending AIDS deaths.
2. Modernize our national HIV surveillance system and develop and monitor actionable metrics in real time to track the epidemic, gauge progress, and ensure that no community or geographic region is left behind.

Eliminate U.S. HIV-related health disparities

To truly end the U.S. epidemic, we must not only achieve these public health goals in absolute terms, but also in a manner that addresses persistent disparities in HIV risk and health outcomes by focusing efforts and increased resources on communities that bear the largest burden of the epidemic.

The U.S. HIV epidemic lies at the intersection of structural inequalities. Poverty, racism, sexism, gender bias, homophobia, and transphobia significantly influence the likelihood of exposure to HIV as well as health outcomes after seroconversion, and societal responses to HIV vary substantially by race, class, and geography.

Social and economic marginalization leaves certain communities to bear the brunt of the U.S. epidemic. Black and Latinx² gay, bisexual, and queer men, cisgender Black and Latinx women, and trans-identified and gender nonconforming women continue to be disproportionately affected by HIV, especially in the Deep South, rural and suburban areas in the Midwest, and urban centers in California and the Northeast. Many recent immigrants are afraid to access HIV prevention and medical care, out of fear of deportation or that the proposed expansion of the “public charge” definition will bar their applications for citizenship, and these barriers have the potential to drive dramatic increases in new HIV cases among Latinx gay and bisexual foreign-born men.

The U.S. HIV epidemic also differs dramatically by region and state, with some epidemics concentrated in urban areas and others more widely dispersed. According to the CDC, “the South now experiences the greatest burden of HIV infection, illness, and deaths of any region in the United States, and lags far behind in providing quality HIV prevention and care to its citizens.”

Stigma in all its manifestations also plays a significant role in perpetuating the U.S. HIV epidemic. Stigma related to age, race, gender, gender identity, sexual orientation, substance use and HIV itself may discourage people from getting tested for HIV and from accessing and engaging in prevention and treatment services.

As detailed starting on page 14 of this Roadmap, the tools of HIV testing, care, treatment, and prevention are evidence-based and well-described. However, to impact the U.S. epidemic they must be offered in a manner that directly addresses the social and structural determinants of pernicious HIV health disparities.

Recommendations for action:

1. The CDC must create new, additional targeted funding opportunities for Community Based Organizations (CBOs) outside the large metropolitan areas, particularly in the U.S. South, and in small cities with high rates of incidence and mortality.
2. The CDC and the Health Resources and Services Administration (HRSA) should seek ways to support non-traditional clinics such as point-of-care services, mobile clinics, telemedicine

² “Latinx” is the gender-neutral form of “Latino/Latina.” <https://www.merriam-webster.com/words-at-play/word-history-latinx>.

facilities, and integrated medical care in other social support service settings to increase access points for vulnerable populations and communities disengaged from the health system.

3. Upgrade treatment and prevention services in Puerto Rico, the U.S. Virgin Islands, and all territories to the level achieved across the mainland, while ensuring representation and leadership by the territories.
4. HRSA should examine the feasibility of distribution of Ryan White Program Part B Supplemental Funding that takes into account the disproportionate impact of HIV incidence and outcomes in the U.S. South and other areas with emerging needs.
5. HHS agencies must fund HIV-related stigma reduction interventions, health literacy, and health system navigation services, with particular efforts to prioritize communities of color and the U.S. South., and expand awareness of and access to PrEP.
6. Strengthen protections from discrimination for lesbian, gay, bisexual, and transgender people under both Title VII of the Civil Rights Act and Title IX of the Education Amendments Act of 1972 and provide better reporting on the health and human services needs of the entire LGBT community with a particular emphasis on the transgender community.
7. Reject proposed changes to the “public charge” definition that would inhibit immigrants from seeking health care, including preventive health services, for themselves and their families.
8. Establish and resource a cross-governmental working group to address issues related to an aging population living with HIV inclusive of inflammation, social isolation, multiple morbidity, polypharmacy, and the need to emphasize maintenance of function.

These and additional recommendations are detailed in this Roadmap starting on page 16.

Pillar 2: Ensure broad and equitable access to effective HIV care and treatment

To sustain optimal health for people living with HIV and stop ongoing transmission, we must maximize the number and proportion of people with a suppressed HIV viral load as rapidly as possible following diagnosis by ensuring effective, high-quality HIV care that leaves no one behind.

Ending the HIV epidemic in the U.S. relies on a robust integrated health care system and equitable access to comprehensive health care coverage for people living with and vulnerable to HIV. An estimated 56 percent of people living with HIV count on Medicaid, Medicare, or both for their health care coverage, an estimated 30 percent are covered through private insurance, and 14 percent are uninsured; the Ryan White HIV/AIDS Program covers 52% of all people living with HIV in the U.S., and, as a non-insurance payer of last resort, fills in payment gaps for people living with HIV who are also enrolled in Medicaid, Medicare, and/or private insurance.

In terms of federal expenditures, Medicare is the largest federal funder of HIV care and treatment at \$10 billion per year, followed by Medicaid at \$5.9 billion, and then the Ryan White HIV/AIDS Program at \$2.3 billion. Further, Medicaid expansion and private insurance reforms under the ACA have allowed tens of thousands of people living with and vulnerable to HIV to access comprehensive, affordable coverage for the first time. The commitment and innovative use of state and local resources to fill gaps and cover costs excluded by federal funding streams is also vital.

Sustain and expand vital health insurance programs

Equitable, sustained access to adequate health coverage is the fundamental building block for ending the U.S. HIV epidemic:

- Medicaid is the largest source of insurance coverage for people with HIV, estimated to cover more than 40% of people with HIV in care.³ Expanded and sustained access to Medicaid coverage across the country, as defined by the ACA, must be a top priority to end HIV as an epidemic. This means protecting and expanding Medicaid as a health care safety net program in every state, ensuring the stability of the Medicaid program, and federal rejection of state proposals that would harm people living with HIV, such as rolling back benefits, restricting access for life-saving medications, imposing work requirements as a condition of continued coverage, or requiring additional cost-sharing beyond the federal limits on low-income beneficiaries.
- The Medicare program is also a critical resource for ending the epidemic, covering twenty percent of people living with HIV in care. Most people with HIV on Medicare are under age 65 and qualify as disabled beneficiaries, and a significantly higher percentage of them are dually-eligible for Medicaid than in the overall Medicare population. With the implementation of the Medicare Part D prescription drug benefit in 2006, Medicare assumed an even more critical role for people living with HIV. Seventy-seven percent of Medicare beneficiaries living with HIV qualify for Part D prescription drug subsidies.
- The ACA's consumer protections that include prohibiting insurers from denying coverage due to pre-existing conditions, premium setting based on community rating, nondiscrimination protections, guaranteed coverage of essential health benefits, premium and cost sharing assistance, and annual caps on out-of-pocket costs are all critical to improving access to health care coverage and services for people with HIV and must be protected.
- Finally, ensuring that people living with HIV can get the care their doctors prescribe requires that all public and private health insurance plans include consumer protections for prescription drug access and cap covered out-of-pocket prescription drug costs.

Recommendations for action:

1. Ensure access to ACA-expanded Medicaid for people living with and vulnerable to HIV in all states and oppose any measures aimed at limiting access to Medicaid.
2. Support implementation of innovative care delivery and payment models through State Medicaid programs, such as coordinated, integrated patient-centered health care programs, incentivizing Medicaid programs to enter into data-sharing agreements with state and local departments of health and requiring Medicaid programs to adopt HIV viral load suppression performance measures.
3. Eliminate the 29-month waiting period before SSDI recipients can obtain Medicare benefits.
4. Maintain in the Medicare Part D Formulary an "all drugs, all classes" rule for FDA-approved antiretroviral drugs.
5. Extend Medicaid drug rebates to Medicare plans covering dually-eligible, low-income beneficiaries.

³ <https://www.kff.org/hiv/aids/issue-brief/assessing-the-impact-of-the-affordable-care-act-on-health-insurance-coverage-of-people-with-hiv/>

6. Direct the Center for Medicare deputy administrator to ensure that beneficiaries have access to and a choice of providers, including pharmacies, and prohibit Part D plans from changing pharmacy networks mid-year to ensure continuity of care and treatment.
7. Take all necessary legislative action to ensure that the ACA continues in full, including the nondiscrimination protections, and to stabilize the ACA insurance marketplace with sufficient funding for enrollment and marketing activities.

These and additional recommendations are detailed in this Roadmap starting on page 25.

Enhance the Ryan White HIV/AIDS Program

The federal Ryan White HIV/AIDS Program provides comprehensive services for the most vulnerable people living with HIV in the U.S. Almost two-thirds of Ryan White Program participants are living at or below 100 percent of the Federal Poverty Level (FPL), and over 90 percent are living at or below 250 percent of the FPL. Racial and ethnic minorities in every congressional district make up nearly three-quarters of Ryan White Program participants.

About eighty percent of all Ryan White Program participants are covered by some form of health care insurance, including about half who are covered by Medicaid and/or Medicare. However, public and private insurance programs do not always provide the comprehensive array of services required to meet the needs of people living with HIV. These include case management, mental health and substance use treatment, adult dental services, and transportation, legal, and nutritional support services.

The Ryan White Program, particularly the AIDS Drug Assistance Program, assists with these costs so that low-income people living with HIV can access comprehensive and effective medical care and treatment. To improve the continuum of care and progress toward an end to the U.S. epidemic, continued and enhanced funding for all parts of the Ryan White Program is crucial. Robust funding for the Ryan White Program is particularly important to fill gaps in health coverage for people with HIV in jurisdictions that have not expanded Medicaid, such as several states in the U.S. South.

Recommendations for action:

1. Increase funding for the Ryan White Program consistent with a growing epidemic and need, ensuring that the program's funding formulas and structure support integrated efforts to end the HIV epidemic.
2. Allow Ryan White Program-funded clinics access to health center reimbursement mechanisms under Medicaid.
3. Create flexibility under program income guidance to ensure critical support for HIV services.

Protect the 340B Drug Pricing Program

Likewise, since 1992 the 340B Drug Pricing Program has provided critical support for HIV services and extends care to many who otherwise would go without. Savings from 340B allow covered entities, including AIDS Service Organizations, to increase health care services and capacity in their communities, offering more health care delivery locations, hours of operation, and an expert workforce. Thanks to the savings covered entities earn through the 340B program, Americans living with and vulnerable to HIV benefit from lifesaving treatment, preventive health care, substance use and mental health services, and chronic disease management.

Recommendation for action:

1. Maintain the 340B Program to ensure critical support for HIV services.

Adopt national strategies to eliminate viral hepatitis and tuberculosis

Sustaining the health of people with and at risk of HIV also requires concrete action to stop the worsening syndemics of viral hepatitis and Tuberculosis (TB). People living with HIV are disproportionately affected by viral hepatitis; about one-third are coinfecting with either hepatitis B virus (HBV) or hepatitis C virus (HCV), and HIV coinfection more than triples the risk for liver disease, liver failure, and liver-related death from HCV. With new highly effective curative treatments for HCV and treatment and a vaccine for HBV, we have the means to eliminate viral hepatitis as a public health threat in the United States. The risk of developing TB from latent infection is also significantly increased for people living with HIV. Decades of declines in federal and state funding for TB prevention and control have led to the deterioration of public health infrastructure and limited the capacity of TB programs to provide prevention, treatment, and monitoring efforts and to prevent and respond to outbreaks, especially to emerging drug-resistant strains. TB is preventable, treatable, and curable, but putting the U.S. back on the track of TB elimination will require national leadership, resources and political will.

Recommendations for action:

1. Fully implement and resource the National Viral Hepatitis Action Plan 2017-2020 and establish, implement, and resource a National Viral Hepatitis Action Plan 2020-2030.
2. Support local, state, and national TB elimination efforts, including implementing and resourcing the National Action Plan to Combat Multidrug-Resistant TB.

These and additional recommendations are detailed in this Roadmap starting on page 39 for viral hepatitis and page 43 for tuberculosis.

Pillar 3: Prevent new HIV transmissions

While we work to diagnose and treat all Americans living with HIV, we also must work to prevent exposure. We know that biomedical, behavioral, and structural interventions used in concert can successfully and significantly reduce HIV transmission. Routine and voluntary universal HIV testing is a gateway to HIV prevention for those who test negative; effective treatment for people living with HIV suppresses viral load to undetectable levels that eliminates sexual transmission; and both groups benefit from interventions to address behavioral and structural factors that increase the risk of acquiring and transmitting HIV.

However, there are still an estimated 40,000 new cases in the U.S. each year, and while rates of new cases are declining in some communities, there are increases or no change in others where resources for prevention and care are limited. The Southern U.S. is particularly affected, accounting for over 50 percent of the estimated new cases while representing only 37 percent of the U.S. population.

Reduce new HIV cases through evidence-based combination HIV prevention strategies

HIV prevention services must be comprehensive and include high quality, medically-accurate, age-appropriate, culturally-responsive, HIV, reproductive, and sexual health education at all levels; truly routine screening for HIV for all persons over age 15 as preventive care; broad and equitable access to pre-exposure prophylaxis (PrEP) for those vulnerable to HIV; wide access to non-occupational and occupational post-exposure prophylaxis (PEP); syringe access and other harm reduction services as needed by people living with HIV and HIV-negative persons; and insurance coverage of HIV prevention, including PEP and PrEP, as essential preventive health care services.

Recommendations for action:

1. The CDC and HRSA should create tools to support providers' deployment of key messaging and training on the use of prevention tools and interventions, including by launching a widespread "Undetectable Equals Untransmittable" social marketing campaign.
2. Expand routine HIV testing for all Americans, including by reviewing and relaunching the CDC recommendation that "Everyone Should be Tested at Least Once," and increase CDC funding streams for age-specific, innovative outreach and testing.
3. Provide support for primary trainings and continuing education for providers through CDC and HRSA in cross-cutting cultural responsiveness.
4. Ensure the availability and affordability of PrEP across all populations through a combination of federal funding, addressing pricing issues for commercially available PrEP already on the market, and investing in development of new PrEP modalities.
5. Support sexual health education programs by supporting increased funding for existing programming for adolescents, such as the CDC's HIV School Health efforts through the Division of Adolescent and School Health (DASH), the Teen Pregnancy Prevention Program (TPPP) through the Office of Adolescent Health, and an extension of the Personal Responsibility Education Program (PREP); by eliminating federal funding for abstinence-only-until-marriage programs, including the Title V "Sexual Risk Avoidance Education" state-based grant program; and requiring that all federally-funded state juvenile detention, foster care, and mental health facilities for youth include sexual health care and literacy in their services for these youth in out-of-home care.
6. Support both the Real Education for Health Youth Act (REHYA) and Youth Access to Sexual Health Services Act (YASHS).
7. Protect and bolster funding for providers of sexual and reproductive health care, especially through the Title X Family Planning Program.

These and additional recommendations are detailed in this Roadmap starting on page 54.

Stop the opioid and injection drug use crises

The overdose crisis and attendant increases in injection drug use are driving a significant increase in the rate of new viral hepatitis infections and threaten to reverse the substantial gains since 1990 in reducing HIV rates among people who inject drugs. Community-based harm reduction, overdose prevention, and syringe services programs have consistently demonstrated the greatest impact and are the most cost-effective interventions available to reverse the overdose and infectious disease crises devastating our communities. Widespread, free, and low barrier access to all forms of Medication Assisted Treatment (MAT) for those who seek it must be a critical component of federal, state, and local strategies to address the opioid epidemic.

Recommendation for action:

Develop, implement, and resource a National Harm Reduction Strategy with particular focus on overdose and infectious disease prevention (recommendations are detailed in this Roadmap starting on page 58), ending criminalization and promoting the rights and dignity of people who use drugs (recommendations are detailed in this Roadmap starting on page 61), and structural interventions and social determinants of health (recommendations are detailed in this Roadmap starting on page 63).

Reduce the syndemic of sexually transmitted infections

The U.S. is experiencing an historic rise in rates of sexually transmitted infections (STIs) —another indication of a public health infrastructure continually strained by budget reductions at every level of government. More than two million cases of chlamydia, gonorrhea, and syphilis were reported in 2016, the highest number ever.

Investment in comprehensive STI prevention, testing, treatment, and research must be an essential component of our comprehensive HIV prevention strategy and is critical to ensuring that individuals can remain healthy, active participants in our workforce and society.

Recommendations for action:

1. Fund STI prevention at a level commensurate with the scope of the epidemic.
2. Include STI screening and treatment as a component of HIV prevention programs.
3. Invest in comprehensive education for providers about the need for three-site testing, culturally responsive language, and methods for eliciting full sexual histories.

These and additional recommendations are detailed in this Roadmap starting on page 64.

Pillar 4: Address social and structural barriers to effective HIV prevention and care

Biomedical treatment and prevention alone will not end the U.S. HIV epidemic. Structural factors including poverty, discrimination, lack of employment and educational opportunities, housing and food insecurity, untreated or undertreated mental health and substance use challenges, and limited transportation infrastructure contribute to poor health outcomes. Other structural contributors to the U.S. HIV epidemic include the criminalization of HIV nondisclosure, exposure, and/or transmission, nonviolent drug violations, and adult consensual sex work; interpersonal violence; the burden of disproportionate incarceration and entanglement with the criminal justice system for young men of color and transgender persons; and barriers to prevention and care services for new immigrants. For many persons living with or vulnerable to HIV, successful prevention and care requires culturally competent services to address these barriers, and evidence demonstrates that interventions to ensure adequate housing, food, transportation, and other critical enablers of health care are both essential and cost-effective.

Ensure availability of essential services that support health, prevention, and retention in care

The federal government has a unique opportunity and responsibility to expand efforts to assure availability of essential services that support health, HIV prevention, and retention in care, including programs that address poverty, unemployment, criminal justice involvement, and other social factors that drive the ongoing U.S. HIV epidemic, as well as programs and supports that address homelessness, hunger, and other unmet subsistence needs that are powerful barriers to effective HIV care and treatment.

This includes the need to address disparities in health care and other structural drivers of the HIV epidemic across U.S. regions and communities.

Recommendations for action:

1. Fund the HUD Housing Opportunities for People with AIDS (HOPWA) program at levels commensurate with the epidemic and increase federal investments in the Housing Choice Voucher Program and other HUD-administered Permanent Supportive Housing programs.
2. Eliminate eligibility restrictions to accessing HUD programs related to drug use or drug-related convictions.

3. Reject the imposition of work requirements, drug screening, or other barriers to food security programs across the government including the Supplemental Nutrition Assistance Program.
4. A federal interagency task force composed of National HIV/AIDS Strategy implementers including HHS, HOPWA, Department of Labor, and Department of Education should develop a plan to support the vocational training and employment of people with HIV.
5. Department of Justice and HHS must collaborate and provide resources to states and localities for preventing and treating HIV during incarceration and upon reentry, as well as improve HIV testing, prevention, and treatment services in federal prisons.
These and additional recommendations are detailed in this Roadmap starting on page 68.

Provide federal leadership to end HIV criminalization

Likewise, laws that criminalize HIV exposure, non-disclosure, transmission, and behaviors that can transmit HIV, despite data showing lack of impact on HIV transmission, are systemic structural barriers that create stigma and discrimination as well as infringing on the civil rights of people living with HIV.

It is time to eliminate HIV-specific and related laws that are outdated, do not reflect current scientific understanding and are at odds with well-tested and effective public health strategies.

Recommendations for action:

1. Support and pass legislation to end HIV criminalization via the REPEAL (Repeal Existing Policies that Encourage and Allow Legal) HIV Discrimination Act.
2. Decriminalize sex work.
3. Repeal the Stop Enabling Sex Traffickers Act (SESTA) and the Allow States and Victims to Fight Online Sex Trafficking Act (FOSTA) and pass anti-trafficking legislation that does not conflate human trafficking with consensual adult sex work.

Pillar 5: Maintain U.S. leadership in lifesaving research

HIV/AIDS research in the last four decades has been responsible for the dramatic transformation of HIV from a uniformly fatal diagnosis to one that can be managed over a near-normal lifespan. Innovations such as highly effective antiretroviral therapy and PrEP give us the tools to bring HIV below epidemic levels in the U.S. when combined with strategies to address health disparities and structural drivers. However, additional research advances will support maximizing the implementation of existing tools and developing new modalities to sustainably end the HIV epidemic in the U.S. and worldwide.

As such, a robust research agenda is an indispensable part of our ability to end the domestic and global epidemics. The federal government must support groundbreaking research within the National Institutes of Health and other publicly-funded research bodies to develop a preventive vaccine, microbicides, a cure for HIV, new HIV treatments, new approaches to PrEP, and implementation science to support scaling up treatment and prevention, including by addressing co-morbidities and related health disparities.

Recommendations for action:

1. Make sustained multi-year increases for HIV/AIDS biomedical research.
2. Increase resources for other HIV/AIDS research activities, including implementation science, across the government; leverage the Centers for AIDS Research (CFAR) national network to enhance collaboration with local AIDS service organizations and community-based organizations

to support implementation science within communities; and continue existing HIV research cohorts.

3. Expand ethical research on treatment, prevention needs, and implementation among vulnerable populations such as youth, people of color, pregnant and lactating women, people of trans experience, and people who use drugs.
4. Establish a federally-supported Structural Interventions Research Committee within the Office of AIDS Research to advance coordination, communication, and furthering of cross-government research.

These and additional recommendations are detailed in this Roadmap starting on page 74.

Pillar 6: Support the meaningful involvement of people living with and vulnerable to HIV

No complex health crisis can be resolved without the leadership of affected communities, and without centering vulnerable individuals within the heart of the response.

The communities and constituencies living with and affected by HIV/AIDS across the United States, Puerto Rico, U.S. Virgin Islands, and all territories are people living with HIV/AIDS, people of color, transgender and cisgender women and men, queer-identified and gender-nonconforming individuals, sex workers, immigrants with and without documentation, people in U.S. jails, prisons, and immigration detention centers, people who use drugs, people living with mental health challenges, people living with physical and intellectual disabilities, people of all religious practices, all languages, all ages, and in all regions. Many daily confront stigma, transphobia, homophobia, unemployment, economic and food insecurity, homelessness, lack of health care, violence, discrimination, criminalization, racism and white supremacy, and, because of that, struggle with self-determination, political participation/inclusion, safety, and equality before the law. Many work to organize, mobilize, and empower the communities they serve – not only to end the HIV epidemic but also to eliminate the structural barriers and vulnerabilities that keep our resilient communities from living fully and with dignity.

The resilience, wisdom, and agency of affected communities must guide the implementation of any national plan to end the HIV epidemic in the U.S. Policymaking to end the epidemic must prioritize opportunities to uplift voices and clear paths for leadership by those most marginalized and affected by the epidemic.

Recommendations for action:

1. Ensure equity in allocation of human, material, and financial resources when implementing the actions recommended in this Roadmap.
2. Center the communities most impacted by the epidemic in leadership and decision-making when crafting policies and solutions in any and all efforts to end the epidemic.

Conclusion

We have made substantial progress in responding to the HIV epidemic. At the beginning of the epidemic, no one could have predicted the incredible success of antiretroviral medications that today permit people living with HIV to live healthy, productive, and long lives. In the last decade, the U.S. has created and implemented the first National HIV/AIDS Strategy, developed antiretroviral prevention technologies like PrEP and treatment as prevention, implemented more syringe services programs, made science-based sexual and reproductive health education available to additional young people, and improved access to health care for millions of Americans.

The U.S. now has the capability to reverse and potentially end the domestic epidemic. The HIV community, in collaboration with state and local jurisdictions, is working to implement plans to do so. Consistent with the recommendations here, the support and intervention of the federal government will be central to ending the epidemic across the U.S. Only with a focused effort that prioritizes the needs of people with HIV, addresses health disparities, prevents new cases, improves the health care system, creates structural mechanisms to improve health outcomes through ancillary services, and produces groundbreaking, cross-cutting research will we together defeat one of the most complex viruses ever encountered.

Implementing this roadmap to end the HIV epidemic in the United States is possible only with decisive action from Congress and the Administration. We must officially declare a goal to end the epidemic by 2025, and the time to make this declaration is now. Consequently, the undersigned call on the U.S. government to officially declare that it is our goal to end the HIV epidemic in the United States by 2025 and to enact legislative and regulatory changes to achieve this goal.

Preamble

Respectfully submitted to our U.S. Representatives and Senators in Congress, incoming members, and the Presidential administration:

We write to you as people, communities, and constituencies living with and impacted by HIV/AIDS across the United States, Puerto Rico, Virgin Islands, and all U.S. territories. We are people living with HIV/AIDS, people of color, Native Americans, transgender and cisgender women and men, queer-identified and gender-nonconforming individuals, sex workers, immigrants with and without documentation, people in U.S. jails, prisons, and immigration detention centers, people who use drugs, people living with mental health conditions, people living with physical and intellectual disabilities, people of all religious practices, all languages, all education levels, all socioeconomic statuses, and all ages. Many of us struggle daily with stigma, transphobia, homophobia, unemployment, economic and food insecurity, homelessness, lack of health care, violence, discrimination, criminalization, racism and white supremacy. Because of that, we struggle with self-determination, political participation/inclusion, safety, and equality before the law. Many of us work to organize, mobilize, and empower the communities we serve – to not only end the epidemic of HIV but eliminate the structural barriers and vulnerabilities that keep all our resilient communities from living fully and with dignity.

We call on you, our elected officials and government, to take bold steps to enforce all recommendations in this comprehensive and ambitious plan, spearheaded by our communities, to “End the Epidemic” across the U.S. However, we strongly caution that any earnest effort to End the HIV Epidemic must first address the myriad structural and systemic inequities our communities face. Otherwise, we will ultimately fail as a nation to end the epidemic.

Scientific innovations in the past decade have created and continue to deliver potent tools to stop HIV in its tracks. Without human rights-based policymaking to expand access to comprehensive culturally responsive and linguistically appropriate care, treatment, prevention, education, and dignity for the most marginalized in our communities, a call to end HIV as an epidemic will remain yet another meaningless slogan – hype without substance.

HIV is not and never has been just a disease; the ongoing epidemic remains proof of injustice. It is up to our government to account for and correct these injustices – many of which are the result of policymaking that disregards human rights, shifts resources and access away from the most

marginalized, and reinforces existing interlocking oppressions upon our communities. As the years of epidemiology and data presented in this plan indicate, HIV disproportionately impacts communities that have long had to fight for basic rights, access to health care and other vital services. Ignoring these structural inequities does not make them go away, nor does individual behavior change by itself. We will only continue to perpetuate disparities and injustices in HIV if we do not reform these very policies, structures, institutions, and systems that underpin the response to the epidemic for the most vulnerable.

We strongly caution that any earnest effort to End the HIV Epidemic must first address the myriad structural and systemic inequities our communities face. Otherwise, we will ultimately fail as a nation to end the epidemic.

What ending the epidemic means for the most vulnerable

Ending the epidemic for communities who are most impacted by HIV will require shoring up health care infrastructure, adopting the comprehensive health policy recommendations outlined in this community strategy, securing the robust funding requests outlined herein, and implementing homegrown and evidence-based treatment, prevention, education, and research interventions articulated throughout.

Our government must also push beyond the edges of what is broadly viewed as politically possible to ensure an equitable response to the root causes of HIV, as well as the economic, social, and political conditions where HIV continues to thrive. Doing so may require disrupting and reforming systems, structures, and practices including those upon which we have traditionally relied while dismantling policies that harmed our communities and erected barriers to addressing the epidemic for those who are most in need.

We must put an end to any and all policies that create an environment that puts communities of color, immigrants, migrants, transgender and gender-nonconforming people, sex workers, the incarcerated, and all populations deeply impacted by and vulnerable to HIV at risk. Any attempts to undermine the Affordable Care Act (including eroding Medicaid benefits and eligibility) combined with draconian policies that put people who use drugs, sex workers, women, people of color, immigrants and low-income persons at risk may be taken as a sign of the administration's lack of concern about ending the HIV epidemic in the United States.

Ending the HIV Epidemic will require strong actions, innovations, and brave visioning to create intersectional responses that address oppression and reclaim and center communal, economic, and political power to end what has always been a disease rooted in social conditions.

Centering policymaking on racial and social justice

As such, it is critical for our nation to center racial justice - the collective practice of people of color and allies to identify, dismantle, and heal from the many external and internal harms of structural and institutional racism - in executing the policy recommendations in this national plan to End the Epidemic. The analysis of the impacts of particular programs and policies as experienced by people of color, especially for community members experiencing the compounding effects of numerous injustices and barriers, must lead the nation's strategy.

Policymaking will require an intentional focus on achieving an equitable allocation of human, material, and financial resources that track the epidemic. For example, though we have the ability to decrease new HIV

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diagnoses through the use of HIV treatment and powerful prevention tools like PrEP, radical changes must be made to expand access for communities most vulnerable to HIV which currently make up only a very small percentage of those on treatment or utilizing PrEP but are simultaneously hampered by the compounding factors of high drug costs, poverty, and a lack of Medicaid expansion in key jurisdictions. Moving forward, ensuring accountability and a commitment to repair decades of divestment will be essential.

The leadership and decision-making at every level by communities and constituencies most impacted must also be centered and elevated. The most marginalized communities living with and impacted by HIV

Policymaking to end the epidemic must provide clear paths and opportunities for the leadership of those most marginalized and impacted by the epidemic.

have always resisted oppression and exclusion. The consequences of the erasure of the voices and stories of people of color in history and representation have had devastating consequences in our progress to end

the epidemic in terms of data collection and research for policymaking, where experiences of communities have not been accurately captured and accounted for.

The resilience, wisdom, and agency of impacted communities must guide the implementation of this national plan. Policymaking to end the epidemic must provide clear paths and opportunities for the leadership of those most marginalized and impacted by the epidemic.

Ensuring community leadership in any plan to End the Epidemic

In 1983, even while facing premature death, the architects of the Denver Principles stormed the stage at a gay and lesbian health conference in Colorado to eloquently demand a community-centered, humanizing approach to addressing the HIV epidemic. Their call for affected communities to be involved in all levels of the response to AIDS has endured well past the voices of those heroic authors; its simple logic changed not only how we approach HIV, but the very field of public health itself. The notion that any complex health crisis may be resolved without the leadership of affected communities and without centering vulnerable individuals within the heart of the response has proven time and again to be absurd. Yet, as we escalate our rhetoric once again at a national level – calling for an end to HIV as an epidemic in the United States – it seems we have never been further from realizing this central tenet of meaningful inclusion and leadership for our most marginalized and most impacted communities.

The following plan, while filled with bold and ambitious vision as well as many sensible recommendations, will only create meaningful change if we place the empowerment and liberation of the most vulnerable and marginalized communities at the very center of our efforts. We must return to a place of rights-based policymaking, viewing access to health care and essential medications as a human right and prioritizing the physical, socioeconomic, and mental well-being of all Americans above the financial interests of those in power. We must eliminate criminalization of poor and marginalized communities of color; turn away from walls, cages, travel bans, and global gag rules on abortion and contraception; and recommit to programs that empower vulnerable communities by investing in their basic needs for housing, transportation, nutrition, physical safety, education, and employment.

We must, as a nation, suppress the rising voices of white supremacy and notions of scarcity and redouble our commitment to pursuing social and economic justice for all communities disproportionately impacted by HIV. Without an explicit commitment to principles of inclusive representative leadership, human rights,

[W]e as the HIV/AIDS community assert that Black lives matter; that no human being is illegal; that health care, including comprehensive sexual and reproductive care, is a human right regardless of country of origin; that love is love, and that our existence is our resistance. We call on you to join us and commit to fighting the systemic barriers to life, health, dignity, and power for all our communities -- your constituents -- to End the HIV Epidemic in the United States.

including comprehensive sexual and reproductive care, is a human right regardless of country of origin; that love is love, and that our existence is our resistance. We call on you to join us and commit to fighting the systemic barriers to life, health, dignity, and power for all our communities -- your constituents -- to End the HIV Epidemic in the United States.

racial, social, cultural, and economic justice, this plan— and any other federal plan – will fall far short of its epidemic-ending targets and leave the communities most in need of support once again in the margins.

To this end, in sharing this national community plan to End the Epidemic with you, our elected officials and federal agency leaders, we as the HIV/AIDS community assert that Black lives matter; that no human being is illegal; that health care,

Introduction

We are at an unprecedented moment in the HIV/AIDS response. Even as we continue to advance the frontiers of science in the quest for a preventative vaccine and a cure for HIV, we have the tools we need to end HIV as an epidemic by stopping AIDS-related deaths and preventing new cases of HIV. Highly effective antiretroviral therapy enables persons living with HIV to maintain optimal health and eliminates new sexual transmissions of HIV if viral loads are sustained at undetectable levels. We also now have medication that is highly successful in preventing HIV transmission when taken by persons at risk of HIV exposure. In spite of these scientific triumphs, however, we are still very far from ending HIV and AIDS in America, for to do so requires ensuring that all people have equitable access to effective prevention tools and information to avert HIV transmission and, if diagnosed with HIV, to access and maintain quality HIV treatment and care.

To end HIV as an epidemic, we must accelerate our scientific progress, but if science is to have meaning, we must comprehensively implement advances with the goal of eliminating health disparities and inequalities and ensuring that all people living with HIV benefit from improved health outcomes and that new prevention technology is available and accessible. To achieve this, we must strengthen support for communities heavily impacted by HIV, particularly those impacted by poverty, racism, homophobia and transphobia, and solve for lack of access to preventive services, lack of access to care and treatment, and endemic drug use.

The science is clear. “Ending the AIDS epidemic in America? It’s possible. I think it could be done in the next three to seven years, if we put our mind to it,” says Dr. Robert Redfield, the current Director of the Centers for Disease Control and Prevention (CDC).⁴

Given this new paradigm, the HIV community – people living with, impacted by, and vulnerable to HIV – today calls on leaders in the Administration, Congress, in states, cities, and counties, and those in the private sector to take action to end HIV as an epidemic in the United States by the year 2025 and to do our part in the US to end the global HIV/AIDS pandemic by the year 2030.

Ten years ago, the HIV community coalesced around the creation of a National HIV/AIDS Strategy (NHAS). The NHAS was intended to create a science-based, data-driven, evaluable, and effective plan to reduce and prevent new cases of HIV and to stem the disastrous toll of the epidemic on health and lives. By 2010 such a strategy was in place, with the strategy updated for 2020 goals and a progress report

Given this new paradigm, the HIV community – people living with, impacted by, and vulnerable to HIV – today calls on leaders in the Administration, Congress, in states, cities, and counties, and those in the private sector to take action to end HIV as an epidemic in the United States by the year 2025 and to do our part in the US to end the global HIV/AIDS pandemic by the year 2030.

⁴ Cone, A. (2018, March 30). New CDC director aims to end AIDS epidemic in seven years. Retrieved from <https://www.upi.com/New-CDC-director-aims-to-end-AIDS-epidemic-in-seven-years/2591522426399/>

released in June 2018.⁵ We continue to reap the benefits of that effort. The National HIV/AIDS Strategy to achieve epidemic control should now be updated to a strategy to end HIV as an epidemic.

Innovation and leadership in the United States on HIV has laid the foundation for decisive action to end the epidemic domestically and globally. Numerous federal government departments, agencies, and programs are involved in the domestic HIV/AIDS response, which together provides disease surveillance, prevention, care, support services, and research. The CDC leads U.S. surveillance and prevention activities, which are carried out in conjunction with state and local health departments and community-based organizations (CBOs). Federal health care programs including Medicaid, Medicare, the Ryan White HIV/AIDS Program, and the Veterans Administration provide care, treatment, and supportive services. The Housing Opportunities for Persons With AIDS (HOPWA) program, as well as other safety net services through the Department of Housing and Urban Development (HUD), provide essential access to affordable housing for low-income persons. The Social Security Administration's income programs for those who are disabled (SSI and SSDI) are important sources of support. The passage of the Affordable Care Act (ACA) in March 2010 provided new opportunities for expanding health care access, prevention, and treatment services for millions of people in the U.S., including many people with or at risk for HIV. Programs outside the Department of Health and Human Services, such as the Department of Justice Civil Rights Division, the Bureau of Prisons, Department of Education, Department of Labor, Department of Transportation, Department of Defense, and the Department of Agriculture are also critical to achieving an end of new HIV cases in the U.S. Yet today, many of these programs are threatened by budget cuts or even elimination, with deadly consequences for people living with HIV and for efforts to curtail the domestic HIV epidemic.

HIV continues to be a major public health burden in the U.S., disproportionately impacting vulnerable individuals and communities. While treatment regimens have allowed those living with HIV to live longer and more productive lives, the CDC estimates that approximately 39,800 people contracted HIV in 2016.

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New HIV cases and AIDS-related deaths are increasingly concentrated in the Southern states and in Black and Latinx/Hispanic populations, both of which represent communities least likely to have been tested and know their HIV status. Approximately 40% of new HIV cases are people who are living with undiagnosed HIV.⁷ While life-saving medications and health care have dramatically reduced HIV/AIDS-related deaths – with more than 1.1 million people in the US living with HIV, 960,400 of whom are aware of their HIV status – we still have an enormous amount of work to do.⁸ According to the CDC, only 63% of people living with HIV engage with HIV medical care at any level, and fewer are virally suppressed

⁵ National HIV/AIDS Strategy for the United States: Updated for 2020. 2017 Progress Report. Retrieved from https://files.hiv.gov/s3fs-public/NHAS_Progress_Report_2017.pdf

⁶ CDC. (2018, August 6). HIV in the United States: At A Glance. Retrieved from <https://www.cdc.gov/hiv/statistics/overview/ata glance.html>

⁷ CDC. (2017, November/December). Retrieved from <https://www.cdc.gov/vitalsigns/pdf/2017-12-vitalsigns.pdf>

⁸ CDC. (2018, August 6). HIV in the United States: At A Glance. Retrieved from <https://www.cdc.gov/hiv/statistics/overview/ata glance.html>

(51%).⁹ Improving engagement in readily available, affordable, culturally sensitive, and non-stigmatizing care continues to be our biggest challenge to ending HIV as an epidemic in the United States. We also face overlapping epidemics of opioid and stimulant abuse, as well as co-morbid mental health and physical conditions that cause burn-out among caregivers, providers, and institutions having to deal with multiple epidemics simultaneously. Failure to accelerate efforts to test, diagnose, and care for people living with HIV will result in an increase in HIV transmission, increased HIV/AIDS-related morbidity and mortality, continued health inequities, and increased costs to health systems and our national economy.

The knowledge that HIV treatment is prevention has created a powerful movement within the HIV community called “Undetectable is Untransmittable” or “U=U.” Not only can this knowledge encourage people to seek information about their HIV status, but it can lead to ending stigma that acts as a barrier to helping people learn their HIV status and engage in care. It can serve as an added incentive to start and stay on treatment for personal and public health. Approximately 61% of new HIV cases arise from persons who are diagnosed but not engaged in care and treatment.¹⁰

To end the domestic HIV epidemic, robust investments from all sectors are needed to protect the health and wellness of people living with and affected by HIV and its comorbidities. Flat funding at the federal level has left many HIV/AIDS service organizations nationwide facing cuts in their programs while the number of clients continues to grow among the nation’s most vulnerable and underserved populations, particularly among young Black men who have sex with men (MSM), young Latinx MSM, and transgender individuals, particularly trans women of color.

The HIV epidemic in the U.S. has always looked different by state, region, and locality, making community-based responses and planning instrumental to our successful HIV response. Increasingly, local community stakeholders and state and local health departments are creating and implementing local plans to end HIV as a public health crisis. “Ending the Epidemic” plans have been announced in eight states and Washington, DC, two counties, and two cities and are being developed in an additional seven states, one county, and nine cities. Many have joined UNAIDS in setting goals of 90% of people living with HIV (PLWH) knowing their HIV status, 90% of PLWH who know their HIV-positive status on antiretroviral therapy (ART), 90% of PLWH on ART achieving viral suppression, and zero stigma and discrimination.¹¹ These efforts must be supported and expanded, with a particular focus on jurisdictions with high rates of new HIV cases in the Deep South, the only region in the U.S. where the HIV epidemic continues to expand.

Excitement over the idea that the U.S. could end the HIV epidemic has resulted in the creation of a coalition of HIV/AIDS advocacy organizations called “ACT NOW: END AIDS” to mobilize community and policy leaders to action and to implement state and local strategic plans to end HIV/AIDS. We now call upon key decision-makers in the Administration, Congress, and the private sector to fully commit to the same. We ask also that all state and local governments commit to the goals of this effort. Finally, we call on the readers of this document, those within and outside of the HIV community, to invest in our strategy. We cannot end HIV/AIDS without the vision, commitment, and will of the millions of people in the United States. We hope that what follows will inspire everyone to take action.

⁹ CDC. (2018, June). Understanding the HIV Care Continuum. Retrieved from <https://www.cdc.gov/hiv/pdf/library/factsheets/cdc-hiv-care-continuum.pdf>

¹⁰ Skarbinski, J., et al. Human Immunodeficiency Virus Transmission at Each Step of the Care Continuum in the United States. *JAMA Intern Med.* doi:10.1001/jamainternmed.2014.8180

¹¹ NASTAD. (2018). Ending the HIV Epidemic: Jurisdictional Plans. Retrieved from <https://www.nastad.org/resource/ending-hiv-epidemic-jurisdiction-plans>

We offer a roadmap developed by experts in the fields of HIV/AIDS prevention, care, treatment, and research about what is needed at the federal level to end HIV as an epidemic in the US by 2025.

Modeling Public Health Goals for Ending the United States HIV Epidemic

While there is still neither a vaccine nor a cure for HIV, we have the knowledge and means to end HIV as an epidemic in the United States by dramatically reducing new HIV transmissions, ending HIV/AIDS-related deaths, and eliminating disparities in access to quality HIV prevention and treatment. Antiretroviral (ARV) medications, taken as treatment or prevention, not only maintain optimal health and quality of life for persons living with HIV but also help prevent the transmission of HIV to others. Yet HIV continues to be a major public health burden in the US, disproportionately affecting marginalized communities, people of color, and the Southern states.

