



**U.S. Department of Health and Human Services**

**Centers for Medicare and Medicaid Services/Office of Civil Rights/Office of the Secretary**

**Section 1557 Non-discrimination Rule**

Regulations released by the Trump Administration reinterpreting Section 1557 of the Affordable Care Act removed essential protections based on gender identity, including protections for transgender individuals — a population that faces extraordinary barriers to health care access and is at high risk for HIV. The rule disregards medical standards and reinforces the health inequities exposed by COVID-19. These inequities — compounded by stigma and discrimination — are among the factors contributing to high rates of HIV among transgender women, with the greatest impacts on African American and Latinx populations: notably, of the 14% of transgender women who are living with HIV, 44% of them are African American and 26% are Latinx.

**We recommend:**

- **Rescinding the Section 1557 regulations promulgated by the Trump Administration and re-establishing broad protections, including for gender identity.**

**ASSISTANT SECRETARY FOR HEALTH**

**Office of Infectious Disease and HIV/AIDS Policy**

**National Vaccine Program**

IIDSA applauds the development of the Vaccines National Strategic Plan 2021-2025 and supports implementation of the five goals:

1. Foster innovation in vaccine development and related technologies.
2. Maintain the highest possible levels of vaccine safety.
3. Increase knowledge of and confidence in routinely recommended vaccines.
4. Increase access to and use of all routinely recommended vaccines.
5. Protect the health of the nation by supporting global immunization efforts.

Lessons learned from the development of several COVID-19 vaccine candidates should be used to inform continued improvements to vaccine research and development, distribution, safety monitoring, access and uptake. Sustained funding is needed to build upon the progress made in the last decade toward new and improved vaccines and technologies, including progress toward a universal flu vaccine and improvements on seasonal flu vaccines. Funding will also be critical to make necessary improvements to our country's vaccine infrastructure, including

improving the interoperability and standardization of immunization information systems across states and jurisdictions.

We support the plan's focus on improving vaccine confidence and addressing access barriers in communities of color that experience significant health disparities. While this includes removing financial barriers, including ensuring that all ACIP-recommended vaccines for adults do not require co-pays or other cost-sharing, we also applaud the plan's goals to combat vaccine misinformation, strengthen health care provider recommendations and ensure diverse clinical trial participation. Partnerships with trusted community leaders and organizations will be essential to meeting these communities where they are in order to improve immunization rates.

Moving forward to the development of the final strategic plan, additional details are needed around the specifics of the plan's implementation. We support continued interagency collaboration in this effort.

**We recommend:**

- **Increased investments to support implementation of the Vaccines National Strategic Plan 2021-2025.**

**Division of HIV/Hepatitis/Sexually Transmitted Infections**

**HIV**

Recent [data published](#) by the Centers for Disease Control and Prevention (CDC) notes that from 2010 to 2017, overall HIV-related death rates decreased by nearly 50% in the U.S. From 2010 to 2018, the percentage of people with HIV aware of their status increased from 82% to 86%, and the viral suppression rate among people with HIV increased from 46% to 65%. However, HIV-related death rates were higher among all women, including transgender women, multiracial individuals, Black/African American persons and younger persons as well as persons diagnosed with HIV who live in the South. The data show important progress in combating the HIV epidemic in the U.S. but also highlight the ongoing work needed to further reduce gender, racial, ethnic, geographic and age-related disparities.

The gains made in improving HIV outcomes [are now at risk](#) due to the coronavirus pandemic. The impact could be profound if attention is not given to mitigating disruptions in access to HIV screening, prevention services that provide pre-exposure prophylaxis (PrEP), treatment services that prevent medication interruptions, care that includes mental health and substance treatment and supportive services that offer housing and food support.

**We recommend:**

- **Supporting funding in COVID-19 relief packages for HIV prevention at CDC and care and treatment programs funded by the Ryan White HIV/AIDS Program;**
- **Reinvigorating the National HIV/AIDS Strategy as a road map for our country's HIV response;**

- **Fully committing to continuing and strengthening the Ending the HIV Epidemic initiative and its goal of reducing new HIV infections by 90% within a decade.**

