



September 8, 2020

ADM Brett Giroir, MD
U.S. Department of Health & Human
Services
200 Independence Avenue, SW
Room 715-G
Washington, D.C. 20201

Harold Phillips
U.S. Department of Health & Human
Services
330 C St., SW
Rm L001
Washington, D.C. 20201

Dear ADM Giroir and Mr. Phillips,

We are writing on behalf of the HIV Prevention Action Coalition (HPAC), a work group of the Federal AIDS Policy Partnership (FAPP), to submit the following comments and recommendations to inform the *Ready, Set, PrEP* (RSP) Program. HPAC is a coalition of national and community-based HIV service organizations representing public health professionals, advocates, and people living with HIV who are all dedicated to ensuring access and resources for HIV prevention.

In December 2019, the Department of Health and Human Services (HHS) launched RSP to provide PrEP to 200,000 uninsured persons. Unfortunately, during a June 2020 Presidential Advisory Council on HIV/AIDS (PACHA) meeting, Admiral Brett Giroir, MD, Assistant Secretary for Health, announced that only 891 individuals have participated in RSP. These numbers are disappointing when the Centers for Disease Control and Prevention (CDC) estimates that [1.1 million people in the US would benefit from PrEP](#), including 175,000 women and 780,000 people of color. There must be a sustained and rapid effort to increase the access, uptake, and adherence to PrEP. By doing so, PrEP alone has the potential to avert approximately 48,000 additional HIV infections over the next five years, supporting the Administration's *Ending the HIV Epidemic: A Plan for America* (EHE) initiative goal to reduce new HIV infections. This reduction, however, cannot be achieved without appropriate federal funding, resources, and support. Unfortunately, many PrEP programs often do not have the resources to reach populations disproportionately impacted by HIV, including men who have sex with men (MSM), transgender and Black cisgender women, and people who use drugs, who cumulatively represent over 90% of all people diagnosed with HIV annually in the U.S.

Now more than ever, we recognize that science has given us the tools we need to create an environment in which our collective vision of getting to zero new HIV infections can be achieved. At the same time, persistent barriers and multifaceted, dynamic and often unpredictable variables (e.g., political, sociocultural, declining resources – financial and human, difficult policy environments, access challenges and stigma and discrimination, etc.) make achieving our vision difficult.

The opportunities afforded by PrEP are unprecedented in the public health response to the HIV epidemic. With over 36,000 new infections annually in the U.S., PrEP should be a critical element in our prevention efforts to reduce new HIV infections. Implementing PrEP in public health settings has proven to be challenging and widespread utilization has been prolonged by numerous barriers, including lack of awareness among populations disproportionately impacted by HIV, resistance from some medical providers, low levels of health literacy, stigma, discrimination, and inconsistent insurance coverage. Furthermore, costs associated with labs and medical visits continue to be a primary barrier to adherence and accessibility of PrEP, especially in communities disproportionately impacted by HIV.

With these and other compelling issues and questions, HPAC offers the following recommendations for RSP:

- Allocate and request additional funding to cover all costs associated with PrEP, including lab tests and visits.
- Work to establish telemedicine services that can provide PrEP through RSP, as this will cut down barriers to access for many in isolated areas.
- Expand the pharmacy network that is allowed to participate in RSP, including Community Health Centers.
- Add information to the website and printed materials to be clear RSP is not subject to Public Charge.
- Add Spanish language to telephone services.
- Place a greater focus on communities and geographic areas disproportionately impacted by HIV.
- Collect and release public information on the location, race and ethnicity, sexual orientation, and gender identify of RSP users.
- Collect and release public information about factors leading to patients ending enrollment in RSP.
- Provide real-time or more frequent updates of RSP enrollment numbers, possibly through integration with the new AHEAD: America's HIV Epidemic Analysis Dashboard.
- Allow insured individuals to participate in the program, including people under 26 on their parent's insurance and individuals experience intimate partner violence.

HPAC's Recommendations for the Ready, Set, PrEP Program

- Address the persistent disparities in PrEP uptake and continuation among communities of color.
- Develop programs and protocols within RSP for patient engagement to ensure that patients remain adherent.
- HPAC supports the following recommendation offered by PACHA in Resolution to Increase Uptake in the Ready, Set, PrEP (RSP) Program: "HHS should acknowledge that there are other mechanisms in place for uninsured individuals to receive PrEP that provide financial benefits for entities prescribing PrEP that then can be used to cover the costs of PrEP services, such as lab tests, outreach and staff. HHS should review the various avenues through which uninsured people receive PrEP and recalibrate the potential number of individuals that might utilize RSP. Based on its findings, HHS may want to revise its education and public relations efforts to be more expansive."

The COVID-19 pandemic provides additional challenges for increasing enrollment in RSP. We understand that the low enrollment numbers may be a result of the impact COVID-19 has had on the public health system. However, we believe that increasing RSP enrollment must continue to be a priority for HHS. As public health departments, providers, and Federally Qualified Health Centers (FQHCs) have been forced to adapt to the realities of providing services during this pandemic, we urge HHS to work with prescribers to appropriately use telemedicine and other innovative ways to reach new patients.

Finally, we urge HHS to reverse their decision to finalize changes to Section 1557 of the Affordable Care Act (85 FR 37160). The goals of RSP and EHE Initiative require non-stigmatizing and culturally competent engagement with the LGBTQ+ community. This rule will lead to mistrust between LGBTQ+ people and federal health programs, which will work against our drive to increase RSP enrollment.

Should you have any questions, please contact the HPAC co-chairs Latisia Grant at LGrant@NACCHO.org, Mike Weir at mweir@NASTAD.org, or Nick Armstrong at NArmstrong@taimail.org.