Achieving optimal individual and public health HIV-related health outcomes requires that persons living with HIV know their serostatus, that they are linked to and retained in appropriate HIV health care, and that they are receiving effective ARV treatment that suppresses the amount of HIV in the blood to an undetectable level (measured as <200 copies/ml) that sustains health and eliminates the transmission of HIV to sexual partners. The CDC reports that among the estimated 1.1 million people in the US living with HIV at the end of 2015, 14% remained unaware of their HIV status and only half were retained in HIV care (49%) and virally suppressed (51%).¹² While some highly affected urban centers like New York City and San Francisco are using comprehensive prevention and care strategies to make dramatic progress towards realistic goals to end their HIV epidemics as early as 2020, the CDC reported only a 5% reduction in new HIV diagnoses nationwide between 2011 and 2015, with almost 40,000 new HIV diagnoses in 2015.¹³

Indeed, some communities and regions are losing ground in the fight, with tragically increasing rates of HIV diagnoses in the Southern US, among young persons, and in low-income communities of color. These health disparities reflect the impact of differing care continuum outcomes. Among persons diagnosed with HIV included in a recent analysis of surveillance data, the CDC reported that young persons (age 13-24), Black/African Americans, and men who inject drugs are least likely to be virally suppressed, that persons diagnosed with HIV in Tennessee are significantly less likely than residents of other states included in the report to be linked to timely HIV care, and that people with HIV living in the District of Columbia, Maryland, Mississippi, and Virginia had the lowest rates of viral suppression.¹⁴ In fact, in 2015 Southern states accounted for 38% of the US population, but half of all new HIV diagnoses.

Changing the trajectory of the US HIV epidemic will require setting the ambitious but achievable goal of reaching a 95/95/95 framework for HIV care: 95% of persons with HIV awareness of their serostatus, 95% of diagnosed individuals retained in care, and 95% of individuals on antiretroviral therapy virally suppressed. Achieving this goal requires a significant scale-up of combination prevention for people who are HIV negative, including PrEP, and action to ensure that these advances in HIV prevention, and care benefit all persons living with and at risk of HIV so that no region or population is left behind. But we must bring available treatment and prevention tools to scale now to have the necessary impact on the epidemic. Failure to act swiftly at the required scale and across all impacted communities and populations will result in more HIV transmissions, more HIV/AIDS-related morbidity and mortality, continued health inequities, and increased health care costs.

¹²CDC. (2018, June).. Understanding the HIV Care Continuum. Retrieved August 23, 2018 from <https://www.cdc.gov/hiv/pdf/library/factsheets/cdc-hiv-care-continuum.pdf>.

¹³ National HIV/AIDS Strategy for the United States: Updated to 2020 (NHAS), 2017 Progress Report. Prepared by the Department of Health and Human Services' Office of HIV/AIDS and Infectious Disease Policy on behalf of the National HIV/AIDS Strategy Federal Interagency Workgroup. Of course, it is important to distinguish new HIV infections from new HIV diagnoses (since diagnoses may occur long after initial infection); trends in new diagnoses may not necessarily indicate trends in HIV incidence.

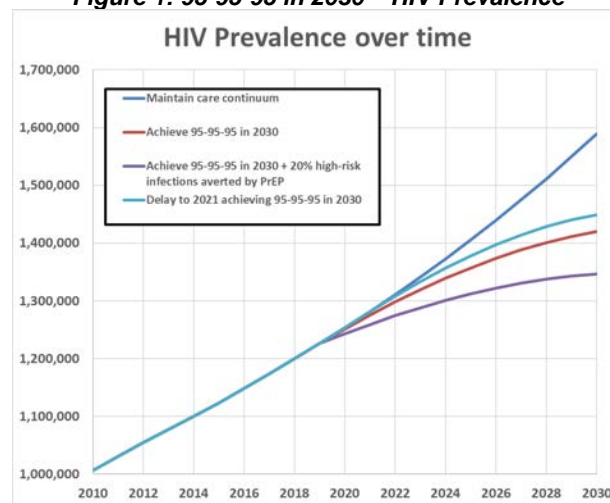
¹⁴ CDC. (2018, June).. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 dependent areas, 2016. HIV Surveillance Supplemental Report 2018; 23(No. 4). Retrieved August 23, 2018 from <http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>.

Achieving 95/95/95 programmatic goals by 2030 is a well-recognized and United Nations-adopted global HIV framework.¹⁵ Realizing the 95/95/95 programmatic framework is seen as feasible in developed countries and the Canadian Province of British Columbia appears on its way to meeting such a standard (as one example).¹⁶ Such time-bound public health targets drive progress, promote accountability, and unite stakeholders.

Mathematical modeling indicates that achieving the 95/95/95 framework by 2030 will have major, favorable impacts on HIV incidence and prevalence in the US.¹⁷ The modeling presented here employs published CDC surveillance data¹⁸ and well-accepted approaches used to set and evaluate public health goals.¹⁹ Note that these estimates are modeled based on an assumption of sustained support for the current HIV prevention and care framework in the US. Any degradation of current health delivery systems, insurance coverage, the Ryan White program, HIV prevention services through state and local health departments, or supportive service systems would undermine the current continuum of HIV care and the potential for rapid scale up to meet the 95/95/95 goals.²⁰

ACHIEVING THE 95/95/95 FRAMEWORK BY 2030

Figure 1: 95-95-95 in 2030 – HIV Prevalence



¹⁵ United Nations General Assembly. Resolution No A/RES/70/266, Political Declaration on HIV and AIDS: On the Fast-Track to Accelerate the Fight against HIV and to End the AIDS Epidemic by 2030 2016 [25 January 2017].

¹⁶ Lima et al. Progress towards the United Nations 90-90-90 and 95-95-95 targets: the experience in British Columbia, Canada. *Journal of the International AIDS Society* 2017, 20:e25011. <http://onlinelibrary.wiley.com/doi/10.1002/jia2.25011/full> | <https://doi.org/10.1002/jia2.25011>

¹⁷ Modeling was performed by Dean David Holtgrave and Dr. Eli Rosenberg of the School of Public Health at the University at Albany, State University of New York, and Dr. Heather Bradley of the Georgia State University School of Public Health.

¹⁸ CDC. (2018, June). Centers for Disease Control and Prevention. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 dependent areas, 2016. HIV Surveillance Supplemental Report 2018; 23(No. 4). Retrieved August 23, 2018 from <http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>. Centers for Disease Control and Prevention. *HIV Surveillance Report, 2016*; vol. 28. <http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>. Published November 2017. Accessed August 3, 2018.

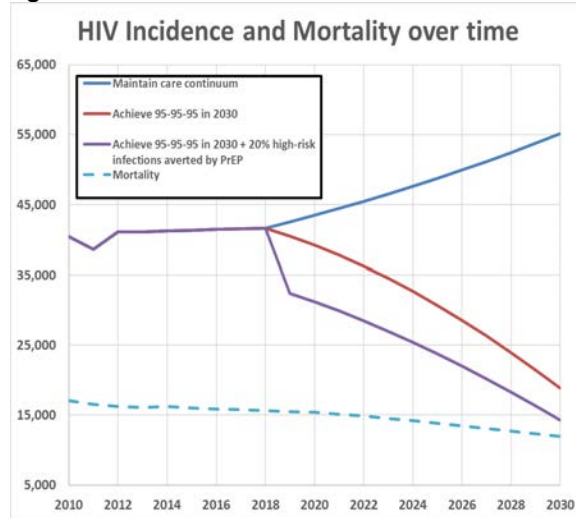
Rosenberg ES, Bradley H, Buchacz K, McKenney J, Paz-Bailey G, Prejean J, Brooks JT, Shouse L, Sullivan PS. Improving Estimation of HIV Viral Suppression in the United States: A Method to Adjust HIV Surveillance Estimates From the Medical Monitoring Project Using Cohort Data. *Am J Epidemiol*. 2018 Apr 4. doi: 10.1093/aje/kwy039. [Epub ahead of print]

¹⁹ Bonacci RA, Holtgrave DR. U.S. HIV Incidence and Transmission Goals, 2020 and 2025. *Am J Prev Med*. 2017 Sep;53(3):275-281. doi: 10.1016/j.amepre.2017.03.012.

Skarbinski J, Rosenberg E, Paz-Bailey G, Hall HI, Rose CE, Viall AH, Fagan JL, Lansky A, Mermin JH. Human immunodeficiency virus transmission at each step of the care continuum in the United States. *JAMA Intern Med*. 2015 Apr;175(4):588-96. doi: 10.1001/jamainternmed.2014.8180.

²⁰ Dawson L & Kates J. *What is at stake in the ACA repeal and replace for people with HIV?* The Henry J. Kaiser Family Foundation. Available at <https://www.kff.org/hiv/aids/issue-brief/what-is-at-stake-in-aca-repeal-and-replace-for-people-with-hiv/> Accessed 27 August 2018.

Figure 2: 95-95-95 in 2030 – Incidence and Mortality



As illustrated by the graphs above, at current levels of HIV care and viral suppression, and assuming the same levels of modest progress achieved since the introduction of the National HIV/AIDS Strategy, we can expect 950,000 new HIV cases by 2030, bringing the number of persons living with HIV in the United States to nearly 1,589,000 (indicated by the solid blue lines). Instead of simply continuing current efforts, achieving the 95/95/95 targets by 2030 (indicated by the solid red lines) would reduce the number of new HIV cases occurring during the years 2019 to 2030 by approximately 210,500 persons, and the number of total people living with HIV in 2030 by nearly 169,000 persons. Increasing uptake of PrEP to achieve 40% coverage of at-risk persons would amplify the 95/95/95 care framework, further decreasing new infections by 82,000 and prevalence by 73,000 persons by 2030 (as indicated by the solid purple lines).

It is important to note that any delay in getting started on an accelerated effort to achieve the 95/95/95 framework will have significant financial, social, and health impacts. As indicated by the teal blue line in the prevalence model above, delaying until 2021 the beginning of substantial progress towards the goal to reach 95-95-95, rather than starting in 2019, results in more than 31,500 additional HIV cases and 29,500 additional persons living with HIV by 2030.

ACHIEVING THE 95/95/95 FRAMEWORK BY 2025

Of course, achieving the 95/95/95 care framework earlier than 2030 would have a larger impact on HIV incidence and prevalence in the US. As illustrated in the graphs below, when compared with a scenario of achieving the framework in 2030, meeting the goals by 2025 would yield an additional 79,500 HIV transmissions averted, and would reduce the number of persons living with HIV in 2030 by more than 75,000 persons. So, when compared with maintaining current levels of HIV care (as indicated by the solid blue lines), achieving the 95/95/95 framework by 2025 would reduce the number of new HIV transmissions occurring during the years 2019 to 2030 by approximately 290,000 persons, and the number of total people living with HIV in 2030 by nearly 244,000 persons. The additional impact of a 40% PrEP coverage by the year 2025 (as indicated by the purple solid lines) would further reduce new transmissions by 63,000 and prevalence by 55,500 by 2030.

Figure 3: 95-95-95 in 2025 – HIV Prevalence

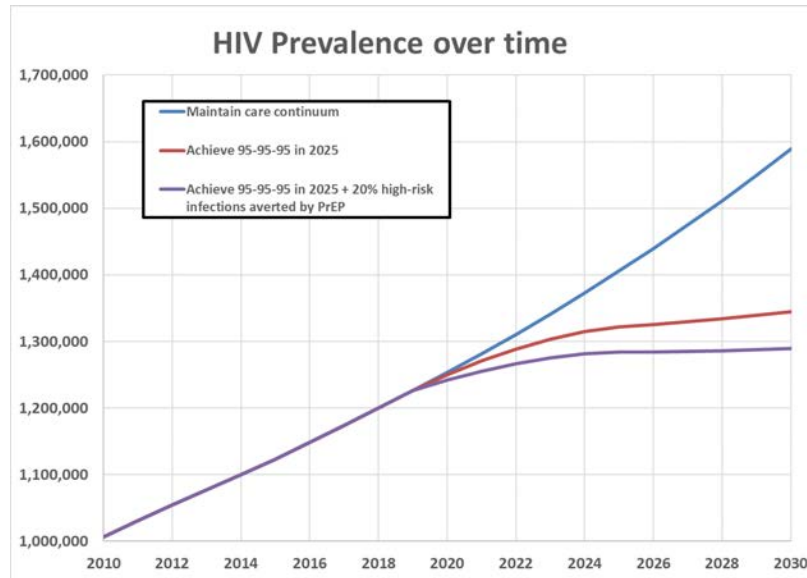
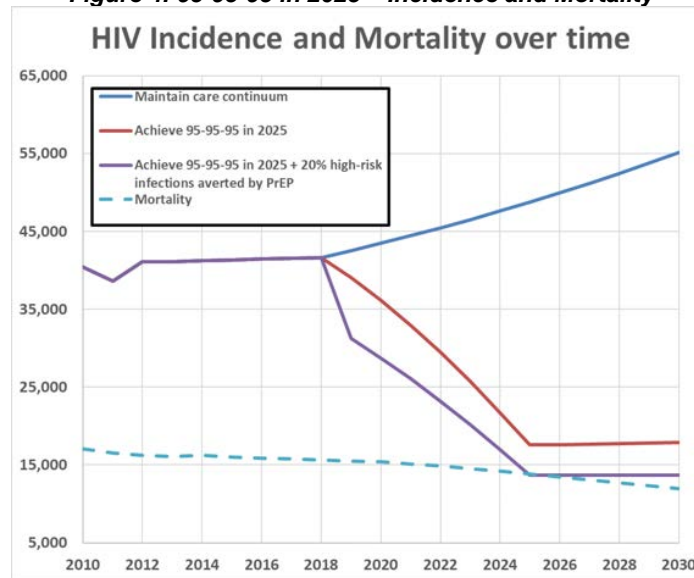


Figure 4: 95-95-95 in 2025 – Incidence and Mortality



BENDING THE CURVE THROUGH SCALE-UP OF PREP

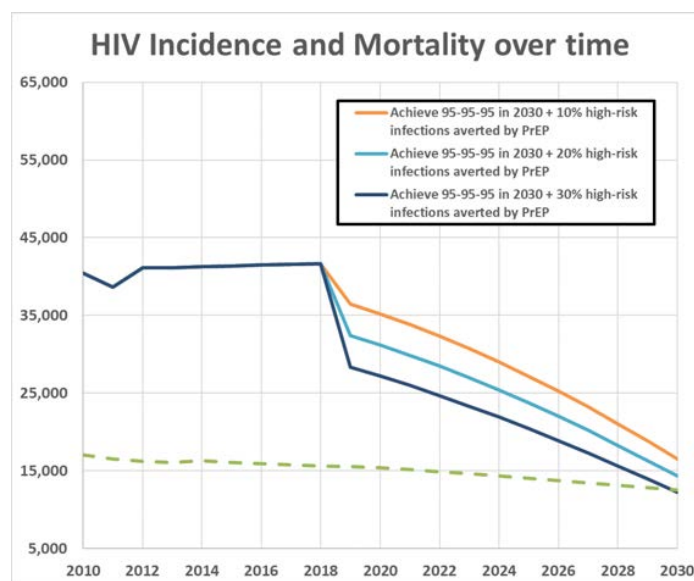
In setting benchmarks and goals for a US plan to end the HIV epidemic, it is useful to consider a scenario in which the number of new infections each year (incidence) finally drops below the annual number of all-cause deaths among persons living with HIV, eventually reducing the total number of people living with HIV in the US (prevalence). Achieving this point will be an important milestone toward ending the US HIV epidemic.

As shown by the 2030 and 2025 models presented above, achieving the 95/95/95 HIV care framework alone is no longer sufficient to “bend the curve” of the US epidemic and to begin to see a decline in the number of persons living with HIV by the year 2030. Accomplishing this milestone will require simultaneous advances in HIV care *and* prevention among HIV-negative persons. The graph below reflects the estimated impact of adding different levels of increased uptake of PrEP biomedical prevention

to efforts to achieve the 95/95/95 HIV treatment framework by the year 2030. While any increase in PrEP uptake adds to the impact of HIV care programs, the model indicates that it will require that about 30% of transmissions among persons at the highest risk for HIV are prevented by 60% PrEP coverage in this group, combined with achieving the 95/95/95 diagnostic, care and viral suppressive goals by 2030, to bring HIV incidence in line with all-cause mortality by the year 2030.

By achieving this level of PrEP coverage, an additional 121,000 HIV transmissions can be averted and 108,000 fewer people will be living with HIV by 2030. It can be seen, therefore, that PrEP is a key additional tool in addressing the HIV epidemic in the US.

Figure 5: 95-95-95 in 2030 – Exploring PrEP variations



ADDRESSING HIV-RELATED HEALTH DISPARITIES

HIV-related disparities across communities continue to persist in the U.S., driven by stigma and social and economic marginalization. In 2014 African-Americans represented 13 % of the US population but accounted for almost half of new HIV cases (49 %) and 43 % of people living with HIV;²¹ MSM accounted for two-thirds (66%) of new diagnoses in 2014, and the number of new infections among the youngest MSM (aged 13-24) increased 22% % from 2008 to 2010;²² an overall HIV case prevalence of 28% has been documented in the transgender community;²³ and the Southern states account for half of all AIDS diagnoses and deaths of people living with HIV s in the U.S.²⁴

Although modeling points to the profound potential impact of progress towards a 95/95/95 HIV care framework by 2030, these gains will not be achieved without addressing the HIV health inequities driven by current levels of HIV-related stigma, racism, homophobia, discrimination, sexism, housing instability, food insecurity, and unemployment (or lack of employment at a living wage). While the tools of HIV testing, care, treatment, and prevention are evidence-based and well-described, to impact the epidemic

²¹ CDC. *HIV Surveillance Report, 2014*; vol. 26. <http://www.cdc.gov/hiv/library/reports/surveillance/> Published November 2015.

²² CDC. Estimated HIV incidence in the United States, 2007– 2010. *HIV Surveillance Supplemental Report* 2012; 17(No. 4). <http://www.cdc.gov/hiv/topics/surveillance/resources/reports/#supplemental>. Published December 2012.

²³ Herbst JH, Jacobs ED, Finlayson TJ, et al. Estimating HIV prevalence and risk behaviors of transgender persons in the United States: a systematic review. *AIDS Behav* 2008;12(1):1-17.

²⁴ CDC. *HIV and AIDS in the United States by Geographic Distribution*. <http://www.cdc.gov/hiv/statistics/overview/geographicdistribution.html> Updated May 2015.

they must be offered in a manner that directly addresses the social and structural determinants of HIV health disparities.

Therefore, it is important that for all of the suggested goals modeled here, they be achieved not only in absolute terms but also in a manner that reduces such disparities. To achieve this goal of social justice will require a substantial intensification of service provision and commitment to high-quality care for gay men (in particular young Black and Latinx men), Black and Latinx communities, and persons residing in key urban areas as well as across the Southern U.S. The numeric goals listed above are important; achieving them in a socially just manner is just as critical and will require a focusing of efforts on communities now bearing the largest burden of the epidemic.

As detailed more fully in Section 6 of this paper, it will be particularly important to assure the availability of essential services that support retention in care and effective ARV treatment and prevention. For many people living with HIV, successful care requires culturally competent, linguistically appropriate services to address a cluster of complex health, behavioral, and structural issues. Housing instability is among the strongest predictors of disparities in viral load suppression,²⁵ while evidence consistently shows that housing assistance improves HIV health outcomes at each stage of the HIV care continuum.²⁶ People living with HIV who experience food insecurity have been found to routinely forego critical medical care and are less likely to be virally suppressed.²⁷ Mental health disorders, significantly more prevalent among people living with HIV compared to the general population, are also strongly associated with poorer outcomes all along the HIV treatment continuum,²⁸ with untreated clinical depression directly related to increased risk of mortality.²⁹ Social and structural drivers such as poverty, homelessness, hunger and un- or undertreated mental health, and substance abuse issues are likewise associated with increased risk of acquiring HIV.³⁰ Services to address these and other social and structural determinants of HIV health outcomes must also be brought to scale to end the US epidemic.

BRINGING EFFECTIVE HIV PREVENTION AND CARE TO SCALE TO MEET 95-95-95 GOALS

To end the US HIV epidemic, we will need to use all of the powerful tools available, hold ourselves and elected officials accountable for results, and make sure that no one is left behind.

In considering the action necessary, it is helpful to model the scale up in HIV prevention and care required to realize our goals. The graph below illustrates the improvements in HIV care delivery required to achieve the 95/95/95 framework by 2030 (dotted lines) and 2025 (solid lines). Compared to the current state of HIV prevention and care in the US, achieving a 95/95/95 framework by 2030 will require retaining 187,500 more persons living with HIV in care (translating to an additional 2,252,000 person-years of care) and helping 199,000 more persons in care achieve and sustain viral suppression (translating to 2,390,000 person-years of viral suppression). PrEP would need to be scaled up to reach at least 231,500 additional persons. Finally, as noted above, these programmatic initiatives must be accompanied by a concerted effort to address social and structural barriers to effective HIV prevention and care.

²⁵ Feller & Agins. Understanding Determinants of Racial and Ethnic Disparities in Viral Load Suppression: A Data Mining Approach. *Journal of the International Association of Providers of AIDS Care* 2017; 16(1): 23-29.

²⁶ Aidala, et al. Housing Status, Medical Care, and Health Outcomes Among People Living With HIV/AIDS: A Systematic Review. *American Journal of Public Health* 2016; 106(1), e1–e23.

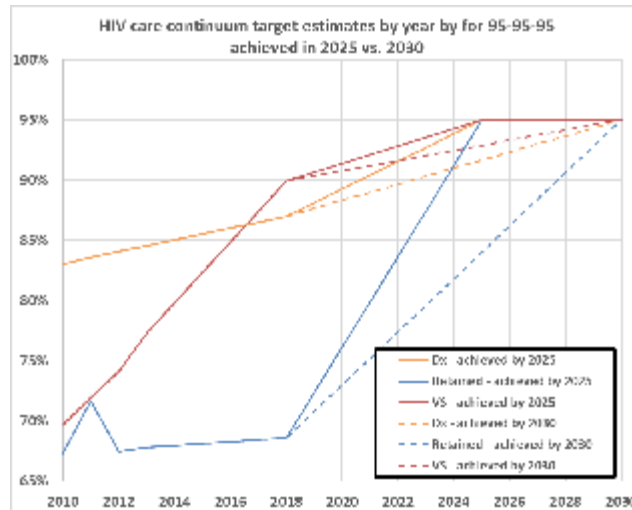
²⁷ [need citation]

²⁸ Bemelmans M et al, *J Int AIDS Soc*, 2016; Gonzalez JS et al, *JAIDS* 2011; Uthman et al, *Curr HIV/AIDS Rep*, 2014; Mayston et al, *AIDS*, 2012; Krumme et al, *J Epidemiol Community Health*, 2014; Musisi et al, *Int J STD AIDS*, 2014; Antelman et al, *JAIDS*, 2007; Remien et al, *AIDS and Behavior*, 2007

²⁹ Pence et al, *JAMA Psychiatry*, Feb 21 2018

³⁰ See, e.g., Gupta, et al. Structural approaches to HIV prevention. *The Lancet* 2008; Volume 372, Issue 9640, 764-775.

Figure 6: Difference in Achieving 95-95-95 by 2025 and 2030



Additional resources will be required to achieve these programmatic service delivery goals. Without such rapid scale-up, however, the US HIV epidemic will continue to outrun the response, increasing the long-term need for HIV treatment and increasing future costs. Indeed, public spending on accelerated scale-up will generate historic health benefits and savings sufficient to offset or exceed the required investments.

While we do not detail in this section the new investments required, we can provide a threshold analysis of the level of investment that would constitute a cost-effective use of public resources. Schackman and colleagues have estimated the present value of medical costs avoided by preventing one HIV transmission at \$263,250 in 2017 dollars³¹ (this is the cost of treating a person diagnosed with HIV minus the cost of medical care for the same person if they were not diagnosed with HIV).³² As set out above, modeling indicates that achieving the 95/95/95 framework by 2030 would reduce the number of new HIV transmissions occurring during the years 2019 to 2030 by approximately 210,500 persons, which translates into a savings in HIV medical treatment costs of \$55.4 billion. Achieving the 95/95/95 framework even earlier, by 2025, would reduce the number of new transmissions occurring between 2019 and 2030 by 290,000 persons, for a projected savings in health spending of \$76.3 billion. Applying the accepted assumption that roughly three-quarters of HIV medical costs are publicly funded, this translates into between \$41.6 and \$57.2 billion in public spending for future HIV treatment that could be better used between now and 2030 to fund the care and services needed to prevent these new infections, stop HIV/AIDS-related deaths and end HIV-related health disparities—to make history by ending the U.S. epidemic, and the investment still be considered cost-saving.³³

Reducing Health Disparities

HIV is an epidemic of intersectional inequality, one where poverty, racial, ethnic, and gender bias, misogyny, homophobia and transphobia, lack of access to preventive services, and endemic drug use significantly influence the likelihood of exposure to HIV and one's health outcomes after infection. The

³¹ \$229,800 in 2012 dollars, adjusted to 2017 dollars using the Medical Care component of the Consumer Price Index.

³² Schackman BR, et al. The lifetime medical cost savings from preventing HIV in the United States. *Med Care*. 2015; 53:293-301.

³³ We note that the estimates of avoided HIV treatment costs presented here are conservative. The CDC has estimated the present value of lifetime medical costs associated with each new HIV infection at the higher amount of \$449,000 (in 2016 U.S. dollars). See: 2017 NHAS Progress Report, citing Farnham et al. Updates of Lifetime Costs of Care and Quality of Life Estimates for HIV-Infected Persons in the United States: Late Versus Early Diagnosis and Entry Into Care. *JAIDS* 2013; 64: 183-189. Employing the CDC estimate of medical costs saved for each averted HIV infection results in projected savings of \$94.5 billion if the 95/95/95 framework is achieved by 2030, and \$130.2 billion if the 95/95/95 goals are reached by 2025—for estimated savings in public spending on HIV medical costs (75% of the total) of between \$71 and \$98 billion.

societal responses to HIV vary significantly by race and class and dramatically impact the realities of living with the disease. As such, the federal response must extend beyond access to care and medications and adopt holistic approaches that address the racial, ethnic, social, economic, and environmental factors that influence health status and quality of life for all people diagnosed with HIV. Eliminating these disparities is the basis for ending HIV as the most stigmatized and marginalized communities are also the ones where HIV incidence continues unabated. Black and Latinx gay, bisexual, and queer men, women of color, and trans-identified and gender nonconforming individuals continue to be disproportionately impacted, especially in rural and suburban areas and the Deep South.

The Minority AIDS Initiative (MAI), established in 1998, is designed to address the racial and ethnic disparities in HIV incidence, prevalence, and health outcomes. The MAI was designed to augment, not replace, pre-existing resources available to minority-serving providers committed to serving people living with HIV. MAI funds play an integral role in developing culturally competent service models, reducing HIV stigma in minority communities, increasing the number of minorities tested, linked to and retained in HIV care, and developing infrastructure and HIV service capacity in underserved communities. The Secretary's MAI Fund (SMAIF) promotes novel cross-cutting programs that respond to critical emerging issues to promote more effective responses in the field. MAI priorities have adapted to the changes in the U.S. epidemic responding to emerging concerns. Despite the success of the MAI over time, Funds invested in MAI must increase, reflecting the extent of the epidemic as minorities continue to make up the largest percentage of new HIV cases. Clearly, the federal government must increase investment in innovative approaches to address the epidemic in these communities and take concerted action to redress persistent disparities.

Stigma in all its manifestations plays a significant role in fueling the HIV epidemic in the United States. Intersectional stigma related to race, gender, gender identity, sexual orientation, homelessness, poverty, mental health, substance use, and HIV status negatively impacts people living with and vulnerable to HIV. Stigma also exacerbate barriers to HIV testing and engagement in care (including adherence to treatment) in already marginalized communities. Creating supportive care environments will improve and promote viral suppression and reduce HIV transmissions. Engaging religious leaders in order to address HIV-related racism and stigma – including homophobia and transphobia – within their congregations will be essential to meaningfully improve linkage to care, treatment, and prevention services within communities.

Stigma remains a significant barrier to HIV treatment, but it is also a barrier to increasing uptake of PrEP. The use of terminology including “Truvada Whore” (a reference to the drug currently being used for PrEP) and the related issue of “slut shaming” reflect stigma associated with PrEP use. It is important to understand the perception and effects of PrEP stigma among gay and bisexual men of color and to recognize that these men often face multiple forms of stigma, including that around living with HIV, being Black gay or bisexual, being Black or Latinx, or being poor or undocumented. Stigma can have a chilling effect, discouraging individuals and communities from considering whether PrEP might be an option for them and their prevention needs.

While stigma has been shown to have a negative impact on PrEP uptake, adherence, and persistence, there is an increasing number of social media campaigns and other interventions designed to combat PrEP stigma and to educate other populations including women. As an increased number of cities, counties, and states develop and implement plans to “End the HIV Epidemic” in their jurisdictions, it is important that they take advantage of opportunities to re-conceptualize PrEP in a manner that reduces and discourages stigma across race, gender, sexual orientation, and other identities.

In order to address the negative role stigma plays in exacerbating barriers to successful care management and viral suppression, we must examine existing care structures and be open to innovative structural change within our communities.

GEOGRAPHIC DISPARITIES

The federal government must ensure that every state in the country receives funding that is equitable in proportion to the disease burden and adequate to mount effective responses to the HIV epidemic. HIV epidemics vary by region, with some focused on urban areas and others predominantly on rural areas. The CDC's direct funding to CBOs is limited to those located within 50 metropolitan statistical areas (MSAs). While significant resources must be targeted to the heavily impacted large urban jurisdictions, this approach does not address HIV epidemics in rural (non-metropolitan) and suburban areas (metropolitan areas with populations between 50,000 and 499,999). The South has significantly higher rates of HIV in rural and suburban areas than other geographic regions. While we support the targeting of significant resources to the large urban jurisdictions heavily impacted by HIV, we also support targeting additional resources for states with more dispersed epidemics, high diagnosis rates, a high prevalence of undiagnosed HIV, and high death rates associated with HIV and AIDS. CDC must also work with state and local funded partners to ensure funds are being targeted adequately to the epidemic in their respective jurisdiction.

The 16 states of the South and the District of Columbia continue to be disproportionately impacted by HIV. According to the CDC, "the South now experiences the greatest burden of HIV infection, illness, and deaths of any U.S. region, and lags far behind in providing quality HIV prevention and care to its citizens." Sadly, the rates of new infections have continued to increase over time and in 2015, the rate of new HIV diagnoses in the South was 37% higher than the national average.³⁴ In 2016, 53% of AIDS-related deaths occurred in the South. Today, the South is home to the most people living with and dying from HIV/AIDS-related complications, most of whom are Black and Latinx gay, bisexual, and other men who have sex with men, Black and Latinx cisgender and transgender women, and Black and Latinx youth.

While HIV remains a major public health concern for the entire region, the Deep South (a subset of nine states that includes Alabama, Florida, Georgia, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, and Texas) is a significant driver of the Southern epidemic.³⁵ Eight of the nine Deep South states are part of the group of 14 states that have not yet expanded Medicaid coverage to low-income adults up to 138% of the federal poverty level.³⁶ The Deep South has high rates of poverty, racial discrimination, homophobia, transphobia, and HIV-related stigma, and these are associated with low social capital and political interest which contributes to negative health outcomes including poorer care and treatment adherence, missed medical appointments, and higher viral load.³⁷

In the Deep South, gay, bisexual, and other men who have sex with men are affected by HIV at rates that are orders of magnitude higher than for Americans who identify as strictly heterosexual. The burden of HIV is even more pronounced for Black and Latinx gay, bisexual, and other MSM, who accounted for more than half of all new HIV diagnoses in the South in 2015. Notably, two out of every three Black gay,

³⁴ CDC HIV Surveillance Report, Vol. 27, 2015.

³⁵ Reif, S., Saffley, D., McAllaster, C., Wilson, E., & Whetten, K. (2017). State of HIV in the U.S. Deep South. *Journal of Community Health*. Oct;42(5):844-853. doi:10.1007/s10900-017-0325-8.

³⁶ The Henry J. Kaiser Family Foundation (KFF). Status of State Action on the Medicaid Expansion Decision as of July 27, 2018.

³⁷ Reif, S., Wilson, E., & McAllaster, C. (2017). HIV Stigma Study in the Deep South: Descriptive Findings.

bisexual, or other men who have sex with men who were diagnosed with HIV in 2015 lived in the South, and 51% lived in the Deep South.³⁸

A report in JMIR Public Health and Surveillance, authored by researchers at Emory University Rollins School of Public Health, provided the first state, city, and county estimates of the rate of MSM living with HIV. According to the report:

- There were six states where more than 15% of MSM were living with diagnosed HIV in 2012, all of which were in the South (Alabama, Arkansas, Georgia, Louisiana, Mississippi, and South Carolina);
- Of the 25 MSAs with the highest levels of MSM living with an HIV diagnosis, 21 were located in southern states;
- Nine out of the ten MSAs with the highest overall HIV rates are in the South: Miami, Orlando, Jacksonville (FL); New Orleans, Baton Rouge (LA), Atlanta (GA), Jackson (MS), Memphis (TN), Houston (TX);
- At least one in four MSM were living with an HIV diagnosis in the following MSAs: Jackson (MS), Columbia (SC), El Paso (TX), Augusta (GA), Baton Rouge (LA), and Washington (DC).

A recent analysis by the Southern HIV/AIDS Strategy Initiative found that the Deep South region received less federal funding per individual living with HIV (\$3,313) in 2015 compared to the US overall (\$3,410).³⁹ Most of this disparity was attributable to a disparity in CDC funding of \$100 per person living with HIV between the Deep South (\$494/PLWH) and the US overall (\$596/PLWH).

This CDC funding disparity is improving: In 2017, direct funding to CBOs pursuant to CDC PS17-1704 almost mirrored new HIV diagnoses in the US South (52%), with 48% of total direct funding to CBOs going to the US South. However, the South has higher HIV diagnosis rates in smaller metropolitan (50,000 – 499,999) and rural areas compared to all other regions.⁴⁰ Despite this, 93% of the PS17-1704 CDC funding for the South and 100% of this funding for the Deep South was distributed to CBOs in large metropolitan areas (MSA ≥ 500,000). The CDC must create targeted funding opportunities for CBOs outside the large metropolitan areas in the US South.

Similarly, ending the HIV epidemic in the United States means that the epidemic must also be ended in all U.S. territories. There are over 18,000 people living with HIV in Puerto Rico, nearly 1,000 people living with HIV in the U.S. Virgin Islands, and approximately 200 people living with HIV in other territories. The Virgin Islands ranks fourth and Puerto Rico ranks sixth in Stage 3 (AIDS) prevalence among the 50 states and territories, reporting 635.5 and 564 cases per 100,000 population respectively. New HIV diagnoses in the San Juan Metropolitan Statistical Area (MSA) in 2016 were 18.4 cases per 100,000 population, making it very similar to the New York City MSA (18.8 cases per 100,000 population).

Last year, Puerto Rico and the U.S. Virgin Islands suffered destruction from hurricanes Irma and Maria. This disaster devastated their public health infrastructure and other facilities for people living with and affected by HIV potentially degrading the response. Many people in both places lost electricity some for as long as a year, repairs to infrastructure were lagging, and bureaucratic hurdles continued to complicate delivery of badly needed supplies throughout the island. The shameful failure of government to

³⁸ CDC HIV Surveillance Report, Vol. 27, 2015.

³⁹ Reif, S., Safley, D., McAllaster, C., Wilson, E., & Whetten, K. (2017). State of HIV in the U.S. Deep South. *Journal of Community Health*, Oct;42(5):844-853. doi:10.1007/s10900-017-0325-8.

⁴⁰ CDC. (2016, May). HIV in the Southern United States. Retrieved from <https://www.cdc.gov/hiv/pdf/policies/cdc-hiv-in-the-south-issue-brief.pdf>

appropriately respond left the residents of these islands on their own and potentially exacerbated the HIV epidemic in the islands. The United States must no longer treat its territories as second class but rather must upgrade infrastructure to ensure that all people living with HIV and at risk for HIV receive quality and timely treatment, care and access to prevention services as in the U.S. Only with a robust response to HIV in the territories will the U.S. be able to claim that it has ended the HIV epidemic.

Disparities also exist in private funding streams as well. According to an analysis conducted by Funders Concerned About AIDS, only 5% of total private HIV philanthropy went to the US South in 2014. This equates to \$59 per PLWH in the South compared to \$116 per PLWH in the US overall. In the Deep South, the discrepancy is even higher at only \$35 per PLWH. These disparities may be improving with the launch of the Southern HIV Impact Fund,⁴¹ the Gilead Compass Initiative,⁴² and other private funding initiatives aimed at the US South, but far more investment is needed.

Too frequently these funding opportunities are largely out of reach for Black and minority CBOs led by gay, bisexual, and other men of color who have sex with men, transgender men and women, and other priority populations. Bureaucratic hurdles and limited organizational capacity make it difficult to compete even when an organization has a proven track record of connecting with vulnerable communities. To be successful with ending HIV as an epidemic for all communities, the playing field must be fair and the criteria transparent. We must establish a concerted effort to award and share funding with these essential CBOs led by people of color and transgender persons, particularly in the U.S. South. To that end the government must seek to simplify application and reporting requirements where feasible. Over the past several years, the federal government has focused on decreasing reporting burden and has made significant improvements. However, we believe that more should be done in order to ensure the federal government and the states and local jurisdictions receiving much of the funding are able to award funds to all types of organizations that show how they can be effective in meeting populations most impacted by HIV.

One of the more important recent scientific advances is the development of Truvada® for pre-exposure prophylaxis (PrEP). When taken as prescribed, this once daily pill significantly reduces the risk of acquiring HIV. Despite a 73% increase in PrEP use from 2012 to 2016, the South has more than half of the new HIV diagnoses in the US but accounts for only 30 % of all PrEP users. The rate of PrEP use in the Northeast region was about two times higher than that of the South, West or Midwest.⁴³

Recommendations for federal action

- I. *The CDC must create new, additional targeted funding opportunities for CBOs outside the large metropolitan areas in the U.S. South, particularly in small cities with high rates of incidence and mortality.*

- II. *The U.S. must upgrade treatment and prevention services in Puerto Rico, the U.S. Virgin Islands and all territories to the same level as achieved in the U.S., including strengthening and expanding PrEP education and access, increasing access to HIV testing and improved surveillance, expanding, integrating, and coordinating HIV prevention and care services for special populations including transgender women and people who inject drugs and ensuring access to HIV treatment for all people in the territories.*

⁴¹ <http://southernfund.org/>

⁴² <http://www.gileadcompass.com/>

⁴³ AIDSvu. (2018). Deeper Look: PrEP. Retrieved from <https://aidsvu.org/deeper-look-prep/>

The U.S. must ensure that its HIV, viral hepatitis, opioid, and STI responses in Puerto Rico, the U.S. Virgin Islands, and the territories include leadership, representation, and voices from the territories. In addition, the U.S. must create the conditions necessary for the islands to withstand future hurricane events. Finally, the U.S. must relieve Puerto Rico, the U.S. Virgin Islands and rest of the territories of their debt. The Health Resources and Service Administration (HRSA) should examine the feasibility of distributing Ryan White Program Part B Supplemental Funding taking into account the disproportionate impact of HIV incidence and outcomes in the Deep South. We ask that the Secretary work with HRSA and CDC to determine the best way to ensure that the most current new HIV diagnosis rates and HIV-related death rates are incorporated into a funding methodology. We recommend that HRSA then reach out specifically to these states to invite each of them to apply for Ryan White Program Part B Supplemental funding, to identify any barriers to applying, and to work with states to overcome the identified barriers.

- III. *The agencies within HHS must fund HIV-related stigma reduction interventions, particularly in the US South.*
- IV. *The federal government must increase funding and outreach for PrEP access in geographic areas disproportionately impacted by the epidemic.*
- V. *CDC and HRSA should seek ways to support non-traditional clinics to increase access points for vulnerable and not engaged communities*
- VI. *CDC and HRSA should create tools to support provider training on communicating to patients key messages on prevention options (including PrEP) and on how to talk to patients (especially newly diagnosed) on the meaning of U=U.*
- VII. *CDC, HRSA, SAMSHA, and NIH must strengthen health literacy and increase health system navigation services.*

Many people of color do not access health care on a regular basis and do not have a relationship with a medical provider. It is essential to promote health literacy by increasing the capacity of these individuals to navigate the health system, including assessing insurance coverage options, enrolling in coverage, identifying a primary care provider, making medical appointments, accessing services, and troubleshooting if problems arise. This may be particularly important in the context of PrEP for HIV-negative individuals who may be unaccustomed to working with the healthcare system specifically, patient assistance programs. But is also important for PLWH, especially those who are newly diagnosed, who may not have experience with navigating health systems prior to their diagnosis.

POPULATION CHARACTERISTIC-BASED DISPARITIES

Disparities in both health care access and outcomes for people living with HIV are unevenly distributed by race, ethnicity, gender, gender identity, socioeconomic status, sexual orientation, age, immigration status, and criminal record. Full enforcement of civil rights and non-discrimination statutes are necessary to end the HIV epidemic in the United States. A federal plan to end the HIV epidemic must include efforts to

address disparities that are socio-economic, racial/ethnic, gender/sexual orientation and status of citizenship in nature if it is to be successful in all impacted communities.

Socioeconomic disparities: In the U.S., as in the rest of the world, poverty is an independent indicator for acquisition of HIV, and the epidemic disproportionately affects impoverished neighborhoods underserved by health care access, transportation, education, and economic opportunity. A person's economic status affects their likelihood of contracting HIV, developing AIDS, accessing care and treatment, and reaching and maintaining viral suppression.⁴⁴

In low-income urban areas, individuals living below the poverty line are twice as likely to be living with HIV as those living in the same community but above the poverty line. Within these high-poverty areas, HIV prevalence is high and comparable across racial/ethnic groups. These communities face overlapping drug and HIV epidemics and have higher levels of substance abuse coupled with decreased access to effective substance use disorder treatment and prevention services. In addition to being more common in low-income households, HIV is also more common among unemployed persons and those with less than a high school education.⁴⁵

Economic status is a key factor in determining health outcomes, and quality of life for individuals with HIV. Food insecurity, housing instability, and unemployment, are associated not only with poorer medication adherence but also with poorer access to health care.⁴⁶

Racial and ethnic disparities: Racism contributes to excess preventable diseases, needless disabilities, and premature deaths including those from HIV. Since the virus was discovered, Black people in the U.S. have made up 43 % of all HIV deaths in the U.S. and its territories. Currently, Black and Latinx people represent the majority of new HIV diagnoses, people living with HIV disease, and deaths among people with HIV.⁴⁷

Black people account for more people living with HIV than any other racial group – an estimated 471,500 of the more than 1.1 million people living with HIV in the U.S. are Black. While Black people represent 12 % of the U.S. population, they accounted for almost half (44% in 2010) of new infections and 40 % of people living with HIV in 2012.⁴⁸ Black gay, bisexual, and other men who have sex with men accounted for 26 % of all new HIV infections in 2016 despite representing less than 2% of the total U.S. population.

