



April 8, 2021

VIA ELECTRONIC MAIL: Xavier.Becerra@HHS.gov

Xavier Becerra, Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Re: URGENT REQUEST TO ALLOW ALL RYAN WHITE CLINICS TO FULLY ENGAGE IN COVID-19 RELIEF EFFORTS

The Honorable Secretary Becerra:

On behalf of Ryan White Clinics for 340B Access (RWC-340B), we write today to applaud you on the outstanding work the Administration is doing to fight COVID-19 and to encourage you to tap into the resources that our members can provide to further those efforts. RWC-340B is an association of HIV/AIDS health care clinics and service providers that receive funding under the Ryan White CARE Act, either through a primary grant or subgrant, and that participate in the 340B Drug Pricing program. We stand ready to leverage our existing resources and expertise to complement testing and vaccine distribution efforts and to further strengthen and support public health.

Specifically, we ask for an immediate distribution of vaccines to Ryan White clinics and a modest relaxation of some program rules, as outlined below, so that we can assist the Administration to increase access to vaccines for the nation's most underserved communities and disproportionately affected populations.

IMMEDIATE ALLOCATION OF VACCINES TO ALL RYAN WHITE CLINICS WOULD FURTHER THE ADMINISTRATION'S GOAL OF ENSURING THE EQUITABLE DISTRIBUTION OF VACCINES

RWC-340B members were very pleased that the Administration designated certain Federally Qualified Health Centers (FQHCs) to receive a direct allocation of COVID-19 vaccines to ensure equity in vaccine distribution.¹ As you may know, some RWCs are also designated as FQHCs;

¹ HRSA, Coronavirus (COVID-19) Information, *Ensuring Equity in COVID-19 Vaccine Distribution*, <https://www.hrsa.gov/coronavirus/health-center-program> (last reviewed Mar. 2021).

however, many clinics are designated as Ryan White providers only. **This latter group of clinics will not receive a direct allocation of COVID-19 vaccines under the Administration's program.**

As you know, Ryan White clinics serve a very vulnerable population. An estimated 1.2 million people are living with HIV/AIDS in the US. Roughly 1 out of 7 of those infected are unaware of their infection and could be unknowingly transmitting the virus. In 2018, the number of new HIV infections was approximately 36,400. Non-white populations are disproportionately affected, with the highest rate of infections in Black/African Americans (45.4 per 100,000) and Hispanic/Latinos (22.4 per 100,000).² HIV/AIDS incidence and prevalence falls disproportionately on populations with lower socioeconomic status, including those with lower income and less education. Living in disenfranchised communities often limits access to prescription drugs, reduces frequency of medical care, fragments patient engagement with HIV clinical and non-clinical care, and leads to worse health outcomes.

RWC caregivers are specially trained and equipped to ensure that diagnostic tests, vaccines, and treatments for infectious diseases are effectively administered and managed. RWCs have a well-documented history of maximizing their resources to educate, support, and treat individuals with HIV/AIDS, an infectious disease that is a primary focus for eradication by this Administration.³ According to the 2019 Ryan White HIV/AIDS Program Annual Client-Level Data Report, the viral suppression rate for Ryan White patients was 88.1 percent, an increase from 69.5 percent in 2010.⁴ This is well above the national viral suppression rate of 64.7%.⁵

In addition to their long history of treating individuals with a potentially deadly infectious disease, RWCs are experienced in combatting misinformation about a stigmatizing condition and advising the public on strategies to reduce disease transmission. RWCs are very often at the forefront of spearheading community health efforts and can leverage existing partnerships with state, local, and other nonprofit organizations to provide the support that is needed to fight COVID-19 and administer vaccines.

RWCs, therefore, are experienced at treating some of the country's most vulnerable patient populations and addressing deadly infectious diseases. An allocation of vaccines to all RWCs would further the Administration's efforts to ensure that COVID-19 vaccines are distributed

² RWC-340B, *Value of Ryan White Providers and Impacts Associated with Resource Reduction*, 2 (Sept. 2020), <https://www.rwc340b.org/wp-content/uploads/2020/09/RWC340B-White-Paper-FINAL.pdf>; HIV.gov, *HIV Basics: Overview: Data & Trends: U.S. Statistics*, <https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics> (last updated Mar. 17, 2021).

³ A. Dempsey, *HRSA Shares First Look at Ryan White HIV/AIDS Program Ending the HIV Epidemic Initiative Data*, HIV.Gov (Mar. 24, 2021), <https://www.hiv.gov/blog/hrsa-shares-first-look-ryan-white-hiv-aids-program-ending-hiv-epidemic-initiative-data>.

