



April 10, 2020

(VIA ELECTRONIC MAIL: Thomas.Engels@hrsa.hhs.gov)

Thomas J. Engels, Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Re: Waiver Request to Allow Ryan White Clinics to Use Existing Resources to Fight COVID-19 Pandemic

Dear Administrator Engels:

I am writing on behalf of Ryan White Clinics for 340B Access (“RWC-340B”) to express RWC-340B’s deep appreciation for the generous allocation of resources and regulatory flexibility given to our nation’s healthcare providers during the COVID-19 pandemic. Over the past few weeks, however, it has become increasingly apparent that, as President Trump recently noted, “[a]dditional measures. . .are needed to successfully contain and combat the virus in the United States.”¹ Members of RWC-340B are reaching out to you today because they have a unique opportunity to use existing resources to strengthen the national fight against this pandemic. Ryan White Clinics (“RWCs”) are ready to mobilize their resources but they need you to exercise your waiver authority first. In particular, RWC-340B asks the Administration to exercise its authority to waive restrictions related to the use of program income earned by RWCs so that RWCs may use their resources and expertise to assist in the fight against the spread of COVID-19.

RWCs Are Uniquely Positioned to Assist in Stemming the Spread of COVID-19

RWCs can play an important role to prevent the spread of COVID-19 because the expertise and programmatic infrastructure that they have developed in addressing HIV/AIDS are exactly the type of resources needed to address this unprecedented pandemic. As you know, the Ryan White Comprehensive AIDS Response Emergency (“CARE”) Act of 1990 established the Ryan White program, the largest federally funded program for people living with HIV/AIDS in the United States. Currently, serving over half a million people each year, RWCs provide a comprehensive system of medical care for HIV/AIDS patients, including case management and other supportive services, to ensure that HIV/AIDS

¹ The White House, *Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak*, WWW.WHITEHOUSE.GOV (Mar. 13, 2020), <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>.

patients remain in treatment. RWCs use their federal grant dollars, as well as income earned on reimbursement from third party payers, to support these health care and support activities.

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. On average, RWC patients have a viral suppression rate of almost 85%, a record high levels in 2019. In addition to experience with treating individuals with a potentially deadly infectious disease, RWCs are also 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 treat COVID-19. Deborah Birx, the response coordinator for the White House Coronavirus Task Force, has noted that, like the silent HIV epidemic, halting the spread of COVID-19 requires large-scale community efforts.²

The Health Resources and Services Administration (“HRSA”) recently recognized the practicality of RWCs joining the battle against COVID-19. In FAQs addressing the COVID-19 pandemic, HRSA advised Ryan White grantees that, “[a]s part of their ongoing health education services, Ryan White HIV/AIDS Program recipients can and should inform and raise awareness among their patients and the community of COVID-19 preventive measures; how to recognize symptoms of COVID-19 infection; and what to do if and when they or a member of their family gets sick.” HRSA further noted that RWCs are experienced with providing this type of information in a culturally appropriate manner.³

Program Income Restrictions Are Preventing RWCs from Fighting the Coronavirus Except for Patients Who 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. 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 RWCs’ 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.⁴ 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 infection.

RWCs are currently unable to fully address the 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 the COVID-19 virus but it represents just a fraction of the U.S. population that must be protected and/or

² Peter Kane, *‘Unresolved grief’: coronavirus presents eerie parallels for many AIDS advocates*, WWW.THEGUARDIAN.COM (Mar. 22, 2020), <https://www.theguardian.com/world/2020/mar/22/coronavirus-aids-epidemic-san-francisco>.

³ HRSA, HIV/AIDS Bureau, Corona Virus 2019 (COVID-19) FAQs (April 2, 2020) <https://hab.hrsa.gov/coronavirus-frequently-asked-questions>.

⁴ 42 C.F.R. § 75.2.

treated. RWCs have the ability to apply their expertise and infrastructure to protecting and caring for the non-HIV population but they lack adequate funding for such services absent the availability of program income.