In 2016, 4,560 Black women received an HIV diagnosis, compared with 1,450 white women and 1,168 Hispanic/Latina women. Black men make up 38% of all new diagnoses among gay and bisexual men, and the CDC predicts that if trends continue as they exist today, one out of every two Black gay, bisexual, and other men who have sex with men can expect to acquire HIV during their lifetime. For Latinx gay, bisexual, and other men who have sex with men, that figure is one of every four. Perhaps the most disturbing finding by the CDC is their recent estimate that 56% of Black transgender women may already be living with HIV.⁴⁹

⁴⁴ Milloy, M. J., Marshall, B. D., Kerr, T., Buxton, J., Rhodes, T., Montaner, J., & Wood, E. Social and structural factors associated with HIV disease progression among illicit drug users: A systematic review. *AIDS*. 2012; 26(9):1049–1063.

⁴⁵ CDC. (2016, August). CDC Fact Sheet: Today's HIV/AIDS Epidemic. Retrieved from <https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/todaysepidemic-508.pdf>

⁴⁶ Surratt et al., 2014

⁴⁷ KFF. (2018). Black Americans and HIV/AIDS: The Basics. Retrieved from <https://www.kff.org/hivaids/fact-sheet/black-americans-and-hivaids-the-basics/>

⁴⁸ CDC. (2016, August). CDC Fact Sheet: Today's HIV/AIDS Epidemic. Retrieved from <https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/todaysepidemic-508.pdf>

⁴⁹ Carey, R., & Milan, J. (2018, June 14). The Whitewashed History of HIV: A Black Teen Died of AIDS in 1969. *Advocate*. Retrieved from <https://www.advocate.com/commentary/2018/6/14/whitewashed-history-hiv-black-teen-died-aids-1969>

Disparities for women: Access to care and health outcomes for people diagnosed with HIV in the U.S. reflect stark gender disparities.⁵⁰ Women account for approximately a quarter of the U.S. HIV epidemic today, and the epidemic among women in the U.S. is disproportionately an epidemic of Black and Latinx/Hispanic women, with Black women comprising 60% of the epidemic among women by the end of 2014 and Latinx/Hispanic women representing 17%. Data on transgender women continue to be lacking and inadequate, hampering the ability to fully understand and respond to the size of their epidemic.

Women with HIV are more likely to be tested and to be retained in care than men living with HIV. However, among those retained in care, women have lower antiretroviral medication use than men in every racial category.⁵¹ Women also were less likely to be virally suppressed than men in every racial category except Black men living with HIV. Black women have significantly higher rates of AIDS-related death than white women,⁵² and women living with HIV overall were more likely to die than men living with HIV in a retrospective cohort study.⁵³

While new data indicate declining HIV transmissions among women nationally, Black and Latinx/Hispanic women continue to be disproportionately impacted by HIV, especially Black women in the South (whom are 18 times more likely to be HIV-positive than their white counterparts). In 2015, Black women accounted for 60% of new HIV cases among women despite representing only 13% of women in the U.S. Nearly two-thirds (63%) of these new diagnoses occurred in the South, and the Deep South accounted for 48% of total new HIV diagnoses among Black women in 2015.⁵⁴

LGBTQ health disparities: Members of lesbian, gay, bisexual, transgender, and queer (LGBTQ) communities are more likely than their heterosexual counterparts to experience extensive barriers to health care access. Although social acceptance of LGBTQ people in the United States has been improving, individuals continue to face cultural incompetence, gender identity bias, stigma, and discrimination from providers who express stigmatizing discomfort in taking sexual histories and providing appropriate examinations critical to accurate diagnosis and care. These negative experiences directly correlate to poor retention in and adherence to care, and result in multiple health disparities for LGBTQ populations.⁵⁵ HIV and other sexually transmitted infections continue to disproportionately impact gay, bisexual, and other men who have sex with men and transgender women.

MSM account for more than two thirds of all people diagnosed with HIV each year in the U.S., despite comprising less than 5% of the general population.⁵⁶ MSM account for 75% of reported primary and secondary syphilis infections and more than one-third of gonorrhea infections.⁵⁷ Outbreaks of hepatitis C infection transmitted by sexual contact have also been reported in MSM living with HIV in urban areas.

⁵⁰ Lesko, C. R., Cole, S. R., Miller, W. C., Westreich, D., Eron, J. J., Adimora, A. A., Moore, R. D., Matthews, W. C., Martin, J. N., Drozd, D. R., Kitahata, M. M., Edwards, J. K., Mugavero, M. J. (2015, March 12). Ten-year Survival by Race/Ethnicity and Sex Among Treated, HIV-infected Adults in the United States. *Clinical Infectious Diseases: An Official Publication of the Infectious Diseases Society of America*, 60(11), 1700–1707. <http://doi.org/10.1093/cid/civ183>

⁵¹ CDC. (2017, September 26). Syphilis and MSM -CDC Fact Sheet. Retrieved from <http://www.cdc.gov/std/Syphilis/STDFact-MSM-Syphilis.htm>.

⁵² Beer, L., Mattson, C. L., Bradley, H., & Skarbinski, J. (2016). Understanding Cross-Sectional Racial, Ethnic, and Gender Disparities in Antiretroviral Use and Viral Suppression Among HIV Patients in the United States. *Medicine*, 95(13), e3171. <http://doi.org/10.1097/MD.0000000000003171>

⁵³ Murphy, K., Hoover, D. R., Shi, Q., Cohen, M., Gandhi, M., Golub, E. T., ... Anastos, K. (2013). Association of self-reported race with AIDS death in continuous HAART users in a cohort of HIV-infected women in the United States. *AIDS (London, England)*, 27(15), 2413–2423. <http://doi.org/10.1097/01.aids.0000432537.92958.73>

⁵⁴ CDC HIV Surveillance Report, Vol. 27, 2015.

⁵⁵ APA Public Interest Government Relations Office. (2013, May). *LGBT Health Disparities*. Retrieved from <https://www.apa.org/advocacy/health-disparities/lgbt-health.pdf>

⁵⁶ CDC. (2015). HIV among gay and bisexual men. Retrieved from <http://www.cdc.gov/hiv/risk/gender/msm/facts/index.html>

⁵⁷ National LGBT Health Education Center. (2016, March). *Understanding the Health Needs of LGBT People*. Retrieved from <https://www.lgbthealtheducation.org/wp-content/uploads/LGBTHealthDisparitiesMar2016.pdf>

Finally, rates of human papilloma virus-associated anal cancers among MSM are seventeen times those of heterosexual men with even higher rates among individuals concurrently living with HIV.⁵⁸

The health disparities for transgender people are among the highest. Many transgender people face stigma, discrimination, social rejection, and exclusion that prevent them from fully participating in society, including accessing health care, education, employment, and housing. These factors, when combined with racism and transphobia, affect the health and well-being of transgender people, placing them at increased risk for HIV. Transgender-specific data is limited because many state, federal, and local agencies do not collect it. However, a 2008 review of HIV studies among transgender women found that, on average, 28% tested positive for HIV. More than half of Black transgender women are estimated to be living with HIV.⁵⁹

Immigrant communities: The zero-tolerance policy toward undocumented immigrants makes addressing the HIV epidemic among this population far more difficult. This is most apparent in the Latinx gay and bisexual communities, which have seen dramatic increases in new infections unlike any other at-risk population. This increase is concentrated in seven jurisdictions with large numbers of undocumented Latinx immigrants and is largely among foreign-born men. Undocumented cisgender and transgender women and young gay men frequently encounter violence, including rape and sexual abuse, and are forced into sexual exploitation, all of which places them at high-risk of HIV, through infection trends are not as clear.

Harsher enforcement of deportation laws, particularly in places where local authorities actively cooperate with ICE, drives immigrants underground where they are subject to abuse with little recourse. Raids on workplaces has made employment in factories, restaurants and other business establishments much more high-risk. This leaves little alternative but to resort to jobs such as house-keeping, sex work and other activities where encounters with ICE are less likely. Immigrants also avoid medical institutions both for lack of insurance coverage and for fear of an encounter with ICE. This includes people living with HIV who are reluctant to come to medical appointments or engage in other health-related activities that they perceive will put them at risk.

There is significant anecdotal evidence that immigrants placed in detention for deportation proceedings are being denied adequate care for HIV and other serious medical conditions, and that members of the LGBT community, especially transgender women and men who are perceived to be gay are subject to poor treatment and to abuse, including sexual assault and violence.

More recently, proposed changes in the “public charge” definition are already having an impact on immigrants with residency who intend to seek citizenship and on family members who are already American citizens. Fear that use of health services, including preventive health services and even HIV care provided through the Ryan White Program, is keeping people from getting screened for HIV, STIs, hepatitis, and tuberculosis. Only two states, Minnesota and New York have created Basic plans under the ACA, that provide coverage to persons with residency, who are otherwise prohibited from using Medicaid or the ACA exchange plans. But even in these two jurisdictions, taking advantage of this, or even enrolling eligible children in Child Health Plus would put these residents at risk of being deemed a public charge when they apply for residency renewal or for citizenship.

⁵⁸ CDC. (2014). Gay and bisexual men's health. Retrieved from <http://www.cdc.gov/msmhealth/STD.htm>

⁵⁹ CDC. (2018, April 23). HIV Among Transgender People. Retrieved from <https://www.cdc.gov/hiv/group/gender/transgender/index.html>

Sex workers: Sex workers continue to face barriers in the context of accessing HIV prevention and treatment services. The stigma associated with sex work, along with the interplay of prosecution of sex workers, the socioeconomic factors, the conflation of sex work and sex trafficking and physical threats can create as nuisance set of challenges when in the context of service provisions.

Additionally, the experience of providing effective health programs for sex workers is also relevant for the wider HIV discussion of the immense clinical benefits of HIV treatment and the potential for population-level HIV prevention impact, HIV treatment alone is insufficient. Access to treatment requires comprehensive services for sex workers, including actions to overcome stigma and discrimination. Treatment adherence among sex workers has powerful behavioral determinants and is reinforced by sex worker-friendly services, peer support, and supportive policy and legal context. Sex worker-friendly services, including STI and sexual health care, can reduce other STIs, which increase HIV susceptibility.

Furthermore, countries that have legalized some aspects of sex work have fewer sex workers living with HIV than countries that criminalize all aspects of sex work, according to an ecological analysis of 27 European countries.⁶⁰ This multiple country analysis highlights the power of decriminalization as a prevention effect.

Recommendations for federal action

I. Fully enforce and monitor civil rights protections

The federal government is responsible for protecting and promoting the civil rights and wellbeing of the people of the U.S. and its territories to ensure that they can live and participate in society free from violations and discrimination. When government steps away from these responsibilities or refuses to enforce civil rights laws and protections, it creates unsafe environments and exacerbates the HIV epidemic. The federal government must uphold civil rights and non-discrimination protections on behalf of LGBTQ people, immigrant communities, Black and Latinx communities, Native American populations, people with disabilities, and other historically disenfranchised populations. We urge Congress to reject proposed and implemented budgetary and regulatory changes that undermine historic protections that are essential to sustaining the gains made in the HIV epidemic.

II. Remove immigration status-related restrictions from HIV programs and Medicaid

Immigration reform is a matter of civil rights for millions of undocumented men, women, and children who work and live in the U.S. today without consistent legal protection. Many individuals face an uncertain future and are less likely to access health services due to fear of deportation. We must ensure access to high-quality health care for immigrants regardless of status including access to medications, hormone treatments, and non-stigmatizing, culturally-relevant, and gender-responsive health care. We recommend that States with continued high rates of HIV and significant numbers of immigrants impacted by HIV obtain CMS waivers that allow outreach and other services to these highly-impacted groups. Removing immigration status-related restrictions from these programs is vital to achieving an end to the epidemic and addressing health disparities among immigrant communities.

⁶⁰ Reeves A et al. [National sex work policy and HIV prevalence among sex workers: an ecological regression analysis of 27 European countries](#). The Lancet HIV, online ahead of print, 2017.

III. Strengthen protections from discrimination for lesbian, gay, bisexual, and transgender people under both Title VII of the Civil Rights Act and Title IX of the Education Amendments Act of 1972 and provide better reporting on the health and human services needs of the entire LGBT community with a particular emphasis on the transgender community.

The federal government must immediately recognize and enact protections from discrimination for LGBTQ people the basis of sexual orientation and gender identity and expression under Title VII of the Civil Rights Act of 1964 and Title IX of the Education Amendments Act of 1972. Further, all federal agencies that provide services to transgender people should be directed to produce annual reports with substantial behavioral or surveillance data specifically focused on the transgender community.

IV. Pass comprehensive immigration reform that allows normalization of status of undocumented immigrants who have not been convicted of any serious criminal offense, that recognizes the economic imperatives that force migration, and that broadens grounds for asylum or other legal status for persons fleeing domestic and gang violence or who cannot receive adequate health care in their country of origin. Until such reform is passed, issue guidance that protects undocumented immigrants from being seized for deportation at health care facilities or in transit to and from such facilities, as well as venues where immigrants might go to seek protection from abuse.

V. Reject proposed changes to the “public charge” definition that would inhibit immigrants from seeking health care, including preventive health services, for themselves and their families.

VI. Develop a national basic health insurance program that pays for basic preventive health and primary care for both documented and undocumented immigrants, including coverage for care associated with HIV, STI’s, hepatitis tuberculosis, other communicable diseases, and behavioral health conditions.

VII. Establish “border” health services in jurisdictions with high concentrations of undocumented immigrants to outreach and provide health services to these constituents in the interest of public health.

VIII. Create meaningful oversight of detention facilities to ensure adequate and respectful provision of health care, respect for the dignity and human rights of people living with HIV and LGBTQ persons, and protection from violence, including sexual violence.

IX. Establish and resource a cross-governmental working group to address issues related to an aging population living with HIV inclusive of inflammation, social isolation, multiple morbidity, polypharmacy, and the need to emphasize maintenance of function.

Improving HIV Care and Treatment

The most critical factor in ending the HIV epidemic is to link and retain persons diagnosed with HIV to the health care they need to stay healthy and to prevent further transmission. Having an integrated healthcare system and affordable access to comprehensive healthcare coverage is crucial to helping people living with HIV link to care, stay in care, and achieve and maintain viral suppression. According to analysis by the Kaiser Family Foundation, an estimated 56 % of people living with HIV rely on Medicaid, Medicare or both for their healthcare coverage, and an estimated 30 percent were covered through private insurance and 14 % were uninsured.⁶¹ In terms of federal expenditures, Medicare is the largest

⁶¹ KFF. (2017, April). Medicaid’s Role for Individuals with HIV.

federal funder of HIV care and treatment at \$10 billion per year, followed by Medicaid at \$5.9 billion, and then the Ryan White HIV/AIDS Program, at \$2.3 billion, the largest HIV-specific discretionary grant program in the U.S.⁶² Furthermore, the Affordable Care Act's private insurance reforms have allowed tens of thousands of people living with HIV to access affordable coverage for the first time.

INCREASE ACCESS TO MEDICAID FOR ALL PEOPLE WITH HIV AND COMMUNITIES AT HIGHER RISK FOR HIV

Medicaid is the single largest source of healthcare access for people living with HIV, estimated to cover more than 40% of people living with HIV in care. It serves a crucial role in ensuring that people living with HIV have access to primary and specialty healthcare and individuals at higher risk for HIV have access to preventive and other health care services that can reduce their chance of acquiring HIV. Medicaid is also the largest public health insurance program in the United States, and the largest insurance plan (public or private) in many states.

The Affordable Care Act significantly increased access to Medicaid, including for people living with HIV, in those states that have expanded the program to non-elderly adults with incomes at or below 138% of the federal poverty level (\$28,180 for a family of three in 2017). One analysis found that if all states expanded their Medicaid programs, nearly 47,000 people with HIV could gain new Medicaid coverage.⁶³

The expansion of Medicaid to low-income childless adults is particularly important for many men who have sex with men who were previously ineligible for Medicaid and are the population most affected by HIV. Further, in states that chose to expand Medicaid, people living with HIV who meet the income threshold no longer must become disabled to become eligible for Medicaid. This means they can get life-extending care and treatment before the disease has significantly damaged their immune system to the point where they are sick and unable to work.⁶⁴ This investment in primary and preventive care, specialty, and pharmacy services for people living with HIV will save lives and avoid higher costs that result from delayed or inadequate treatment. Despite these benefits, 17 states have not adopted the Medicaid expansion. Medicaid eligibility for adults in states that do not expand their programs is extremely limited: the median income limit for parents in these states is just 44% of the federal poverty level, or an annual income of \$8,985 a year for a family of three in 2017. And in nearly all states that have not expanded Medicaid, childless adults remain ineligible for Medicaid unless they are found to be disabled. Additionally, because the ACA assumed that low-income people would receive coverage through Medicaid, it does not provide financial assistance to people below the federal poverty level for other coverage options. This means that in states that do not expand Medicaid, many adults fall into a "coverage gap" of having incomes above Medicaid eligibility limits but below the minimum income required to receive Marketplace premium tax credits.

Expanded and sustained access to Medicaid coverage must be a top priority to end HIV as an epidemic. This means protecting Medicaid as a healthcare safety net program and ensuring the stability of the Medicaid program including the expansion. Additionally, it is imperative that states that have not expanded Medicaid reverse course. Lastly, we encourage CMS to reject state proposals under 1115 waivers that will harm people living with HIV. This includes proposals to roll back benefits, impose work

⁶² KFF. (2017, November). U.S. Federal Funding for HIV/AIDS: Trends Over Time. Retrieved from <http://files.kff.org/attachment/Fact-Sheet-US-Federal-Funding-for-HIV/AIDS-Trends-Over-Time>

⁶³ KFF. Medicaid and HIV. (2016, October 14). Retrieved from <https://www.kff.org/hiv/aids/fact-sheet/medicaid-and-hiv/>

⁶⁴ HIV.gov. The Affordable Care Act and HIV/AIDS. (2017, January 31). Retrieved from <https://www.hiv.gov/federal-response/policies-issues/the-affordable-care-act-and-hiv-aids>

requirements as a condition of continued coverage, and impose additional cost-sharing beyond the federal limits on low-income beneficiaries. This also must include continued consumer protections for prescription drug access.

A significant share – about 31% – of Medicaid enrollees living with HIV are eligible to enroll in both Medicaid and Medicare, compared to just 15% of the overall Medicaid population.⁶⁵ Medicare-Medicaid enrollees are among the most chronically ill and costly Medicaid enrollees, with many having multiple chronic conditions and requiring long-term care. Importantly, the population of people living with HIV who are eligible for both Medicare and Medicaid is rising as people living with HIV live longer.

Recommendations for federal action

I. Ensure access to Medicaid for people living with HIV in all states and maintain the Medicaid expansion

The Medicaid expansion significantly reduced the uninsured rate in states that implemented it.⁶⁶ Currently, most individuals with HIV/AIDS in non-Medicaid expansion states who qualify for Medicaid do so because they have very low incomes, have progressed to AIDS and are disabled and unable to work. Providing earlier access to Medicaid coverage for low income individuals at higher income levels and without requiring disability promotes earlier access to the comprehensive care and treatment that keeps people living with healthy and stops diseases transmission. Congress and the Administration must maintain the healthcare safety net structure of the Medicaid program, including the Medicaid expansion to maintain the progress we have made in increasing the amount of people living with HIV with regular access to care and coverage.

Many states fail to make the necessary investments to improve health outcomes in their jurisdictions. A clear example is the lack of Medicaid expansion in eighteen states which would have infused millions of federal dollars into areas of great need. Expanding Medicaid is the single most important systemic change that would provide greater access to medical care for people living with HIV and those at risk for HIV. The federal government must incentivize states to expand Medicaid without adversely impacting the flow of resources that benefit persons living with HIV.

II. Oppose measures limiting access to Medicaid

The Administration must immediately halt the approval of waivers that are counter to the intent of the Medicaid program and that restrict rather than improve access to healthcare for low-income Americans. The imposition of work requirements, premiums, burdensome reporting requirements, limits to prescription drug coverage, and coverage lockouts threaten the health of people living with HIV and millions of other Americans who count on the program. Conditioning Medicaid eligibility on a work requirement is particularly problematic for our efforts to end the epidemic. A large majority of Medicaid beneficiaries already work but their employer does not provide healthcare coverage and their positions are often seasonal or temporary. Placing additional barriers to care on Medicaid beneficiaries living with HIV will have individual and public health consequences. As early reports from states that have implemented work requirements indicate,

⁶⁵ KFF. (2016, October 14). Medicaid and HIV. Retrieved from <https://www.kff.org/hivaids/fact-sheet/medicaid-and-hiv/>

⁶⁶ KFF. (2017, February 14). Insurance Coverage Changes for People with HIV Under the ACA. Retrieved from <https://www.kff.org/health-reform/issue-brief/insurance-coverage-changes-for-people-with-hiv-under-the-aca/>

individuals will soon lose access to coverage, not because they are not working, but because they are unable to document compliance due to complicated reporting systems.⁶⁷ For people living with HIV, interruptions in access to antiretrovirals jeopardize viral suppression and consequently their health status. Without Medicaid coverage, people living with HIV and millions of others are unable to work. We strongly recommend that CMS stop encouraging and approving Medicaid waivers that will put coverage for people with HIV at risk.

It is also critically important that Medicaid maintains consumer protections that ensure access to medication for people living with HIV. HIV medications, particularly newer single tablet regimens, are increasingly subject to utilization management techniques that are counter to clinical guidelines and act as a barrier to accessing the most effective treatment. While we support innovative solutions to drug pricing that will promote competition and increase access to lifesaving medications, it is important to preserve protections that ensure coverage decisions are based on clinical guidelines and recommendations, rather than purely on cost.

III. Support implementation of innovative care delivery and payment models

States' efforts to develop innovative care delivery and coverage/payment models through their Medicaid programs should be supported. These efforts might include managed care and/or disease management programs lead by AIDS services organizations that have a long history of providing coordinated primary, specialty, and pharmacy care for people living with HIV. These programs should recognize the value that AIDS services organizations provide to payors and the health care system in general and should reward these providers for their ability to move the needle on outcomes.

Innovative service delivery, benefit design, and payment models should also address social determinants of health, including housing, food, and others. CMS's Accountable Health Communities Model is currently testing models that systematically identify and address health-related social needs of Medicaid beneficiaries through screening, referral, and community navigation services, with the goal of increasing coverage, improving access, impacting health care costs, and reducing service utilization. We applaud CMS' recognition that factors outside of the health care delivery system have a significant effect on the health and wellbeing of Americans, and we encourage additional models to further test these theories.

The Medicaid health home benefit allows states to cover additional services to improve care management and coordination for beneficiaries with two or more chronic conditions to improve health outcomes and reduce costs. States receive an enhanced rate of 90 % for the health home services for the first eight quarters of implementation. Several state Medicaid programs have implemented health homes for people with HIV with promising results. We urge CMS to continue to educate state Medicaid programs on the effectiveness of the Medicaid health benefit and encourage states to implement the Medicaid health home benefit for individuals with HIV, substance use disorder, hepatitis C and other complex chronic conditions.

IV. Medicaid programs should be incentivized to enter into data sharing agreements with Departments of Public Health

⁶⁷ Hellmann, J. (2018, July 16). More than 7,000 fail to meet Medicaid work requirements in Arkansas. The Hill. Retrieved from <http://thehill.com/policy/healthcare/397260-more-than-7000-fail-to-meet-medicaid-work-requirements-in-arkansas>

Advances in HIV surveillance systems and methods have improved federal, state, and local efforts to evaluate and improve outcomes along the HIV care continuum. Given the heightened role Medicaid now plays in paying for and providing care for people living with HIV, Medicaid should create stronger collaborative partnerships with state-operated programs that have a history of providing care to the HIV population, such as Departments of Public Health. Specifically, Medicaid programs should enter into data sharing agreements with departments of public health to enable Medicaid programs to better measure HIV utilization and outcomes for Medicaid beneficiaries.

V. Medicaid programs should be encouraged to adopt a HIV viral load suppression measure of performance

Improving rates of viral load suppression among people living with HIV is critical to realizing individual, population, and community health improvements, as well as any cost savings associated with them. To help facilitate this outcome, all state Medicaid programs should be encouraged to adopt a HIV viral load suppression measure of performance.

VI. Allow Ryan White Program-funded clinics access to health center reimbursement mechanisms under Medicaid

Extend to Ryan White grantees who are funded to provide health care the ability to receive enhanced or cost-based Medicaid reimbursement for the provision of medical services similar to the reimbursement levels for FQHC/CHCs. This would help alleviate capacity challenges that create barriers to HIV care. This would also increase access to care by affording organizations interested in developing health clinics the opportunity to build new clinics to serve the growing number of HIV patients and give current clinics that face higher costs and or declining revenue an opportunity to extend their current capacity and provide additional access to care for new patients. This proposal does not change Medicaid eligibility for patients or expand services available.

VII. Ensure Access to Medicaid for People Living with HIV in all States

Currently, most people living with HIV in non-Medicaid expansion states who qualify for Medicaid do so because they are determined to be disabled after they have received an AIDS diagnosis. Providing better access to treatment immediately upon HIV diagnosis, increasing the health of people living with HIV and greatly reducing the risk of transmission to HIV negative sexual partners is critical to ending the epidemic. We can do so by ensuring Medicaid eligibility for low-income people living with HIV and aligning Medicaid eligibility rules with current federal government guidelines on the standard of care for treating HIV and ensuring access to Medicaid for people living with HIV immediately upon diagnosis.

Federal law *requires* states to cover certain population groups and *allows* them to cover others. In general, Medicaid covers low-income mothers and children, elderly people, and people with disabilities, although specific income and other requirements vary by state. States set individual eligibility criteria within federal minimum standards; they are also able to request from CMS a waiver of federal law to expand health coverage beyond these groups. Many states have expanded coverage above the federal minimums. Currently, adults who are childless, nonelderly, or do not have a disability cannot qualify for Medicaid, regardless of their income level. An

exception exists for states that have expanded Medicaid under the ACA and for states that have a waiver that allows coverage.

State Medicaid program efforts that provide early intervention access to Medicaid ensure early intervention, treatment, and good outcomes for people living with HIV. Such efforts include Medicaid expansion under the ACA, as well as Section 1115 and 1915(c) waivers for services. Many states have or have had waivers that provide home- and community-based services, including case management, for people living with HIV (through 1915(c) waivers), or use 1115 waiver authority to provide Medicaid eligibility to individuals living with HIV who would not otherwise be Medicaid-eligible unless their health deteriorated to the point of disability. States should consider using these mechanisms to provide needed services that will keep people living with HIV healthy.

PROTECT MEDICARE

The Medicare program covers 20 % of people living with HIV in care. Most people with HIV on Medicare are under age 65 and qualify as disabled beneficiaries and a significantly higher percentage of them are dually eligible for Medicaid than in the overall Medicare population.⁶⁸ With the implementation of the Medicare Part D prescription drug benefit in 2006, Medicare assumed an even more critical role for people with HIV. Seventy seven percent of HIV-positive Medicare beneficiaries qualify for Part D prescription drug subsidies.⁶⁹ In FY 2016, Medicare spending on HIV totaled \$10 billion, representing 51% of federal spending on HIV care, but just 2% of total Medicare spending.⁷⁰ While Medicare provides coverage of important medical benefits, it requires relatively high cost-sharing except for individuals who are dually eligible for Medicaid coverage or have other forms of assistance. Under traditional Medicare, there is not a cap on out-of-pocket spending for Parts A and B and traditional Medicare does not cover critical services, such as long-term care and dental services. Because of this, Medicare beneficiaries living with HIV who are not dually eligible for Medicaid coverage require assistance with cost sharing or coverage for wrap around services.

Recommendations for federal action:

I. Eliminate the 29-month waiting period before SSDI recipients can obtain Medicare benefits.

The more than two-year waiting period for Medicare is a major hurdle for many PLWH receiving SSDI who are already disabled. In order to get everyone living with HIV into sustained treatment, this barrier to care should be eliminated.

II. Formulary “all drugs, all classes” rule - widen access by allowing for all and removing barriers

The addition of the Part D benefit to Medicare in 2006 marked an important change for Medicare beneficiaries, especially those with illnesses and chronic conditions treated by costly medications, including those with HIV. Plans under Part D are required to cover all approved antiretrovirals (ARVs), designating ARVs as one of “six protected” drug classes. There is no requirement for

⁶⁸ KFF. (2016, October 14). Medicaid and HIV. Retrieved from November 12, 2017 from <https://www.kff.org/hiv/aids/fact-sheet/medicaid-and-hiv/>

⁶⁹ KFF. (2016, October). *Medicare and HIV Fact Sheet*. 2016. Retrieved from <http://files.kff.org/attachment/Fact-Sheet-Medicare-and-HIV>

⁷⁰ KFF. (n.d.). Retrieved from <https://kaiserfamilyfoundation.files.wordpress.com/2016/10/7171-05-medicare-and-hiv-figure-1.png?w=735&h=551&crop=1>

plans to cover all other non-ARV drugs that might be needed to treat HIV-related illness or other comorbidities, however. PLWH should have access to all the medications they need to survive and thrive, not just ARVs.

III. Extend Medicaid drug rebates to low-income Medicare beneficiaries

Medicare should benefit from the same discounts for prescription drugs as Medicaid. Low-income dually-eligible people (people eligible for both Medicare and Medicaid) comprise one-fourth of all Medicare drug users and are among the most costly beneficiaries. Because Medicare, rather than Medicaid, covers most of their drugs and because Medicare cannot negotiate drug prices, these drugs are not eligible for the same rebates as they were, and would be, under the Medicaid program. Extending Medicaid rebates for dually-eligible and other low-income people could save more than \$145 billion over ten years. Extending drug rebates to all Medicare beneficiaries would yield even more savings.

IV. Direct the Center for Medicare deputy administrator to ensure beneficiaries have access to and choice of provider, including pharmacies and to prohibit Part D plans from changing pharmacy networks mid-year to ensure continuity of care and treatment

VI. Direct the CMMI to support innovative Medicaid payment and delivery reform models that include HIV prevention and care services and HIV providers and that promote and leverage coordination and integration of CDC, HIV/AIDS Bureau and SAMHSA programs and resources. Examples include reimbursing for peer supports and employing Community Health Workers and other community-based providers

PROTECT THE HEALTH CARE GAINS MADE UNDER THE AFFORDABLE CARE ACT

Prior to the Affordable Care Act (ACA), people living with HIV were locked out of the individual insurance market either due to coverage denials or unaffordable premiums. The ACA's consumer protections that include not allowing insurers to deny coverage due to pre-existing conditions, premium setting based on community rating, non-discrimination protections (Sect.1557), guaranteed coverage of essential health benefits, premium and cost sharing assistance, and annual caps on out of pocket costs have all been critical to improving access to health care coverage and services for people living with HIV. The Kaiser Family Foundation report, "Insurance Changes for People with HIV Under the ACA,"⁷¹ provides a comprehensive accounting of the insurance coverage gains for PLWH. Nationwide, Medicaid coverage increased from 36 % before ACA implementation (2012) to 42 % after (2014). The increase was more striking in expansion states, from 39 % to 51 % over the same time period. Eroding or eliminating these protections that helped to level the playing field in ensuring people living with HIV have access to the health care that they need and that they are not discriminated against because of their health status or gender will be a major setback to the fight against HIV and to the health and public health of our country. The ACA must continue to be strengthened if we are to end the impact of the HIV epidemic in the U.S.

⁷¹ Kates, J. & Dawson, L. (2017). Insurance Coverage Changes for People with HIV Under the ACA. Kaiser Family Foundation. Retrieved from <https://www.kff.org/hiv/aids/issue-brief/insurance-coverage-changes-for-people-with-hiv-under-the-aca/>

Recommendations for federal action:

I. The Administration should repeal regulations expanding access to Association Health Plans and short-term limited duration health plans.

Association health plans (AHP) and short-term limited duration plans (STLDP) plans will reintroduce discrimination to the individual insurance market, increase premiums and restrict rather than increase access to the ACA-compliant plans that people living with HIV and others with pre-existing conditions rely on for the health care coverage. AHP and STLDP plans are not meaningful forms of insurance and will not be viable coverage options for people with HIV and millions of other Americans with pre-existing conditions. What's worse by segregating the individual market and syphoning off an estimated 400,000 to 800,000 younger and healthier individuals, the ACA-compliant plans that people living with HIV count on are likely to be priced out of reach⁷². The rules expanding AHPs and STLDP must be repealed or these plans should be subject to the same rules as the ACA compliant plans. The Administration's regulatory actions are already resulting in increases in the number of uninsured after the uninsured rate reached an historical low of 10.4% in 2016⁷³.

II. Members of Congress must stop attempting to repeal the ACA

Congress must turn its focus to strengthening our healthcare system rather than weakening it in ways that would that would undermine the progress that has been made and that would have devastating consequences for people living with HIV and upwards of 20 million other Americans.⁷⁴

Millions of Americans have gained health insurance coverage under the ACA, including tens of thousands of people living with HIV. Since the ACA was enacted in 2010, people living with HIV have come to count on basic protections that ensure they will not be denied coverage because of their health status and they will have coverage for basic services, including prescription drugs, mental health and substance use treatment.

III. Congress must pass legislation to stabilize private insurance markets and to ensure sufficient funding for ACA enrollment and marketing activities

The Administration's regulatory actions to undercut the ACA and to significantly limit support for marketing and assistance during open enrollment have already contributed to a rise in the number of Americans who are uninsured and to premium increases in the ACA-compliant individual market.

Actions must be taken by Congress, such as funding a reinsurance program and requiring the Administration to promote and restore funding for marketing and enrollment assistance throughout the open enrollment process to prevent further weakening of the individual health insurance market and significant increases in uninsured Americans, including among people living with HIV.

IV. Enforce the ACA's nondiscrimination protections

⁷² Wakely Consulting Group. Effects of Short-Term Limited Duration Plans on the ACA Compliant Individual Market. April 2018.

⁷³ Kaiser Family Foundation. (2018, August 28). Uninsured Rate Among the Non-elderly Population, 1972 to 2017. Retrieved from <https://www.kff.org/uninsured/slide/uninsured-rate-among-the-nonelderly-population-1972-2017/>

⁷⁴ Congressional Budget Office. (n.d.) Affordable Care Act. Retrieved from <https://www.cbo.gov/topics/health-care/affordable-care-act>

The ACA's nondiscrimination protections have been critical to ensuring access to care and treatment for people living with HIV and other chronic conditions. This has been particularly important to ensure that issuers do not design plans in ways that discourage enrollment from individuals with high-cost conditions (e.g., through placing all or most drugs used to treat HIV on the highest cost-sharing tier or implementing formulary restrictions that are counter to HIV federal treatment guidelines).

Congress and the Administration must preserve these important non-discrimination protections, including the protections as part of the Essential Health Benefits prescription drug standards.

V. Bolster healthcare infrastructure in the U.S. South and rural areas

Many parts of the South have a weaker healthcare infrastructure, with limited ability to respond to sexually transmitted infection (STI) epidemic, HIV treatment and prevention service needs, and an insufficient number of providers, especially in rural areas. Need strategies that support healthcare access to rural settings must be developed and deployed to cover service gaps. Solutions such as Medicaid expansion and support the adoption of telehealth models with equitable reimbursement policies as well as other investments in geographic regions with high HIV burdens or significant barriers to treatment and prevention access are needed additions to lower and change the coverage gap.

STRENGTHEN THE RYAN WHITE HIV/AIDS PROGRAM

The Ryan White HIV/AIDS Program (RWP) administered by the Health Resources and Services Administration (HRSA), is the payer of last resort that fills critical gaps in a comprehensive system of HIV care, including primary medical care, antiretroviral and other drug treatment and essential support services for uninsured and underinsured people living with HIV across the United States. With the goal of equitable access to quality, comprehensive HIV care, the RWP funds systems of care across localities, states, and territories that serve diverse populations and have diverse underlying HIV health resources and challenges. The program has evolved since its creation in 1990, and continues to play a leading, vital role in supporting the delivery of comprehensive and effective care, treatment and supportive services to people living with HIV who otherwise would go without lifesaving services that improve both individual and public health.

Currently, the RWP serves roughly 1 in 2 people living with HIV in the United States, with the majority of funds supporting access to primary medical care and essential support services. RWP is divided into 5 operational parts plus the Minority AIDS Initiative that support programs and services for people living with HIV, as described below:

Part A provides dedicated funding to local jurisdictions that meet certain criteria related to overall population and the number of people living with HIV in those areas. Part A funding is awarded using a formula plus a competitive supplemental award to a local jurisdiction's chief elected officer and is typically then awarded to subgrantees based on community and client needs. (FY17 \$654,296,000).

Part B provides funding directly to state departments of health based on a formula. Part B funds are designed to improve access to care and treatment services. State ADAPs are also federally funded through Part B (FY17 \$411,524,000 care and treatment; \$900,313,000 ADAP).

Part C funds are competitive grants that support approximately 350 clinics nationwide hosted by community health centers, academic medical centers, and stand-alone HIV clinics to ensure access to comprehensive HIV primary care (\$200,585,000).

Part D is designed to support care and treatment services to women, infants, and youth living with HIV (FY17 \$74,907,000).

Part F supports access to dental care, research, and technical assistance for RWP services and service providers. Part F includes Special Projects of National Significance, and AIDS Education and Training Centers funding on innovative care models and their implementation, and training and technical assistance for RWP service providers. Part F includes funding for Special Projects of National Significance and the AIDS Education and Training Centers (FY17 \$71,560,000).

Minority AIDS Initiative (MAI) was established in 1998 and in 1999 was funded by Congress under the Ryan White HIV/AIDS Program Parts A, B, C, and D to improve access to HIV care and health outcomes for disproportionately affected minority populations, including black populations. Under Part A, MAI formula grants provide core medical and related support services to improve access and reduce disparities in health outcomes in metropolitan areas hardest hit HIV/AIDS. Under Part B, MAI formula grants fund outreach and education services designed to increase minority access to needed HIV/AIDS medications through Part B AIDS Drug Assistance Programs (ADAP). Under Part C, MAI funds are used by community health centers and other service providers to improve access to early intervention HIV services. Other examples include technical assistance to expand the capacity of agencies to deliver HIV care to minority populations and training to expand the pool of minority providers in underserved communities.

The success of the RWP can best be measured by rates of viral suppression the final step in the HIV care continuum. In 2016, 84.9% of RWP clients achieved viral suppression, an improvement from 69.5% in 2010⁷⁵. Nationally, only 59% of all persons with an HIV diagnosis are virally suppressed.⁷⁶ This is particularly notable considering that the majority of persons receiving RWP services have low incomes and require substantial social services for optimal care.

Within the confines of the statutory limitations on RWP, HRSA attempts to ensure that funding is awarded in such a way so as to minimize a broad range in per case funding when comparing one state to another. Unfortunately, as evidenced by surveillance data, epidemiology, and reported viral suppression data, while there may be a relative equality in investment of RWP funding across the United States, there is not a commensurate equality of patient outcomes or service delivery infrastructure.

According to the CDC: “In the United States, HIV diagnoses are not evenly distributed across states and regions. Southern states accounted for more than half of new HIV diagnoses in 2016, while making up 38% of the national population”. In all regions of the United States, the majority of people who receive an HIV diagnosis live in urban areas. But in the South, 23% of new HIV diagnoses are in suburban and rural

⁷⁵ <https://hab.hrsa.gov/sites/default/files/hab/data/datareports/RWP-annual-client-level-data-report-2016.pdf>

⁷⁶ CDC. (2018, June). Understanding the HIV Care Continuum. Retrieved from <https://www.cdc.gov/hiv/pdf/library/factsheets/cdc-hiv-care-continuum.pdf>

areas, and in the Midwest 21% are suburban or rural—higher proportions than in the North and West. The South's larger and more geographically dispersed population of people living with HIV creates unique challenges and opportunities for prevention and treatment.”⁷⁷

Fewer people living with HIV in the South are aware of their infection than in any other region. Consequently, fewer people in the South who are living with HIV receive timely medical care or treatment, fewer have their virus suppressed, and a disproportionate number are missing out on the opportunity to preserve their health and avoid transmitting HIV to their partners. Mortality remains alarmingly high as a result and people living with HIV in some southern states have death rates that are three times higher than people living with HIV in some other states. Although death rates have declined recently, the South still accounted for nearly half (47%) of the 16,281 individuals diagnosed with HIV who died in 2013 nationwide.⁷⁸

Ryan White Part B Supplemental Funding, a funding stream that is designed to meet unmet need, that is distributed by competitive application making the process vulnerable to state decisions on whether to apply, and on the relative strength of applications in a competitive environment. In 2016, the South received 29 % of total Ryan White Part B Supplemental funding compared to 52% of the funding going to two high prevalence states.⁷⁹ In 2017, the South received only 12%% of total Ryan White Part B Supplemental funds.⁸⁰ HRSA should explore new mechanisms within the current legislative mandate to ensure that Part B Supplemental funds reach areas most in need, particularly the Deep South. The Ryan White Part D program is a collaborative model that developed an evidence-based approach for intervening to improve HIV clinical outcomes. Part D is known for its integrated, network-based models, which rely on collaboration and communication among a multidisciplinary group of providers, including community-based organizations. During the 2006 Ryan White Program reauthorization, the legislation was expanded to explicitly permit coverage of a range of non-medical services by Part D funding since many of Part D clients have access to health care through the Medicaid program or other Parts of the Ryan White Program. Part D services included family-centered case management, referrals for substance use, mental health services, other social and support services and other services needed to support the patient and patient's family's participation in Part D services.

The flexibility under which services supporting engagement in care can be funded by Part D grants contrasts sharply with Parts A, B and C of the Ryan White Program legislation, each of which have been bound by a requirement to spend a minimum of 75% of their funds on “core medical services,” such as medical, pharmaceutical, and behavioral health care and insurance premium cost sharing, since the 2006 reauthorization. Remaining funds in Parts A, B and C may be used to resource the provision of “supportive services” that help meet HIV-related medical outcomes.

The Ryan White Part F AIDS Education and Training Center (AETC) program was developed to ensure a public health response to HIV that builds capacity and develops a skilled and culturally competent workforce. The AETC program, has evolved from training providers about palliative care in the beginning of the HIV epidemic to building a robust workforce and supporting systems of care in the most impacted communities. The AETC program facilitates practice change to build HIV capacity in federally qualified health centers (FQHCs) and enhance outcomes in Ryan White Program clinics; utilizes principles of

⁷⁷ CDC. (2018, June 25). HIV in the United States by Geography. Retrieved from <https://www.cdc.gov/hiv/statistics/overview/geographicdistribution.html>

⁷⁸ CDC. (2016, May). HIV in the Southern United States. Retrieved from <https://www.cdc.gov/hiv/pdf/policies/cdc-hiv-in-the-south-issue-brief.pdf>

⁷⁹ <https://hab.hrsa.gov/about-ryan-white-hiv-aids-program/fy-2016-ryan-white-hiv-aids-program-part-b-grant-awards>

⁸⁰ Health Resources and Services Administration (HRSA). (2018, March). FY 2017 Ryan White HIV/AIDS Program Part B Grant Awards. Retrieved from <https://hab.hrsa.gov/awards/fy-2017-ryan-white-hiv-aids-program-part-b-grant-awards>

interprofessional education to integrate HIV into medical, nursing and pharmacy school curricula and clinical experiences; and develops the resources and local expertise in common comorbid conditions including substance use and other mental illnesses that stand in the way of engagement and retention in care and viral suppression.

