Ryan White Clinics for 340B Access

June 20, 2018

VIA FEDERAL EXPRESS

The Honorable Alex M. Azar II
Secretary of Health & Human Services
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Response to the Opioid Crisis Without Use of Federal Funds

Dear Secretary Azar:

Attached is a memorandum that proposes an effective response to the opioid addiction crisis that would not require any federal spending. As explained in the memorandum, Ryan White clinics are equipped to help address the opioid addiction crisis and can do so with a simple waiver of requirements related to the use of the non-federal funds that they earn by providing grant services. We believe that the solution described in the attached memorandum aligns perfectly with the Administration's commitment to solving the opioid addiction crisis and its belief that entities like ours, which are in the private sector, are often the best equipped to deal this type of issue.

I would be happy to address any questions that you have about this memorandum or you can contact RWC-340B's attorneys, whose contact information is included on the last page of the memo.

Sincerely,

Sara Dingwall, Pharm.D.
President
RWC-340B

Cc: Laura Cheever, MD. ScM. Associate Administrator

HHS Waiver Authority Should Be Used to Address the Opioid Abuse Epidemic and Prevent the Spread of HIV/AIDS

Executive Summary

On October 26th, 2017, President Donald Trump directed the Secretary of Health and Human Services ("the Secretary") to declare the opioid epidemic a national public health emergency under the Public Health Service Act and the acting Secretary renewed the declaration on January 24, 2018 and on April 24, 2018.[1] President Trump directed federal agencies to use every appropriate emergency authority to fight the opioid crisis. In his State of the Union address on January 30, President Trump addressed "terrible crisis of opioid and drug addiction." President Trump stated that, "[m]y Administration is committed to fighting the drug epidemic and helping get treatment for those in need." Under a public health emergency declaration, the Secretary has the authority to waive certain regulatory requirements, including requirements applicable to Ryan White clinics ("RWCs").

While President Trump recognizes that the opioid epidemic is a national public health emergency, only approximately $57,000 was in the Public Health Emergency Fund when the President declared the emergency and the Administration is still searching for ways to address the crisis. Delays in implementing solutions may result from a lack of financial resources, or because the Administration has not yet identified experienced health care providers uniquely situated to address the crisis.

RWCs have unparalleled experience in addressing the needs of vulnerable patient populations with chronic conditions like opioid abuse and have the tools to prevent opioid abusers from becoming infected with HIV/AIDS. Importantly, RWCs also have the financial resources to do this work without the need for additional federal dollars. The only barriers to this solution are regulatory prohibitions that prevent RWCs from putting their resources and expertise to work to assist with the opioid crisis.

To address this national crisis, the Secretary should exercise his authority under the public health emergency declaration to reduce regulatory "program income" restrictions currently preventing RWCs from fully responding to the opioid crisis. This waiver would allow RWCs to deploy their resources to meet the needs of individuals with opioid use disorder, as well as prevent HIV transmission among this population. The waiver could be implemented by publication of a guidance document on the website of the Health Resources and Services Administration HIV/AIDS Bureau. The proposed guidance would permit Ryan White grant recipients to provide the full range of services that are provided to HIV patients to non-HIV patients who have opioid use disorder, to provide other appropriate care and services to address the nexus between HIV and opioid addiction, such as treatment and interventions for HIV prevention, and to obtain facilities to provide this care.

For more information, contact Barbara Straub Williams at 202-872-7633 or Barbara.Williams@PowersLaw.com, William von Oehsen at 202-872-6765 or William.vonOehsen@PowersLaw.com, or Peggy Tighe at 202-872-6752 or Peggy.Tighe@PowersLaw.com.

[1] The White House, *President Donald J. Trump is Taking Action on Drug Addiction and the Opioid Crisis* (Oct. 26, 2017) https://www.whitehouse.gov/briefings-statements/president-donald-j-trump-taking-action-drug-addiction-opioid-crisis/. The declaration was last renewed on April 24, 2018. Renewal of Determination that a Public Health Emergency Exists (Apr. 24, 2018) https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioid-20Apr2018.aspx. The public health emergency may be renewed every 90 days. 42 U.S.C. § 247d(a).

HHS Waiver Authority Should Be Used to Address the Opioid Abuse Epidemic and Prevent the Spread of HIV/AIDS

On October 26th, 2017, President Donald Trump directed the Secretary of Health and Human Services ("the Secretary") to declare the opioid epidemic a national public health emergency under the Public Health Service Act and the acting Secretary renewed the declaration on January 24, 2018 and on April 24, 2018.[1] President Trump directed federal agencies to use every appropriate emergency authority to fight the opioid crisis. In his State of the Union address on January 30, President Trump addressed "terrible crisis of opioid and drug addiction." President Trump stated that, "[m]y Administration is committed to fighting the drug epidemic and helping get treatment for those in need." Congress is also concerned about the burgeoning opioid crisis. Senate Finance Chairman Orrin Hatch R-Utah) and ranking member Sen Ron Wyden (D-Ore.) sent a letter on February 2, 2018 to industry and patient groups stating that about one in three Medicare beneficiaries in 2016 were prescribed an opioid, resulting in about $4 billion in Medicare Part D spending and that Medicaid spent $9 billion on opioid use disorder treatment in 2013. Under a public health emergency declaration, the Secretary has the authority to waive certain regulatory requirements, including requirements applicable to Ryan White clinics ("RWCs").