The Requested Program Income Waiver Aligns with the Administration’s Push to Employ All Available Resources to Fight COVID-19 and Would Not Require Use of Federal Funds

RWC-340B asks that you grant a waiver of these restrictions on program income so that RWCs can assist in the fight against the spread of COVID-19 regardless of whether the individual being treated, or educated about preventative measures, has HIV/AIDS. For instance, with flexibility in use of program income funds to provide services to individuals without HIV/AIDS during this crisis, RWCs could assist their communities by setting up COVID-19 laboratories, testing, screening, and treatment sites or paying for laboratory costs and medical supplies related to COVID-19 tests and treatment, or by hosting webinars and engaging in social media efforts to educate communities about COVID-19 risks. RWCs could also assist in efforts to transport people to care, prevent food shortages, address local housing issues, and help to manage individuals with substance use disorders that are exacerbated by the COVID-19 pandemic. In addition, use of program income to assist individuals without HIV/AIDS could be used to provide remote support and coaching to patients diagnosed with, or convalescing from, COVID-19 and to collaborate with other grantees for provision of telehealth services and expansion of mobile care unit services across state lines where there is a need for COVID-19 related care. RWCs could accomplish these goals by engaging volunteer staff or hiring additional healthcare staff and by being permitted to prescribe drugs from expanded formularies.

Your declaration of a public health emergency under section 319 of the Public Health Service Act, the President’s declaration of the novel coronavirus outbreak in the United States as a national emergency and the World Health Organization’s (“WHO”) declaration of COVID-19 as a global pandemic on March 11, 2020^{5,6} demonstrate the urgency of using all available resources to combat COVID-19. We specifically note your authority to waive grant requirements in a public health emergency under title XXVI of the Public Health Service Act “to improve the health and safety of those receiving care [under Ryan White grants]...and the general public”⁷ as providing the authority to grant this request.

More specifically, we note regulatory authority and precedence for our request in the Administration’s approval of a multitude of waivers of federal requirements to fight the COVID-19 pandemic.⁸ As just a few examples, the Administration has instituted the “hospitals without walls” program to allow hospitals to provide healthcare in expansion sites, significantly expanded Medicare coverage of telehealth services, and approved waivers of state Medicaid requirements at an unprecedented rate. The waiver that RWC-340B is requesting would simply allow RWCs to expand the patient population that they currently treat and is a waiver that aligns with the Administration’s efforts to use every available health care resource to address COVID-19.

⁵ Alex M. Azar II, *Determination that a Public Health Emergency Exists*, U.S. of Health & Human Servs. (Mar. 10, 2020), available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>; 42 U.S.C. § 247d.

⁶ The World Health Organization, *WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020*, WWW.WHO.INT (Mar. 11, 2020), <https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020>.

⁷ 42 U.S.C. § 300ff-83.

⁸ See generally, The White House, *Briefings & Statements*, WWW.WHITEHOUSE.COM, <https://www.whitehouse.gov/briefings-statements/> (last visited Mar. 25, 2019).

With overwhelming bipartisan support, Congress passed three separate stimulus packages to, among other things, attempt to flatten the contagion curve and provide resources to overwhelmed health care providers and facilities. These actions were undoubtedly necessary, but were costly and required Congressional action. Significantly, waiver of program income restrictions would not impose any additional costs on the federal government nor would they require legislative action.

Conclusion

RWCs have the unique expertise and capacity to address the COVID-19 emergency and to prevent the spread of COVID-19; however, regulatory restrictions currently limit RWCs' ability to fully leverage their existing resources to assist in this historic fight. A targeted waiver of program income restrictions would allow RWCs to tap into their unique expertise, without the need for additional federal spending or legislation, and would allow them to assist in this historic fight against COVID-19.

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Sincerely,



Shannon Stephenson
President

cc: Traci Vitek
Garrick Groves