Provider education and training has been shown to improve clinicians' HIV knowledge, attitudes, skills, and practices and system processes including care integration and interagency coordination. Health care professionals who receive ongoing education are more likely to provide the most up-to-date treatment. Filling the gap of well-trained HIV health workforce as a crucial step toward the elimination of HIV in the U.S., and the AETC program needs continued robust support.

Recommendations for federal action

I. Increase funding of the Ryan White HIV/AIDS Program

We should capitalize on the program's effectiveness to promote the health of people living with HIV and increase funding to meet the needs of a growing number of persons living with HIV who need Ryan White Program services.

II. Ensure Ryan White Program funding formulas and structure create the utmost impact toward ending the HIV epidemic

Ryan White Program has successfully reduced disparities in health outcome for PLWH across the country and, by distributing funds through formula and direct grants, has been able to address gaps in service both geographically and by type. Local planning has allowed each jurisdiction and state to respond to its local needs and allocate scarce resources based on the mix of resources available in the state or jurisdiction.

In order to end the epidemic, the Ryan White Program must be scaled up to fill all gaps from the current healthcare system to ensure that treatment is readily available and easily accessible. If the Ryan White Program were to be increased, this also provides an opportunity to review current infrastructure to ensure that the needs of people living with HIV are fully met. At an appropriate future time, when the healthcare coverage and policy environment is not in such a high state of uncertainty and instability, it will be important to explore how to further improve the program so that it can address HIV-related disparities, target new populations, and support the latest prevention and treatment advances that have made it possible to envision an end to the HIV epidemic.

Care continuum models which narrowly focus on medical visits, prescription refill status, and CD4 and viral suppression measures mask the actual experiences of people living with HIV in their attempts to engage with care as well as their experiences of wellness and quality of life. As the US HIV epidemic has become increasingly an epidemic which impacts those living in poverty, people of color, and communities facing multiple forms of discrimination, a spectrum of non-medical services has become progressively necessary to reduce barriers to medical care for people living with HIV.

III. Create flexibility under program income rules to ensure critical support for HIV services

Congress should clarify that Program Income may be used to help to advance the mission of AIDS clinical programs and services organizations and to substantially expand and improve services. To do so, Congress could institute language that maximizes flexibility and HRSA should also interpret program income rules to maximize flexibility to include: HIV Prevention services

including Pre-Exposure Prophylaxis (PrEP); funding for STI prevention services; construction of facilities used for the benefit of clients; and reasonable reserve funding (6 months) for use when regular income is disrupted or decreased in order for typical operations to continue.

IV. Bolster investment in non-medical case management

The federal government should invest in dedicated capacity building for non-clinical staff providing services related to medication-assisted treatment in community-based organizations (CBOs) such as social workers and case managers. The Ryan White program receives \$2.3 billion annually to care for those living with HIV/AIDS. Non-medical case management only accounts for roughly 3.25% of Part A and B spending.^{81 82} In 2014, 150,515 Ryan White (RW) clients received nonmedical case management contrasted to 285,531 RW clients who received medical case management and 512,214 clients who received any service from RW.⁸³ This figure does not include case management services for those living with HIV/AIDS covered by Medicaid, Medicare, or private insurance companies. Despite only 3.25% of RW dollars spent on non-medical case management, 29% of RW clients utilize this valuable service.

The figures highlight the lack of prioritization and recognition of the role of non-clinical staff, including social workers, have in addressing overall care and well-being along the HIV Care Continuum. Social workers and other non-clinical staff provide and navigate the array of services that ensure access to care and improved well-being. Access to such services as mental health care, substance abuse treatment, affordable housing, employment, and other social services are crucial to ensuring that the social determinants are addressed, and improvement are seen along the HIV Care Continuum. This workforce must be supported through ongoing training opportunities because they play a critical role in ending the HIV epidemic.

PREVENT AN HIV WORKFORCE SHORTAGE

Ending HIV as an epidemic in the US will only be accomplished when significant health care system and HIV workforce challenges are addressed. Increasing survival and almost 40,000 new infections annually have greatly expanded the number of PLWH who need ongoing medical care. Advances in HIV treatment have allowed people living with HIV to live near normal life expectancies but many individuals who have been living longer with HIV also develop comorbidities common among older individuals and individuals with chronic complex conditions. The rapid translation of science into evidence-based practice standards is key to quality care. However, the first generation of HIV healthcare providers are aging and retiring without a sufficient pool of HIV providers to meet the increased demand for HIV care as the number of people living with HIV continues to grow. It is well documented that experienced HIV providers deliver higher quality and are more cost effective. The CDC estimated that by 2019 there be a significant shortfall in the number of expert HIV providers relative to the demand for HIV care.⁸⁴

⁸¹ FY14 Part A Expenditures Report. (n.d.) Retrieved May 2017, https://hab.hrsa.gov/sites/default/files/hab/data/allocationsexpenditures/FY14_Part_A_Aggregate_Expenditures_Report_Final_Web.pdf.

⁸² FY13 Part B & MAI Final Expenditures Report. (n.d.) Retrieved May 2017 https://hab.hrsa.gov/sites/default/files/hab/data/allocationsexpenditures/FY13_Part_B_Aggregate_Expenditures_Report_Final_web_012317.pdf.

⁸³ The United States Ryan White HIV/AIDS Program Services Received (n.d.). Retrieved April 2017 from <https://hab.hrsa.gov/stateprofiles/Services-Received.aspx>.

⁸⁴ Weiser, J., Beer, L., West, B.T., Duke, C. C., Gremel, G. W., Skarbinski, J. (2016, October 1). Qualifications, Demographics, Satisfaction, and Future Capacity of the HIV Care Provider Workforce in the United States, 2013–2014. *Clin Infect Dis*. 63(7):966-975. doi: 10.1093/cid/ciw442.

Recent studies project an increase in the demand for HIV healthcare providers while the supply is expected to decrease or will grow at a rate insufficient to accommodate the demand. Surveys of Ryan White Part C clinics reveal the majority of the clinics are seeing an increase in the number of clients served yet are experiencing barriers to recruiting and retaining qualified providers, because of dissatisfaction with pay and lack of providers with HIV expertise. Increase and make competitive provider and staff compensation in Ryan White Program funded clinics while allowing Ryan White Program clinics to be designated as medical homes for both treatment and preventive care.

The Ryan White Part F AIDS Education and Training Center (AETC) program was developed to ensure a public health response to HIV that builds capacity and develops a skilled and culturally competent workforce. The AETC program, has evolved from training providers about palliative care in the beginning of the HIV epidemic to building the workforce and supporting systems of care in the most impacted communities. The AETC program facilitates practice change to build HIV capacity in federally qualified health centers (FQHCs) and enhance outcomes in Ryan White Program clinics; utilizes principles of interprofessional education to integrate HIV into medical, nursing and pharmacy school curricula and clinical experiences; and develops the resources and local expertise in common comorbid conditions including substance use and other mental illnesses that stand in the way of engagement and retention in care and viral suppression.

Provider education and training has been shown to improve providers' HIV knowledge, attitudes, skills, and practices and system processes including care integration and interagency coordination. Health care professionals who receive ongoing education are more likely to provide the most up-to-date treatment. In addition, filling the gap of a well-trained HIV health workforce is a crucial step toward the elimination of HIV in the U.S. The AETC program provides these educational and training opportunities and should continue to be robustly supported.

Recommendations for federal action

I. Enhance payment for cognitive care services that are reimbursed through Evaluation and Management Codes

II. Provide loan forgiveness through the National Health Service Corps for HIV providers who are working in Ryan White Program funded clinics and facilities

Even if all PLWH were diagnosed and linked to care, challenges remain with the capacity of the current system of care. Many clinical and professional responders of the original HIV workforce are now retiring, and it is not clear where their replacements will come from. Providing loan forgiveness for HIV providers to work in Ryan White Program funded clinics will help alleviate this workforce shortage.

III. Expand telehealth programs by increasing grant funding and reimbursement especially from Medicaid and Medicare

IV. Evaluate innovative payment models under Medicare and Medicaid for the comprehensive, high quality care provided at Ryan White Program Clinics

V. Support robust funding for the Ryan White AETC program.

VI. Allow the AETCs to partner with medical schools and residency programs to create rotations at Ryan White Program Clinics for medical students and residents, and HIV clinical fellowships for residents who are not going into Infectious Diseases

PROTECT THE 340B DRUG DISCOUNT PROGRAM

The 340B Drug Pricing Program was created in 1992 and signed into law by President George H.W. Bush to provide certain outpatient medications at reduced costs to “covered entities” (including Ryan White Program clinics, STI clinics, and Federally Qualified Health Centers) that serve vulnerable populations. The purpose of the 340B program is to allow covered entities to reinvest the savings they earn by purchasing medications at lower rates, and “to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”

The program provides critical support for HIV services and extends care to many who otherwise would go without. The program has become even more vital as the demand for care and treatment has increased while federal funding for the Ryan White Program has remained flat for nearly a decade. Thanks to the savings covered entities earn through the 340B program, Americans living with and at risk for HIV benefit from lifesaving treatment, preventive healthcare, substance use and mental health services, and chronic disease management. Savings from 340B allow covered entities to increase healthcare services and capacity in their communities, offering more healthcare delivery locations, hours of operation, and an expert workforce.

Recent growth in the program and pressure from pharmaceutical companies have put the 340B Drug Pricing Program under the Congressional spotlight and raised misinformed concerns that the program is contributing to high drug prices. In those hearings, some have claimed that the 340B program is not working as was originally intended and that the program is contributing to the rise in prescription drug prices. This is not true. In reality, in 2015 (the last year for which data is available) the 340B program was shown to represent only 1.3% to 1.4% of total drug spending.

Recommendation for federal action

Maintain the 340B Program to ensure critical support for HIV services

The 340B Program is a critical component of HIV care in this country and is working to ensure that safety-net providers are able to expand the reach of their services, as is the original intent of the legislation. We urge Congress to ensure that the program is maintained as is and will continue to contribute towards the end of the HIV epidemic through the creation of HIV health care infrastructure in the U.S.

ELIMINATE VIRAL HEPATITIS AS A PUBLIC HEALTH CRISIS IN THE UNITED STATES

People living with HIV are also disproportionately affected by viral hepatitis; about one-third are coinfecting with either hepatitis B virus (HBV) or hepatitis C virus (HCV), which can cause long-term illness and death. (More people living with HIV have HCV than HBV.) Viral hepatitis progresses faster and causes more liver-related health problems among people living with HIV than among those who are not. Although drug therapy has extended the life expectancy of people with HIV, liver disease—much of which is related to HCV and HBV—has become the leading cause of non-AIDS-related deaths in this population. HIV coinfection more than triples the risk for liver disease, liver failure, and liver-related death

from HCV.

The CDC estimates that 2.7 to 3.9 million persons in the United States are living with HCV and 1.2 million people are living with HBV. In 2016, an estimated 18,153 people died of HCV and 1,698 people died of HBV, either as an underlying or contributing cause of death. With highly effective curative treatments for HCV and treatment and a vaccine for HBV, the federal government must adequately resource HHS, the Veterans Administration, the Department of Justice, and other federal agencies to eliminate viral hepatitis as a public health threat in the United States.

Recommendations for federal action

I. Fully Implement and Resource the National Viral Hepatitis Action Plan, 2017-2020

The National Viral Hepatitis Action Plan, 2017-2020, establishes clear goals, strategies, and indicators for improving the national HCV and HBV responses. HHS should establish an interagency work group and a separate community stakeholder group that follows the principles of meaningful involvement of people living with and affected by HCV and HCV, dedicated to fully implementing the Action Plan and should revive the practice of publishing an annual progress report.

II. Establish and Implement a National Viral Hepatitis Elimination Plan, 2020-2030

The federal government must immediately establish and begin implementing a national plan to eliminate HCV and HBV as public health threats in the United States. The World Health Organization has committed to the goal of eliminating viral hepatitis as a public health threat by 2030. Jurisdictions across the U.S, such as San Francisco, New York, and Louisiana have begun to take concrete steps toward establishing plans to eliminate their local HCV epidemics.

There is already broad consensus among experts that viral hepatitis elimination is feasible. The National Viral Hepatitis Elimination Plan should draw from recommendations from international and local elimination efforts and the National Academies of Sciences, Engineering, and Medicine reports on Eliminating the Public Health Problem of Hepatitis B and C in the United States.

The National Viral Hepatitis Elimination Plan should include:

- a. Opportunities for community engagement in shaping the plan, including meaningful involvement of people living with and affected by HCV and HBV, and groups at higher risk of viral hepatitis infection, such as people who use injection drugs, people with a history of incarceration, and people who are homeless or marginally housed, and people from countries with high HBV prevalence.
- b. Specific HCV and HBV elimination metrics and targets.
- c. Recommendations for federal agencies, as well as the creation of an interagency implementation group required to follow time-based recommendations and targets for federal agencies.
- d. The U.S. Congress and Federal agencies should undertake all necessary actions to ensure that public and private health plans remove restrictions on HBV and HCV treatment that are not medically indicated and offer direct-acting antivirals to all chronic hepatitis C patients.

Ensure that States and public health plans receiving federal dollars remove HCV treatment restrictions that are not medically indicated. In addition, federal agencies and states should eliminate all payer-based barriers to care, such as on-treatment viral load tests and expiration dates on prior authorizations for DAA treatment.

e. The CDC, in partnership with state and local health departments, should support standard hepatitis case finding measures and the follow-up and monitoring of all viral hepatitis cases reported through public health surveillance. CDC should work with the National Cancer Institute to attach viral etiology to reports of liver cancer in its periodic national reports on cancer.

f. The CDC should support cross-sectional and cohort studies to measure HBV and HCV infection incidence and prevalence in high-risk populations.

g. The CDC, the American Association for the Study of Liver Diseases (AASLD), the Infectious Diseases Society of America (IDSA), the American College of Obstetricians and Gynecologists (ACOG), along with the NMA, NHMA, and other targeted community-focused organizations should establish clear recommendations and support detailing for OBGYNs to eliminate mother-to-child transmission of HBV and HCV.

h. The National Committee for Quality Assurance should establish measures to monitor compliance with viral hepatitis screening guidelines and HBV vaccine birth dose coverage and include the new measures in the Healthcare Effectiveness Data and Information Set.

i. Federal and state criminal justice systems should screen, vaccinate, and treat HBV and HCV in correctional facilities according to national clinical practice guidelines. (Since there have been recent hepatitis A (HAV) outbreaks in homeless populations, HAV vaccinations should also be provided at intake.) The federal government should support financing to scale up HCV and HBV treatment in state departments of corrections with mechanisms to ensure that states are following national clinical practice guidelines and track progress toward micro-elimination within state correctional facilities. Federal or state prisons should implement opt-out HCV antibody screening with reflexive RNA confirmatory testing for all persons entering a facility, and case finding for persons who are currently incarcerated but whose HCV status is not known.

j. Syringe Service Programs (SSPs) should receive a significant federal funding investment from SAMHSA and other federal agencies and should be expanded and scaled-up across the nation. Federal agencies should support a multi-pronged approach to improve the health of people who use drugs: increased access to sterile syringes, access to medication-assisted therapy, and HCV treatment and HIV treatment and prevention for people who inject drugs, and other health and mental health services. Agencies should support the authorization of Syringe Service Programs (SSPs), drug user health hubs, and overdose prevention centers (supervised consumption spaces), which reduce HIV, HCV infections and drug overdose fatalities. The federal government should eliminate regulatory, and administrative barriers to evidence-based harm reduction interventions such as syringe exchange programs, medication assisted treatment, and overdose prevention centers.

k. DOJ should reduce at every opportunity the criminalization of people who use drugs and their communities. Drug criminalization is inherently harmful and a primary driver of drug-related harm.

l. DOJ should take action to end the criminalization of viral hepatitis. Local and federal statutes that criminalize viral hepatitis discourage testing and increase stigma. The federal government should promote pre-arrest diversion programs

m. Federal and state agencies should support reimbursement of telemedicine for medically assisted treatment for opioid use disorder to expand the provider base, particularly in rural areas.

n. Federal and state agencies should support the extension of primary care practice licenses for community-based organizations to receive reimbursement for viral hepatitis testing, vaccination and case management services they currently provide for patients who often face stigma in medical settings.

o. CMS should direct the realignment of reimbursement mechanisms to support case management services for Medicare/Medicaid recipients with viral hepatitis and/or substance use disorders.

p. HHS should conduct a fiscal and epidemiological cost-benefit analysis of the federal purchase the rights to a direct-acting antiviral for use in neglected market segments, such as Medicaid, the Indian Health Service, and prisons. This analysis should explore licensing or financing mechanisms.

III. Provide recommendations, resources, and technical assistance for state and jurisdictional plans to eliminate viral hepatitis

- HHS should work with states to build a comprehensive system of care and support for special populations with HBV and HCV on the scale of the Ryan White system (while ensuring that Ryan White is fully funded to address the U.S. HIV epidemic)
- States should expand access to adult hepatitis B vaccination, removing barriers to free immunization in pharmacies and other easily accessible settings.
- The CDC should work with states to identify settings appropriate for enhanced viral hepatitis testing based on expected prevalence.
- The American Association for the Study of Liver Diseases and the Infectious Diseases Society of America should partner with primary care providers and their professional organizations to build capacity to treat hepatitis B and C in primary care. The program should set up referral systems for medically complex patients.
- Similar to what many States have done for people living with HIV to help alleviate the capacity challenges accessing health care, through 1915(C) and 1115 waiver authority under Title XIX of the Social Security Act, State Medicaid programs should expand reimbursement mechanisms to support case management services for recipients with chronic viral hepatitis and/or substance use disorders.
- State Medicaid programs should cover all medically necessary treatment for people with Hepatitis C Virus and remove unnecessarily restrictive prior authorization criteria. State policies that restrict access to direct-acting antiviral medications, through methods such as threshold fibrosis scores or sobriety requirements, violate federal law.

IV. Invest in support for research and surveillance and standard viral hepatitis case finding measures and follow-up monitoring that will advance the goals of the viral hepatitis elimination plan

ELIMINATE TUBERCULOSIS AS AN EPIDEMIC

One fourth of the world's population is living with tuberculosis (TB) and individuals with compromised immune systems such as people living with HIV/AIDS (PLWHA) are at high risk for developing active TB disease and dying. Presently, TB is the leading global infectious disease and the leading infectious cause of death among PLWHA. The World Health Organization estimates that there are 10.4 million new cases each year and 1.6 million deaths globally.⁸⁵ In parts of the world where HIV prevalence is high, drug-resistant TB has reached epidemic levels despite being treatable and curable – contributing to 390,000 deaths among PLHIV.⁸⁶

In the U.S., an estimated 13 million individuals are latently-infected with TB (LTBI) and are at risk for developing active TB disease.⁸⁷ Although the number of PLWHA among the 13 million with LTBI is unknown, the risk of developing TB is significantly increased for PLWHA, with estimates of 16-27 times greater risk than exists for those with LTBI who are also living with HIV.⁸⁸ In 2017, there were 9,093 new cases of active TB in the U.S. and the majority of these cases emerged from the reservoir of individuals with LTBI. While TB has declined nationally, the rate of decline has slowed with some states showing worrisome rising trends in new TB cases, especially among vulnerable populations such as communities of color, homeless, elderly and PLHIV. In 2016, approximately 6% of TB cases were among PLWHA, but not all states report HIV status with TB cases, so this is an underestimated of the true prevalence.⁸⁹ The impact of the disease is horrific; if left untreated, TB kills about 55% of PLWHA, nearly all of whom are dually-diagnosed.⁹⁰

A heavily publicized TB outbreak in Marion, Alabama posted an incidence rate about 100 times greater than the rest of the state and was considered higher than in many developing countries – overlapping with the well-documented HIV and poverty epidemic in the deep Southern U.S.⁹¹ Further, seemingly low-burden states such as Colorado and Wisconsin have shown increases of 37% to 45% in their TB rates respectively.

High-burden states such as New York also are seeing increases. New York City in particular saw a peak in cases in 1992, at the height of the HIV/AIDS epidemic, costing nearly \$1 billion in resources to control, and catalyzing an influx of new resources and attention from the federal government. However, presently New York City is reporting its largest increase in new TB cases in over 25 years.⁹² This situation, along with current national trends in TB incidence, concerns public health officials that TB is on the rise, following years of successfully driving down the epidemic, and more recently maintaining a plateau with very limited resources.

Years of stagnant funding at the CDC Division of TB Elimination (DTBE), the lead federal agency of our nation's domestic TB program, has placed immense resource constraints for frontline TB controllers and public health workers. Following the historical epidemic in the U.S. in the early 1990's, the federal government provided a substantial boost in new resources to DTBE to \$142.2 million.⁹³ Since then, decades of declining funding have led to the deterioration of public health infrastructure and limited the capacity of TB programs to provide prevention, treatment and monitoring efforts, and prevent and respond to outbreaks, especially to emerging drug-resistant forms of TB. This stagnation of funding is seen across all the domestic programs housed in CDC's National Center for HIV, Hepatitis, STI, and TB Prevention (NCHHSTP).

⁸⁵ <http://www.who.int/news-room/fact-sheets/detail/tuberculosis>

⁸⁶ http://www.unaids.org/sites/default/files/media_asset/UNAIDS_FactSheet_en.pdf

⁸⁷ <https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/tb-in-the-us-a-snapshot.pdf>

⁸⁸ <http://www.who.int/hiv/topics/tb/en/>

⁸⁹ <https://www.cdc.gov/hiv/pdf/library/factsheets/hiv-tb.pdf>

⁹⁰ http://www.who.int/tb/publications/tbhiv_factsheet.pdf

⁹¹ <https://harpers.org/archive/2017/06/where-health-care-wont-go/>

⁹² <https://www1.nyc.gov/assets/doh/downloads/pdf/tb/tb2017.pdf>

⁹³ http://www.treatmentactiongroup.org/sites/default/files/crag_tbtc_brief_1_10_18.pdf

Lack of political commitment and complacency has led to issues such as acute and chronic TB drug shortages, market instability and price spikes of key treatments needed to both prevent future outbreaks, but also address ongoing public health crises. Additionally, individual treatment and hospitalization costs increase for the treatment of drug-resistant TB. The CDC estimates that a single case of drug-susceptible TB can cost \$18,000 to treat and upwards of \$134,000 for a single case of multi-drug resistant (MDR-TB) and upwards of \$400,000 for extremely-drug resistant (XDR-TB).⁹⁴ All these costs coming at the expense of extremely scarce and precious public-sector resources.

Due to years of limited investment in research and development, current TB treatments are lengthy with high pill burden and in some cases daily injections, with side-effects ranging from hearing loss to mental health issues – making it difficult for vulnerable communities to achieve cure. Only two new drugs have been developed in the past 40 years, with only one of them being FDA-approved. Increasing resources for TB across federal research institutions from basic sciences to product development is needed to provide public health practitioners with new tools to combat all forms of TB, but more importantly to improve treatment adherence and outcomes among those with TB, as well as effectively reduce harmful side-effects of TB treatments.

Ending the epidemic nationally, along with HIV, viral hepatitis, and STIs, is similarly achievable for TB. A multi-pronged strategy of increasing resources for DTBE, and overall for NCHHSTP, combined with strengthening our TB programs across the country and the nation's biomedical research engine for TB is needed to put the U.S. back on the path of elimination, and will only happen through political will. By doing so we prevent illness and deaths, particularly among vulnerable communities, from a disease that is preventable, treatable and curable.

Recommendations for federal action

I. Support local and state TB elimination efforts

- Opportunities for the community to draft the elimination plan including providers who treat TB and LTBI, persons with medical conditions at high-risk for developing active TB (such as HIV) and other individuals who would benefit from preventive treatment.
- Support for reporting, with the following conditions, of LTBI to obtain better estimates of LTBI burden and focus intervention efforts on areas with high rates of rates of infection
 - Reporting should focus on incentives not penalties
 - Where they exist, penalties for not reporting must be rooted in civil, not criminal, law
 - Reporting must be accompanied by strict standards for data protection, privacy, and confidentiality and must be separated from the enforcement of immigration-related laws, rules, and regulations
- Setting TB elimination targets and performance measure nationally.
- CMS expanding reimbursement for testing and treatment of LTBI using the latest diagnostic and treatment options.
- Support use of local epidemiology to identify high-risk populations to inform targeted testing and treatment efforts.

II. Support national TB elimination efforts

⁹⁴ https://wwwnc.cdc.gov/eid/article/20/5/13-1037_article

- Support the development and implementation of a national LTBI surveillance system currently being piloted by CDC to obtain better estimates of LTBI burden and focus intervention efforts on areas with high rates of infection
- Incorporate indicators into the national LTBI surveillance system that capture LTBI diagnosis and treatment during pregnancy and the postpartum period to inform intervention efforts in this particularly vulnerable population
- Fund the Division of TB Elimination (DTBE) to implement a LTBI prevention initiative to prioritize prevention among those highest-risk for active TB.

The federal government must commit funding to a level of least \$195.7 million for DTBE, with at least \$35 million to begin supporting a LTBI prevention initiative that prioritizes testing and access to treatment for those communities at highest-risk of transition to active TB disease, which includes PLHIV.

- Implement the National Action Plan (NAP) to Combat Multidrug Resistant TB (MDR-TB) with appropriate levels of funding.

This seminal plan was developed as a cross-agency collaboration and introduced in late 2015. The NAP outlines essential steps to address drug-resistant TB both globally and domestically and was heralded as a thoughtful, comprehensive and strategic plan. However, despite its potential as a pathway to combat MDR-TB, the NAP was introduced without funding. The federal government must commit funding for USAID and DTBE to successfully implement the NAP and bring the U.S. and the world closer to addressing the deadlier drug-resistant forms of TB.

III. Consider novel strategies to stabilize and maintain supply for vital TB drugs.

The TB drug supply is prone to shortages and supply disruptions, primarily due to the vulnerabilities associated with single manufacturers of the first-line drugs used to treat TB. U.S. TB control programs need access to affordable and available medications, including those medications and combination regimens not currently available in the U.S. This includes appropriately dosed pediatric fixed-dose formulations of first-line TB drugs.

The federal government should prioritize addressing this TB drug supply vulnerability to maintain the supply of TB medications, including consideration of a centralized procurement system, allowing procurement from the Global Drug Facility (GDF) which is largely supported by U.S.-funding but from which U.S. TB programs are unable to access. Impactful programs modeled after ADAP that can potentially expand access to TB treatment are desperately needed for the TB community.

IV. Strengthen TB research and development undertaken by the Tuberculosis Clinical Trials Consortium (TBTC) at CDC and other agencies

Congress must expand resources to strengthen current and future clinical research undertaken by the TBTC at CDC for the development of new and needed diagnostics, prevention, and treatments to combat all forms of TB, but also improve adherence, minimize side-effects, and shorten timelines to cure. This includes increased resources for HIV/TB comorbidities research at the National Institutes for Health, National Institute for Allergy and Infectious Diseases (NIAID). Additional resources and mandate to expand TB research is needed across U.S. Agency for International Development (USAID), Department of Defense Congressionally Directed Medical Research Programs (CDMRP), and the Biomedical Advanced Research Development Authority (BARDA).

With many countries across the world also mobilizing to contribute their 'fair share' in research funding for TB, the U.S. government should boost their contributions to TB research to at least \$444.5 million. This is a recommended increase of \$128.0 million, spread across the aforementioned agencies and additionally include the Office of the Global AIDS Coordinator (OGAC), the Food and Drug Administration (FDA), and the National Science Foundation (NSF).

PROVIDE UNIVERSAL HEALTH CARE ACCESS

A universal health care system would be more economical, eliminate financial barriers to care, afford people a choice of doctor/hospital, stop medical-related bankruptcy, and cover all medically necessary care. Public health care systems are better equipped to deal with a public health crisis, moving us closer to ending the epidemic because of the emphasis on primary care.

Many gaps exist in health coverage for Americans, especially people living with HIV and other serious medical conditions. While the ACA did a great deal to expand coverage to people living with HIV, particularly through the Medicaid expansion, "individuals who live in non-expansion states and are below 100% Federal Poverty Level (FPL) fall into what is known as the "coverage gap" – neither eligible for the Medicaid program nor subsidies to make purchasing coverage through the Marketplaces more affordable. It is estimated that there are over 2.5 million individuals in the coverage gap, including thousands with HIV."

The fragmented nature of our health care system creates a lot of "churn," that is, moving in and out of a healthcare setting or moving from different types of coverage to no coverage based on changing jobs, losing income, moving, getting married, etc. With each new plan comes new challenges in accessing the preferred doctors and formularies, with potentially devastating consequences for patients who have chronic health conditions. It is not unusual to experience gaps in access to necessary medications because of these bureaucratic issues, to the detriment of everyone.

There are also many examples of private health insurance companies prioritizing profits over the well-being of their patients. A few years ago, Blue Cross Blue Shield refused to accept premium payment checks from the local Ryan White Program. Another common and problematic practice of private health insurance companies is offering drug formularies that are too expensive for people with chronic conditions like HIV.

To eliminate HIV as an epidemic, it is crucial that PLWH have affordable high-quality health coverage that includes continuous access to ART. But it is also crucial that persons who may be at risk for HIV acquisition have access to health care including a wide array of preventative services including screening for HIV and other STIs, access to PrEP and PEP, and access to mental health services and treatment for substance use disorders.

Recommendation for federal action

The federal government must ensure that all people living within the United States have access to universal healthcare

The government should guarantee that every single resident in the United States can obtain high-quality, low-cost health care, when they need it, regardless of age, income, or pre-existing condition. This care should be at least as good as we have currently, and cost only what we can afford out-of-pocket: free for people with low incomes and a modest sum for middle income people.

Preventing New Transmissions

The most effective prevention measure is to identify PLWHA through testing, facilitate immediate treatment, and assist everyone living with HIV in staying on their HIV medications so that they remain healthy and their viral loads reach and are kept at undetectable levels, thus preventing sexual transmission of the virus.

We must also expand access to PrEP and PEP for key populations to keep them HIV negative, increase access to mental health, harm reduction and substance use disorder treatment services; decrease the comorbidities of sexually transmitted infections (STIs), viral hepatitis and tuberculosis; and recognize the key role of substance use disorders in maintaining the syndemics of STIs and viral hepatitis.

INCREASE TESTING AND LINKAGE TO CARE

Ensuring that all individuals living with HIV, and those vulnerable to HIV, are tested in a timely fashion, are covered by or placed in appropriate insurance coverage, and immediately linked to care is critical to ending the epidemic. The goal is to have 90% of people living with HIV aware of their status by 2020 and linked to insurance and care within 30 days. Although we are fairly close to this goal at 85%, there are still 162,500 people undiagnosed.⁹⁵ It should also be noted that the rates of people undiagnosed with HIV is not evenly distributed, as disparities in diagnoses exist geographically and in key populations and can be much higher than the average. There are far too many avoidable delays in diagnosing HIV. The CDC released an analysis in December 2017 showing that 1 in 2 people with HIV have been living with the virus for at least 3 years before diagnosis. One in four have been living with HIV for 7 or more years, and 7 in 10 people most vulnerable to HIV infection saw a healthcare provider but were not tested for HIV.⁹⁶

While a focus on people who are undiagnosed is important, the fact remains that two-thirds of new infections are caused by people living with HIV aware of their diagnosis but not in care. The National HIV/AIDS Strategy has a goal of ensuring that 80% of those who are diagnosed with HIV achieve viral load suppression. Multiple modelling analysis have demonstrated that increasing the durability of viral suppression by ensuring continuous retention in care will have a greater long-term impact on the number of new transmissions as well as the health of each individual living with HIV. If PLWH are covered by insurance and retained in care and the 80% viral load suppression goal is met, an estimated 168,000 infections would be prevented over the next five years. By comparison, only increasing the use of PrEP would prevent an estimated 48,000 infections over five years. Both approaches are critical.

Efforts should be made to expand access to HIV treatment and PrEP among people of color, especially gay and bisexual men and transgender women, there needs to be providers who are: (1) willing and equipped to discuss sexual behavior; (2) willing to treat those with HIV and to prescribe PrEP; and (3) willing to provide respectful and appropriate care, free of stigma and judgment with a contextualized understanding of race.

Recommendations for federal action

I. Promote the U=U message to the U.S populace

⁹⁵ CDC. (2018, August 6). *HIV in the United States: At a Glance*. Retrieved from <https://www.cdc.gov/hiv/statistics/overview/ataglance.html>

⁹⁶ CDC.(2017, November/December). Retrieved from <https://www.cdc.gov/vitalsigns/pdf/2017-12-vitalsigns.pdf>

The CDC should launch a widespread “*HIV Undetectable = Untransmittable*” social marketing campaign to individuals, providers, and educators to consistently share the message and overwhelming evidence that demonstrates that a person living with HIV who has a sustained, undetectable viral load cannot sexually transmit HIV to another person.

II. Review and relaunch the CDC recommendation that everyone should be tested at least once

Since 2006, CDC has recommended that all Americans aged 13 to 64 get tested for HIV at least once as part of routine health care, and that people with certain factors like community prevalence should get tested more often. This recommendation needs to be implemented with a fresh marketing campaign, both to clinicians and individuals. For sexually active adults, routine testing should always be offered by medical providers.

III. Improve age-specific testing programming

We must increase CDC funding streams for innovative outreach and testing for youth. According to the CDC, people ages 13 to 24 represent the age group with the highest rate of undiagnosed HIV, with 51% of teenagers and young adults living with HIV were undiagnosed as of 2013. In numbers, more than 31,000 youth are undiagnosed out of an estimated 60,900 youth living with the disease. Disproportionately high rates of new HIV transmissions also occur among individuals ages 25 to 34. While a ramp up and intensity needs to focus on young people, CDC must also think about tools and interventions to help maintain health status as across the life span.

IV. Expand testing for aging populations

Adults age 50 and older account for 15 % of all new HIV diagnoses and 29% of all people living with HIV. Research shows that heterosexual and LGBTQ older adults are sexually active well into their mid-80s with a 2007 national study showing 53% of adults age 65-74 and 26% of adults age 75-85 report having one or more sexual partners, yet CDC guidelines recommend routine testing for people only up to age 65, leaving out people over age 65 who could benefit from regular HIV testing. Few national or regional HIV prevention campaigns explicitly target older people, especially older people of color and LGBT older people. CDC should update their recommendations to anyone who reports high risk activity, regardless of age.

V. Promote more frequent HIV testing for those who report recent or regular high-risk activity

The CDC's August 2017 recommendations regarding the benefits of regular HIV testing of gay and bisexual men need further promotion and clarification. First, the CDC should invest in widely promoting the screening campaign and educational materials to clinicians and varied health care settings. As educational outreach efforts to clinicians who are outside of the usual public health channels need targeted, identifying the settings and types of providers who are missing even routine annual screening and providing education and materials to them is critical. The CDC must better explain the difference between screening a defined population and testing individuals for whom testing may be medically warranted and emphasize the importance of prompt testing of individuals who present with symptoms indicating possible HIV infection, or who report recent high-risk activity, or a pattern of such activity. In addition, public health agencies in some urban

areas hard-hit by the epidemic – particularly among MSM of color and transgender women – are urging more frequent screening of sexually active MSM. (e.g., once every 3 or 6 months).⁹⁷

VI. Provide support for primary trainings and continuing education for providers through CDC and HRSA in crosscutting cultural responsiveness

We must rethink our assumptions about risk and risk assessment. Traditional risk assessment describing groups with higher rates of HIV incidence as “high-risk” contributes to stigma and may make people less likely to seek services. To provide effective HIV treatment and prevention, we need providers to eliminate terminology that can be stigmatizing. Moreover, provider biases may cause a clinician to improperly assess someone’s risk.

To address provider implicit biases, trainings for current and future providers that increase racial and sexual orientation/gender-related cultural competencies need to be expanded and routinized, as well as models for integrating biomedical interventions in clinical and non-clinical settings.

VII. Provide funding for independent HIV popular opinion leaders at grassroots level

Funding for special projects and initiatives including social media marketing campaigns at the community grassroots level could maximize the effectiveness and augment the work of independent popular opinion leaders (POLs). The recommendation includes the development of a special council to award this funding directly to independent POLs who can make the largest positive impact. Independent POLs at the community grassroots level have demonstrated their unyielding commitment and ability to reach population groups (such as people living with HIV not in the system of care and those who need to be diagnosed) that aren’t being reached any other way. They can physically and digitally reach these groups through community grassroots efforts that have been widely successful. The U=U message is a proven example of a social marketing campaign spearheaded by independent POLs that has gained tremendous support and momentum.

VIII. Decriminalize sex work

Decriminalizing sex would prevent 33-46% of new HIV cases among sex workers and clients, according to the Lancet.⁹⁸ Decriminalizing sex work would have a greater impact on reducing new HIV transmissions than increased access to antiretroviral therapy, safer work environments, or elimination of sexual violence. It would also vastly reduce violence against sex workers.

IX. Provide comprehensive and integrated health programs to ensure equitable access to health services for individuals involved in all forms of sex work

Sex workers are at increased risk for HIV, but due to stigma associated with sex work and the fear of being not only judged but criminally prosecuted, many sex workers may avoid STI and HIV testing, or seeking HIV treatment or PrEP services. Because many policing jurisdictions use condoms as evidence of sex work in arrests, even accessing free condom programs at most CBOs or clinics can be undesirable for sex workers. In addition to working with sex workers,

⁹⁷ DiNenno, E. A., Prejean, J., Irwin, K., et al. (2017). Recommendations for HIV screening of gay, bisexual, and other men who have sex with men – United States. *MMWR*. 66(31): 830–832.

⁹⁸ Shannon, K., Strathdee, S., Goldenberg, S., Duff, P., Mwangi, P., Rusakova, M., et al. (2014). Global epidemiology of HIV among female sex workers: influence of structural determinants. *The Lancet*. 385 (9962): 55-71.

people who seek their services should also be engaged in testing, prevention and treatment programs, which can offer sex workers additional protection from clients living with HIV, who may or may not be on treatment and virally suppressed. Funding programs and support groups for sex workers can create group solidarity and empowerment and can be more cost-effective than criminal justice approaches.

X. Sustain funding for the Title X program and repeal the “domestic gag rule”

In rural and medically underserved urban areas in every state, Title X clinics are often the only source of both HIV and STI screening and other preventive services for low-income women and LGBTQ populations at higher risk for acquiring HIV. Prior to the 2015 HIV outbreak in Scott County, Indiana, a family clinic that was a critical source for HIV screening to county residents closed due to lack of funding, allowing a serious HIV outbreak to spread for too long without detection. The opioid epidemic in America has created many potential Scott Counties, and one lesson that should have been learned is that more prevention services—not fewer—are needed to prevent new HIV, and hepatitis C, outbreaks. Maintaining funding for Title X is important to the HIV response and to women’s health. Title X funding must be maintained without restrictions such as the proposed “domestic gag” rule that violates the Medical Code of Ethics and would be an unacceptable intrusion of the doctor-patient relationship.

INCREASE THE USE OF BIOMEDICAL PREVENTION INTERVENTIONS

The daily use of tenofovir disoproxil fumarate and emtricitabine (TDF/FTC) by HIV negative people -- known as pre-exposure prophylaxis (PrEP) -- is the most effective method of primary HIV prevention known. Consistent, daily use of TDF/FTC is associated with a 99% reduction in risk of HIV acquisition sexually, while the scale up of TDF/FTC PrEP programs in the “real world” are associated with a 86% reduction in the number of new HIV transmissions in treated populations. According to a new CDC analysis released on March 6, 2018, “...only a small percentage of Americans who could benefit from PrEP ... have been prescribed it.” Further, although “two-thirds of people who could potentially benefit from PrEP are African-American or Latinx, they account for the smallest percentage of prescriptions to date”.⁹⁹ And according to AIDSvu.org, although the South accounted for more than half of all new HIV diagnoses in the U.S. in 2016, it accounted for only 30% of all PrEP users. Although PrEP is a highly effective, woman-controlled prevention option for HIV-negative women, PrEP use among women has been very low. Women comprise only 20% of those who have initiated PrEP, and Black women were over four times less likely to have initiated PrEP compared to white women.¹⁰⁰

We should also ensure that individuals have access to post-exposure prophylaxis (PEP) as part of the overall prevention toolbox. PEP is likely underutilized as awareness is often low among those who would most benefit and mechanisms for timely access are inadequate. For those who think they may have been exposed to HIV, better awareness and immediate access to PEP is needed. PEP is also seen as a bridge to PrEP for those with recurrent high-risk events.

⁹⁹ <https://www.cdc.gov/nchhstp/newsroom/2018/croi-2018-PrEP-press-release.html>

¹⁰⁰ Kwakwa, H. A., Bessias, S., Sturgis, D., Walton, G., Wahome, R., Gaye, O., Jackson, M. (2018, February 1). Engaging United States Black Communities in HIV Pre-exposure Prophylaxis: Analysis of a PrEP Engagement Cascade. *Journal of the National Medical Association*. <https://www.sciencedirect.com/science/article/pii/S002796841730189X>.

Recommendations for federal action

I. Facilitate the creation of national or state PrEP Drug Assistance Programs (PrEP DAP)

Expansion of PrEP drug assistance is needed to ensure equitable access to this crucial tool. Several states have created PrEP DAPs in order to increase access to drug, labs, and clinical care for providing and monitoring PrEP. Similar to ADAPs for people living with HIV, PrEP DAPs can potentially serve as the payer of last resort for low-income HIV negative people who are either uninsured or underinsured and are therefore unable to afford PrEP and its associated laboratory testing and follow-up care. In addition to providing free PrEP and fee-for-service reimbursement to contracted labs and providers, premium and cost-sharing for uninsured individuals may be possible under established financing mechanisms.

While there are legal restrictions on the use of Ryan White funds to serve HIV negative individuals, states may use the federally funded infrastructure to run and staff state or locally funded PrEP DAP programs. (1) States should work with HRSA to clarify rules related to the use of ADAP infrastructure, and implement models that integrate federal, state, and local resources to run statewide PrEP programs. (2) Congress could expand the use of Ryan White funds, notably those for Part C Early Intervention Services, to include biomedical primary HIV prevention methods in modernization of the program during a congressional review, (3) a separate federal funding stream for biomedical comprehensive prevention services could be created to fund, or supplement HRSA funding of, PrEP DAP programs at the state level, and (4) a PrEP DAP Task Force, similar to the ADAP Crisis Task Force, should be formed to ensure discounted purchasing of current and future PrEP modalities on behalf of state PrEP DAPs.