Although opioid misuse has been declared a public health emergency, federal funding is limited and there is a dearth of qualified health care providers currently available to treat the disorder. This memorandum provides a solution to address this urgent and growing problem. The Secretary should use his authority under the Public Health Service Act to waive regulatory requirements applicable to RWCs so that they can use their resources to address the opioid crisis and avoid HIV infections at no cost to the federal government. RWCs are uniquely situated to respond to this crisis, but face significant regulatory barriers in employing their resources to do so. The recommendations below would allow RWCs to provide a rapid, comprehensive, and efficient response to the opioid crisis.

The Opioid Crisis

There is an urgent need to leverage existing resources to address opioid abuse in the United States. The opioid epidemic is the deadliest drug crisis in American history with 116 people each day dying from opioid-related drug overdose.[2] Drug overdose deaths are now the leading cause of death for Americans under the age of 50, killing roughly 64,000 people in 2016.[3] If

[1] The White House, *President Donald J. Trump is Taking Action on Drug Addiction and the Opioid Crisis* (Oct. 26, 2017) https://www.whitehouse.gov/briefings-statements/president-donald-j-trump-taking-action-drug-addiction-opioid-crisis/; Renewal of Determination that Public Health Emergency Exists (Jan. 24, 2018) https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioid-24Jan2018.aspx; Renewal of Determination that a Public Health Emergency Exists (Apr. 24, 2018) https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioid-20Apr2018.aspx. The public health emergency may be renewed every 90 days. 42 U.S.C. § 247d(a).

[2] U.S. Dep't Health & Human Servs., *The Opioid Epidemic in Numbers*, https://www.hhs.gov/opioids/.

[3] Nat'l Institute on Drug Abuse, *Overdoes Death Rates* (Sept. 2017), https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates.

action is not taken to allow a swift and comprehensive response that employs a holistic approach to treatment and prevention, the epidemic will only continue to grow.

The opioid abuse epidemic also threatens to roll back many of the gains that the United States has made in combatting HIV/AIDS. Particularly in rural areas, the opioid epidemic has already sparked HIV outbreaks and threatens to deepen the damage in places already suffering under the opioid crisis. As an early example, in 2015, Scott County, Indiana experienced a dramatic increase in HIV infections as the result of opioid misuse.[4] The small town where the majority of the cases occurred went from reporting less than five new infections per year from 2004 to 2013 to reporting 181 cases of HIV in a single year.[5]

The outbreak in Scott County could be repeated in other parts of the country. The Center for Disease Control ("CDC") has identified 220 specific counties at high risk for a spike in HIV infections as a result of opioid use if something is not done to address this crisis.[6] CDC researchers compiled the list after analyzing factors such as pharmacy sales of prescription painkillers, overdose deaths, and rates of unemployment. The counties are primarily in Kentucky, West Virginia, Indiana, Ohio, Michigan, Missouri, and Tennessee. These counties also suffer from some of the largest instances of opioid related deaths. For example, West Virginia currently leads the nation in overdose deaths and is home to 28 of the counties identified as at high risk for HIV outbreaks.

The opioid epidemic is already killing people at a faster pace than the HIV/AIDS epidemic did in its most deadly era.[7] The Secretary's Office of HIV/AIDS and Infectious Disease Policy has called the intersection of the opioid epidemic and HIV transmission "a perfect storm."[8]

The Ryan White HIV/AIDS Program

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. The Ryan White program is administered by the Health Resources and Services Administration HIV/AIDS Bureau ("HAB") and provides federal grants to state and local government and private organizations to furnish services to individuals living with HIV/AIDS.

RWCs provide a comprehensive system of medical care for HIV/AIDS patients, including essential support and case management services to ensure that HIV/AIDS patients remain in

[4] Michelle M. Van Handel, et al., *County-Level Vulnerability Assessment for Rapid Dissemination of HIV or HCV Infections Among Persons Who Inject Drugs, United States*, 73(3) J. Acquir. Immune Defic. Syndr. 323 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5479631/.
[5] *Id.*
[6] *Id.* An easily accessible list of the counties can be seen here: http://opioid.amfar.org/TN.
[7] Dennis H. Osmond, *Epidemiology of HIV/AIDS in the United States* (Mar. 2003) http://hivinsite.ucsf.edu/InSite-KB-ref.jsp?page=kb-01-03&ref=kb-01-03-tb-03&no=3.
[8] Richard Wolitski, *Interconnected, Intertwined, and Colliding: Co-Occurring Epidemics of HIV, Viral Hepatitis, and Opioids* (May 17, 2017) https://www.hiv.gov/blog/co-occurring-epidemics-of-hiv-viral-hepatitis-and-opioids.

