



June 26, 2020

VIA ELECTRONIC MAIL: PandemicPreparedness@HELP.SENATE.GOV

The Honorable Lamar Alexander, Chair
Senate Committee on Health, Education, Labor and Pensions
428 Dirksen Senate Office Building
Washington, D.C. 20510

Re: Response to Request for Recommendations: Preparing for the Next Pandemic

Chairman Alexander:

Ryan White Clinics for 340B Access (“RWC-340B”) appreciates the opportunity to respond to your request for recommendations regarding how Congress can work with federal departments and agencies, states, and the private sector to better prepare this nation for the next public health pandemic. 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. Ryan White clinics (“RWCs”) are dedicated to caring for low-income and vulnerable patients suffering from HIV/AIDS and, according to the Secretary of Health and Human Services, “are serving on the frontlines of this pandemic, supporting clients and communities at higher risk from COVID-19.”¹

Members of RWC-340B are reaching out to you today because they have a unique opportunity to use existing resources to strengthen and support public health preparedness at all levels of government in order to fight future pandemics. RWC caregivers are specially trained and equipped to ensure that diagnostics, vaccines, and treatments for infectious diseases are effectively administered and managed, but they need the Health Resources and Services Administration (“HRSA”) to revisit its restrictive policies on the use of program income first. These policies are preventing RWCs from fully deploying their valuable expertise and resources to meet the complex demands of the current COVID-19 pandemic and any future pandemics. ***RWC-340B asks Congress and the Administration to waive restrictions related to the use of program income earned by RWCs during declared public health emergencies so that RWCs may use their resources and expertise to increase testing capacity and ensure our country is prepared in the event of a pandemic.***

¹ Health and Human Services (HHS) Secretary Alex Azar, HHS Awards \$90 Million to Ryan White HIV/AIDS Program Recipients for COVID-19 Response, April 15, 2020, available at <https://www.hhs.gov/about/news/2020/04/15/hhs-awards-90-million-ryan-white-hiv-aids-program-recipients-for-covid-19-response.html>.

PROGRAM INCOME RESTRICTIONS ARE PREVENTING RWCS FROM FIGHTING PANDEMICS EXCEPT FOR WITH PATIENTS WHO HAVE HIV/AIDS

RWC-340B submitted a request to HRSA Administrator Thomas Engels on April 10, 2020 requesting that the Administration use its waiver authority to suspend regulatory requirements related to the use of program income generated through Ryan White funds. Administrator Engels responded on May 13, 2020 stating that he, as the Administrator of HRSA, lacked the authority to grant RWC-340B's waiver request. Additionally, Administrator Engels stated that "re-allocating program income to non-HIV populations would be a disservice to the marginalized, low-income population we serve."² RWC-340B respectfully disagrees with Administrator Engel's statement and believes that RWCs are capable of protecting and caring for the non-HIV population during a public health crisis without compromising the system of care they have built around the HIV population.

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. Besides using grant dollars to support their services, RWCs rely on the income they receive by billing and collecting reimbursement from patients and third-party payers. This revenue source, referred to under federal law as "program income," varies in size depending on the payer mix of the RWC's patient population. 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.³ Many RWCs find that their program income receipts significantly exceed their grant dollars. ***Indeed, some RWCs have more than enough program income to pay for the services and supplies needed by patients who have contracted COVID-19 or are at risk of contracting the virus.***

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 they generate from treating HIV/AIDS patients. 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. RWC-340B is concerned that their expertise and resources will continue to be underutilized throughout the duration of the COVID-19 pandemic, as well as for future public health emergencies.

THE REQUESTED PROGRAM INCOME WAIVER WOULD NOT REQUIRE USE OF FEDERAL FUNDS AND ALIGNS WITH CONGRESS'S PUSH TO EMPLOY ALL AVAILABLE RESOURCES DURING A PANDEMIC

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. According to the 2018 Ryan White HIV/AIDS Program Annual Client-Level Data Report, the viral suppression rate for Ryan White patients was 87.1% in 2018.⁴ This is well above the national

² Letter from HRSA Administrator Thomas J. Engels, dated May 13, 2020, on file with author.

³ 42 C.F.R. § 75.2.

⁴ HRSA, Ryan White HIV/AIDS Program Annual Client-Level Data Report 2018, available at <https://hab.hrsa.gov/sites/default/files/hab/data/datareports/RWHAP-annual-client-level-data-report-2018.pdf>.

viral suppression rate of 67.2%.⁵ In addition to their long history of treating individuals with a potentially deadly infectious disease, RWCs are experienced in combatting misinformation about a potentially stigmatizing condition and advising the public on strategies to reduce disease transmission. RWCs are 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 combat future pandemics.

As Congress considers how the federal government can better prepare for the next pandemic, we ask that it consider providing HRSA with the authority to waive restrictions on program income during declared public health emergencies so that RWCs can assist in preventing the spread of future infectious disease outbreaks. Giving RWCs flexibility to use program income for the non-HIV population would allow them to offer a wide range of valuable services that individuals need during an infectious disease public health emergency. For instance, RWCs could assist their communities by setting up infectious disease laboratories, testing, screening, and treatment sites, by paying for laboratory costs and medical supplies related to infectious disease tests and treatment, or 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 and provide related services to ameliorate the broader problems caused or exacerbated by a public health emergency.

CONCLUSION

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, without the need for additional federal spending, and would allow them to assist in increasing testing capacity and ensure that our country is better prepared for the next pandemic.

For more information, please contact Peggy Tighe at 202-872-6752 or Peggy.Tighe@PowersLaw.com.

Sincerely,



Shannon Stephenson
President

⁵ See Norma S. Harris Et Al., Vital Signs: Status of Human Immunodeficiency Virus Testing, Viral Suppression, and HIV Preexposure Prophylaxis — United States, 2013–2018, Centers for Disease Control and Prevention, Dec. 6, 2019, available at <https://www.cdc.gov/mmwr/volumes/68/wr/mm6848e1.htm>.