II. Ensure that TDF/FTC and future biomedical prevention tools are affordable and fund programs to expand access to PrEP at a national-level scale

To achieve the greatest potential benefit, access to TDF/FTC PrEP must be scaled up for all individuals at risk for HIV and most especially for vulnerable populations that currently are greatly underutilizing this intervention. At the same time, jurisdictions including the federal government would be better able to purchase TDF/FTC to prevent HIV at a population level if the price were lower. The wholesale acquisition cost (the list price before negotiated discounts with payers) of Truvada – the only version of TDF/FTC available in the United States -- is more than \$1,600 per 30-day supply¹⁰¹, despite generic versions costing less than \$6 internationally.¹⁰² All payers should and must be required to cover Truvada for PrEP, but its high price – even after manufacturer discounts and rebates are applied – continues to be met with restrictive barriers implemented by public and private payers to discourage its use, the exact opposite of the desired outcome.

Achieving a cost-effective pricing point for a national access program must become a high priority. Gilead Sciences, the manufacturer of Truvada, has established PrEP access programs for low-income, uninsured individuals and insured individuals with prohibitive out-of-pocket expenditures (deductibles, copays, or coinsurance costs). However, these programs are too small

¹⁰¹ United States Department of Health and Human Services, Centers for Medicare and Medicaid Services. (2018, August 28). National Average Drug Acquisition Cost Database. Retrieved from <https://data.medicare.gov/Drug-Pricing-and-Payment/NADAC-National-Average-Drug-Acquisition-Cost-/a4y5-998d>

¹⁰² Hill, A. M., Pozniak, A.L. (2016, October 5). How can we achieve universal access to low-cost treatment for HIV? *Journal of Virus Eradication*. 2(4):193-197. Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5075345/>

to scale up the use of PrEP at a national level and are not able to meet the needs of all people vulnerable to HIV in the U.S. For example, copay accumulators prevent commercial copay assistance programs from defraying high deductible costs.

Additionally, some commercial payers (e.g., Medicare Part D plans) prohibit the use of any commercial or other third-party copay assistance. Dramatically scaling up access to PrEP must be an essential component of any effort to end HIV as an epidemic. A dramatic reduction in the price of TDF/FTC by Gilead Sciences, or a commitment from the company to provide the drug at minimal cost to all individuals and health systems who cannot access it otherwise, could help mitigate these barriers.

Regardless, the federal government must act to ensure that access to TDF/FTC is affordable and sustainable. Some options that might be considered include establishing federal funding for PrEP DAPs and the creation of a task force to secure free drug or sub-340B discounts on current and future PrEP modalities (per the recommendation above) and ensuring that local public health offices have free PrEP starter packs and navigation services to a PrEP program, voluntary licensing agreements between the patent-holder and the federal government, compulsory licensing under patent or copyright law (28 U.S.C. §1498), potential invocation of march-in rights (35 U.S.C. §203), or other similar mechanisms.

Most importantly the federal government must scale up TDF/FTC at the level necessary for population-wide prevention. Funding and access must be provided not only specifically to TDF/FTC but also for associated medical and laboratory costs including testing for STIs.

III. Support implementation of the U.S. Preventive Services Task Force’s “A” rating to PrEP as a primary prevention intervention

The U.S. Preventive Services Task Force (USPSTF) has determined PrEP to be a primary prevention intervention within its scope of review. USPSTF had been waiting on completion of 12 U.S. based studies that were open in 2016 at the time of its determination that should now be final. The clear evidence in their review and subsequent “A” grade of PrEP as an intervention will help ensure PrEP is fully integrated into regular provider practice as well as standard insurance coverage.

IV. Federal agencies should increase efforts to educate providers regarding both PrEP and PEP

Many of the same barriers prevent individuals from accessing PEP as for PrEP, including lack of provider awareness and/or knowledge and lack of healthcare coverage, particularly in the Deep South. Federal agencies should increase efforts to educate and train infectious disease and non-infectious disease providers, including primary care and pharmacists, regarding both PrEP and PEP.

V. CDC funding of projects for PrEP should allow flexibility in the use of funds to pay for labs and provider time

Despite the fact that some financial assistance is available to prospective PrEP users to help cover the costs of the drug, for many individuals, particularly uninsured individuals, gaining access to PrEP can still be a costly and, in some cases, prohibitively complicated, process. Successful utilization of PrEP requires a number of actions beyond just taking the daily

medication--including frequent medical visits, regular HIV tests and other lab tests, all of which involve additional expenses that may or may not be covered by insurance or other financial assistance programs. CDC funding for PrEP projects should allow funds to be used to pay for necessary labs and medical visits.

VI. Target and incentivize non-traditional venues to offer PrEP

Black men who have sex with men, individuals who inject drugs, and other populations who are higher risk for HIV are less likely to have access to routine medical care. Creative and innovative partnerships should be supported to offer PrEP to individuals where they are including in community-based programs, health centers, Title X clinics, syringe services programs and substance use treatment programs.

SCALE UP HARM REDUCTION & SUBSTANCE USE DISORDER TREATMENT SERVICES

Drug use continues to be a major factor fueling the HIV epidemic, both through sharing injection equipment and through sexual risk behaviors associated with drug use. The opioid crisis that is gripping the U.S. is fueling increases in new viral hepatitis infections through injection drug use, which also increases risk for HIV. Infected injection equipment results in 3,000 to 5,000 new cases of HIV and approximately 10,000 new cases of hepatitis C in the United States each year.

The number of HIV diagnoses among people who inject drugs (PWID) in the United States had declined substantially over the past decade, then increased slightly in 2015, the year of a large HIV outbreak among PWID in Scott County, Indiana. Even if you remove the Scott County cases, declines in HIV rates among PWID stalled nationally during 2014-2015. The growing number of PWID in the United States demands increased preventative services so that longstanding gains in preventing HIV among PWID are not reversed. Furthermore, as many people with substance use disorders are dually diagnosed with mental health conditions, increased access for mental health services is needed, and many (especially rural) areas have few or even no nearby treatment services available.

Key steps include expanding access to medication-assisted treatment and access to sterile syringes through syringe services programs (including mobile service systems) that can offer testing for HIV and viral hepatitis and connect clients to treatment for infection, mental health, and for substance use disorders.

Recommendations for federal action

I. Strengthen and expand federal support for Syringe Service Programs (SSPs)

SSPs are a proven and cost-effective HIV and hepatitis prevention tool, providing PWID with sterile injection equipment, overdose prevention education, naloxone, and related health messaging to reduce the potential harms of injection drug use and improve their overall health. These services are frequently the only pathway for people who inject drugs to substance use disorder treatment programs as well as other public health, medical, mental health, and social services.

Congress must ensure that SSPs remain a key part of the federal effort to respond to the current opioid epidemic and end the HIV and viral hepatitis epidemics. Additional support to federal viral hepatitis programs will help scale up SSPs in areas seeing the highest number of new infections of HIV and hepatitis C related to injection drug use, increase education resources and increase linkages to infectious diseases testing, and increase the availability of medication assisted therapy within harm reduction programs. Additionally, HRSA and SAMHSA funding to expand

medication-assisted treatment and overdose prevention programming must include funding support for syringe services programs' crucial role in delivering and linking people who use drugs to these services and should foster the development of innovative service models such as mobile units.

II. Update the DOJ's Model Drug Paraphernalia Act to assist state reform efforts

In 1979, the White House requested that the DOJ Drug Enforcement Administration (DEA) draft legislation that individual states could enact to combat the sale and distribution of illicit drug paraphernalia. The result was the Model Drug Paraphernalia Act, and at least 45 states and the District of Columbia adopted laws that criminalized the possession of drug paraphernalia based on this Act. The term "drug paraphernalia" is widely defined in these statutes to include any equipment, product, or material of any kind that is primarily intended for use in introducing controlled substances into the human body. Typically, hypodermic syringes and needles were seen to fall within this domain.

At the time, the health consequences of making sterile injection equipment more difficult to obtain were unknown, and the spread of hepatitis C and HIV was not understood. As states have changed their laws to allow syringe services programs, they have taken various approaches to language categorizing injection equipment as drug paraphernalia. The DOJ should revise the Model Drug Paraphernalia act to modernize this recommendation, paving the way for states to more easily revise their laws. The new definition of drug paraphernalia must explicitly exclude injection equipment. For example, Nevada's updated paraphernalia law states, "The term does not include any type of hypodermic syringe, needle, instrument, device or implement intended or capable of being adapted for the purpose of administering drugs by subcutaneous, intramuscular or intravenous injection."¹⁰³

III. Increase access to substance use disorder treatment

Evidence-based drug treatment programs have been shown to reduce HIV transmission among injection and non-injection drug users by reducing the frequency of drug use, risk behaviors, and infections.¹⁰⁴ Drug treatment programs that utilize medication-assisted treatment – such as methadone and/or buprenorphine – drastically reduce overdose mortality and improve access and adherence to antiretroviral treatment. Injection drug users living with HIV who engage in evidence-based drug treatment are more likely to achieve sustained viral suppression.¹⁰⁵ Congress should support increasing resources for comprehensive substance disorder and addiction treatment – including resources to support syringe services programs' linkage-to-care activities – as part of our HIV prevention strategy.

IV. Increase the workforce for medication-assisted treatment by providing ongoing training opportunities for care providers, including those in Ryan White Program clinics.

V. Integrate Screening for HIV, Viral Hepatitis and STIs into Substance Use Treatment Programs

¹⁰³ Justia US Law. (2013). 2013 Nevada Revised Statutes Chapter 453 - Controlled Substances NRS 453.554 - Drug paraphernalia defined. Retrieved from <https://law.justia.com/codes/nevada/2013/chapter-453/statute-453.554/>

¹⁰⁴ Metzger, D., Woody, G.E., & O'Brien, C. P. (2010, December 1) Drug Treatment as HIV Prevention: A Research Update. *Journal of Acquired Immune Deficiency Syndromes*. 55(Suppl 1): S32–S36.

¹⁰⁵ Metzger, D. & Zhang, Y. (2010, November). Drug treatment as HIV prevention: expanding treatment options. *Curr HIV/AIDS Reports*, 2010 Nov;7(4):220-5. doi: 10.1007/s11904-010-0059-z.

VI. Co-locate medical care with behavioral health programs including substance use and mental health treatment

Co-location of medical and behavioral health care including substance use, mental health treatment and supportive services is critical to facilitate access to the range of services that individuals living with HIV and substance use and mental health disorders need to improve short and long-term health outcomes (especially for those in rural areas). Providing incentives for substance use and mental health treatment programs to partner with Ryan White clinics could expand access to these services while maximizing the impact of funding for all programs.

ENSURE YOUNG PEOPLE HAVE ACCESS TO COMPREHENSIVE, AGE-APPROPRIATE, EVIDENCE-BASED SEXUAL HEALTH EDUCATION

More comprehensive, age-appropriate, culturally appropriate, and evidence-based sexual health education for youth and young people. One of the driving factors behind increasing STI/HIV transmissions among young people in many states is the lack of comprehensive sexuality education (CSE). What's more, many of the stigmatizing curriculum programs that are not medically accurate receive pass-through Title X funds. The New York City Mayoral Sexual Health Education Task Force's "Sexual Health Education in New York City: Findings and Recommendations" report compiles national data and builds a strong case that comprehensive sex education equips young people with the skills, knowledge, and confidence to make healthy decisions about their sexual health, including reducing behaviors that may put them at risk for HIV and other STIs.¹⁰⁶

Recommendations for federal action

I. Support increased funding for, and protecting the original evidence-based intent of, adolescent sexual health promotion programs, including the CDC's HIV School Health efforts through the Division of Adolescent and School Health (DASH), the Teen Pregnancy Prevention Program (TPPP) through the Office of Adolescent Health, and extension of the Personal Responsibility Education Program (PREP) through the Family and Youth Services Bureau (FYSB).

Congress provides funding for evidence-based and innovative approaches to adolescent sexual health promotion programs that are medically accurate and age-appropriate through FYSB's PREP, the CDC HIV School Health program, and OAH's TPPP. These programs support implementation of CSE components and prioritize prevention of unintended pregnancy, HIV, and other STIs among young people.

II. Eliminate federal funding for abstinence-only-until-marriage programs, including the Title V "Sexual Risk Avoidance Education" state-based grant program.

Since 1981, the federal government has spent over \$2 billion on ineffective and shaming abstinence-only-until-marriage programs. Most recently in FY 2018, the Title V "Abstinence Education" state-grant program was renamed the "Sexual Risk Avoidance Education" program. It now mandates that grantees adhere to strict program requirements that often prohibit from

¹⁰⁶ Sexual Health Education TaskForce. Sexual Health Education in New York City: Findings and Recommendations. (2018, July 17). Retrieved from <https://www1.nyc.gov/assets/genderequity/downloads/pdf/Sex-Ed-Task-Force-Report-2018.pdf>

teaching young people about the benefits of condoms and contraception. These programs also fail to address the needs of young people who are already sexually active, survivors of sexual abuse, and LGBTQ youth. The federal government also supports another federal funding stream (established in FY 2015) called the "Sexual Risk Avoidance Education" (SRAE) competitive grant program. As of FY 2019, this program was funded at \$35 million--a seven-fold increase in funding since its inception. It is past time to end funding for these programs. Decades of research prove that they are ineffective at achieving their intended goal of getting young people to remain abstinent until marriage, and, too often, shame or fail to address young people's lived experiences.

III. Support the Real Education for Healthy Youth Act (REHYA), which would provide the first-ever federal funding for comprehensive sex education for young people in elementary and secondary schools and institutions of higher education.

It also establishes teacher training for school-based sex education, amends current federal law to enable LGBTQ-inclusive education, and allows the provision of condoms and contraception on school grounds. Additionally, REHYA prohibits spending federal funds on programs that withhold life-saving information about sexuality-related topics; are medically inaccurate; promote gender stereotypes; are insensitive or unresponsive to the needs of young people who are sexually active, LGBTQ, survivors of sexual abuse or assault, of varying abilities, and/or pregnant or parenting; or are otherwise inconsistent with the ethical imperatives of medicine and public health.

IV. Support the Youth Access to Sexual Health Services Act (YASHS), which would provide grants to increase and improve the linkage and access of marginalized young people, who have some of the nation's highest rates of new HIV cases, to sexual and reproductive health care and related services.

To ensure lifelong sexual health, all young people need information about, and access to, affordable, youth-friendly, and linguistically and culturally competent health care, as well as providers who respect patient privacy and support them in making their own choices. Unfortunately, far too many young people in the United States face barriers—including stigma and discrimination, lack of knowledgeable providers, cost, transportation, and perceived lack of confidentiality—that prevent them from accessing recommended and necessary sexual health services. These barriers contribute to health challenges and disparities, as evidenced by the continued high rates of HIV and other sexually transmitted infections (STIs), and unintended pregnancy among young people. The YASHS Act would enable our nation's most vulnerable youth to bridge these barriers by providing communities with resources to support partnerships and programs that: 1) Equip young people with medically-accurate and complete, age-appropriate information and skills on how to access and obtain sexual health care and related services; 2) Promote effective communication regarding sexual health; 3) Promote and support better health, educational, and economic opportunities for young parents and families; and/or 4) Train those working with young people to promote their sexual health and well-being. The YASHS Act would ensure that no federal funds go to programs that withhold health promoting or life-saving information about sexuality-related topics; are inaccurate or ineffective, promote gender stereotypes; are insensitive and unresponsive to the needs of LGBTQ youth, sexually active youth, youth of varying abilities, school-age parents, survivors of sexual assault and abuse; or are otherwise inconsistent with the ethical imperatives of medicine and public health.

V. Protect and bolster funding for providers of sexual and reproductive health care, especially through the Title X Family Planning Program.

IMPLEMENT A NATIONAL HARM REDUCTION STRATEGY

The current opioid overdose, HIV, viral hepatitis and STI syndemic in the United States represents one of the greatest public health crises of the modern age. Harm reduction approaches have succeeded in limiting prior health crises related to drug use and should shape the response to the current opioid crisis.

So great is the threat posed by this rapidly escalating syndemic that it has driven down the average life expectancy for two consecutive years (2015-2016). Since 2014, drug overdose fatalities have cost more Americans their lives each year than the HIV/AIDS crisis at its peak, and the rates of fatal overdose have only continued to rise with the emerging threat of widespread fentanyl contamination in the domestic illicit drug supply. The CDC predicts that there were nearly 66,000 fatal drug overdoses in 2016, and roughly 72,000 in 2017. Across the nation, there are no communities that have not been affected by the crisis.

Further, the overdose crisis and attendant increases in injection drug use are driving a significant increase in the rate of new viral hepatitis infections and threaten to reverse the gains in reducing HIV rates among people who inject drugs since 1990. The outbreak of injection-related HIV in rural Scott County, Indiana, over the course of 2014-2015 has come to emblemize this threat. In 2016, the CDC identified 220 counties, the top 5% of counties, across the nation vulnerable to similar explosive outbreaks driven by the overdose crisis. Continued injection-related HIV clusters in Northern Kentucky, Massachusetts, and Southern West Virginia in 2017 and 2018 make clear the threat posed by this ever-expanding syndemic. Additionally, data show that an increasing proportion of syphilis transmission among heterosexuals is occurring among people who use drugs, including people who inject drugs (PWID). Even as these health crises challenge communities across the country, meaningful federal response has been slow to mobilize and often lackluster in execution. Critical public health, behavioral health, and treatment infrastructure has been allowed to atrophy due to lack of federal investment. Significant, sustained, and rapid investment is needed to sufficiently scale up these systems and expand access to evidence-based interventions that prevent overdose and disease transmission.

While the scope of this crisis is daunting, in truth we already know many of the most effective tools needed to mitigate the harms caused by the syndemics of substance use and HIV. For decades, people who use drugs have worked to keep themselves safe, pioneering many of the most effective and successful HIV, viral hepatitis, overdose prevention, and public health interventions. Community-based harm reduction programs, focusing on the inherent dignity of people who use drugs, coupled with people who use drugs and a willingness to “meet them where they’re at,” have saved countless lives through distribution of naloxone directly into the hands of those who need it most and virtually eliminated the incidence of HIV among people who inject drugs (PWID) in the jurisdictions willing to bring Syringe Services Programs (SSPs) to scale. Harm reduction provides an incredibly powerful platform of engagement for those most vulnerable to the harms of this syndemic and future drug-related epidemics. Harm reduction programs provide evidence-based and life-saving interventions to communities that traditional health care and treatment providers struggle to reach, and often serve as the linchpin linking people who use drugs to broader systems of care and helping to retain them in care. It is time to recognize the central role that harm reduction must play in our national response to overdose, HIV, and viral hepatitis epidemics.

We can no longer afford to blindly place our faith in the failed policies of interdiction, mass criminalization, and misplaced moralization and stigmatization of people who use drugs. Nor can we afford to continue to demonize, marginalize, and criminalize communities of color who long have suffered under the weight of punitive drug policies in an era before the “new face of heroin” emerged as white, young, and nonurban. Finally, we can no longer afford to abdicate our responsibility to those we continue to lose to overdose, infectious disease, and mass incarceration.

The Administration and Congress, as well as leaders in state and local government, must fully embrace and implement a National Harm Reduction Strategy as part of a comprehensive and sustained public health response to the overdose and infectious disease syndemic, remove the unnecessary and burdensome barriers that deny access to lifesaving behavioral health, substance use treatment, medical care, and social supports, and make the sustained investments needed to support these efforts.

Overdose and Infectious Disease Prevention

The rapid rise in fatal drug overdoses across the United States particularly over the past three years following the widespread contamination of the illicit drug supply with fentanyl, represents an existential threat to people who use drugs and their communities. This threat is further exacerbated by significant and widespread barriers to implementing effective, evidence-informed overdose prevention interventions in many communities. Such overdose prevention interventions exist, but communities often face significant hurdles when attempting to bring these interventions to scale or even to initiate them. Action must be taken to address the unnecessary regulatory burdens, insufficient public investment, and misdirected prioritization of resources which hamstring the community-led overdose prevention efforts needed to meaningfully slow or reduce rapidly rising overdose mortality.

Additionally, negative health outcomes associated with the precipitous increases in injection-related viral hepatitis, HIV, and endocarditis are responsible for further morbidity and mortality, reduced quality of life, and significant financial costs to individuals and communities impacted by the syndemic. Communities which have long lacked harm reduction and syringe services programs across much of Appalachia, the South, and the Midwest are experiencing unprecedented outbreaks of HCV and HIV, prompting a second wave of statewide legalization of SSPs in response. However, many of these jurisdictions struggle to create and rapidly bring to scale the necessary harm reduction infrastructure required to meet the need and demand. Faced with limited financial resources and often legislative barriers to securing state public health funding, many communities will be unable to adopt integrated harm reduction interventions needed to contain these growing epidemics without dedicated, significant, and sustained appropriations and funding support for SSPs from the federal government.

Community-based harm reduction, overdose prevention, and syringe services programs remain the most immediately impactful and cost-effective intervention available to reverse the overdose and infectious disease crises devastating our communities. They represent the ideal centerpiece and central hub around which to build the comprehensive public health and treatment infrastructure our communities so desperately need, and all other overdose prevention and treatment interventions are strengthened through close partnership with harm reduction programs and services.

Further, there are two core interventions that, when provided to best practice, have the most significant impact on reducing overdose fatality:

The first core intervention is community-based naloxone distribution programs, that seek to put naloxone directly into the hands of people who use drugs and other layperson bystanders and seek to saturate their

community in low-barrier naloxone. People who use drugs themselves and other laypersons are almost universally more likely to be present at an overdose event before law enforcement or emergency medical services. People who use drugs and their community are, in an overwhelming majority of cases, the true “first responders.” People who use drugs are strong, resilient, and care about saving the lives of their friends and family members. By ensuring that all members of our communities – especially people who use drugs themselves – most likely to encounter an overdose event are carrying naloxone and are trained to recognize an overdose, we will significantly reduce overdose fatalities.

Overwhelming evidence demonstrates the efficacy of overdose education and naloxone distribution programs centered on people who use drugs and other bystanders, in saturating the local community with low-barrier naloxone. Every effort should be taken to remove any barrier to implementing such programs in all communities, and to secure the funding needed to sustain such lifesaving programs.

The second core intervention is widespread, free, and low barrier access to all forms of Medication Assisted Treatment (MAT) for those who seek it. MAT (including methadone and buprenorphine) is the gold standard treatment for individuals with an opioid use disorder (OUD), and overwhelming evidence demonstrates that MAT offers vastly improved health and treatment outcomes when compared to abstinence-based treatment for OUD. MAT is proven to significantly reduce the risk of fatal overdose as well as provide greater stability for individuals whose OUD may be causing significant disruption in their lives, leading to sustained recovery and a return to gainful employment for many. These benefits persist even in instances where patients are not totally abstinent, and individuals engaged in polydrug use continue to see significant health and social benefits once stabilized on buprenorphine. Further, MAT – alongside SSPs – is a critical component of successful HIV and HCV prevention efforts among PWID.

Despite the unparalleled effectiveness of MAT in treating OUD, many who seek treatment are unable to access it. Demand for MAT far outstrips treatment capacity, and there are widespread shortages in MAT providers. Only 23% of publicly-funded treatment programs report offering any form of MAT, and less than 50% of private treatment programs do. Regulatory barriers further restrict access to MAT, particularly buprenorphine (that requires a provider to receive a special waiver to dispense and has strict patient caps) and methadone (which has extremely strict limitations on how and where it can be prescribed as well as high reporting burdens for providers), each of these forms of MAT have the strongest evidence demonstrating effectiveness at reducing overdose fatality among the three medications approved by FDA to treat opioid use disorders. Additionally, there are many financial barriers that make it difficult for patients to access MAT, especially in states which have chosen not to expand Medicaid. Restrictions are also commonly imposed by both private and publicly funded insurance plans. It is critical that Congress continue to take steps to reduce the regulatory barriers impeding widespread expansion of MAT treatment capacity and secure sustainable financing to support that expansion.

Finally, there are a wide variety of additional harm reduction prevention strategies which, if implemented broadly, would positively impact the rates of fatal overdose. These include efforts to ensure that prescription opioid diversion efforts do not place undue restrictions on access to prescription opioids for chronic pain patients who otherwise may be forced into the illicit opioid market; expanding access to medical cannabis as an alternative to prescription opioids for pain management; allowing federal funds to purchase fentanyl testing strips and other drug-checking services for people who use drugs; the establishment of Safer Consumption Spaces (also referred to as Supervised Injection Facilities or Overdose Prevention Sites); and efforts to reduce the exposure of people who use drugs to structural risk environments – such as correctional facilities, abstinence-based residential treatment programs that deny access to MAT, homelessness and housing instability, etc. – which contribute to increased risk of overdose.

Recommendations for federal action

I. Bolster syringe services programs and community-based harm reduction programs

- Dedicated federal funding should be directed to support the establishment or expansion of syringe services programs. Congress should seek to appropriate sustained, multi-year funding dedicated to SSPs, and ensure that SSPs are eligible for any federal opioid funding.
- Community-based harm reduction organizations which center the leadership and involvement of people who use drugs should be prioritized for all federal SSP and drug-user health funding.
- Federal agencies must be proactive around communicating the availability of federal funds to support SSPs by issuing guidance, providing technical assistance, and widely distributing resources to promote the use of federal funds to support SSPs along with other syringe access strategies, including non-prescription pharmacy sale.
- Harm Reduction plays a vital role along the recovery spectrum, providing a highly effective platform for engagement to the most vulnerable people who use drugs, providing lifesaving supportive services for individuals who are unable or unwilling to seek treatment, and providing linkage-to-care for those who are. SAMHSA should formally acknowledge that harm reduction is an integral part of recovery by updating their *Working Definition of Recovery* and their *Principles of Recovery* to explicitly integrate harm reduction into each.
- In recognition of their critical role in outreach, engagement, and linkage-to-care for people who use drugs, SAMHSA must work to integrate harm reduction CBOs and SSPs into a comprehensive continuum of care for people along the spectrum of recovery. SAMHSA should seek to identify mechanisms to encourage the Single State Agencies and other recipients of federal opioid and substance use treatment and prevention funding to collaborate with and provide funding support to harm reduction programs and SSPs.
 - Specifically, funding through the Substance Abuse Treatment and Prevention Block Grants, MAT-PDOA, the Opioid State Targeted Response Grant (O-STR), the State Opioid Response Grant (SOR), and all other current and future funding streams which seek to expand access to treatment or prevent overdose.
 - SAMHSA's current reporting system GRPA places an incredibly high data collection burden upon grantees, which effectively prevents many CBOs from being able to access SAMHSA funding. SAMHSA should seek to reduce GRPA's negative impact on smaller programs and create lower threshold reporting tiers for CBOs.
 - SSPs must be involved wherever possible in the planning and implementation of SAMHSA-systems planning, scale up, or expansion.
 - SSPs must be promoted as an integral part of any state's two-year Behavioral Health Systems Assessment and Plan.
- The Administration and Congress should expand funding to the CDC to expand SSP availability and critically needed surveillance infrastructure, particularly within the Division of Viral Hepatitis.

II. Facilitate unfettered access to community-based Naloxone

- The Administration and Congress should advance expanded naloxone access through low-barrier naloxone saturation models that prioritize increased funding for community-based harm reduction and syringe services programs as the most effective platform to reach people who use drugs.
- Federal agencies that administer funding streams that can be used to purchase naloxone or to fund overdose prevention outreach should use their existing authority to prioritize harm reduction and syringe services programs in allocation and use of federal funding. Specifically, the Administration should 1) recognize that that people who use drugs themselves and layperson bystanders are the "true first responders" in the overwhelming majority of cases and the best

positioned to intervene in an overdose event; 2) ensure that no funding appropriated to the Department of Health and Human Services is diverted to purchase naloxone for law enforcement or the criminal justice system; and 3) prioritize use of funds for coverage of programs directly equipping people who use drugs and laypersons with naloxone before using these funds for EMS or other non-LEO government agencies.

- Encourage development of programs that allow for waiving or covering co-payments when accessing naloxone through a pharmacy on an individual's insurance, as well as waiving payment for those without health coverage or who choose to not charge their insurance. This will help address funding barriers and can be spearheaded by local health departments with collaboration through insurance companies.
- Congress must ensure that federal overdose prevention funding – including both naloxone and MAT funding – is equitably allocated to jurisdictions facing the greatest burden of overdose fatalities.
- Congress and federal agencies administering overdose prevention funding should seek to promote best practice overdose prevention programming by issuing guidance which encourages grantees to pursue community-based naloxone distribution programs and seek to fully saturate as many communities as possible with easy-to-access naloxone.
- The Food and Drug Administration should promote increased access to naloxone by removing prescriber requirements and allow for over-the-counter access for some formulations.
- Congress should ensure sufficient-funding is available to provide all state, local, and federal inmates and criminal justice involved individuals discharged with naloxone, using appropriate Department of Justice funding streams.
- Publicly funded SUD treatment programs should be mandated, as a prerequisite to receive federal funding, to provide naloxone freely to their patients as well as keep emergency overdose response kits with naloxone accessible to all program participants and staff.

III. Ensure equitable access to MAT

- Congress and the Administration should ensure that all individuals seeking MAT have full, free or low-cost access to all forms of MAT, as well as the freedom to choose the medication that best fits their needs. Federally-funded or regulated drug courts, jails, prisons, and drug treatment programs must be required to provide access to all forms of MAT.
- Repeal the buprenorphine prescribing waiver requirement and prescriber patient caps, which perpetuate the treatment gap by limiting expansion of buprenorphine access.
- SAMHSA should commission the National Academies of Science, Engineering, and Medicine (NASEM) to produce a report analyzing options for removing regulatory barriers to methadone for opioid use disorder treatment.
- Congress and federal agencies should seek opportunities to fund research and promising pilot practices, such as heroin-assisted treatment, as well as medication to treat stimulant use disorder (including methamphetamine use disorder).
- Congress and SAMHSA should promote and fund lower threshold MAT models, including on-demand buprenorphine outside of clinical settings and the integration of buprenorphine into SSPs.
- All Medicaid, Medicare, Veterans Affairs, and Indian Health Service health plans must mandate coverage of all forms of MAT and eliminate restrictive policies which inhibit low-barrier access to MAT.

IV. Institute additional harm reduction strategies

- The Administration should explicitly allow localities to move forward in implementation of Safer Consumption Spaces without threat of federal law enforcement action. Federal agencies which

administer overdose and infectious disease funding should identify ways in which SCS programs are in-alignment with the goals and priorities of each of their funding streams and issue guidance on use of such funding within an SCS program.

- Allow for research and development around additional supervised consumption programs, including the use of video chat technology as a mobile health option.
- SAMHSA and other federal agencies should allow use of federal funding to support purchase of fentanyl test strips, as well as other people who use drugs-focused drug checking services and people who use drugs-focused emerging drug trend/overdose alert systems.
- Federal agencies, including the Departments of Justice and Housing and Urban Development, should issue guidance and resources to grantees and partners recognizing that structural risk environments – such as corrections, homelessness and unstable housing, etc. – contribute to overdose risk, and that reducing exposure to those environments is a form of overdose prevention.
- Congress and the Administration should remove federal barriers to access to medical cannabis.

Ending Criminalization: Promoting the Rights and Dignity of People Who Use Drugs

Over the last decade, as public narratives about the “face” of opioid overdose have primarily centered on white communities, our nation has slowly shifted towards recognizing that substance use and its attendant harms should be treated as a public health, rather than a criminal justice, crisis. Increasing calls for a more compassionate approach to people struggling with a substance use disorder emerged in the context of an overdose crisis that, initially, resulted in disproportionate deaths among white Americans. These calls for compassion posed a stark contrast to previous responses to drug problems among communities of color, which had long suffered not only the overdose and infectious disease related harms of substance use, but also overwhelming criminalization and mass incarceration. Yet even as the public narrative around the overdose crisis came to center newly impacted white communities, communities of color face rapidly growing rates of fatal overdose and infectious disease associated with injection drug use.

However, this newfound compassion has not stopped a movement to reassert the criminalization of substance use and a double down on the very same punitive and inherently self-defeating criminal justice interventions. Even as local communities, law enforcement officials, public health professionals, and many other stakeholders openly state that “we cannot arrest our way out of this problem,” funding which could be used to scale up the evidence-based public health interventions necessary to truly end this crisis is increasingly being diverted towards the criminal justice system. Drug-induced homicide prosecutions, supposedly aimed at disrupting international criminal organizations and high-level narcotics distributors, instead charge the often-also-addicted siblings, partners, and friends of those who’ve suffered a fatal overdose. In many cases, drug-induced homicide charges are brought against the very same individuals who attempted to intervene and save the life of a peer by calling emergency services in the first place. With the widespread contamination of the illicit drug supply with the powerful synthetic opioid fentanyl, street-level dealers are being swept up and excessively punished by “fentanyl sentencing enhancement” legislation. None of these criminal justice interventions help to expand access to evidence-based substance use treatment, nor mitigate the economic and social factors underpinning this crisis. In fact, the involvement of the criminal justice system actively impedes efforts to end the overdose crisis and drives drug-related harm.

The criminalization of people who use drugs and their communities laid the foundation for the syndemic our nation faces today. The over-policing of communities of color and immigrant communities fuels mass incarceration, devastates the lives of our most vulnerable citizens, utterly fails to prevent drug-related

harms, and massively accelerates the overdose crisis. It is the lives of our friends, our families, and our communities we condemn to misery and death when turn away from the fundamental humanity and dignity of people who use drugs. We must seek to end the criminalization of people who use drugs and other vulnerable and marginalized communities if we ever wish to see an end to the overdose crisis.

Recommendations for federal action

I. Affirm that the overdose crisis is primarily a public health crisis and as such requires a comprehensive public health response.

Punitive drug policy that centers a criminal justice strategy in response to the overdose crisis and promotes mass incarceration will only exacerbate the crisis and maximize the harm suffered by our communities. Public health *is* public safety and must always be prioritized.

In the event that the priorities of the criminal justice system and the priorities of the public health system come into conflict, the Administration and Congress must *always* prioritize the needs and priorities of the public's health and seek at every turn to minimize the involvement of the criminal justice system in the lives of people who use drugs.

II. Oppose any proposals which would expand or promote punitive drug policy

This include expanding or promoting any of the following:

- Enhanced penalties for drug related offenses involving fentanyl
- "Drug-Induced Homicide" prosecutions of any kind
- "Infant Endangerment" or "drug-endangerment of children" penalties for pregnant people and parents who use drugs or the criminalization of women whose children are born with neonatal abstinence syndrome
- Drug-use-only justifications for CPS involvement in families

III. Reject and disavow rhetoric which seeks to justify xenophobic, racist, and inhumane immigration policies, and reverse and undo the harassment and criminalization of immigrant communities by Immigration and Customs Enforcement – especially any actions taken in the name of combatting the overdose crisis

IV. Promote pre-arrest, pre-booking, and non-coercive diversion programs that seek to minimize criminal justice involvement for people who use drugs

V. Repeal the Stop Enabling Sex Traffickers Act (SESTA) and the Allow States and Victims to Fight Online Sex Trafficking Act (FOSTA) and pass anti-trafficking legislation that does not conflate human trafficking with consensual adult sex work.

This legislation was opposed both by sex worker rights advocates and the largest coalition of anti-trafficking service providers, infringes on First Amendment rights, and has utterly failed in its stated goals by making it harder for individuals engaged in commercial sex – whether under coercion or not – to be reached by social service providers and advocates.

VI. Promote sweeping criminal justice reforms to reduce both mass incarceration and the harms of criminalization, such as promoting the elimination of cash bail, mandatory minimums for drug offenses,

and statutory or regulatory barriers to accessing public housing and other social benefits for individuals with past drug convictions.

VII. Reject drug testing requirements for recipients of any federal welfare program, including Medicaid, SNAP, and TANF.

Structural Interventions and Social Determinants of Health

The overdose crisis did not emerge within a vacuum. Contributing social and structural drivers include rising economic and income inequality, deep disinvestment across the social safety net, and over a decade and a half of perpetual war abroad -- coupled with the failure to adequately provide for veterans harmed by those wars. The deregulation of financial institutions, leading to the collapse of the housing market and near collapse of the global economy in 2008, occurred in parallel with increasing rates of opioid use and fatal drug overdose. If we are to reverse the course of this crisis, it is essential that we address not just the biomedical needs of people who use drugs, but also the structural and social determinants of health that increased their vulnerability in the first place and continue to pose significant barriers along their path to health, safety, stability, and recovery.

Recommendations for federal action

The Administration and the Department of Housing and Urban Development (HUD) should affirm through policy, guidance, and communications that housing is both healthcare as well as overdose and infectious disease prevention. Homelessness and housing instability are significant risk factors for fatal overdose and infectious disease and create often insurmountable barriers to accessing and maintaining medical care and substance use treatment. Specifically:

- Congress must cease the divestment of public low-income housing and reject any proposals from the Administration to shrink or dismantle HUD
- HUD, SAMHSA, and Congress should increase funding for and promote the expansion of a Housing First orientation across all federally funded housing programs, including among recovery housing programs
- The Administration and Congress should increase federal investments in the Housing Choice Voucher Program and other HUD-administered Permanent Supportive Housing programs
- HUD should aggressively enforce existing Americans with Disabilities Act protections for MAT patients in Fair Housing Act-covered housing
- Congress should eliminate eligibility restrictions to accessing HUD programs related to drug use or drug-related convictions
- The United States Interagency Council on Homelessness (USICH) should promote coordination between HUD and HHS on reducing overdose
- The Administration and Congress should oppose drug testing requirements for accessing public benefits, as well as Medicaid work requirements

REDUCE THE SYNDEMICS OF SEXUALLY TRANSMITTED INFECTIONS

The US is experiencing an historic rise in rates of STIs. More than two million cases of chlamydia, gonorrhea, and syphilis were reported in 2017, the highest number ever. There is a syndemic relationship between STIs and HIV: in addition to similar modes of transmission, the presence of certain STIs increases the likelihood of HIV acquisition. Additionally, STI trends and outbreaks can provide important

warning signs that communities are at risk for an HIV outbreak, making STI surveillance an important priority for municipal and state departments of public health. Comprehensive STI prevention, testing, and treatment play an important role in any effort to prevent the sexual transmission of HIV. There is also an increasing incidence of multidrug resistant (MDR) STIs, such as gonorrhea and chlamydia.

We recommend educating the public and health care providers about the risk of STI acquisition when biological prevention is used without risk reduction counseling or condom use, while stressing that concerns about risk compensation are not a valid reason to withhold PrEP or comprehensive messaging on U=U. When patients are unable to, or choose not to use condoms, they are most in need of understanding the value of PrEP and viral suppression. Providers should also be aware of the importance of screening and treatment for STIs among individuals who protect themselves and their partners with PrEP or TasP. We also recommend increasing surveillance for MDR STIs, funding research on the role that reliance on PrEP and TasP may play in changing STI trajectories among at risk populations and educating the public and health care providers about the potential for increase in STIs as sexual behaviors change in the era of biological prevention. As condoms and behavioral interventions can present challenges in terms of adherence and scale up, we also recommend greater investment in research for vaccines, improved treatment, and better prevention modalities for STIs. We also propose significantly increased focus on the structural and social drivers of these pathogens as opposed to a return to a moralizing focus on the individual sexual behaviors, particularly in terms of marginalized populations who are already stigmatized in terms of their sexuality.

Budget cuts and flat funding at the federal, state and local levels have severely weakened the public health infrastructure including the workforce on the frontlines of the STI response. Insufficient resources have created significant gaps in services including HIV and STI screening for those at highest risk, limited partner notification services, insufficient provider education, and restricted access to affordable STI screening and treatment due to the high prices imposed by industry on STI diagnostics and treatment.

Recommendations for federal action

I. Declare the STI epidemic a Public Health Emergency to generate the attention and more rapidly leverage the resources necessary to effectively respond to this growing public health crisis before it worsens.

STIs are at their highest levels ever and only continue to grow. We need to mobilize resources to identify new and creative solutions to STI prevention, and to ensure that health departments that are working to identify and prevent new cases have additional support from throughout the public and private health care sphere to address this crisis. To do so, the President and Surgeon General need to declare STIs a public health emergency.

II. Fund STI prevention at a level commensurate with the scope of the epidemic

To properly address the STI epidemic, funding for the Division of STD Prevention at CDC should be dramatically increased through, multi-year sustained increased investments. Public health is buckling under the weight of dramatic STI increases and the current under-funded system cannot leverage an appropriate response with the current level of funding. This funding increase should also include a special initiative to increase STI screening and treatment throughout the country.

III. Include STIs screening and treatment as a component of HIV prevention programs

Early detection and treatment of curable STIs should become a major, explicit component of comprehensive HIV prevention programs at national, state, and local levels. In areas where STIs that facilitate HIV transmission are prevalent, screening and treatment programs should be expanded; Individuals who are diagnosed with or suspected to have an STI when diagnosed with HIV, should be immediately linked to HIV care and ART.

IV. Ramp up comprehensive education for providers about the need for STI diagnosis and treatment recommendations, including three site testing, culturally responsive language and methods for eliciting full sexual histories

Many health care providers providing primary care lack knowledge regarding the latest STI and treatment recommendations and may not have the tools to counsel patients on STI prevention. With STIs on the rise, providers must be reeducated on the importance of screening in addition to symptoms of STIs to allow for timely diagnosis and treatment.

V. Commit to ending congenital syphilis

Syphilis is associated with significant complications if left untreated and facilitates transmission and acquisition of HIV. Congenital syphilis is now at the highest rate since 2000. Congenital syphilis is totally preventable, and each new case represents a major failure of our health care system. Passing on syphilis during pregnancy can lead to infant death in 40% of all births. Infants who survive may experience severe health and development issues. We have the tools to eliminate congenital syphilis and must invest the resources necessary to do so.

VI. Work to ensure penicillin stays in stock

In 2016 the Food and Drug Administration (FDA) was warned about a dangerous shortage of Bicillin L-A. Bicillin is the only known treatment for syphilis, and without adequate supply the efforts to prevent new cases of syphilis could be harmed. There needs to be a federal review of this shortage to assess its causes and develop solutions to address immediate issues and help ensure a reliable supply of this important medicine.

VII. End drug pricing tactics that allow drug companies to profit off older drugs with limited competition like the preferred treatment for syphilis Pfizer's Bicillin® L-A (penicillin G benzathine or BPG)

The price of BPG has increased to \$350 per dose for some clinics without access to 340B pricing, with rumors of an additional price increase on the horizon. Until recently, BPG also was on the FDA's drug shortage list. Due to its high price, some health insurers place BPG on a high cost-sharing tier leaving this critical treatment priced out of reach. In addition, the preferred lab tests for chlamydia and gonorrhea can be more than \$600 for screening as recommended at three anatomic sites with high cost sharing for patients. We urge industry to address price and supply issues for BPG and for STI laboratory diagnostics to ensure cost is not a barrier to diagnosing and treating STIs. We urge HHS and Congress to act to stop drug companies from price gouging older medications with limited or no competition that are critical to public health.