**National HIV/AIDS Strategy (NHAS):** As the first national, comprehensive plan for responding to the HIV epidemic in the U.S., the NHAS first released in 2010 was important to focus programmatic efforts toward achieving national targets and improve the coordination of HIV policies and programs across HHS and other federal agencies. While the NHAS has been overshadowed by the Ending the HIV Epidemic (EHE) initiative, the synergy between the EHE and NHAS's goals and indicators can drive progress in reducing new HIV infections and improving health outcomes across the country. A draft update renamed the National HIV/AIDS Plan was released on Dec. 1 for comment. While still under review, the final plan should clearly articulate actions to reduce the impacts of the coronavirus pandemic including the health disparities that have been exacerbated by the pandemic and address the critical role of the Affordable Care Act and, in particular, the Medicaid expansion in achieving success in combating HIV across the country. In addition, the NHAS should outline clear strategies, including loan repayment for HIV providers,<sup>1</sup> for building a robust, qualified HIV workforce with a focus on areas with limited experienced HIV clinicians, incentivize the integration of HIV, viral hepatitis and sexually transmitted infections (STI) programs and address the need for an expansion of harm reduction services, including syringe services programs.

**Ending the HIV Epidemic Initiative:** By directing increased resources and technical assistance to the communities and populations most heavily impacted by HIV, the EHE initiative has been an important extension of the NHAS. In the 48 counties, San Juan, Puerto Rico and Washington, DC representing more than 50% of new cases, the investment of resources and focus on engaging local communities (both impacted and serving those impacted) in driving the response is critical to addressing the unique barriers to HIV screening, prevention and care and treatment in each community. **The EHE activities in these communities that have struggled to control their local epidemics will be even more important now to prevent increases in cases and worsening health outcomes due to the pandemic.**

### **Sexually Transmitted Infections (STI)**

IDSA and HIVMA **applauded the release of the inaugural STI National Strategic Plan** when the draft was released for comment in September. With STI rates increasing at record levels for five consecutive years, a comprehensive national plan with strong federal leadership for responding to the STI epidemic is urgently needed. Rapid implementation of the plan is even more important now given the impact of the coronavirus pandemic on access to STI services prompted by clinic closures and reduced clinic hours due in part to the deployment of health department staff to assist with their local COVID-19 response.

In our comments, we noted support for the plan being data-driven, its recognition of the role that social determinants of health play in fueling the STI epidemic and the call for the

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<sup>1</sup>See [H.R. 7543 - HELP Act of 2020](#).

integration and coordination of service delivery across infectious diseases programs. We also identified the following gaps in the plan: **the need for a strong federal implementation plan with details on the financial and workforce resources necessary to meet the plan's goals; the need to invest in more timely surveillance data and in new and affordable STI treatment options; the need to address shortages of tests and testing supplies; the need to address the cost and regulatory barriers to home-based STI testing; and the need to add transgender individuals as a priority population.**

**We recommend:**

- **Committing to the STI National Strategic Plan and developing a strong federal implementation plan to accompany it;**
- **Addressing the gaps highlighted above if they are not addressed in the final plan, which is anticipated to be released by the end of the year.**

### **Viral Hepatitis**

IDSAs and HIVMA call for heightened commitment and increased federal investment to achieve elimination of viral hepatitis in U.S. When the *Viral Hepatitis Strategic Plan 2021-2025: A Roadmap to Elimination* draft was released in October for comment, we applauded the comprehensiveness of the plan but noted that important details were still needed on how to address the issues identified in the plan. We called out the need for specifics on how barriers to viral hepatitis care and treatment will be addressed and, in that regard, recommended support for creating a federal discretionary program to support care and treatment for individuals with substance use disorders without other sources of care. We also recommended incentivizing the integration of viral hepatitis, HIV and substance use treatment programs and leveraging the “subscription” payment model to expand access to hepatitis C treatment within federal programs. We also noted the need for greater attention to hepatitis B in the plan.

Given the coronavirus pandemic’s impact on access to substance use treatment services and harm reduction services, there is an urgent need for a federal implementation plan to prevent a worsening of the viral hepatitis epidemic.

**We recommend:**

- **Committing to the elimination of viral hepatitis in the U.S.;**
- **Developing a comprehensive federal implementation plan to accompany the viral hepatitis strategic plan to mitigate disruptions caused by the coronavirus pandemic in harm reduction, including syringe services programs, testing and treatment services.**

*For questions regarding our recommendations, please contact Amanda Jezek, IDSA Senior Vice President for Public Policy and Government Relations at [ajezek@idsociety.org](mailto:ajezek@idsociety.org) or Andrea Weddle, HIVMA Executive Director at [aweddle@hivma.org](mailto:aweddle@hivma.org).*