⁴ HRSA, *Ryan White HIV/AIDS Program Annual Client-Level Data Report 2019*, <https://hab.hrsa.gov/sites/default/files/hab/data/datareports/RWHAP-annual-client-level-data-report-2019.pdf>.

⁵ L. Cheever, *HRSA Announces Record High HIV Viral Suppression Rate in New 2019 Ryan White HIV/AIDS Program Client-Level Data Report*, HIV.Gov (Dec. 7, 2020), <https://www.hiv.gov/blog/hrsa-announces-record-high-hiv-viral-suppression-rate-new-2019-ryan-white-hiv-aids-program>.

equitably. **As such, we ask that RWCs immediately receive an allocation of COVID-19 vaccines as part of the Administration's program to ensure equity in vaccine distribution.**

FEDERAL RESTRICTIONS THAT PREVENT RWCS FROM USING AVAILABLE RESOURCES TO FIGHT COVID FOR ALL PATIENT POPULATIONS SHOULD BE LIFTED

HRSA's restrictive policies on the use of program income prevent RWCs from fully deploying their valuable expertise and resources to meet the complex demands of the current COVID-19 pandemic and any future pandemics. We ask that you also consider waiving restrictions on program income during declared public health emergencies so that RWCs can assist in preventing the spread of infectious diseases to individuals who do not have HIV/AIDS.

RWCs receive a range of grants and subgrants under the Ryan White CARE Act to test, treat and otherwise care for people living with HIV/AIDS. In addition to using grant dollars to provide services, RWCs rely on the income they receive by billing and collecting reimbursement from third-party payers. As you know, program income is gross income earned by a grantee that is directly generated by a supported activity or earned as a result of a federal grant award during the grant period.⁶ Many RWCs have significant program income receipts, in large part due to the savings that they realize through participation in the 340B program. ***Indeed, some RWCs have sufficient program income to pay entirely for the administration of COVID-19 vaccines and to provide services and supplies needed by individuals who have contracted COVID-19.***

RWCs are currently unable to fully address the current COVID-19 emergency in their communities due to federal regulations that restrict the use of program income funds to services provided only to persons living with HIV/AIDS (PLWHA). Specifically, these restrictions prevent RWCs from using program income to provide care to individuals who are not diagnosed with HIV/AIDS. The HIV/AIDS population is clearly vulnerable to infectious disease outbreaks, but it represents just a fraction of the U.S. population that must be protected and/or treated.

Giving RWCs flexibility to use program income for the non-HIV population would allow them to offer a wide range of valuable services that communities need during a public health emergency. For instance, RWCs could assist their communities by administering vaccines, setting up infectious disease testing, screening, and treatment sites, paying for laboratory costs and medical supplies related to infectious disease tests and treatment, and by hosting webinars and engaging in social media efforts to educate communities about risks related to the pandemic. RWCs could also help transport people to care, prevent food shortages, address local housing issues, manage individuals with substance use disorders or other comorbidities and provide related services to ameliorate the broader problems caused or exacerbated by a public health emergency.

⁶ 42 C.F.R. § 75.2.

RWCs have the unique expertise and capacity to address infectious disease outbreaks; however, regulatory restrictions currently limit RWCs' ability to fully leverage their existing resources during a declared public health emergency. A targeted waiver of program income restrictions during a public health emergency would allow RWCs to tap into their unique expertise and financial resources without the need for additional federal spending.

RWC-340B submitted a request to former HRSA Administrator Thomas Engels on April 10, 2020 requesting a waiver of regulatory requirements on the use of program income generated through Ryan White funds to address the COVID-19 pandemic. Administrator Engels responded on May 13, 2020 stating that, as the Administrator of HRSA, he lacked the authority to grant RWC-340B's waiver request. Administrator Engels also contended that, "re-allocating program income to non-HIV populations would be a disservice to the marginalized, low-income population we serve."⁷ RWC-340B members strongly disagree with Administrator Engels' statement and believe that RWCs can protect and care for the non-HIV/AIDS population during a declared public health emergency without compromising the care that they provide to the HIV/AIDS population.

RWC-340B asks the Administration to waive restrictions related to the use of program income earned by RWCs so that RWCs may use their resources and expertise during the public health emergency to assist in the national efforts to address the COVID-19 pandemic.

For more information, please contact Peggy Tighe at 202-256-6241 or Peggy.Tighe@PowersLaw.com.

Sincerely,



Shannon Stephenson
President

CC: Admiral Krista Pedley, Director
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⁷ Letter from HRSA Administrator Thomas J. Engels, dated May 13, 2020, on file with author.