VIII. Research and develop a new gonorrhea antibiotic treatment

Gonorrhea has become resistant to all but one antibiotic. The UK has already seen one case of

antibiotic resistant gonorrhea, or “super gonorrhea.” If we do not work to identify alternative medication options gonorrhea is at risk of becoming an untreatable epidemic. Funding and resources should be put towards identifying alternative treatment options.

IX. Commit to and promote proven interventions such as comprehensive sexual education rather than interventions that have been proven to be ineffective at reducing STIs, including abstinence-only education

X. Work to re-establish clinical quality measures for STI screening

When the National Quality Forum (NQF) last undertook review of the infectious diseases measures set (the clinical quality measures that are used in the various federal quality improvement and value-based incentive programs), many measures were retired or dropped including the measure for STI screening. The CDC and HRSA should work with the NQF to develop and submit for NQF endorsement updated STI screening measures to promote clinician adherence to treatment guidelines with regard to STI screening.¹⁰⁷

XI. Include STIs as a core quality Medicaid measure

CMS has core quality measurements for HIV and Hep C, however, there are none for STIs. Part of the reason that STIs are at such high levels are because health care providers are not thinking to test for STIs. By developing quality measures for Medicaid health care providers will be reminded and encouraged to regularly test for STIs.

XII. Develop sex positive messaging

The federal government should work to create a sex positive STI prevention campaign. Much like PrEP has helped people take control over their sex lives, knowing about and preventing STIs can also help to support a pleasurable sex life. The federal government should work to create messaging that is sex positive to encourage people to take control over knowing their STI status.

Investing in Structural Interventions

Structural factors including poverty, lack of employment opportunities, insecure housing, and limited transportation infrastructure are contributors to new HIV cases and poor health care engagement. Studies repeatedly show that, in addition to improving quality of life, supportive services facilitate care engagement, enhance adherence, and reduce health-risk behavior. In turn, supportive services have been shown to improve health outcomes and reduce costs. *The National HIV/AIDS Strategy: Updated to 2020* (NHAS) has a strong emphasis on structural supports as key to keeping PLWH in care and healthy: “Structural approaches can reduce risk of HIV transmission at community and societal levels... It has become abundantly clear that these social and economic determinants of health are significant factors in the ability to meet the goals of the Strategy.”

The need for increased focus and investment in structural interventions comes at a time when ending the epidemic seems within reach for some communities, but far away for others. We know that biomedical

¹⁰⁷ <https://www.idsociety.org/uploadedFiles/IDSA/Global/HIVMAIDSACHACTestimony.pdf>.

treatment alone will not end the epidemic. The federal government has a unique opportunity and responsibility to expand efforts to address the need for housing, employment services, and adequate food and nutrition, and to leverage the impact and cost-effectiveness of structural interventions in preventing, treating, and ending AIDS in the U.S. Structural interventions, most often in the form of support services, are fundamental to making health care work for people living with HIV. In addition, laws that criminalize HIV exposure, non-disclosure, or transmission, despite data showing lack of impact on HIV transmission, are systemic structural barriers that create stigma and discrimination as well as infringing on the civil rights of PLWH. The following outlines specific actions that the Administration can take to expand structural interventions that, when coupled with biomedical treatment and care, are essential to ending the AIDS as an epidemic in our country.

FOOD AS MEDICINE FOR PEOPLE LIVING WITH HIV

The Food and Nutrition Services (FNS) category has been an integral part of the Ryan White HIV/AIDS Program since its inception. The program created through this category is now arguably the most robust FNS program in the country for people living with chronic illness. PLWH who are food insecure often forego critical medical care, including medical appointments, prescriptions, and other treatment – and are less likely to be virally suppressed. For PLWH, proper nutrition is required to increase medication absorption, reduce side effects, and maintain a healthy body weight.

Food and Nutritional Services are a low-cost, high-impact intervention: one hospital night averted could provide medically tailored meals for half a year, and the health benefit is rapid. Research demonstrates that when PLWH are nourished, health outcomes and well-being improve, and reliance on emergency rooms and hospitals decreases. The provision of meals has been shown to be important in helping PLWH adhere to their treatment while also improving health outcomes, and a recent pilot done in San Francisco, showed 40-70% increased adherence to ART, a reduction in hospital stays (63%), and a reduction in ER visits (36%) for those who received medically tailored meals.

Furthermore, a recent pilot study showed a 28% drop (from \$38,937 to \$28,183) in average monthly healthcare costs for patients battling life-threatening illnesses who received medically tailored meals and medical nutrition therapy. The cost decline was even more significant for PLWH on the program. When compared to similar patients who did not receive these services, study participants also experienced 50% fewer hospital admissions and were 23% more likely to be discharged to their homes rather than another facility. Unfortunately, even with research demonstrating the effectiveness of food and nutrition services, too many PLWH remain food insecure.

The only dedicated funding stream for FNS for PLWH is the Ryan White Program. Coverage for those not qualifying for Ryan White Program services is lacking. The lack of additional funding streams has forced some FNS agencies to institute waiting lists or reduce services. Even within some RWPs, funding may be inadequate to provide as much FNS as is needed by the most food insecure clients. There remains a tremendous variation by state in coverage of food and nutrition outside of Ryan White. In states where RWP continues to pay for the majority of medical expenses for PLWH due to lack of Medicaid expansion, comprehensive coverage of FNS remains lacking. Medicaid and other public insurance do not provide FNS in a comprehensive manner.

HOUSING IS HEALTHCARE AND PREVENTION

Housing is one of the greatest unmet needs for people living with HIV/AIDS. An estimated half of all people living with HIV will need housing assistance at some point in their lives. In 2016, approximately 138,400 people living with HIV were in need of housing assistance. For very low-income people living with HIV, consistent, affordable and safe housing is difficult to obtain. Compared to people living with HIV who are stably housed, people living with HIV who are homeless are more likely to delay entry to care, be less adherent to medication, have worse overall health outcomes, and are more likely to use emergency rooms and be hospitalized. People who are homeless or unstably housed have HIV infection rates as much as 16 times higher than people who have a stable place to live. When housed, people are more likely to gain access to treatment and adhere to treatment. Housing assistance for people living with HIV is significantly associated with increased rates of viral suppression.

A growing concern is the need for housing for people living with HIV as they age. More than half of people living with HIV are 50 years or older. Those moving into assisted living facilities or nursing homes face a new set of needs. Due to the stigma surrounding HIV and issues of homophobia, older LGBTQ Americans transitioning into new housing choose to go back into the closet in fear of discrimination associated with disclosing their HIV status.

The Housing Opportunities for Persons with HIV/AIDS (HOPWA) program provides housing assistance and supportive services for low-income people living with HIV/AIDS and their families. Due to funding constraints, HOPWA was only able to serve 55,000 households with housing assistance in 2016. The HOPWA program formula was modernized by Congress and implemented in 2017 to better direct the funding to current needs. With changes to the HOPWA formula, some jurisdictions will lose significant funds, jeopardizing stable housing for thousands of households. Due to modernization and the existing underfunding of the HOPWA program, significant additional funds are needed to prevent new HIV infections and house those currently living with HIV.

EMPLOYMENT

Data shows that PLWH who are employed have better adherence to treatment and better physical and mental health outcomes.^{108, 109} However, PLWH often face myriad barriers to entering or re-entering the workforce, including risking the loss of lifesaving HIV care and treatment and other essential services. The key service systems developed to improve health outcomes and reduce inequities related to HIV have not evolved to effectively address profoundly unequal access to employment opportunity among communities most impacted by the virus today. Public workforce programs can play an important role in increasing access to targeted information, services and resources needed by PLWH seeking to enter and/or re-enter the workforce. Thus, changes required include interventions to equip individuals living with or at greater risk for HIV to make well-informed, self-determined choices regarding employment, with access to information, services, resources and policies to increase opportunities and reduce barriers to healthy, living wage work. Importantly, initiatives to address employment needs must also be planned and implemented with the guidance and meaningful involvement of people living with HIV and communities at greater vulnerability to HIV to ensure that the policies and initiatives are responsive to the need. Ryan White Program funds cannot be directly used for employment-related services, yet the Ryan White

¹⁰⁸ International Labour Office. (2013). The Impact of Employment on HIV Treatment Adherence. Retrieved from http://www.ilo.org/wcmsp5/groups/public/--ed_protect/--protrav/--ilo_aids/documents/publication/wcms_230625.pdf

¹⁰⁹Hergenrather, K. C., Zeglin, R. J., Conyers, L., Misrok, M., & Rhodes, S. D. (2016, February 1). Persons Living With HIV/AIDS: Employment as a Social Determinant of Health. Retrieved from <http://www.ingentaconnect.com/content/springer/rrpe/2016/00000030/00000001/art00002>

Program infrastructure should be leveraged to deliver such services. The two lead federal partners in implementing NHAS that hold primarily responsibility in employment and labor-related initiatives, the Department of Labor (DOL) and the Department of Education (DoED), have to date not allocated resources to sustain or build the capacity of the relatively few, underfunded HIV employment initiatives that do exist, nor to support development of any new ones.

Recommendations for federal action

I. Expand and increase funding for food as medicine for PLWH

Increasing funding for FNS for PLWH is critical if the epidemic is going to end, as FNS services often serve as a gateway to care and then help PLWH remain in care, adhere to their medication regimens and achieve viral suppression. While increasing overall Ryan White Program funding is certainly the most important objective, increased funding for support services is even more complicated since their priority is governed by local Planning Councils. Especially in low resources states and localities, the primary focus of Ryan White Program spending will continue to be on medical services and medication until Medicaid is expanded and until FNS is a covered benefit in Medicaid for those living with HIV and other severe illnesses who are too sick to shop or cook for themselves. The federal government must assess the gap in funding for the Ryan White Program FNS Category, and subsequently fully fund the FNS Category.

Additionally, the federal government should clarify the status of Medically Tailored Meals (MTM) within the HHS Portfolio. Specific federal action is needed to call on HHS to issue sub-regulatory guidance on MTM integration into HHS programs and clarify when MTM can be paid for within Medicare and Medicaid programs.

II. Address Food and Nutrition Research gaps to inform policy

Two key areas preclude a full understanding of the potential impact of FNS. First, we do not know the scope of food insecurity among PLWH, even in the Ryan White Program. Second, although initial research is promising, we do not fully understand the impact of different levels of food-based interventions on health outcomes and cost savings.

In-line with the subsequent recommendation to support HIV/AIDS research, the federal government should establish a federally supported Structural Interventions Research Committee within the Office of AIDS Research to advance coordination, communication, and furtherance of research throughout Federal agencies. Additionally, Health Resources and Services Administration (HRSA) HIV/AIDS Bureau (HAB) Division of Policy and Data must monitor and track provision of food and nutrition services through the Ryan White HIV/AIDS Program (RWP) and their related health outcomes and cost savings, reporting on this annually, to demonstrate the nationwide impact of these programs.

III. Enhance training and technical assistance in the provision of food and nutrition services

The changing epidemic requires a responsive system of care to ensure the prevention and treatment of HIV/AIDS. Dedicated training that addresses the shifting policy landscape and new opportunities for access to coverage is imperative if we are to end the epidemic.

The federal government should invest in dedicated capacity building and technical assistance (TA) on food and nutrition services, by recommending that training and TA on the importance of and access to food and nutrition services for PWH be provided in HHS by HRSA/HAB, including within the AIDS Education and Training Center (AETC) Program for HIV care providers; by the CDC for HIV prevention providers; and by HUD's Office of HIV/AIDS Housing (OHAH) for HOPWA providers.

Furthermore, the federal government should direct HRSA's Special Projects of National Significance (SPNS) program to specifically target social and economic determinants of health; specifically, the importance of structural interventions in highly impacted states/communities, facilitation of cross-sector multidirectional training, collaboration and service coordination. Outcomes should include integration of assessment of structural intervention needs at intake and follow up throughout HIV care and prevention service delivery, with delivery of or linkage to appropriate information, services and resources.

IV. Continued and expanded support of federal initiatives to address homelessness and housing insecurity among people living with HIV, including the HOPWA program, as well as increasing access to housing opportunities to support both transitional & subsidized housing for PLWH who engage in substance use.

V. Provide more funding for HOPWA and housing programs

HUD needs more federal funding in order to ensure housing programs to prevent homelessness, rapidly rehouse homeless persons, and sustain housing for those who need it most. The HOPWA program is drastically underfunded. The requested funding for FY 2019 is \$393M. As Modernization phases in and inflation occurs, HOPWA will need more money each year so that very low-income people living with HIV do not lose their homes.

VI. Encourage Ryan White grantees to use funding for housing

HRSA issued guidance that Ryan White funds can be used to house people living with HIV/AIDS. HRSA and HUD continue to collaborate to ensure housing is integral to care and treatment for people living with HIV. Grantees should assess their ability and knowledge to provide housing services and collaborate with housing agencies.

VII. Encourage Medicaid programs to fund supportive housing

CMS has approved use of Medicaid for supportive housing services. For people who are chronically homeless or have histories of institutionalization, stable supportive housing will drastically improve their health outcomes. We advocate for states to use Medicaid dollars for housing.

VIII. Develop interventions to respond to employment needs of PLWH

A federal interagency task force of NHAS implementers including HHS, HOPWA, DOL, and DoED should develop a plan to support the vocational training and employment of PLWH. The plan should, at least, include:

- The AIDS Education and Training Centers should provide education and Capacity Building Assistance (CBA) to RWP grantees/providers on strategies and resources to

address the employment needs of people living with HIV leveraging existing service systems and infrastructure.

- The CDC should make education and CBA on strategies and resources to address the employment needs of PLWH available through CBA consultants to its prevention grantees.
- HUD allows HOPWA funding to be used to address employment needs. This should be promoted to its HOPWA grantees, and HUD should increase CBA to grantees to support implementation of employment-related programs. Promoting eligibility for and benefits of the Earned Income Disregard (also known as the Earned Income Disallowance) for HOPWA HUD-subsidized housing.
- DOL, through its Employment and Training Administration (ETA) and its Office of Disability Employment Policy (ODEP) should: i) provide education and CBA across its public workforce programs, to ensure the capacity to provide effective, non-stigmatizing and affirming services to PLWH, and communities most impacted by HIV and ii) create targeted employment initiatives for PLWH iii) direct public workforce funds to initiate and/or sustain HIV employment initiatives through its Employment and Training Administration (ETA) in conjunction with its Office of Disability Employment Policy (ODEP) and iv) increase protections against employment discrimination based on gender identity and sexual orientation for PLWH.
- DoED's Rehabilitation Services Administration (RSA) should establish a national demonstration project to fund community-based partners embedded within HIV service settings to coordinate access for PLWH to information, services and resources to achieve self-chosen goals for employment, empowered and supported for well-informed decision-making about employment, with non-stigmatizing, affirming and well-informed service delivery. This will increase utilization and efficacy of vocational rehabilitation services among and for PLWH.

Ending HIV Criminalization

In the United States, more than 30 states and territories have criminal and civil laws that criminalize HIV exposure, non-disclosure, or transmission, or that apply harsher penalties for sex work or injection drug use on the basis of HIV status. Prosecution may result in mandatory sentence enhancement and sex offender registration, targeting people with HIV on the basis of their status. Traditional offenses such as aggravated assault, reckless endangerment, and attempted murder are also used to prosecute HIV exposure. Most cases involve spitting and biting, or sexual contact without prior disclosure of status. Transmission of HIV is often unnecessary for arrest and prosecution; exposure, the definition of which is often unclear or medically inaccurate, is sufficient. Courts rarely consider factors affecting transmission risk (e.g., condom use, viral load) or whether the prosecution establishes proof of intent to harm.

HIV criminalization is also a problem in several states without HIV specific laws. For example, Texas has no HIV specific law and uses general criminal laws to prosecute PLWH. We have several men serving more than 20 years for spitting. We must eliminate the practice and policies related to HIV criminalization. Just eliminating HIV specific laws does not mean that criminalization ends.

Addressing overrepresentation of PLWH in the criminal legal system requires elimination of HIV-specific criminal laws and other reforms to address systemic barriers to housing, healthcare, and employment. These laws perpetuate stigma, undercut public health, and disproportionately affect women, sex workers,

people of color, and LGBTQ communities. At the same time, there is no scientific evidence that laws criminalizing non-disclosure, perceived or potential exposure, or transmission have any public health benefit. In fact, a growing body of evidence points to these laws as potential drivers of the epidemic because they may discourage HIV testing, treatment, and disclosure of HIV positive status. To reduce HIV transmission, we call on Congress to support federal legislation such as the REPEAL HIV Discrimination Act, and repeal or modernize federal and state laws, policies, and regulations that place unique or additional burdens on individuals with HIV solely as a result of their HIV status."

HIV among America's prison population is four times higher than the prevailing rate of HIV in the general population, and the infection rates are even higher for women inmates than their male counterparts. While in prison, PLWH face widespread discrimination and difficulty accessing appropriate medical care. At least 95 % of people incarcerated in state prisons will be released back to their communities at some point. Upon release their problems are intensified for those who are living with HIV. For people living with HIV involved with the criminal justice system, data shows that women are significantly less likely than men to report taking prescribed antiretroviral medication prior to jail entry,¹¹⁰ to fill a prescription for antiretroviral medication in the 60 days following release,¹¹¹ or to be retained in medical care with sustained viral suppression.¹¹² Transition upon incarceration release is a particularly vulnerable period during which PLWH are at high risk for lapses in ART and lack of engagement in HIV medical care.

In addition to the disproportionately large percentage of prisoners being HIV-positive prior to entering prison, there are many factors putting prisoners at risk of contracting the virus while incarcerated. The frequency of high-risk sexual behavior and sexual assault in jails and prisons is difficult to estimate, yet several reports indicate that male prisoners who have sex with other men (MSM) range from 2% to 65%, and 4.5% of all inmates reported at least one incident of sexual victimization by other inmates or staff.

Furthermore, sharing needles and other injecting equipment are high risk behaviors that contribute to the spread of HIV among people incarcerated. Studies estimate that between 10-48% of male prisoners are dependent upon or use injection drugs, and between 56% and 90% of people who inject drugs have been imprisoned. In one study, 25% of prisoners reported using needles to inject drugs, and half of those surveyed reported sharing needles.

Implementing comprehensive criminal justice reform will be critical to efforts to end the epidemic by reducing interactions between people living with or affected by HIV and the criminal justice system. Federal and state policies should emphasize linking individuals to treatment and care mechanisms instead of incarcerating them. This includes the removal of HIV/STI specific criminal laws and the use of general criminal laws to prosecute people living with HIV, as well as laws that criminalize sex workers and people who use drugs. Steps must also be taken to reduce HIV-related stigma among prisons and to ensure that people living with HIV who are incarcerated have access to comprehensive health care services.

¹¹⁰ Lemly, D. C., Shepherd, B. E., Hulgán, T., Rebeiro, P., Stinnette, S., Blackwell, R. B., Bebaawy, S., Kheshti, A., Sterling, T. R., & Raffanti, S. P. (2009). Race and Sex Differences in Antiretroviral Therapy Use and Mortality among HIV-Infected Persons in Care, *The Journal of Infectious Diseases*, 199(7), 991–998. <https://doi.org/10.1086/597124>

¹¹¹ Chen, N. E., Meyer, J. P., Avery, A. K., Draine, J., Flanigan, T. P., Lincoln, T., Spaulding, A. C., Springer, S. A., & Altice, F. L. (2013). Adherence to HIV treatment and care among previously homeless jail detainees. *AIDS Behav.* 17(8), 2654-66.

¹¹² Meyer, J. P., Zelenev, A., Wickersham, J. A., Williams, C. T., Teixeira, P. A., & Altice, F. L. (2014).

Recommendations for federal action

I. Support and pass legislation to end HIV criminalization

We call on Congress to support federal legislation such as the REPEAL (Repeal Existing Policies that Encourage and Allow Legal) HIV Discrimination Act, which would repeal all federal laws, policies, and regulations allowing the criminal prosecution of individuals for HIV-specific offenses and incentivize states to do the same.

II. Improve HIV testing, prevention, and treatment services in federal prisons

Comprehensive HIV care and prevention in federal and state prisons and local jails is needed. The Bureau of Prisons (BOP) and state and local departments of corrections should implement routine, confidential, opt-out HIV testing on the way in and out of prison or jail. PLWH should receive comprehensive medical care in a timely fashion, and in compliance with DHHS guidelines on ART. Prisons and jails should provide linkage to services, or ensure appropriate linkage to medical and community services, upon release so that PLWH know where to receive treatment and care in the community and have adequate navigation to ensure successful care linkage.

Upon release, every PLWH should receive adequate ART to ensure continuity of treatment until care linkage can be achieved. Moreover, the BOP and state and local departments of corrections should implement essential HIV prevention services including providing condoms, PrEP, and PEP for those at high risk. DOH and HHS should collaborate to provide resources to states and localities including training, technical assistance, and model best practices for state prisons and local jails for addressing, preventing, and treating HIV during incarceration and upon reentry. Because 95% of the incarcerated population in the US is housed in state prisons or local jails, such resources would reduce HIV transmission and connect individuals to HIV care and treatment.

III. Build on the Prison Rape Elimination Act

Inmates are now reporting more and more when sexual assault happens, but we still have no idea how/when consensual sex occurs because sex in prison is a felony in most if not all states. This prevents researchers from understanding what is happening in prison settings when it comes to sexual contact in any form (inmate with inmate, inmate with staff, etc.). Of paramount importance in building on PREA is distinguishing between sexual assault and consented sex with an inmate. The federal government must allow for research that would not penalize, via increased sentencing, the offender for disclosing with whom or how they had sex.

IV. DOJ and HHS must collaborate and provide resources to states and localities for preventing and treating HIV during incarceration and upon reentry

DOJ and HHS must collaborate and provide resources to states and localities, including training, TA, and model best practices for state prisons and local jails for addressing, preventing, and treating HIV during incarceration and upon reentry. 95% of the incarcerated population in the US is incarcerated in a state prison or local jail. Such resources would reduce HIV transmission and connect individuals to HIV care and treatment is necessary if the US is going to achieve an AIDS-Free generation.

V. Support housing assistance as a primary HIV prevention intervention for at risk groups

Rates of homelessness are high among persons at greatest risk of HIV due to substance use, mental illness, intimate partner violence, and other vulnerabilities. While it is difficult to estimate total housing need among people at risk, at least one half of homeless persons in any community fall into one or more of these highest risk categories, and research indicates that the condition of homelessness itself places all persons who lack stable housing at increased risk of HIV transmission. To prevent new infections, we should support housing assistance for homeless and unstably housed persons at risk of HIV transmission.

Investing in Research

HIV/AIDS research over the last four decades has been responsible for the dramatic transformation of HIV from a uniformly fatal infection to a manageable one that can be successfully treated over a near-normal lifespan. Therefore, a robust research agenda is an indispensable part of our ability to end the domestic and global epidemics. Now is the time to prioritize HIV/AIDS research within NIH and support groundbreaking research to develop a preventive vaccine, microbicides, a cure for HIV infection, new HIV treatments, new approaches to pre-exposure prophylaxis, and implementation science to advance scale up of treatment and prevention directed toward HIV co-morbidities and health disparities as well as HIV itself. While we could theoretically bring new infections below epidemic levels thanks to the prevention benefits of treatment and PrEP, additional research advances will be necessary to maximize the implementation of existing tools and develop new modalities that will sustainably end the AIDS epidemic.

Half of all people living with HIV in the U.S. are over the age of 50. By 2020, more than 70 % of Americans living with HIV are expected to be age 50 and older. These older adults report three times as many comorbidities as older adults living without HIV, with rates of depression up to five times what is observed in older adults not diagnosed with HIV. Older adults living with HIV often lack the informal social supports and caregiving resources utilized by older people to meet the challenges of aging. There is a gap in programs and interventions.

HIV/AIDS research not only supports advancements in care and treatment for persons living with HIV and AIDS in the United States, it is also responsible for much of the scientific groundwork driving effective and efficient global HIV/AIDS programming in resource-poor settings. In 2015, the NIH-funded START (“Strategic Timing of Antiretroviral Treatment”) trial established that immediate treatment reduced rates of both serious AIDS and serious non-AIDS mortality and morbidity – resulting in updated World Health Organization guidelines, now widely adopted globally, recommending immediate initiation of treatment for all HIV-positive people, regardless of their disease progression. Programs such as the NIH Fogarty International Center HIV Research Training Program have allowed the U.S. to lead in shaping the global body of knowledge on HIV/AIDS and support vital research in areas heavily impacted by HIV/AIDS to inform the response globally and in the U.S.

Finally, HIV/AIDS research investment continues to reap ancillary benefits in developing therapies and cures for other diseases that afflict Americans such as Alzheimer’s, heart disease, cancer, diabetes, autoimmune disorders, and other infectious diseases such as tuberculosis and hepatitis B and C. Advanced diagnostic techniques originally developed for HIV are now used to detect and prevent the spread of numerous other infectious diseases – an important contribution to protecting the health of all Americans.

Recommendations for federal action

I. Make sustained multi-year increases for HIV/AIDS biomedical research

It is critical to realize the unprecedented promise in U.S. biomedical research by ensuring stable, substantial, sustained multi-year increases (10-15% per annum) for biomedical research overall by the U.S. National Institutes of Health (NIH), especially within NIH's National Institute for Allergy and Infectious Diseases (NIAID), as well as targeted increases for the NIH HIV/AIDS research program carried out by the institutes, networks and coordinated by the Office of AIDS Research (OAR) to sustain current progress and expand upon emerging research opportunities across microbicides, prevention, cure, and comorbidities such as hepatitis C, tuberculosis, and cancer.

The HIV/AIDS research portfolio has been flat-funded at the NIH since FY 2014. Increases are particularly critical to support HIV cure and vaccine preclinical and clinical research to capitalize on a long-term commitment by the U.S. government on advancing ongoing research and promising vaccine candidates. It is time for targeted increases to address unfunded HIV research projects identified in the most recent FY2018 OAR by-pass budget.

II. Increase resources for other HIV/AIDS research activities, including implementation science

Increase resources are needed for HIV/AIDS research activities undertaken and supported by other federally funded institutions such as the U.S. Agency for International Development, Department of Defense, Federal Food and Drug Administration, and the Agency for Healthcare Quality and Research. A robust implementation science agenda is critical to the real-life application of scientific discoveries and their interaction with social determinants of health, particularly health disparities.

The federal government can do so by supporting and facilitating interagency collaboration to promote an implementation science agenda. This includes leveraging the Centers for AIDS Research (CFARs) national network to enhance collaboration with local ASO's and CBO's to support implementation science agenda on implementing emerging HIV prevention and treatment science within communities. The federal government should also expand the CFAR model within the hardest-hit jurisdictions, particularly the Southeastern U.S. to test new innovative approaches with non-traditional partnership. This should could work into implementation science.

III. Expand research among vulnerable populations

Resources and regulatory policy are needed to expand ethical research on treatment, prevention needs and implementation among vulnerable populations - such as youth, people of color, pregnant and lactating women, people of trans experience, and people who use drugs. This includes ensuring the appropriate recruitment of PLWH into clinical studies that are non-HIV specific and ensuring meaningful involvement of these populations in study design.

IV. Support a bold agenda for HIV/AIDS research related to structural interventions

Establish a federally-supported Structural Interventions Research Committee within the Office of AIDS Research to advance coordination, communication, and furtherance of research throughout federal agencies, especially HHS, CDC, NIH, HUD, and DOL. This Committee should:

- Recommend funding of research vetted by the Structural Interventions Research Committee in the President's Budget for Fiscal Year 2020.
- Call on HRSA's HIV/AIDS Bureau Division of Policy and Data to monitor and track provision of food and nutrition services and employment services and their related health outcomes and cost savings, reporting on this annually, to demonstrate the nationwide impact of these programs.
- Call on HUD's Office of Policy Development and Research to research the efficacy of various housing approaches and their impact on ensuring PLWH link to care, maintain care, and have improved health and well-being.

V. Advance a behavioral and social science research agenda for HIV/AIDS research

Recent advances have pivoted HIV research to examine acceptability, adherence, scalability of interventions within and across communities affected by HIV. Game-changing interventions such as PrEP have shown effectiveness for some users, but not for all for reasons of acceptability, and reveals challenges of prevention use in the real-world. In treatment, addressing questions of why certain people are better able to engage in care and use and adhere to treatment are critical to ending the epidemic.

Answering these critical questions through a comprehensive behavioral and social science research agenda for HIV is essential in determining and overcoming social and behavioral barriers and to developing appropriate strategies to enhance acceptability and adherence of prevention modalities and/or treatment, unique to communities that are hit hard by the HIV epidemic.

VI. Implement a research agenda focused on the health impacts of HIV-related inflammation

The prevalence of noncommunicable diseases and age-related morbidities may be the cumulative effects of longstanding inflammation in PLWH. The increasing burden of diseases accelerates HIV morbidity and mortality and complicates health management for PLWH. More focus is needed to investigate the physiological impact of HIV-related inflammation on the health outcomes of PLWH and help inform better treatments and interventions to minimize effects.

VII. Continue existing HIV research cohorts

Large comprehensive research cohorts like MACS (Multicenter AIDS Cohort Study) and WIHS (Women's Interagency HIV Study) have played a critical role and continue to be essential to understanding the complexities of HIV disease and progression, as well as informing treatments for co-morbidities and HIV. Bolstering resources to protect and expand these research cohorts is needed to continue to enrich data on the scientific understanding on HIV, from pathogenesis to treatment.

VIII. NIH should support more research on HIV and aging including research on key populations with high HIV prevalence

Research should look closely at differences within more marginalized and less studied subgroups of these populations (e.g., transgender and gender non-conforming people, Southeast Asian communities). Specifically:

- NIH should support research in the priority areas identified by the NIH Office of AIDS Research (OAR) Special Working Group on HIV and Aging, including but not limited to multi-morbidity management, behavioral health needs and caregiver support resources.
- NIH should reconvene the NIH-OAR aging working group to assess progress on its recommendations since early 2012, address research gaps, particularly with regard to older adults, and provide updated recommendations based on the current science on HIV and aging.

Conclusion

We have made substantial progress in responding to the HIV epidemic. At the beginning of the epidemic, no one could have predicted the incredible success of antiretroviral medications that today permit people living with HIV to live healthy, productive, and long lives. In the last decade, the U.S. has created and implemented the first National HIV/AIDS Strategy, developed antiretroviral prevention technologies like PrEP and treatment as prevention, implemented more syringe services programs, made science-based sexual and reproductive health education available to additional young people, and improved access to health care for millions of Americans.

The U.S. now has the capability to reverse and potentially end the domestic epidemic. The HIV community, in collaboration with state and local jurisdictions, is working to implement plans to do so. Consistent with the recommendations here, the support and intervention of the federal government will be central to ending the epidemic across the U.S. Only with a focused effort that prioritizes the needs of people with HIV, addresses health disparities, prevents new cases, improves the health care system, creates structural mechanisms to improve health outcomes through ancillary services, and produces groundbreaking, cross-cutting research will we together defeat one of the most complex viruses ever encountered.

Implementing this roadmap to end the HIV epidemic in the United States is possible only with decisive action from Congress and the Administration. We must officially declare a goal to end the epidemic by 2025, and the time to make this declaration is now. Consequently, the undersigned call on the U.S. government to officially declare that it is our goal to end the HIV epidemic in the United States by 2025 and to enact legislative and regulatory changes to achieve this goal.

Appendix A: Organizations Signing on to the Roadmap at Launch

National Organizations

African American Health Alliance	Dunkirk, MD	Latinos Unidos Contra el SIDA	Miami, FL
AIDS United	Washington, DC	Let's Kick ASS-AIDS Survivor Syndrome	San Francisco, CA
American Academy of HIV Medicine	Washington, DC	Los Angeles LGBT Center	Los Angeles, CA
American Medical Student Association	Sterling, VA	NASTAD	Washington, DC
Arcos Communications	New York, NY	National Action Network	New York, NY
Black AIDS Institute	Los Angeles, CA	National AIDS Housing Coalition	Washington, DC
CAEAR Coalition	Washington, DC	National Association of County and City Health Officials	Washington, DC
CenterLink: The Community of LGBT Centers	Fort Lauderdale, FL	National Center for Lesbian Rights	San Francisco, CA
Coalición CERO VIH PR	San Juan, PR	National Coalition for LGBT Health	Washington, DC
Collaborative Solutions	Birmingham, AL	National Coalition of STD Directors	Washington, DC
Dirt Advocacy Movement	Cleveland, OH	National Family Planning & Reproductive Health Association	Washington, DC
Family Equality Council	New York, NY	National LGBTQ Task Force	Washington, DC
FORGE	Milwaukee, WI	National Tuberculosis Controllers Association	Smyrna, GA
GLMA: Health Professionals Advancing LGBTQ Equality	Washington, DC	National Working Positive Coalition	New York, NY
Harm Reduction Coalition	New York, NY	Natural Spiritual Wholistic Health & Wellness Research Center	Yucca Valley, CA
HCV Advocate: Hepatitis C Support Project	Sacramento, CA	New York University Center for Latino Adolescent and Family Health	New York, NY
HealthHIV	Washington, DC	NMAC	Washington, DC
Healthy Teen Network	Baltimore, MD	Nu Phi Zeta Fraternity	Atlanta, GA
Hep B United	Washington, DC	PFLAG National	Washington, DC
Hepatitis B Foundation	Doylestown, PA	Planned Parenthood Federation of America	Washington, DC
Hepatitis Education Project	Seattle, WA	Positive Heterosexual Network	Miami Beach, FL
Hispanic Federation	New York, NY	Positive Women's Network	Oakland, CA
Hispanic Health Network	New York, NY		
HIV Medicine Association	Arlington, VA		
House of Blahnik	Philadelphia, PA		
Housing Works	New York, NY		
Lambda Legal	New York, NY		
Latino Commission on AIDS	New York, NY		

Presbyterian AIDS Network (PAN) PHEWA, Presbyterian Church, USA	Washington, DC
Pride at Work	Washington, DC
Professional Association of Social Workers in HIV and AIDS	Birmingham, AL
Project Inform	San Francisco, CA
Ryan White Medical Providers Coalition	Arlington, VA
Sexuality Information and Education Council of the United States (SIECUS)	Washington, DC
Stop TB USA	Atlanta, GA
Transgender Law Center	Oakland, CA
TransLatin@ Coalition	Los Angeles, CA
Treatment Action Group	New York, NY
United States People Living with HIV Caucus	San Marcos, CA
Urban Coalition for HIV/AIDS Prevention Services	Washington, DC
URGE: Unite for Reproductive & Gender Equity	Washington, DC

Regional Organizations

Advocacy House Services	Greensboro, NC
Caracole	Cincinnati, OH
Cascade AIDS Project	Portland, OR
Central Alabama Alliance, Resource & Advocacy Center	Wetumpka, AL
Coalition on Positive Health Empowerment	New York, NY
Food & Friends	Washington, DC
Midwest AIDS Training and Education Center	Chicago, IL
NME	Fayetteville, NC
One in Four Chronic Health	Portland, OR
Saint Louis County Department of Public Health	Berkeley, MO
San Antonio AIDS Foundation	San Antonio, TX
San Francisco AIDS Foundation	San Francisco, CA
SisterLove	Atlanta, GA
South Bay LGBTQ Alliance	San Diego, CA

Southern AIDS Coalition	Birmingham, AL
Southern Black Policy and Advocacy Network, Inc.	Dallas, TX
Southern HIV/AIDS Strategy Initiative	Durham, NC
The Bros in Convo Initiative	Orlando, FL
The Poverello Center	Wilton Manors, FL
Trillium Health - Rochester	Rochester, NY
Valley AIDS Council	Harlingen, TX
Washington AIDS Partnership	Washington, DC
Washington University School of Medicine	St. Louis, MO
West Ohio AIDS Action	Columbus, OH
Western North Carolina AIDS Project	Asheville, NC
Whitman-Walker Health	Washington, DC

State Organizations

AIDS Alabama	Birmingham, AL
AIDS CT	Hartford, CT
AIDS Foundation of Chicago	Chicago, IL
AIDS Project Rhode Island	Providence, RI
AIDS Resource Alliance	Williamsport, PA
AIDS Resource Center of Wisconsin	Milwaukee, WI
APNH: A Place to Nourish your Health	New Haven, CT
Arkansas RAPPS	Little Rock, AR
Bailey House	New York, NY
California State University, Long Beach	Long Beach, CA
Clare Housing	Minneapolis, MN
Columbia University/NYSPI	New York, NY
Community Servings	Jamaica Plain, MA
Delaware HIV Consortium	Wilmington, DE
Diversity Family Health	Oklahoma City, OK
Equality Alabama	Birmingham, AL
Equality California	Los Angeles, CA
Equality New Mexico	Albuquerque, NM
Equality North Carolina	Raleigh, NC
Equitas Health	Columbus, OH

Fenway Health - AIDS Action Committee of Massachusetts	Boston, MA
Garden Valley Neighborhood House	Cleveland, OH
Georgia AIDS Coalition	Snellville, GA
Georgia Equality	Atlanta, GA
Harlem United	New York, NY
Hep Free Hawaii	Honolulu, HI
HIV Modernization Movement - Indiana	Indianapolis, IN
Hope and Help Center of Central Florida	Orlando, FL
iHealth	New York, NY
JustUs Health	St. Paul, MN
Maui AIDS Foundation	Wailuku, HI
New Jersey Association on Correction	Trenton, NJ
No One Left Behind	Lexington, SC
NuCara Pharmacy	Des Moines, IA
Oklahoma AIDS Care Fund	Oklahoma City, OK
Pacientes de SIDA pro Politica Sana	San Juan, PR
Positive Impact Health Centers	Lawrenceville, GA
Positive Women's Network USA - Indiana Chapter	Fort Wayne, IN
Sonya's House	Dallas, TX
South Carolina Black Pride	Columbia, SC
The Low Income Housing Coalition of Alabama	Birmingham, AL
UNC Infectious Disease Clinic	Chapel Hill, NC
Urban Sanctuary	Little Rock, AR
Visiting Nurse Service of New York	New York, NY

Local Organizations

Access Health Louisiana	Kenner, LA
AIDS Action Baltimore	Baltimore, MD
AIDS Alabama South	Mobile, AL
AIDS Outreach Center	Fort Worth, TX
AIDS Research Consortium of Atlanta	Atlanta, GA
Aliveness Project of NWI	Merrillville, IN
Alliance for Positive Change	New York, NY

Allies for Health + Wellbeing	Pittsburgh, PA
Amida Care	New York, NY
Atchason Environmental Health Consultants	Springfield, FL
Being Alive: People with HIV/AIDS Action Coalition	West Hollywood, CA
Big Cities Health Coalition	Washington, DC
Bill's Kitchen	San Juan, PR
Birmingham AIDS Outreach	Birmingham, AL
Bronx Care Service Organization	Bronx, NY
Callen-Lorde Community Health Center	New York, NY
CAMBA	Brooklyn, NY
CARES Outreach Services	Sarasota, FL
Cempa Community Care	Chattanooga, TN
Chicago House and Social Service Agency	Chicago, IL
Children's Place Association	Chicago, IL
Community Healthcare Network	New York, NY
CrescentCare	New Orleans, LA
DC Fights Back!	Washington, DC
Desert AIDS Project	Palm Springs, CA
Diverse and Resilient	Milwaukee, WI
East Los Angeles Women's Center	Los Angeles, CA
Family Initiative of the CSRA	Augusta, GA
Five Horizons Health Services	Tuscaloosa, AL
GMHC	New York, NY
God Can Ministries United Church of Christ	Ford Heights, IL
God's Love We Deliver	New York, NY
Hawai'i Health and Harm Reduction Center	Honolulu, HI
Heart to Hand	Largo, MD
Howard Brown Health	Chicago, IL
HRA Wellness Resource Center	New Britain, CT
iknowAwareness	Atlanta, GA
Imani Unidad	South Bend, IN
Iris House, Inc.	New York, NY
JASMYN	Jacksonville, FL
LAISP Church	New York, NY

Lansing Area AIDS Network	Lansing, MI
Lee's Rig Hub	Minneapolis, MN
Let's Talk About It	Gainesville, FL
Life Progressive Service Group	Mt. Vernon, NY
Los Angeles County Commission on HIV	Los Angeles, CA
Los Angeles County Department of Public Health Division of HIV and STD Programs	Los Angeles, CA
MANNA	Philadelphia, PA
Mazzoni Center	Philadelphia, PA
Metro Community Provider Network	Englewood, CO
Metropolitan Community Church of New York	New York, NY
Mile High Behavioral Healthcare	Denver, CO
Moveable Feast Lexington, Inc.	Lexington, KY
Mujeres Unidas Contra El SIDA	San Antonio, TX
Nashville CARES	Nashville, TN
Oklahoma City Indian Clinic	Oklahoma City, OK
One Stop Career Center of PR	San Juan, PR
Open Door Clinic of Greater Elgin	Elgin, IL
Open Hand Atlanta	Atlanta, GA
Parish of St. John the Beloved	Washington, DC
Pierce County AIDS Foundation	Tacoma, WA
Pitt County AIDS Service Organization	Greenville, NC
Positive Mind and Body Support Group Network	Vero Beach, FL
Positive Women's Network USA - Greater Houston Chapter	Houston, TX
Positively U	Davenport, FL
Prism Health North Texas	Dallas, TX
Puerto Rico CoNCRA	San Juan, PR
Radiant Health Centers	Irvine, CA
RAIN	Charlotte, NC
Resource Center	Dallas, TX
Rocky Mountain CARES	Denver, CO
San Antonio Ryan White Planning Council	San Antonio, TX

SC HIV Council	Columbia, SC
Shelter Resources, Inc. d.b.a. Belle Reve NOLA	New Orleans, LA
Sierra Foothills AIDS Foundation	Auburn, CA
SLO Bangers SEP/OPP	San Luis Obispo, CA
St. Louis Effort for AIDS	St. Louis, MO
St. Simon Stock St. Joseph Parish	New York, NY
Sunshine Cathedral	Fort Lauderdale, FL
Taller Salud	Loiza, PR
TEC	Durham, NC
The African American AIDS Task Force	Minneapolis, MN
The Joy Bus	Phoenix, AZ
The Philadelphia Center	Shreveport, LA
The Wall Las Memorias Project	Highland Park, CA
The Women's Collective	Washington, DC
Thrive Alabama	Huntsville, AL
Tulsa CARES	Tulsa, OK
Unity Fellowship of Christ Church Philadelphia	Philadelphia, PA
Upper Savannah Care Services	Greenwood, SC
VIDA	San Diego, CA
Wellness Services	Flint, MI
WNY End the Epidemic Initiative	Buffalo, NY

Global Organizations

Aspirations	Baton Rouge, LA
AVAC	New York, NY
CALOR	Los Angeles, CA
Center for BlackEquity (CBE-PRIDE)	Washington, DC
Francois-Xavier Bagnoud Center, Rutgers School of Nursing	Newark, NJ
Friends of the Global Fight Against AIDS, TB and Malaria	Washington, DC
GLAAD	New York, NY
HIVenas Abiertas: A Network of Latinx People Living with HIV	Sacramento, CA

International Association of Providers of AIDS Care	Washington, DC
International Place for People with HIV/AIDS	Miami, FL
Medical IMPACT	Mexico City, Mexico
MPact Global Action for Gay Men's Health and Rights	Oakland, CA

Prevention Access Campaign	Brooklyn, NY
TalkAIDS	New York, NY
The Center for HIV Law and Policy	Brooklyn, NY
The Well Project	Brooklyn, NY
Under One Roof Productions	New York, NY
YTH (Youth+Tech+Health)	Oakland, CA

Appendix B: Legislative Recommendations

The federal government must increase funding and outreach for PrEP access in geographic areas disproportionately impacted by the epidemic.

Pass comprehensive immigration reform that allows normalization of status of undocumented immigrants who have not been convicted of any serious criminal offense, that recognizes the economic imperatives that force migration, and that broadens grounds for asylum or other legal status for persons fleeing domestic and gang violence or who cannot receive adequate health care in their country of origin. Until such reform is passed, issue guidance that protects undocumented immigrants from being seized for deportation at health care facilities or in transit to and from such facilities, as well as venues where immigrants might go to seek protection from abuse.

Create meaningful oversight of detention facilities to ensure adequate and respectful provision of health care, respect for the dignity and human rights of people living with HIV and LGBTQ persons, and protection from violence, including sexual violence.

Establish and resource a cross-governmental working group to address issues related to an aging population living with HIV inclusive of inflammation, social isolation, multiple morbidity, polypharmacy, and the need to emphasize maintenance of function.

Members of Congress must stop attempting to repeal the ACA

Congress must turn its focus to strengthening our healthcare system rather than weakening it in ways that would undermine the progress that has been made and that would have devastating consequences for people living with HIV and upwards of 20 million other Americans.¹¹³

Millions of Americans have gained health insurance coverage under the ACA, including tens of thousands of people living with HIV. Since the ACA was enacted in 2010, people living with HIV have come to count on basic protections that ensure they will not be denied coverage because of their health status and they will have coverage for basic services, including prescription drugs, mental health and substance use treatment.

Congress must pass legislation to stabilize private insurance markets and to ensure sufficient funding for ACA enrollment and marketing activities

The Administration's regulatory actions to undercut the ACA and to significantly limit support for marketing and assistance during open enrollment have already contributed to a rise in the number of Americans who are uninsured and to premium increases in the ACA-compliant individual market.

Actions must be taken by Congress, such as funding a reinsurance program and requiring the Administration to promote and restore funding for marketing and enrollment assistance throughout the open enrollment process to prevent further weakening of the individual health

¹¹³ Congressional Budget Office. (n.d.) Affordable Care Act. Retrieved from <https://www.cbo.gov/topics/health-care/affordable-care-act>

insurance market and significant increases in uninsured Americans, including among people living with HIV.

Increase funding of the Ryan White HIV/AIDS Program

We should capitalize on the program's effectiveness to promote the health of people living with HIV and increase funding to meet the needs of a growing number of persons living with HIV who need Ryan White Program services.

Provide loan forgiveness through the National Health Service Corps for HIV providers who are working in Ryan White Program funded clinics and facilities

Even if all PLWH were diagnosed and linked to care, challenges remain with the capacity of the current system of care. Many clinical and professional responders of the original HIV workforce are now retiring, and it is not clear where their replacements will come from. Providing loan forgiveness for HIV providers to work in Ryan White Program funded clinics will help alleviate this workforce shortage.

Expand telehealth programs by increasing grant funding and reimbursement especially from Medicaid and Medicare

Evaluate innovative payment models under Medicare and Medicaid for the comprehensive, high quality care provided at Ryan White Program Clinics

Support robust funding for the Ryan White AETC program.

Provide recommendations, resources, and technical assistance for state and jurisdictional plans to eliminate viral hepatitis

- States should expand access to adult hepatitis B vaccination, removing barriers to free immunization in pharmacies and other easily accessible settings.
- The American Association for the Study of Liver Diseases and the Infectious Diseases Society of America should partner with primary care providers and their professional organizations to build capacity to treat hepatitis B and C in primary care. The program should set up referral systems for medically complex patients.

Invest in support for research and surveillance and standard viral hepatitis case finding measures and follow-up monitoring that will advance the goals of the viral hepatitis elimination plan

Support national TB elimination efforts

- Support the development and implementation of a national LTBI surveillance system currently being piloted by CDC to obtain better estimates of LTBI burden and focus intervention efforts on areas with high rates of infection
- Incorporate indicators into the national LTBI surveillance system that capture LTBI diagnosis and treatment during pregnancy and the postpartum period to inform intervention efforts in this particularly vulnerable population

- Fund the Division of TB Elimination (DTBE) to implement a LTBI prevention initiative to prioritize prevention among those highest-risk for active TB.

The federal government must commit funding to a level of least \$195.7 million for DTBE, with at least \$35 million to begin supporting a LTBI prevention initiative that prioritizes testing and access to treatment for those communities at highest-risk of transition to active TB disease, which includes PLHIV.

Provide funding for independent HIV popular opinion leaders at grassroots level

Funding for special projects and initiatives including social media marketing campaigns at the community grassroots level could maximize the effectiveness and augment the work of independent popular opinion leaders (POLs). The recommendation includes the development of a special council to award this funding directly to independent POLs who can make the largest positive impact. Independent POLs at the community grassroots level have demonstrated their unyielding commitment and ability to reach population groups (such as people living with HIV not in the system of care and those who need to be diagnosed) that aren't being reached any other way. They can physically and digitally reach these groups through community grassroots efforts that have been widely successful. The U=U message is a proven example of a social marketing campaign spearheaded by independent POLs that has gained tremendous support and momentum.

Sustain funding for the Title X program and repeal the “domestic gag rule”

In rural and medically underserved urban areas in every state, Title X clinics are often the only source of both HIV and STI screening and other preventive services for low-income women and LGBTQ populations at higher risk for acquiring HIV. Prior to the 2015 HIV outbreak in Scott County, Indiana, a family clinic that was a critical source for HIV screening to county residents closed due to lack of funding, allowing a serious HIV outbreak to spread for too long without detection. The opioid epidemic in America has created many potential Scott Counties, and one lesson that should have been learned is that more prevention services—not fewer—are needed to prevent new HIV, and hepatitis C, outbreaks. Maintaining funding for Title X is important to the HIV response and to women's health. Title X funding must be maintained without restrictions such as the proposed “domestic gag” rule that violates the Medical Code of Ethics and would be an unacceptable intrusion of the doctor-patient relationship.

Increase access to substance use disorder treatment

Evidence-based drug treatment programs have been shown to reduce HIV transmission among injection and non-injection drug users by reducing the frequency of drug use, risk behaviors, and infections.¹¹⁴ Drug treatment programs that utilize medication-assisted treatment – such as methadone and/or buprenorphine – drastically reduce overdose mortality and improve access and adherence to antiretroviral treatment. Injection drug users living with HIV who engage in evidence-based drug treatment are more likely to achieve sustained viral suppression.¹¹⁵ Congress should support increasing resources for comprehensive substance disorder and

¹¹⁴ Metzger, D., Woody, G.E., & O'Brien, C. P. (2010, December 1) Drug Treatment as HIV Prevention: A Research Update. *Journal of Acquired Immune Deficiency Syndromes*. 55(Suppl 1): S32–S36.

¹¹⁵ Metzger, D. & Zhang, Y. (2010, November). Drug treatment as HIV prevention: expanding treatment options. *Curr HIV/AIDS Reports*, 2010 Nov;7(4):220-5. doi: 10.1007/s11904-010-0059-z.

addiction treatment – including resources to support syringe services programs’ linkage-to-care activities – as part of our HIV prevention strategy.

Support increased funding for, and protecting the original evidence-based intent of, adolescent sexual health promotion programs, including the CDC’s HIV School Health efforts through the Division of Adolescent and School Health (DASH), the Teen Pregnancy Prevention Program (TPPP) through the Office of Adolescent Health, and extension of the Personal Responsibility Education Program (PREP) through the Family and Youth Services Bureau (FYSB).

Congress provides funding for evidence-based and innovative approaches to adolescent sexual health promotion programs that are medically accurate and age-appropriate through FYSB’s PREP, the CDC HIV School Health program, and OAH’s TPPP. These programs support implementation of CSE components and prioritize prevention of unintended pregnancy, HIV, and other STIs among young people.

Eliminate federal funding for abstinence-only-until-marriage programs, including the Title V “Sexual Risk Avoidance Education” state-based grant program.

Since 1981, the federal government has spent over \$2 billion on ineffective and shaming abstinence-only-until-marriage programs. Most recently in FY 2018, the Title V "Abstinence Education" state-grant program was renamed the "Sexual Risk Avoidance Education" program. It now mandates that grantees adhere to strict program requirements that often prohibit from teaching young people about the benefits of condoms and contraception. These programs also fail to address the needs of young people who are already sexually active, survivors of sexual abuse, and LGBTQ youth. The federal government also supports another federal funding stream (established in FY 2015) called the "Sexual Risk Avoidance Education" (SRAE) competitive grant program. As of FY 2019, this program was funded at \$35 million--a seven-fold increase in funding since its inception. It is past time to end funding for these programs. Decades of research prove that they are ineffective at achieving their intended goal of getting young people to remain abstinent until marriage, and, too often, shame or fail to address young people’s lived experiences.

Support the Real Education for Healthy Youth Act (REHYA), which would provide the first-ever federal funding for comprehensive sex education for young people in elementary and secondary schools and institutions of higher education.

It also establishes teacher training for school-based sex education, amends current federal law to enable LGBTQ-inclusive education, and allows the provision of condoms and contraception on school grounds. Additionally, REHYA prohibits spending federal funds on programs that withhold life-saving information about sexuality-related topics; are medically inaccurate; promote gender stereotypes; are insensitive or unresponsive to the needs of young people who are sexually active, LGBTQ, survivors of sexual abuse or assault, of varying abilities, and/or pregnant or parenting; or are otherwise inconsistent with the ethical imperatives of medicine and public health.

Support the Youth Access to Sexual Health Services Act (YASHS), which would provide grants to increase and improve the linkage and access of marginalized young people, who have some of the nation’s highest rates of new HIV cases, to sexual and reproductive health care and related services.

To ensure lifelong sexual health, all young people need information about, and access to, affordable, youth-friendly, and linguistically and culturally competent health care, as well as providers who respect patient privacy and support them in making their own choices. Unfortunately, far too many young people in the United States face barriers—including stigma and discrimination, lack of knowledgeable providers, cost, transportation, and perceived lack of confidentiality—that prevent them from accessing recommended and necessary sexual health services. These barriers contribute to health challenges and disparities, as evidenced by the continued high rates of HIV and other sexually transmitted infections (STIs), and unintended pregnancy among young people. The YASHS Act would enable our nation's most vulnerable youth to bridge these barriers by providing communities with resources to support partnerships and programs that: 1) Equip young people with medically-accurate and complete, age-appropriate information and skills on how to access and obtain sexual health care and related services; 2) Promote effective communication regarding sexual health; 3) Promote and support better health, educational, and economic opportunities for young parents and families; and/or 4) Train those working with young people to promote their sexual health and well-being. The YASHS Act would ensure that no federal funds go to programs that withhold health promoting or life-saving information about sexuality-related topics; are inaccurate or ineffective, promote gender stereotypes; are insensitive and unresponsive to the needs of LGBTQ youth, sexually active youth, youth of varying abilities, school-age parents, survivors of sexual assault and abuse; or are otherwise inconsistent with the ethical imperatives of medicine and public health.

Protect and bolster funding for providers of sexual and reproductive health care, especially through the Title X Family Planning Program.

Federal agencies that administer funding streams that can be used to purchase naloxone or to fund overdose prevention outreach should use their existing authority to prioritize harm reduction and syringe services programs in allocation and use of federal funding. Specifically, the Administration should 1) recognize that that people who use drugs themselves and layperson bystanders are the “true first responders” in the overwhelming majority of cases and the best positioned to intervene in an overdose event; 2) ensure that no funding appropriated to the Department of Health and Human Services is diverted to purchase naloxone for law enforcement or the criminal justice system; and 3) prioritize use of funds for coverage of programs directly equipping people who use drugs and laypersons with naloxone before using these funds for EMS or other non-LEO government agencies.

Congress must ensure that federal overdose prevention funding – including both naloxone and MAT funding – is equitably allocated to jurisdictions facing the greatest burden of overdose fatalities.

Congress should ensure sufficient-funding is available to provide all state, local, and federal inmates and criminal justice involved individuals discharged with naloxone, using appropriate Department of Justice funding streams.

Repeal the Stop Enabling Sex Traffickers Act (SESTA) and the Allow States and Victims to Fight Online Sex Trafficking Act (FOSTA) and pass anti-trafficking legislation that does not conflate human trafficking with consensual adult sex work.

This legislation was opposed both by sex worker rights advocates and the largest coalition of anti-trafficking service providers, infringes on First Amendment rights, and has utterly failed in its stated goals by making it harder for individuals engaged in commercial sex – whether under coercion or not – to be reached by social service providers and advocates.

Congress must cease the divestment of public low-income housing and reject any proposals from the Administration to shrink or dismantle HUD.

Congress should eliminate eligibility restrictions to accessing HUD programs related to drug use or drug-related convictions.

Fund STI prevention at a level commensurate with the scope of the epidemic

To properly address the STI epidemic, funding for the Division of STD Prevention at CDC should be dramatically increased through, multi-year sustained increased investments. Public health is buckling under the weight of dramatic STI increases and the current under-funded system cannot leverage an appropriate response with the current level of funding. This funding increase should also include a special initiative to increase STI screening and treatment throughout the country.

Ramp up comprehensive education for providers about the need for STI diagnosis and treatment recommendations, including three site testing, culturally responsive language and methods for eliciting full sexual histories

Many health care providers providing primary care lack knowledge regarding the latest STI and treatment recommendations and may not have the tools to counsel patients on STI prevention. With STIs on the rise, providers must be reeducated on the importance of screening in addition to symptoms of STIs to allow for timely diagnosis and treatment.

Expand and increase funding for food as medicine for PLWH

Increasing funding for FNS for PLWH is critical if the epidemic is going to end, as FNS services often serve as a gateway to care and then help PLWH remain in care, adhere to their medication regimens and achieve viral suppression. While increasing overall Ryan White Program funding is certainly the most important objective, increased funding for support services is even more complicated since their priority is governed by local Planning Councils. Especially in low resources states and localities, the primary focus of Ryan White Program spending will continue to be on medical services and medication until Medicaid is expanded and until FNS is a covered benefit in Medicaid for those living with HIV and other severe illnesses who are too sick to shop or cook for themselves. The federal government must assess the gap in funding for the Ryan White Program FNS Category, and subsequently fully fund the FNS Category.

Additionally, the federal government should clarify the status of Medically Tailored Meals (MTM) within the HHS Portfolio. Specific federal action is needed to call on HHS to issue sub-regulatory guidance on MTM integration into HHS programs and clarify when MTM can be paid for within Medicare and Medicaid programs.

Continued and expanded support of federal initiatives to address homelessness and housing insecurity among people living with HIV, including the HOPWA program, as well as increasing access to housing opportunities to support both transitional & subsidized housing for PLWH who engage in substance use.

Support and pass legislation to end HIV criminalization

We call on Congress to support federal legislation such as the REPEAL (Repeal Existing Policies that Encourage and Allow Legal) HIV Discrimination Act, which would repeal all federal laws, policies, and regulations allowing the criminal prosecution of individuals for HIV-specific offenses and incentivize states to do the same.

Make sustained multi-year increases for HIV/AIDS biomedical research

It is critical to realize the unprecedented promise in U.S. biomedical research by ensuring stable, substantial, sustained multi-year increases (10-15% per annum) for biomedical research overall by the U.S. National Institutes of Health (NIH), especially within NIH's National Institute for Allergy and Infectious Diseases (NIAID), as well as targeted increases for the NIH HIV/AIDS research program carried out by the institutes, networks and coordinated by the Office of AIDS Research (OAR) to sustain current progress and expand upon emerging research opportunities across microbicides, prevention, cure, and comorbidities such as hepatitis C, tuberculosis, and cancer.

The HIV/AIDS research portfolio has been flat-funded at the NIH since FY 2014. Increases are particularly critical to support HIV cure and vaccine preclinical and clinical research to capitalize on a long-term commitment by the U.S. government on advancing ongoing research and promising vaccine candidates. It is time for targeted increases to address unfunded HIV research projects identified in the most recent FY2018 OAR by-pass budget.

Increase resources for other HIV/AIDS research activities, including implementation science

Increase resources are needed for HIV/AIDS research activities undertaken and supported by other federally funded institutions such as the U.S. Agency for International Development, Department of Defense, Federal Food and Drug Administration, and the Agency for Healthcare Quality and Research. A robust implementation science agenda is critical to the real-life application of scientific discoveries and their interaction with social determinants of health, particularly health disparities.

The federal government can do so by supporting and facilitating interagency collaboration to promote an implementation science agenda. This includes leveraging the Centers for AIDS Research (CFARs) national network to enhance collaboration with local ASO's and CBO's to support implementation science agenda on implementing emerging HIV prevention and treatment science within communities. The federal government should also expand the CFAR model within the hardest-hit jurisdictions, particularly the Southeastern U.S. to test new innovative approaches with non-traditional partnership. This should could work into implementation science.

Expand research among vulnerable populations

Resources and regulatory policy are needed to expand ethical research on treatment, prevention needs and implementation among vulnerable populations - such as youth, people of color, pregnant and lactating women, people of trans experience, and people who use drugs. This includes ensuring the appropriate recruitment of PLWH into clinical studies that are non-HIV specific and ensuring meaningful involvement of these populations in study design.

Appendix C: Regulatory Recommendations by Department/Agency

Department of Health and Human Services

Centers for Disease Control

The CDC must create new, additional targeted funding opportunities for CBOs outside the large metropolitan areas in the U.S. South, particularly in small cities with high rates of incidence and mortality.

The CDC, in partnership with state and local health departments, should support standard hepatitis case finding measures and the follow-up and monitoring of all viral hepatitis cases reported through public health surveillance. CDC should work with the National Cancer Institute to attach viral etiology to reports of liver cancer in its periodic national reports on cancer.

The CDC should support cross-sectional and cohort studies to measure HBV and HCV infection incidence and prevalence in high-risk populations.

The CDC, the American Association for the Study of Liver Diseases (AASLD), the Infectious Diseases Society of America (IDSA), the American College of Obstetricians and Gynecologists (ACOG), along with the NMA, NHMA, and other targeted community-focused organizations should establish clear recommendations and support detailing for OBGYNs to eliminate mother-to-child transmission of HBV and HCV.

The CDC should work with states to identify settings appropriate for enhanced viral hepatitis testing based on expected prevalence.

The CDC should make education and CBA on strategies and resources to address the employment needs of PLWH available through CBA consultants to its prevention grantees.

Promote the U=U message to the U.S populace

The CDC should launch a widespread “HIV Undetectable = Untransmittable” social marketing campaign to individuals, providers, and educators to consistently share the message and overwhelming evidence that demonstrates that a person living with HIV who has a sustained, undetectable viral load cannot sexually transmit HIV to another person.

Review and relaunch the CDC recommendation that everyone should be tested at least once

Since 2006, CDC has recommended that all Americans aged 13 to 64 get tested for HIV at least once as part of routine health care, and that people with certain factors like community prevalence should get tested more often. This recommendation needs to be implemented with a fresh marketing campaign, both to clinicians and individuals. For sexually active adults, routine testing should always be offered by medical providers.

Expand testing for aging populations

Adults age 50 and older account for 15 % of all new HIV diagnoses and 29% of all people living with HIV. Research shows that heterosexual and LGBTQ older adults are sexually active well into their mid-80s with a 2007 national study showing 53% of adults age 65-74 and 26% of adults age 75-85 report having one or more sexual partners, yet CDC guidelines recommend routine testing for people only up to age 65, leaving out people over age 65 who could benefit from regular HIV testing. Few national or regional HIV prevention campaigns explicitly target older people, especially older people of color and LGBT older people. CDC should update their recommendations to anyone who reports high risk activity, regardless of age.

Promote more frequent HIV testing for those who report recent or regular high-risk activity

The CDC's August 2017 recommendations regarding the benefits of regular HIV testing of gay and bisexual men need further promotion and clarification. First, the CDC should invest in widely promoting the screening campaign and educational materials to clinicians and varied health care settings. As educational outreach efforts to clinicians who are outside of the usual public health channels need targeted, identifying the settings and types of providers who are missing even routine annual screening and providing education and materials to them is critical. The CDC must better explain the difference between screening a defined population and testing individuals for whom testing may be medically warranted and emphasize the importance of prompt testing of individuals who present with symptoms indicating possible HIV infection, or who report recent high-risk activity, or a pattern of such activity. In addition, public health agencies in some urban areas hard-hit by the epidemic – particularly among MSM of color and transgender women – are urging more frequent screening of sexually active MSM. (e.g., once every 3 or 6 months).¹¹⁶

Health Resources and Services Administration

The AIDS Education and Training Centers should provide education and Capacity Building Assistance (CBA) to RWP grantees/providers on strategies and resources to address the employment needs of people living with HIV leveraging existing service systems and infrastructure.

Call on HRSA's HIV/AIDS Bureau Division of Policy and Data to monitor and track provision of food and nutrition services and employment services and their related health outcomes and cost savings, reporting on this annually, to demonstrate the nationwide impact of these programs.

Substance Abuse and Mental Health Services Administration

Syringe Service Programs (SSPs) should receive a significant federal funding investment from SAMHSA and other federal agencies and should be expanded and scaled-up across the nation. Federal agencies should support a multi-pronged approach to improve the health of people who use drugs: increased access to sterile syringes, access to medication-assisted therapy, and HCV treatment and HIV treatment and prevention for people who inject drugs, and other health and mental health services. Agencies should support the authorization of Syringe Service Programs (SSPs), drug user health hubs, and overdose prevention centers (supervised consumption spaces), which reduce HIV, HCV infections and drug overdose fatalities. The federal government should eliminate regulatory, and administrative barriers to evidence-based harm reduction interventions such as syringe exchange programs, medication assisted treatment, and overdose prevention centers.

¹¹⁶ DiNenno, E. A., Prejean, J., Irwin, K., et al. (2017). Recommendations for HIV screening of gay, bisexual, and other men who have sex with men – United States. *MMWR*. 66(31): 830–832.

Harm Reduction plays a vital role along the recovery spectrum, providing a highly effective platform for engagement to the most vulnerable people who use drugs, providing lifesaving supportive services for individuals who are unable or unwilling to seek treatment, and providing linkage-to-care for those who are. SAMHSA should formally acknowledge that harm reduction is an integral part of recovery by updating their Working Definition of Recovery and their Principles of Recovery to explicitly integrate harm reduction into each.

In recognition of their critical role in outreach, engagement, and linkage-to-care for people who use drugs, SAMHSA must work to integrate harm reduction CBOs and SSPs into a comprehensive continuum of care for people along the spectrum of recovery. SAMHSA should seek to identify mechanisms to encourage the Single State Agencies and other recipients of federal opioid and substance use treatment and prevention funding to collaborate with and provide funding support to harm reduction programs and SSPs.

- Specifically, funding through the Substance Abuse Treatment and Prevention Block Grants, MAT-PDOA, the Opioid State Targeted Response Grant (O-STR), the State Opioid Response Grant (SOR), and all other current and future funding streams which seek to expand access to treatment or prevent overdose.
- SAMHSA's current reporting system GRPA places an incredibly high data collection burden upon grantees, which effectively prevents many CBOs from being able to access SAMHSA funding. SAMHSA should seek to reduce GRPA's negative impact on smaller programs and create lower threshold reporting tiers for CBOs.
- SSPs must be involved wherever possible in the planning and implementation of SAMHSA-systems planning, scale up, or expansion.
- SSPs must be promoted as an integral part of any state's two-year Behavioral Health Systems Assessment and Plan.

SAMHSA should commission the National Academies of Science, Engineering, and Medicine (NASEM) to produce a report analyzing options for removing regulatory barriers to methadone for opioid use disorder treatment.

National Institutes of Health

NIH should support more research on HIV and aging including research on key populations with high HIV prevalence

Research should look closely at differences within more marginalized and less studied subgroups of these populations (e.g., transgender and gender non-conforming people, Southeast Asian communities). Specifically:

- NIH should support research in the priority areas identified by the NIH Office of AIDS Research (OAR) Special Working Group on HIV and Aging, including but not limited to multi-morbidity management, behavioral health needs and caregiver support resources.
- NIH should reconvene the NIH-OAR aging working group to assess progress on its recommendations since early 2012, address research gaps, particularly with regard to older adults, and provide updated recommendations based on the current science on HIV and aging.

Centers for Medicare and Medicaid Services

Oppose measures limiting access to Medicaid

The Administration must immediately halt the approval of waivers that are counter to the intent of the Medicaid program and that restrict rather than improve access to healthcare for low-income Americans. The imposition of work requirements, premiums, burdensome reporting requirements, limits to prescription drug coverage, and coverage lockouts threaten the health of people living with HIV and millions of other Americans who count on the program. Conditioning Medicaid eligibility on a work requirement is particularly problematic for our efforts to end the epidemic. A large majority of Medicaid beneficiaries already work but their employer does not provide healthcare coverage and their positions are often seasonal or temporary. Placing additional barriers to care on Medicaid beneficiaries living with HIV will have individual and public health consequences. As early reports from states that have implemented work requirements indicate, individuals will soon lose access to coverage, not because they are not working, but because they are unable to document compliance due to complicated reporting systems.¹¹⁷ For people living with HIV, interruptions in access to antiretrovirals jeopardize viral suppression and consequently their health status. Without Medicaid coverage, people living with HIV and millions of others are unable to work. We strongly recommend that CMS stop encouraging and approving Medicaid waivers that will put coverage for people with HIV at risk.

It is also critically important that Medicaid maintains consumer protections that ensure access to medication for people living with HIV. HIV medications, particularly newer single tablet regimens, are increasingly subject to utilization management techniques that are counter to clinical guidelines and act as a barrier to accessing the most effective treatment. While we support innovative solutions to drug pricing that will promote competition and increase access to lifesaving medications, it is important to preserve protections that ensure coverage decisions are based on clinical guidelines and recommendations, rather than purely on cost.

Support implementation of innovative care delivery and payment models

States' efforts to develop innovative care delivery and coverage/payment models through their Medicaid programs should be supported. These efforts might include managed care and/or disease management programs lead by AIDS services organizations that have a long history of providing coordinated primary, specialty, and pharmacy care for people living with HIV. These programs should recognize the value that AIDS services organizations provide to payors and the health care system in general and should reward these providers for their ability to move the needle on outcomes.

Innovative service delivery, benefit design, and payment models should also address social determinants of health, including housing, food, and others. CMS's Accountable Health Communities Model is currently testing models that systematically identify and address health-related social needs of Medicaid beneficiaries through screening, referral, and community navigation services, with the goal of increasing coverage, improving access, impacting health care costs, and reducing service utilization. We applaud CMS' recognition that factors outside of the health care delivery system have a significant effect on the health and wellbeing of Americans, and we encourage additional models to further test these theories.

¹¹⁷ Hellmann, J. (2018, July 16). More than 7,000 fail to meet Medicaid work requirements in Arkansas. The Hill. Retrieved from <http://thehill.com/policy/healthcare/397260-more-than-7000-fail-to-meet-medicaid-work-requirements-in-arkansas>

The Medicaid health home benefit allows states to cover additional services to improve care management and coordination for beneficiaries with two or more chronic conditions to improve health outcomes and reduce costs. States receive an enhanced rate of 90 % for the health home services for the first eight quarters of implementation. Several state Medicaid programs have implemented health homes for people with HIV with promising results. We urge CMS to continue to educate state Medicaid programs on the effectiveness of the Medicaid health benefit and encourage states to implement the Medicaid health home benefit for individuals with HIV, substance use disorder, hepatitis C and other complex chronic conditions.

Medicaid programs should be incentivized to enter into data sharing agreements with Departments of Public Health

Advances in HIV surveillance systems and methods have improved federal, state, and local efforts to evaluate and improve outcomes along the HIV care continuum. Given the heightened role Medicaid now plays in paying for and providing care for people living with HIV, Medicaid should create stronger collaborative partnerships with state-operated programs that have a history of providing care to the HIV population, such as Departments of Public Health. Specifically, Medicaid programs should enter into data sharing agreements with departments of public health to enable Medicaid programs to better measure HIV utilization and outcomes for Medicaid beneficiaries.

Medicaid programs should be encouraged to adopt a HIV viral load suppression measure of performance

Improving rates of viral load suppression among people living with HIV is critical to realizing individual, population, and community health improvements, as well as any cost savings associated with them. To help facilitate this outcome, all state Medicaid programs should be encouraged to adopt a HIV viral load suppression measure of performance.

Direct the Center for Medicare deputy administrator to ensure beneficiaries have access to and choice of provider, including pharmacies and to prohibit Part D plans from changing pharmacy networks mid-year to ensure continuity of care and treatment

Direct the CMMI to support innovative Medicaid payment and delivery reform models that include HIV prevention and care services and HIV providers and that promote and leverage coordination and integration of CDC, HIV/AIDS Bureau and SAMHSA programs and resources. Examples include reimbursing for peer supports and employing Community Health Workers and other community-based providers

CMS should direct the realignment of reimbursement mechanisms to support case management services for Medicare/Medicaid recipients with viral hepatitis and/or substance use disorders.

Include STIs as a core quality Medicaid measure

CMS has core quality measurements for HIV and Hep C, however, there are none for STIs. Part of the reason that STIs are at such high levels are because health care providers are not thinking to test for STIs. By developing quality measures for Medicaid health care providers will be reminded and encouraged to regularly test for STIs.

Multiple Departments within HHS

The agencies within HHS must fund HIV-related stigma reduction interventions, particularly in the US South.

CDC and HRSA should seek ways to support non-traditional clinics to increase access points for vulnerable and not engaged communities

CDC and HRSA should create tools to support provider training on communicating to patients key messages on prevention options (including PrEP) and on how to talk to patients (especially newly diagnosed) on the meaning of U=U.

CDC, HRSA, SAMSHA, and NIH must strengthen health literacy and increase health system navigation services.

Many people of color do not access health care on a regular basis and do not have a relationship with a medical provider. It is essential to promote health literacy by increasing the capacity of these individuals to navigate the health system, including assessing insurance coverage options, enrolling in coverage, identifying a primary care provider, making medical appointments, accessing services, and troubleshooting if problems arise. This may be particularly important in the context of PrEP for HIV-negative individuals who may be unaccustomed to working with the healthcare system specifically, patient assistance programs. But is also important for PLWH, especially those who are newly diagnosed, who may not have experience with navigating health systems prior to their diagnosis.

Strengthen protections from discrimination for lesbian, gay, bisexual, and transgender people under both Title VII of the Civil Rights Act and Title IX of the Education Amendments Act of 1972 and provide better reporting on the health and human services needs of the entire LGBT community with a particular emphasis on the transgender community.

The federal government must immediately recognize and enact protections from discrimination for LGBTQ people the basis of sexual orientation and gender identity and expression under Title VII of the Civil Rights Act of 1964 and Title IX of the Education Amendments Act of 1972. Further, all federal agencies that provide services to transgender people should be directed to produce annual reports with substantial behavioral or surveillance data specifically focused on the transgender community.

Allow Ryan White Program-funded clinics access to health center reimbursement mechanisms under Medicaid

Extend to Ryan White grantees who are funded to provide health care the ability to receive enhanced or cost-based Medicaid reimbursement for the provision of medical services similar to the reimbursement levels for FQHC/CHCs. This would help alleviate capacity challenges that create barriers to HIV care. This would also increase access to care by affording organizations interested in developing health clinics the opportunity to build new clinics to serve the growing number of HIV patients and give current clinics that face higher costs and or declining revenue an opportunity to extend their current capacity and provide additional access to care for new patients. This proposal does not change Medicaid eligibility for patients or expand services available.

The Administration should repeal regulations expanding access to Association Health Plans and short term limited duration health plans.

Association health plans (AHP) and short term limited duration plans (STLDP) plans will reintroduce discrimination to the individual insurance market, increase premiums and restrict rather than increase access to the ACA-compliant plans that people living with HIV and others with pre-existing conditions rely on for the health care coverage. AHP and STLDP plans are not meaningful forms of insurance and will not be viable coverage options for people with HIV and millions of other Americans with pre-existing conditions. What's worse by segregating the individual market and syphoning off an estimated 400,000 to 800,000 younger and healthier individuals, the ACA-compliant plans that people living with HIV count on are likely to be priced out of reach¹¹⁸. The rules expanding AHPs and STLDP must be repealed or these plans should be subject to the same rules as the ACA compliant plans. The Administration's regulatory actions are already resulting in increases in the number of uninsured after the uninsured rate reached an historical low of 10.4% in 2016¹¹⁹.

Enhance payment for cognitive care services that are reimbursed through Evaluation and Management Codes

Fully Implement and Resource the National Viral Hepatitis Action Plan, 2017-2020

The National Viral Hepatitis Action Plan, 2017-2020, establishes clear goals, strategies, and indicators for improving the national HCV and HBV responses. HHS should establish an interagency work group and a separate community stakeholder group that follows the principles of meaningful involvement of people living with and affected by HCV and HCV, dedicated to fully implementing the Action Plan and should revive the practice of publishing an annual progress report.

Establish and Implement a National Viral Hepatitis Elimination Plan, 2020-2030

The federal government must immediately establish and begin implementing a national plan to eliminate HCV and HBV as public health threats in the United States. The World Health Organization has committed to the goal of eliminating viral hepatitis as a public health threat by 2030. Jurisdictions across the U.S, such as San Francisco, New York, and Louisiana have begun to take concrete steps toward establishing plans to eliminate their local HCV epidemics.

There is already broad consensus among experts that viral hepatitis elimination is feasible. The National Viral Hepatitis Elimination Plan should draw from recommendations from international and local elimination efforts and the National Academies of Sciences, Engineering, and Medicine reports on Eliminating the Public Health Problem of Hepatitis B and C in the United States.

The National Viral Hepatitis Elimination Plan should include:

Opportunities for community engagement in shaping the plan, including meaningful involvement of people living with and affected by HCV and HBV, and groups at higher risk of viral hepatitis

¹¹⁸ Wakely Consulting Group. Effects of Short-Term Limited Duration Plans on the ACA Compliant Individual Market. April 2018.

¹¹⁹ Kaiser Family Foundation. (2018, August 28). Uninsured Rate Among the Non-elderly Population, 1972 to 2017. Retrieved from <https://www.kff.org/uninsured/slide/uninsured-rate-among-the-nonelderly-population-1972-2017/>

infection, such as people who use injection drugs, people with a history of incarceration, and people who are homeless or marginally housed, and people from countries with high HBV prevalence.

Specific HCV and HBV elimination metrics and targets.

Recommendations for federal agencies, as well as the creation of an interagency implementation group required to follow time-based recommendations and targets for federal agencies.

The National Committee for Quality Assurance should establish measures to monitor compliance with viral hepatitis screening guidelines and HBV vaccine birth dose coverage and include the new measures in the Healthcare Effectiveness Data and Information Set.

Federal and state criminal justice systems should screen, vaccinate, and treat HBV and HCV in correctional facilities according to national clinical practice guidelines. (Since there have been recent hepatitis A (HAV) outbreaks in homeless populations, HAV vaccinations should also be provided at intake.) The federal government should support financing to scale up HCV and HBV treatment in state departments of corrections with mechanisms to ensure that states are following national clinical practice guidelines and track progress toward micro-elimination within state correctional facilities. Federal or state prisons should implement opt-out HCV antibody screening with reflexive RNA confirmatory testing for all persons entering a facility, and case finding for persons who are currently incarcerated but whose HCV status is not known.

Federal and state agencies should support reimbursement of telemedicine for medically assisted treatment for opioid use disorder to expand the provider base, particularly in rural areas.

Federal and state agencies should support the extension of primary care practice licenses for community-based organizations to receive reimbursement for viral hepatitis testing, vaccination and case management services they currently provide for patients who often face stigma in medical settings.

HHS should conduct a fiscal and epidemiological cost-benefit analysis of the federal purchase the rights to a direct-acting antiviral for use in neglected market segments, such as Medicaid, the Indian Health Service, and prisons. This analysis should explore licensing or financing mechanisms.

HHS should work with states to build a comprehensive system of care and support for special populations with HBV and HCV on the scale of the Ryan White system (while ensuring that Ryan White is fully funded to address the U.S. HIV epidemic)

Similar to what many States have done for people living with HIV to help alleviate the capacity challenges accessing health care, through 1915(C) and 1115 waiver authority under Title XIX of the Social Security Act, State Medicaid programs should expand reimbursement mechanisms to support case management services for recipients with chronic viral hepatitis and/or substance use disorders.

State Medicaid programs should cover all medically necessary treatment for people with Hepatitis C Virus and remove unnecessarily restrictive prior authorization criteria. State policies that restrict access to

direct-acting antiviral medications, through methods such as threshold fibrosis scores or sobriety requirements, violate federal law.

Implement the National Action Plan (NAP) to Combat Multidrug Resistant TB (MDR-TB) with appropriate levels of funding.

This seminal plan was developed as a cross-agency collaboration and introduced in late 2015. The NAP outlines essential steps to address drug-resistant TB both globally and domestically and was heralded as a thoughtful, comprehensive and strategic plan. However, despite its potential as a pathway to combat MDR-TB, the NAP was introduced without funding. The federal government must commit funding for USAID and DTBE to successfully implement the NAP and bring the U.S. and the world closer to addressing the deadlier drug-resistant forms of TB.

Consider novel strategies to stabilize and maintain supply for vital TB drugs.

The TB drug supply is prone to shortages and supply disruptions, primarily due to the vulnerabilities associated with single manufacturers of the first-line drugs used to treat TB. U.S. TB control programs need access to affordable and available medications, including those medications and combination regimens not currently available in the U.S. This includes appropriately dosed pediatric fixed-dose formulations of first-line TB drugs.

The federal government should prioritize addressing this TB drug supply vulnerability to maintain the supply of TB medications, including consideration of a centralized procurement system, allowing procurement from the Global Drug Facility (GDF) which is largely supported by U.S.-funding but from which U.S. TB programs are unable to access. Impactful programs modeled after ADAP that can potentially expand access to TB treatment are desperately needed for the TB community.

Strengthen TB research and development undertaken by the Tuberculosis Clinical Trials Consortium (TBTC) at CDC and other agencies

Congress must expand resources to strengthen current and future clinical research undertaken by the TBTC at CDC for the development of new and needed diagnostics, prevention, and treatments to combat all forms of TB, but also improve adherence, minimize side-effects, and shorten timelines to cure. This includes increased resources for HIV/TB comorbidities research at the National Institutes for Health, National Institute for Allergy and Infectious Diseases (NIAID). Additional resources and mandate to expand TB research is needed across U.S. Agency for International Development (USAID), Department of Defense Congressionally Directed Medical Research Programs (CDMRP), and the Biomedical Advanced Research Development Authority (BARDA).

With many countries across the world also mobilizing to contribute their 'fair share' in research funding for TB, the U.S. government should boost their contributions to TB research to at least \$444.5 million. This is a recommended increase of \$128.0 million, spread across the aforementioned agencies and additionally include the Office of the Global AIDS Coordinator (OGAC), the Food and Drug Administration (FDA), and the National Science Foundation (NSF).

Provide support for primary trainings and continuing education for providers through CDC and HRSA in crosscutting cultural responsiveness

We must rethink our assumptions about risk and risk assessment. Traditional risk assessment describing groups with higher rates of HIV incidence as "high-risk" contributes to stigma and may

make people less likely to seek services. To provide effective HIV treatment and prevention, we need providers to eliminate terminology that can be stigmatizing. Moreover, provider biases may cause a clinician to improperly assess someone's risk.

To address provider implicit biases, trainings for current and future providers that increase racial and sexual orientation/gender-related cultural competencies need to be expanded and routinized, as well as models for integrating biomedical interventions in clinical and non-clinical settings.

Provide comprehensive and integrated health programs to ensure equitable access to health services for individuals involved in all forms of sex work

Sex workers are at increased risk for HIV, but due to stigma associated with sex work and the fear of being not only judged but criminally prosecuted, many sex workers may avoid STI and HIV testing, or seeking HIV treatment or PrEP services. Because many policing jurisdictions use condoms as evidence of sex work in arrests, even accessing free condom programs at most CBOs or clinics can be undesirable for sex workers. In addition to working with sex workers, people who seek their services should also be engaged in testing, prevention and treatment programs, which can offer sex workers additional protection from clients living with HIV, who may or may not be on treatment and virally suppressed. Funding programs and support groups for sex workers can create group solidarity and empowerment and can be more cost-effective than criminal justice approaches.

Support implementation of the U.S. Preventive Services Task Force's "A" rating to PrEP as a primary prevention intervention

The U.S. Preventive Services Task Force (USPSTF) has determined PrEP to be a primary prevention intervention within its scope of review. USPSTF had been waiting on completion of 12 U.S. based studies that were open in 2016 at the time of its determination that should now be final. The clear evidence in their review and subsequent "A" grade of PrEP as an intervention will help ensure PrEP is fully integrated into regular provider practice as well as standard insurance coverage.

Federal agencies should increase efforts to educate providers regarding both PrEP and PEP

Many of the same barriers prevent individuals from accessing PEP as for PrEP, including lack of provider awareness and/or knowledge and lack of healthcare coverage, particularly in the Deep South. Federal agencies should increase efforts to educate and train infectious disease and non-infectious disease providers, including primary care and pharmacists, regarding both PrEP and PEP.

Target and incentivize non-traditional venues to offer PrEP

Black men who have sex with men, individuals who inject drugs, and other populations who are higher risk for HIV are less likely to have access to routine medical care. Creative and innovative partnerships should be supported to offer PrEP to individuals where they are including in community-based programs, health centers, Title X clinics, syringe services programs and substance use treatment programs.

Federal agencies must be proactive around communicating the availability of federal funds to support SSPs by issuing guidance, providing technical assistance, and widely distributing resources to promote the use of federal funds to support SSPs along with other syringe access strategies, including non-prescription pharmacy sale.

- Encourage development of programs that allow for waiving or covering co-payments when accessing naloxone through a pharmacy on an individual's insurance, as well as waiving payment for those without health coverage or who choose to not charge their insurance. This will help address funding barriers and can be spearheaded by local health departments with collaboration through insurance companies.
- Publicly funded SUD treatment programs should be mandated, as a prerequisite to receive federal funding, to provide naloxone freely to their patients as well as keep emergency overdose response kits with naloxone accessible to all program participants and staff.
- SAMHSA and other federal agencies should allow use of federal funding to support purchase of fentanyl test strips, as well as other people who use drugs-focused drug checking services and people who use drugs-focused emerging drug trend/overdose alert systems.

Declare the STI epidemic a Public Health Emergency to generate the attention and more rapidly leverage the resources necessary to effectively respond to this growing public health crisis before it worsens.

STIs are at their highest levels ever and only continue to grow. We need to mobilize resources to identify new and creative solutions to STI prevention, and to ensure that health departments that are working to identify and prevent new cases have additional support from throughout the public and private health care sphere to address this crisis. To do so, the President and Surgeon General need to declare STIs a public health emergency.

Include STIs screening and treatment as a component of HIV prevention programs

Early detection and treatment of curable STIs should become a major, explicit component of comprehensive HIV prevention programs at national, state, and local levels. In areas where STIs that facilitate HIV transmission are prevalent, screening and treatment programs should be expanded; Individuals who are diagnosed with or suspected to have an STI when diagnosed with HIV, should be immediately linked to HIV care and ART.

Work to re-establish clinical quality measures for STI screening

When the National Quality Forum (NQF) last undertook review of the infectious diseases measures set (the clinical quality measures that are used in the various federal quality improvement and value-based incentive programs), many measures were retired or dropped including the measure for STI screening. The CDC and HRSA should work with the NQF to develop and submit for NQF endorsement updated STI screening measures to promote clinician adherence to treatment guidelines with regard to STI screening.¹²⁰

Develop sex positive messaging

¹²⁰ <https://www.idsociety.org/uploadedFiles/IDSA/Global/HIVMAIDSACHACTestimony.pdf>.

The federal government should work to create a sex positive STI prevention campaign. Much like PrEP has helped people take control over their sex lives, knowing about and preventing STIs can also help to support a pleasurable sex life. The federal government should work to create messaging that is sex positive to encourage people to take control over knowing their STI status.

Address Food and Nutrition Research gaps to inform policy

Two key areas preclude a full understanding of the potential impact of FNS. First, we do not know the scope of food insecurity among PLWH, even in the Ryan White Program. Second, although initial research is promising, we do not fully understand the impact of different levels of food-based interventions on health outcomes and cost savings.

In-line with the subsequent recommendation to support HIV/AIDS research, the federal government should establish a federally supported Structural Interventions Research Committee within the Office of AIDS Research to advance coordination, communication, and furtherance of research throughout Federal agencies. Additionally, Health Resources and Services Administration (HRSA) HIV/AIDS Bureau (HAB) Division of Policy and Data must monitor and track provision of food and nutrition services through the Ryan White HIV/AIDS Program (RWP) and their related health outcomes and cost savings, reporting on this annually, to demonstrate the nationwide impact of these programs.

Enhance training and technical assistance in the provision of food and nutrition services

The changing epidemic requires a responsive system of care to ensure the prevention and treatment of HIV/AIDS. Dedicated training that addresses the shifting policy landscape and new opportunities for access to coverage is imperative if we are to end the epidemic.

The federal government should invest in dedicated capacity building and technical assistance (TA) on food and nutrition services, by recommending that training and TA on the importance of and access to food and nutrition services for PWH be provided in HHS by HRSA/HAB, including within the AIDS Education and Training Center (AETC) Program for HIV care providers; by the CDC for HIV prevention providers; and by HUD's Office of HIV/AIDS Housing (OHAH) for HOPWA providers.

Furthermore, the federal government should direct HRSA's Special Projects of National Significance (SPNS) program to specifically target social and economic determinants of health; specifically, the importance of structural interventions in highly impacted states/communities, facilitation of cross-sector multidirectional training, collaboration and service coordination. Outcomes should include integration of assessment of structural intervention needs at intake and follow up throughout HIV care and prevention service delivery, with delivery of or linkage to appropriate information, services and resources.

Encourage Medicaid programs to fund supportive housing

CMS has approved use of Medicaid for supportive housing services. For people who are chronically homeless or have histories of institutionalization, stable supportive housing will drastically improve their health outcomes. We advocate for states to use Medicaid dollars for housing.

Develop interventions to respond to employment needs of PLWH

A federal interagency task force of NHAS implementers including HHS, HOPWA, DOL, and DoED should develop a plan to support the vocational training and employment of PLWH.

Support a bold agenda for HIV/AIDS research related to structural interventions

Establish a federally-supported Structural Interventions Research Committee within the Office of AIDS Research to advance coordination, communication, and furtherance of research throughout federal agencies, especially HHS, CDC, NIH, HUD, and DOL. This Committee should:

- Recommend funding of research vetted by the Structural Interventions Research Committee in the President's Budget for Fiscal Year 2020.

Advance a behavioral and social science research agenda for HIV/AIDS research

Recent advances have pivoted HIV research to examine acceptability, adherence, scalability of interventions within and across communities affected by HIV. Game-changing interventions such as PrEP have shown effectiveness for some users, but not for all for reasons of acceptability, and reveals challenges of prevention use in the real-world. In treatment, addressing questions of why certain people are better able to engage in care and use and adhere to treatment are critical to ending the epidemic.

Answering these critical questions through a comprehensive behavioral and social science research agenda for HIV is essential in determining and overcoming social and behavioral barriers and to developing appropriate strategies to enhance acceptability and adherence of prevention modalities and/or treatment, unique to communities that are hit hard by the HIV epidemic.

Implement a research agenda focused on the health impacts of HIV-related inflammation

The prevalence of noncommunicable diseases and age-related morbidities may be the cumulative effects of longstanding inflammation in PLWH. The increasing burden of diseases accelerates HIV morbidity and mortality and complicates health management for PLWH. More focus is needed to investigate the physiological impact of HIV-related inflammation on the health outcomes of PLWH and help inform better treatments and interventions to minimize effects.

Continue existing HIV research cohorts

Large comprehensive research cohorts like MACS (Multicenter AIDS Cohort Study) and WIHS (Women's Interagency HIV Study) have played a critical role and continue to be essential to understanding the complexities of HIV disease and progression, as well as informing treatments for co-morbidities and HIV. Bolstering resources to protect and expand these research cohorts is needed to continue to enrich data on the scientific understanding on HIV, from pathogenesis to treatment.

Department of Justice

DOJ should reduce at every opportunity the criminalization of people who use drugs and their communities. Drug criminalization is inherently harmful and a primary driver of drug-related harm.

DOJ should take action to end the criminalization of viral hepatitis. Local and federal statutes that criminalize viral hepatitis discourage testing and increase stigma. The federal government should promote pre-arrest diversion programs

The Administration should explicitly allow localities to move forward in implementation of Safer Consumption Spaces without threat of federal law enforcement action. Federal agencies which administer overdose and infectious disease funding should identify ways in which SCS programs are in-alignment with the goals and priorities of each of their funding streams and issue guidance on use of such funding within an SCS program.

DOJ and HHS must collaborate and provide resources to states and localities for preventing and treating HIV during incarceration and upon reentry

DOJ and HHS must collaborate and provide resources to states and localities, including training, TA, and model best practices for state prisons and local jails for addressing, preventing, and treating HIV during incarceration and upon reentry. 95% of the incarcerated population in the US is incarcerated in a state prison or local jail. Such resources would reduce HIV transmission and connect individuals to HIV care and treatment is necessary if the US is going to achieve an AIDS-Free generation.

Food and Drug Administration

The Food and Drug Administration should promote increased access to naloxone by removing prescriber requirements and allow for over-the-counter access for some formulations.

Work to ensure penicillin stays in stock

In 2016 the Food and Drug Administration (FDA) was warned about a dangerous shortage of Bicillin L-A. Bicillin is the only known treatment for syphilis, and without adequate supply the efforts to prevent new cases of syphilis could be harmed. There needs to be a federal review of this shortage to assess its causes and develop solutions to address immediate issues and help ensure a reliable supply of this important medicine.

Department of Housing and Urban Development

Federal agencies, including the Departments of Justice and Housing and Urban Development, should issue guidance and resources to grantees and partners recognizing that structural risk environments – such as corrections, homelessness and unstable housing, etc. – contribute to overdose risk, and that reducing exposure to those environments is a form of overdose prevention.

HUD should aggressively enforce existing Americans with Disabilities Act protections for MAT patients in Fair Housing Act-covered housing

The United States Interagency Council on Homelessness (USICH) should promote coordination between HUD and HHS on reducing overdose

Encourage Ryan White grantees to use funding for housing

HRSA issued guidance that Ryan White funds can be used to house people living with HIV/AIDS. HRSA and HUD continue to collaborate to ensure housing is integral to care and treatment for people living with HIV. Grantees should assess their ability and knowledge to provide housing services and collaborate with housing agencies.

HUD allows HOPWA funding to be used to address employment needs. This should be promoted to its HOPWA grantees, and HUD should increase CBA to grantees to support implementation of employment-related programs. Promoting eligibility for and benefits of the Earned Income Disregard (also known as the Earned Income Disallowance) for HOPWA HUD-subsidized housing.

Support housing assistance as a primary HIV prevention intervention for at risk groups

Rates of homelessness are high among persons at greatest risk of HIV due to substance use, mental illness, intimate partner violence, and other vulnerabilities. While it is difficult to estimate total housing need among people at risk, at least one half of homeless persons in any community fall into one or more of these highest risk categories, and research indicates that the condition of homelessness itself places all persons who lack stable housing at increased risk of HIV transmission. To prevent new infections, we should support housing assistance for homeless and unstably housed persons at risk of HIV transmission.

Call on HUD's Office of Policy Development and Research to research the efficacy of various housing approaches and their impact on ensuring PLWH link to care, maintain care, and have improved health and well-being.

Department of Labor

DOL, through its Employment and Training Administration (ETA) and its Office of Disability Employment Policy (ODEP) should: i) provide education and CBA across its public workforce programs, to ensure the capacity to provide effective, non-stigmatizing and affirming services to PLWH, and communities most impacted by HIV and ii) create targeted employment initiatives for PLWH iii) direct public workforce funds to initiate and/or sustain HIV employment initiatives through its Employment and Training Administration (ETA) in conjunction with its Office of Disability Employment Policy (ODEP) and iv) increase protections against employment discrimination based on gender identity and sexual orientation for PLWH.

Department of Education

DoED's Rehabilitation Services Administration (RSA) should establish a national demonstration project to fund community-based partners embedded within HIV service settings to coordinate access for PLWH to information, services and resources to achieve self-chosen goals for employment, empowered and supported for well-informed decision-making about employment, with non-stigmatizing, affirming and well-informed service delivery. This will increase utilization and efficacy of vocational rehabilitation services among and for PLWH.

Appendix D: Hybrid Legislative and Regulatory Recommendations

The United States must upgrade treatment and prevention services in Puerto Rico, the U.S. Virgin Islands and all territories to the same level as achieved in the U.S. including strengthening and expanding PrEP education and access, increasing access to HIV testing and improved surveillance, expanding, integrating, and coordinating of HIV prevention and care services for special populations including transgender women and people who inject drugs and ensuring access to HIV treatment for all people in the territories. The U.S. must ensure that its HIV, viral hepatitis, opioid, and STI responses in Puerto Rico, the U.S. Virgin Islands, and the territories include leadership, representation, and voices from the territories. In addition, the U.S. must create the conditions necessary for the islands to withstand future hurricane events. Finally, the U.S. must relieve Puerto Rico, the U.S. Virgin Islands and rest of the territories of their debt. The Health Resources and Service Administration (HRSA) should examine the feasibility of distributing Ryan White Program Part B Supplemental Funding taking into account the disproportionate impact of HIV incidence and outcomes in the Deep South. We ask that the Secretary work with HRSA and CDC to determine the best way to ensure that the most current new HIV diagnosis rates and HIV-related death rates are incorporated into a funding methodology. We recommend that HRSA then reach out specifically to these states to invite each of them to apply for Ryan White Program Part B Supplemental funding, to identify any barriers to applying, and to work with states to overcome the identified barriers.

Fully enforce and monitor civil rights protections

The federal government is responsible for protecting and promoting the civil rights and wellbeing of the people of the U.S. and its territories to ensure that they can live and participate in society free from violations and discrimination. When government steps away from these responsibilities or refuses to enforce civil rights laws and protections, it creates unsafe environments and exacerbates the HIV epidemic. The federal government must uphold civil rights and non-discrimination protections on behalf of LGBTQ people, immigrant communities, Black and Latinx communities, Native American populations, people with disabilities, and other historically disenfranchised populations. We urge Congress to reject proposed and implemented budgetary and regulatory changes that undermine historic protections that are essential to sustaining the gains made in the HIV epidemic.

Remove immigration status-related restrictions from HIV programs and Medicaid

Immigration reform is a matter of civil rights for millions of undocumented men, women, and children who work and live in the U.S. today without consistent legal protection. Many individuals face an uncertain future and are less likely to access health services due to fear of deportation. We must ensure access to high-quality health care for immigrants regardless of status including access to medications, hormone treatments, and non-stigmatizing, culturally-relevant, and gender-responsive health care. We recommend that States with continued high rates of HIV and significant numbers of immigrants impacted by HIV obtain CMS waivers that allow outreach and other services to these highly-impacted groups. Removing immigration status-related restrictions from these programs is vital to achieving an end to the epidemic and addressing health disparities among immigrant communities.

Reject proposed changes to the “public charge” definition that would inhibit immigrants from seeking health care, including preventive health services, for themselves and their families.

Develop a national basic health insurance program that pays for basic preventive health and primary care for both documented and undocumented immigrants, including coverage for care associated with HIV, STI’s, hepatitis tuberculosis, other communicable diseases, and behavioral health conditions.

Establish “border” health services in jurisdictions with high concentrations of undocumented immigrants to outreach and provide health services to these constituents in the interest of public health.

Ensure access to Medicaid for people living with HIV in all states and maintain the Medicaid expansion

The Medicaid expansion significantly reduced the uninsured rate in states that implemented it.¹²¹ Currently, most individuals with HIV/AIDS in non-Medicaid expansion states who qualify for Medicaid do so because they have very low incomes, have progressed to AIDS and are disabled and unable to work. Providing earlier access to Medicaid coverage for low income individuals at higher income levels and without requiring disability promotes earlier access to the comprehensive care and treatment that keeps people living with healthy and stops diseases transmission. Congress and the Administration must maintain the healthcare safety net structure of the Medicaid program, including the Medicaid expansion to maintain the progress we have made in increasing the amount of people living with HIV with regular access to care and coverage.

Many states fail to make the necessary investments to improve health outcomes in their jurisdictions. A clear example is the lack of Medicaid expansion in eighteen states which would have infused millions of federal dollars into areas of great need. Expanding Medicaid is the single most important systemic change that would provide greater access to medical care for people living with HIV and those at risk for HIV. The federal government must incentivize states to expand Medicaid without adversely impacting the flow of resources that benefit persons living with HIV.

Ensure Access to Medicaid for People Living with HIV in all States

Currently, most people living with HIV in non-Medicaid expansion states who qualify for Medicaid do so because they are determined to be disabled after they have received an AIDS diagnosis. Providing better access to treatment immediately upon HIV diagnosis, increasing the health of people living with HIV and greatly reducing the risk of transmission to HIV negative sexual partners is critical to ending the epidemic. We can do so by ensuring Medicaid eligibility for low-income people living with HIV and aligning Medicaid eligibility rules with current federal government guidelines on the standard of care for treating HIV and ensuring access to Medicaid for people living with HIV immediately upon diagnosis.

Federal law *requires* states to cover certain population groups and *allows* them to cover others. In general, Medicaid covers low-income mothers and children, elderly people, and people with disabilities, although specific income and other requirements vary by state. States set individual eligibility criteria within federal minimum standards; they are also able to request from CMS a

¹²¹ KFF. (2017, February 14). Insurance Coverage Changes for People with HIV Under the ACA. Retrieved from <https://www.kff.org/health-reform/issue-brief/insurance-coverage-changes-for-people-with-hiv-under-the-aca/>

waiver of federal law to expand health coverage beyond these groups. Many states have expanded coverage above the federal minimums. Currently, adults who are childless, nonelderly, or do not have a disability cannot qualify for Medicaid, regardless of their income level. An exception exists for states that have expanded Medicaid under the ACA and for states that have a waiver that allows coverage.

State Medicaid program efforts that provide early intervention access to Medicaid ensure early intervention, treatment, and good outcomes for people living with HIV. Such efforts include Medicaid expansion under the ACA, as well as Section 1115 and 1915(c) waivers for services. Many states have or have had waivers that provide home- and community-based services, including case management, for people living with HIV (through 1915(c) waivers), or use 1115 waiver authority to provide Medicaid eligibility to individuals living with HIV who would not otherwise be Medicaid-eligible unless their health deteriorated to the point of disability. States should consider using these mechanisms to provide needed services that will keep people living with HIV healthy.

Eliminate the 29-month waiting period before SSDI recipients can obtain Medicare benefits.

The more than two-year waiting period for Medicare is a major hurdle for many PLWH receiving SSDI who are already disabled. In order to get everyone living with HIV into sustained treatment, this barrier to care should be eliminated.

Formulary “all drugs, all classes” rule - widen access by allowing for all and removing barriers

The addition of the Part D benefit to Medicare in 2006 marked an important change for Medicare beneficiaries, especially those with illnesses and chronic conditions treated by costly medications, including those with HIV. Plans under Part D are required to cover all approved antiretrovirals (ARVs), designating ARVs as one of “six protected” drug classes. There is no requirement for plans to cover all other non-ARV drugs that might be needed to treat HIV-related illness or other comorbidities, however. PLWH should have access to all the medications they need to survive and thrive, not just ARVs.

Extend Medicaid drug rebates to low-income Medicare beneficiaries

Medicare should benefit from the same discounts for prescription drugs as Medicaid. Low-income dually-eligible people (people eligible for both Medicare and Medicaid) comprise one-fourth of all Medicare drug users and are among the most costly beneficiaries. Because Medicare, rather than Medicaid, covers most of their drugs and because Medicare cannot negotiate drug prices, these drugs are not eligible for the same rebates as they were, and would be, under the Medicaid program. Extending Medicaid rebates for dually-eligible and other low-income people could save more than \$145 billion over ten years. Extending drug rebates to all Medicare beneficiaries would yield even more savings.

Enforce the ACA’s nondiscrimination protections

The ACA’s nondiscrimination protections have been critical to ensuring access to care and treatment for people living with HIV and other chronic conditions. This has been particularly important to ensure that issuers do not design plans in ways that discourage enrollment from individuals with high-cost conditions (e.g., through placing all or most drugs used to treat HIV on

the highest cost-sharing tier or implementing formulary restrictions that are counter to HIV federal treatment guidelines).

Congress and the Administration must preserve these important non-discrimination protections, including the protections as part of the Essential Health Benefits prescription drug standards.

Bolster healthcare infrastructure in the U.S. South and rural areas

Many parts of the South have a weaker healthcare infrastructure, with limited ability to respond to sexually transmitted infection (STI) epidemic, HIV treatment and prevention service needs, and an insufficient number of providers, especially in rural areas. Need strategies that support healthcare access to rural settings must be developed and deployed to cover service gaps. Solutions such as Medicaid expansion and support the adoption of telehealth models with equitable reimbursement policies as well as other investments in geographic regions with high HIV burdens or significant barriers to treatment and prevention access are needed additions to lower and change the coverage gap.

Ensure Ryan White Program funding formulas and structure create the utmost impact toward ending the HIV epidemic

Ryan White Program has successfully reduced disparities in health outcome for PLWH across the country and, by distributing funds through formula and direct grants, has been able to address gaps in service both geographically and by type. Local planning has allowed each jurisdiction and state to respond to its local needs and allocate scarce resources based on the mix of resources available in the state or jurisdiction.

In order to end the epidemic, the Ryan White Program must be scaled up to fill all gaps from the current healthcare system to ensure that treatment is readily available and easily accessible. If the Ryan White Program were to be increased, this also provides an opportunity to review current infrastructure to ensure that the needs of people living with HIV are fully met. At an appropriate future time, when the healthcare coverage and policy environment is not in such a high state of uncertainty and instability, it will be important to explore how to further improve the program so that it can address HIV-related disparities, target new populations, and support the latest prevention and treatment advances that have made it possible to envision an end to the HIV epidemic.

Care continuum models which narrowly focus on medical visits, prescription refill status, and CD4 and viral suppression measures mask the actual experiences of people living with HIV in their attempts to engage with care as well as their experiences of wellness and quality of life. As the US HIV epidemic has become increasingly an epidemic which impacts those living in poverty, people of color, and communities facing multiple forms of discrimination, a spectrum of non-medical services has become progressively necessary to reduce barriers to medical care for people living with HIV.

Create flexibility under program income rules to ensure critical support for HIV services

Congress should clarify that Program Income may be used to help to advance the mission of AIDS clinical programs and services organizations and to substantially expand and improve services. To do so, Congress could institute language that maximizes flexibility and HRSA should also interpret program income rules to maximize flexibility to include: HIV Prevention services including Pre-Exposure Prophylaxis (PrEP); funding for STI prevention services; construction of

facilities used for the benefit of clients; and reasonable reserve funding (6 months) for use when regular income is disrupted or decreased in order for typical operations to continue.

Bolster investment in non-medical case management

The federal government should invest in dedicated capacity building for non-clinical staff providing services related to medication-assisted treatment in community-based organizations (CBOs) such as social workers and case managers. The Ryan White program receives \$2.3 billion annually to care for those living with HIV/AIDS. Non-medical case management only accounts for roughly 3.25% of Part A and B spending.¹²² ¹²³ In 2014, 150,515 Ryan White (RW) clients received nonmedical case management contrasted to 285,531 RW clients who received medical case management and 512,214 clients who received any service from RW.¹²⁴ This figure does not include case management services for those living with HIV/AIDS covered by Medicaid, Medicare, or private insurance companies. Despite only 3.25% of RW dollars spent on non-medical case management, 29% of RW clients utilize this valuable service.

The figures highlight the lack of prioritization and recognition of the role of non-clinical staff, including social workers, have in addressing overall care and well-being along the HIV Care Continuum. Social workers and other non-clinical staff provide and navigate the array of services that ensure access to care and improved well-being. Access to such services as mental health care, substance abuse treatment, affordable housing, employment, and other social services are crucial to ensuring that the social determinants are addressed, and improvement are seen along the HIV Care Continuum. This workforce must be supported through ongoing training opportunities because they play a critical role in ending the HIV epidemic.

Allow the AETCs to partner with medical schools and residency programs to create rotations at Ryan White Program Clinics for medical students and residents, and HIV clinical fellowships for residents who are not going into Infectious Diseases.

Maintain the 340B Program to ensure critical support for HIV services

The 340B Program is a critical component of HIV care in this country and is working to ensure that safety-net providers are able to expand the reach of their services, as is the original intent of the legislation. We urge Congress to ensure that the program is maintained as is and will continue to contribute towards the end of the HIV epidemic through the creation of HIV health care infrastructure in the U.S.

The U.S. Congress and Federal agencies should undertake all necessary actions to ensure that public and private health plans remove restrictions on HBV and HCV treatment that are not medically indicated and offer direct-acting antivirals to all chronic hepatitis C patients. Ensure that States and public health

¹²² FY14 Part A Expenditures Report. (n.d.) Retrieved May 2017,

https://hab.hrsa.gov/sites/default/files/hab/data/allocationsexpenditures/FY14_Part_A_Aggregate_Expenditures_Report_Final_Web.pdf.

¹²³ FY13 Part B & MAI Final Expenditures Report. (n.d.) Retrieved May 2017

https://hab.hrsa.gov/sites/default/files/hab/data/allocationsexpenditures/FY13_Part_B_Aggregate_Expenditures_Report_Final_web_012317.pdf.

¹²⁴ The United States Ryan White HIV/AIDS Program Services Received (n.d.). Retrieved April 2017 from <https://hab.hrsa.gov/stateprofiles/Services-Received.aspx>.

plans receiving federal dollars remove HCV treatment restrictions that are not medically indicated. In addition, federal agencies and states should eliminate all payer-based barriers to care, such as on-treatment viral load tests and expiration dates on prior authorizations for DAA treatment.

Support local and state TB elimination efforts

- Opportunities for the community to draft the elimination plan including providers who treat TB and LTBI, persons with medical conditions at high-risk for developing active TB (such as HIV) and other individuals who would benefit from preventive treatment.
- Support for reporting, with the following conditions, of LTBI to obtain better estimates of LTBI burden and focus intervention efforts on areas with high rates of rates of infection
 - Reporting should focus on incentives not penalties
 - Where they exist, penalties for not reporting must be rooted in civil, not criminal, law
 - Reporting must be accompanied by strict standards for data protection, privacy, and confidentiality and must be separated from the enforcement of immigration-related laws, rules, and regulations
- Setting TB elimination targets and performance measure nationally.
- CMS expanding reimbursement for testing and treatment of LTBI using the latest diagnostic and treatment options.
- Support use of local epidemiology to identify high-risk populations to inform targeted testing and treatment efforts.

The federal government must ensure that all people living within the United States have access to universal healthcare

The government should guarantee that every single resident in the United States can obtain high-quality, low-cost health care, when they need it, regardless of age, income, or pre-existing condition. This care should be at least as good as we have currently, and cost only what we can afford out-of-pocket: free for people with low incomes and a modest sum for middle income people.

Improve age-specific testing programming

We must increase CDC funding streams for innovative outreach and testing for youth. According to the CDC, people ages 13 to 24 represent the age group with the highest rate of undiagnosed HIV, with 51% of teenagers and young adults living with HIV were undiagnosed as of 2013. In numbers, more than 31,000 youth are undiagnosed out of an estimated 60,900 youth living with the disease. Disproportionately high rates of new HIV transmissions also occur among individuals ages 25 to 34. While a ramp up and intensity needs to focus on young people, CDC must also think about tools and interventions to help maintain health status as across the life span.

Decriminalize sex work

Decriminalizing sex would prevent 33-46% of new HIV cases among sex workers and clients, according to the Lancet.¹²⁵ Decriminalizing sex work would have a greater impact on reducing new HIV transmissions than increased access to antiretroviral therapy, safer work environments, or elimination of sexual violence. It would also vastly reduce violence against sex workers.

Facilitate the creation of national or state PrEP Drug Assistance Programs (PrEP DAP)

Expansion of PrEP drug assistance is needed to ensure equitable access to this crucial tool. Several states have created PrEP DAPs in order to increase access to drug, labs, and clinical care for providing and monitoring PrEP. Similar to ADAPs for people living with HIV, PrEP DAPs can potentially serve as the payer of last resort for low-income HIV negative people who are either uninsured or underinsured and are therefore unable to afford PrEP and its associated laboratory testing and follow-up care. In addition to providing free PrEP and fee-for-service reimbursement to contracted labs and providers, premium and cost-sharing for uninsured individuals may be possible under established financing mechanisms.

While there are legal restrictions on the use of Ryan White funds to serve HIV negative individuals, states may use the federally funded infrastructure to run and staff state or locally funded PrEP DAP programs. (1) States should work with HRSA to clarify rules related to the use of ADAP infrastructure, and implement models that integrate federal, state, and local resources to run statewide PrEP programs. (2) Congress could expand the use of Ryan White funds, notably those for Part C Early Intervention Services, to include biomedical primary HIV prevention methods in modernization of the program during a congressional review, (3) a separate federal funding stream for biomedical comprehensive prevention services could be created to fund, or supplement HRSA funding of, PrEP DAP programs at the state level, and (4) a PrEP DAP Task Force, similar to the ADAP Crisis Task Force, should be formed to ensure discounted purchasing of current and future PrEP modalities on behalf of state PrEP DAPs.

Ensure that TDF/FTC and future biomedical prevention tools are affordable and fund programs to expand access to PrEP at a national-level scale

To achieve the greatest potential benefit, access to TDF/FTC PrEP must be scaled up for all individuals at risk for HIV and most especially for vulnerable populations that currently are greatly underutilizing this intervention. At the same time, jurisdictions including the federal government would be better able to purchase TDF/FTC to prevent HIV at a population level if the price were lower. The wholesale acquisition cost (the list price before negotiated discounts with payers) of Truvada – the only version of TDF/FTC available in the United States -- is more than \$1,600 per 30-day supply¹²⁶, despite generic versions costing less than \$6 internationally.¹²⁷ All payers should and must be required to cover Truvada for PrEP, but its high price – even after manufacturer discounts and rebates are applied – continues to be met with restrictive barriers implemented by public and private payers to discourage its use, the exact opposite of the desired outcome.

¹²⁵ Shannon, K., Strathdee, S., Goldenberg, S., Duff, P., Mwangi, P., Rusakova, M., et al. (2014). Global epidemiology of HIV among female sex workers: influence of structural determinants. *The Lancet*. 385 (9962): 55-71.

¹²⁶ United States Department of Health and Human Services, Centers for Medicare and Medicaid Services. (2018, August 28). National Average Drug Acquisition Cost Database. Retrieved from <https://data.medicare.gov/Drug-Pricing-and-Payment/NADAC-National-Average-Drug-Acquisition-Cost/a4y5-998d>

¹²⁷ Hill, A. M., Pozniak, A.L. (2016, October 5). How can we achieve universal access to low-cost treatment for HIV? *Journal of Virus Eradication*. 2(4):193-197. Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5075345/>

Achieving a cost-effective pricing point for a national access program must become a high priority. Gilead Sciences, the manufacturer of Truvada, has established PrEP access programs for low-income, uninsured individuals and insured individuals with prohibitive out-of-pocket expenditures (deductibles, copays, or coinsurance costs). However, these programs are too small to scale up the use of PrEP at a national level and are not able to meet the needs of all people vulnerable to HIV in the U.S. For example, copay accumulators prevent commercial copay assistance programs from defraying high deductible costs.

Additionally, some commercial payers (e.g., Medicare Part D plans) prohibit the use of any commercial or other third-party copay assistance. Dramatically scaling up access to PrEP must be an essential component of any effort to end HIV as an epidemic. A dramatic reduction in the price of TDF/FTC by Gilead Sciences, or a commitment from the company to provide the drug at minimal cost to all individuals and health systems who cannot access it otherwise, could help mitigate these barriers.

Regardless, the federal government must act to ensure that access to TDF/FTC is affordable and sustainable. Some options that might be considered include establishing federal funding for PrEP DAPs and the creation of a task force to secure free drug or sub-340B discounts on current and future PrEP modalities (per the recommendation above) and ensuring that local public health offices have free PrEP starter packs and navigation services to a PrEP program, voluntary licensing agreements between the patent-holder and the federal government, compulsory licensing under patent or copyright law (28 U.S.C. §1498), potential invocation of march-in rights (35 U.S.C. §203), or other similar mechanisms.

Most importantly the federal government must scale up TDF/FTC at the level necessary for population-wide prevention. Funding and access must be provided not only specifically to TDF/FTC but also for associated medical and laboratory costs including testing for STIs.

CDC funding of projects for PrEP should allow flexibility in the use of funds to pay for labs and provider time

Despite the fact that some financial assistance is available to prospective PrEP users to help cover the costs of the drug, for many individuals, particularly uninsured individuals, gaining access to PrEP can still be a costly and, in some cases, prohibitively complicated, process. Successful utilization of PrEP requires a number of actions beyond just taking the daily medication--including frequent medical visits, regular HIV tests and other lab tests, all of which involve additional expenses that may or may not be covered by insurance or other financial assistance programs. CDC funding for PrEP projects should allow funds to be used to pay for necessary labs and medical visits.

Strengthen and expand federal support for Syringe Service Programs (SSPs)

SSPs are a proven and cost-effective HIV and hepatitis prevention tool, providing PWID with sterile injection equipment, overdose prevention education, naloxone, and related health messaging to reduce the potential harms of injection drug use and improve their overall health. These services are frequently the only pathway for people who inject drugs to substance use disorder treatment programs as well as other public health, medical, mental health, and social services.

Congress must ensure that SSPs remain a key part of the federal effort to respond to the current opioid epidemic and end the HIV and viral hepatitis epidemics. Additional support to federal viral hepatitis programs will help scale up SSPs in areas seeing the highest number of new infections of HIV and hepatitis C related to injection drug use, increase education resources and increase linkages to infectious diseases testing, and increase the availability of medication assisted therapy within harm reduction programs. Additionally, HRSA and SAMHSA funding to expand medication-assisted treatment and overdose prevention programming must include funding support for syringe services programs' crucial role in delivering and linking people who use drugs to these services and should foster the development of innovative service models such as mobile units.

Update the DOJ's Model Drug Paraphernalia Act to assist state reform efforts

In 1979, the White House requested that the DOJ Drug Enforcement Administration (DEA) draft legislation that individual states could enact to combat the sale and distribution of illicit drug paraphernalia. The result was the Model Drug Paraphernalia Act, and at least 45 states and the District of Columbia adopted laws that criminalized the possession of drug paraphernalia based on this Act. The term "drug paraphernalia" is widely defined in these statutes to include any equipment, product, or material of any kind that is primarily intended for use in introducing controlled substances into the human body. Typically, hypodermic syringes and needles were seen to fall within this domain.

At the time, the health consequences of making sterile injection equipment more difficult to obtain were unknown, and the spread of hepatitis C and HIV was not understood. As states have changed their laws to allow syringe services programs, they have taken various approaches to language categorizing injection equipment as drug paraphernalia. The DOJ should revise the Model Drug Paraphernalia act to modernize this recommendation, paving the way for states to more easily revise their laws. The new definition of drug paraphernalia must explicitly exclude injection equipment. For example, Nevada's updated paraphernalia law states, "The term does not include any type of hypodermic syringe, needle, instrument, device or implement intended or capable of being adapted for the purpose of administering drugs by subcutaneous, intramuscular or intravenous injection."¹²⁸

Increase the workforce for medication-assisted treatment by providing ongoing training opportunities for care providers, including those in Ryan White Program clinics.

Integrate Screening for HIV, Viral Hepatitis and STIs into Substance Use Treatment Programs

Co-locate medical care with behavioral health programs including substance use and mental health treatment

Co-location of medical and behavioral health care including substance use, mental health treatment and supportive services is critical to facilitate access to the range of services that individuals living with HIV and substance use and mental health disorders need to improve short and long-term health outcomes (especially for those in rural areas). Providing incentives for substance use and mental health treatment programs to partner with Ryan White clinics could expand access to these services while maximizing the impact of funding for all programs.

¹²⁸ Justia US Law. (2013).2013 Nevada Revised Statutes Chapter 453 - Controlled Substances NRS 453.554 - Drug paraphernalia defined. Retrieved from <https://law.justia.com/codes/nevada/2013/chapter-453/statute-453.554/>

Bolster syringe services programs and community-based harm reduction programs

- Dedicated federal funding should be directed to support the establishment or expansion of syringe services programs. Congress should seek to appropriate sustained, multi-year funding dedicated to SSPs, and ensure that SSPs are eligible for any federal opioid funding.
- Community-based harm reduction organizations which center the leadership and involvement of people who use drugs should be prioritized for all federal SSP and drug-user health funding.
- The Administration and Congress should expand funding to the CDC to expand SSP availability and critically needed surveillance infrastructure, particularly within the Division of Viral Hepatitis.

Facilitate unfettered access to community-based Naloxone

- The Administration and Congress should advance expanded naloxone access through low-barrier naloxone saturation models that prioritize increased funding for community-based harm reduction and syringe services programs as the most effective platform to reach people who use drugs.
- Congress and federal agencies administering overdose prevention funding should seek to promote best practice overdose prevention programming by issuing guidance which encourages grantees to pursue community-based naloxone distribution programs and seek to fully saturate as many communities as possible with easy-to-access naloxone.

Ensure equitable access to MAT

- Congress and the Administration should ensure that all individuals seeking MAT have full, free or low-cost access to all forms of MAT, as well as the freedom to choose the medication that best fits their needs. Federally-funded or regulated drug courts, jails, prisons, and drug treatment programs must be required to provide access to all forms of MAT.
- Repeal the buprenorphine prescribing waiver requirement and prescriber patient caps, which perpetuate the treatment gap by limiting expansion of buprenorphine access.
- Congress and federal agencies should seek opportunities to fund research and promising pilot practices, such as heroin-assisted treatment, as well as medication to treat stimulant use disorder (including methamphetamine use disorder).
- Congress and SAMHSA should promote and fund lower threshold MAT models, including on-demand buprenorphine outside of clinical settings and the integration of buprenorphine into SSPs.
- All Medicaid, Medicare, Veterans Affairs, and Indian Health Service health plans must mandate coverage of all forms of MAT and eliminate restrictive policies which inhibit low-barrier access to MAT.
- Allow for research and development around additional supervised consumption programs, including the use of video chat technology as a mobile health option.
- Congress and the Administration should remove federal barriers to access to medical cannabis.

Affirm that the overdose crisis is primarily a public health crisis and as such requires a comprehensive public health response.

Punitive drug policy that centers a criminal justice strategy in response to the overdose crisis and promotes mass incarceration will only exacerbate the crisis and maximize the harm suffered by our communities. Public health *is* public safety and must always be prioritized.

In the event that the priorities of the criminal justice system and the priorities of the public health system come into conflict, the Administration and Congress must *always* prioritize the needs and

priorities of the public's health and seek at every turn to minimize the involvement of the criminal justice system in the lives of people who use drugs.

Oppose any proposals which would expand or promote punitive drug policy

This include expanding or promoting any of the following:

- Enhanced penalties for drug related offenses involving fentanyl
- "Drug-Induced Homicide" prosecutions of any kind
- "Infant Endangerment" or "drug-endangerment of children" penalties for pregnant people and parents who use drugs or the criminalization of women whose children are born with neonatal abstinence syndrome
- Drug-use-only justifications for CPS involvement in families

Reject and disavow rhetoric which seeks to justify xenophobic, racist, and inhumane immigration policies, and reverse and undo the harassment and criminalization of immigrant communities by Immigration and Customs Enforcement – especially any actions taken in the name of combatting the overdose crisis

Promote pre-arrest, pre-booking, and non-coercive diversion programs that seek to minimize criminal justice involvement for people who use drugs

Promote sweeping criminal justice reforms to reduce both mass incarceration and the harms of criminalization, such as promoting the elimination of cash bail, mandatory minimums for drug offenses, and statutory or regulatory barriers to accessing public housing and other social benefits for individuals with past drug convictions.

Reject drug testing requirements for recipients of any federal welfare program, including Medicaid, SNAP, and TANF.

HUD, SAMHSA, and Congress should increase funding for and promote the expansion of a Housing First orientation across all federally funded housing programs, including among recovery housing programs

The Administration and Congress should increase federal investments in the Housing Choice Voucher Program and other HUD-administered Permanent Supportive Housing programs

The Administration and Congress should oppose drug testing requirements for accessing public benefits, as well as Medicaid work requirements

Commit to ending congenital syphilis

Syphilis is associated with significant complications if left untreated and facilitates transmission and acquisition of HIV. Congenital syphilis is now at the highest rate since 2000. Congenital syphilis is totally preventable, and each new case represents a major failure of our health care system. Passing on syphilis during pregnancy can lead to infant death in 40% of all births. Infants who survive may experience severe health and development issues. We have the tools to eliminate congenital syphilis and must invest the resources necessary to do so.

End drug pricing tactics that allow drug companies to profit off older drugs with limited competition like the preferred treatment for syphilis Pfizer's Bicillin® L-A (pencillin G benzathine or BPG)

The price of BPG has increased to \$350 per dose for some clinics without access to 340B pricing, with rumors of an additional price increase on the horizon. Until recently, BPG also was on the FDA's drug shortage list. Due to its high price, some health insurers place BPG on a high cost-sharing tier leaving this critical treatment priced out of reach. In addition, the preferred lab tests for chlamydia and gonorrhea can be more than \$600 for screening as recommended at three anatomic sites with high cost sharing for patients. We urge industry to address price and supply issues for BPG and for STI laboratory diagnostics to ensure cost is not a barrier to diagnosing and treating STIs. We urge HHS and Congress to act to stop drug companies from price gouging older medications with limited or no competition that are critical to public health.

Research and develop a new gonorrhea antibiotic treatment

Gonorrhea has become resistant to all but one antibiotic. The UK has already seen one case of antibiotic resistant gonorrhea, or "super gonorrhea." If we do not work to identify alternative medication options gonorrhea is at risk of becoming an untreatable epidemic. Funding and resources should be put towards identifying alternative treatment options.

Commit to and promote proven interventions such as comprehensive sexual education rather than interventions that have been proven to be ineffective at reducing STIs, including abstinence-only education

Improve HIV testing, prevention, and treatment services in federal prisons

Comprehensive HIV care and prevention in federal and state prisons and local jails is needed. The Bureau of Prisons (BOP) and state and local departments of corrections should implement routine, confidential, opt-out HIV testing on the way in and out of prison or jail. PLWH should receive comprehensive medical care in a timely fashion, and in compliance with DHHS guidelines on ART. Prisons and jails should provide linkage to services, or ensure appropriate linkage to medical and community services, upon release so that PLWH know where to receive treatment and care in the community and have adequate navigation to ensure successful care linkage.

Upon release, every PLWH should receive adequate ART to ensure continuity of treatment until care linkage can be achieved. Moreover, the BOP and state and local departments of corrections should implement essential HIV prevention services including providing condoms, PrEP, and PEP for those at high risk. DOH and HHS should collaborate to provide resources to states and localities including training, technical assistance, and model best practices for state prisons and local jails for addressing, preventing, and treating HIV during incarceration and upon reentry. Because 95% of the incarcerated population in the US is housed in state prisons or local jails, such resources would reduce HIV transmission and connect individuals to HIV care and treatment.

Build on the Prison Rape Elimination Act

Inmates are now reporting more and more when sexual assault happens, but we still have no idea how/when consensual sex occurs because sex in prison is a felony in most if not all states. This prevents researchers from understanding what is happening in prison settings when it

comes to sexual contact in any form (inmate with inmate, inmate with staff, etc.). Of paramount importance in building on PREA is distinguishing between sexual assault and consented sex with an inmate. The federal government must allow for research that would not penalize, via increased sentencing, the offender for disclosing with whom or how they had sex.