treatment. The program currently serves more than half a million people each year.[9] The program plays an essential role in decreasing costs for other federal health care programs, such as Medicaid and Medicare, by providing holistic care to HIV/AIDS patients and preventing health complications. These clinics have a well-documented history of maximizing the impact of federal dollars to educate, support, and treat individuals and communities affected by HIV. Ryan White clinics use their federal grant dollars and reimbursement from third party payers to help almost 85% of their patients achieve viral suppression, according to 2016 data from the Health Resources and Services Administration.[10] The national viral suppression rates is estimated to be less than 50% on a national level. When patients achieve viral suppression, HIV is not detectable in their blood and they cannot pass HIV to others.

Unique Experience of RWCs

RWCs are uniquely situated to address "the connection between HIV transmission and substance abuse" emphasized by President Trump in the declaration of a public health emergency.[11] RWCs have the experience to identify opioid users and particularly those with a high risk of contracting HIV/AIDS, thereby helping to prevent the spread of HIV, and curbing the high costs associated with HIV/AIDS treatment. RWCs also are experienced in providing the type of holistic care that is needed to address opioid addiction, as well as providing care to vulnerable individuals who are routinely stigmatized. Accordingly, there is no need for the federal government to expend resources in recruiting, training and deploying a new generation of providers to treat opioid users at risk of contracting HIV. RWCs are already prepared to meet this challenge ***without using any federal dollars***.

First, there is a significant overlap of the opioid and HIV/AIDS epidemics, which means that RWCs have already developed the expertise and infrastructure to identify, treat and support HIV-infected patients struggling with opioid addiction. Moreover, using opioids dramatically increases the risk that a person will contract HIV.[12] The lessons of Scott County, discussed above, demonstrate the danger of the "perfect storm" of HIV and opioid use. However, the Scott County experience also demonstrates that comprehensive and integrated actions to increase the availability of resources, such as drug treatment, HIV testing, and prevention education and services can stem or perhaps even prevent further HIV outbreaks.[13] RWCs offer the unique potential to apply their HIV and addiction care services to all opioid users, not just those who already have HIV.

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[9] HRSA, *About the Ryan White HIV/AIDS Program*, https://hab.hrsa.gov/about-ryan-white-hivaids-program/about-ryan-white-hivaids-program.

[10] HRSA, *Ryan White HIV/AIDS Program, Annual Client-Level Data Report, Ryan White HIV/AIDS Program Services Report (RSR) 2016*, p. 66; available at: https://hab.hrsa.gov/sites/default/files/hab/data/datareports/RWHAP-annual-client-level-data-report-2016.pdf .

[11] The White House, *President Donald J. Trump is Taking Action on Drug Addiction and the Opioid Crisis* (Oct. 26, 2017) https://www.whitehouse.gov/briefings-statements/president-donald-j-trump-taking-action-drug-addiction-opioid-crisis/.

[12] U.S. Dep't of Health & Human Servs., *Alcohol and Drug Use and HIV Risk*, https://www.hiv.gov/hiv-basics/hiv-prevention/reducing-risk-from-alcohol-and-drug-use/alcohol-and-drug-use-and-hiv-risk.

[13] Richard Wolitski, *Interconnected, Intertwined, and Colliding: Co-Occurring Epidemics of HIV, Viral Hepatitis, and Opioids* (May 17, 2017) https://www.hiv.gov/blog/co-occurring-epidemics-of-hiv-viral-hepatitis-and-opioids.

Second, RWCs have special expertise in the comprehensive care model needed to address opioid addiction. The treatment model employed to treat HIV/AIDS patients is precisely the model needed to treat individuals with opioid addiction. Like HIV, opioid misuse is a chronic condition that typically requires long-term treatment and management.[14] Much like efforts to achieve HIV viral suppression, successfully treating opioid use disorder requires a sequential approach to care "from screening and detection of opioid use disorder, to linkage to care, to medication initiation, and long-term retention."[15] RWCs have experience in providing comprehensive services beyond medical care, including but not limited to housing assistance, help finding employment, transportation, and assistance with food insecurity and nutrition. As with the HIV/AIDS patients, treating individuals with a drug addiction requires intensive case management services to coordinate care and keep individuals in treatment.

Third, RWCs have extensive experience meeting the unique needs of high risk, vulnerable and stigmatized patient populations. 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 opioid use disorder. RWCs recognize the stigma associated with both HIV and substance use disorders and can effectively address the barriers that this stigma can create for effective treatment and patient retention.

Lastly, RWCs have available financial resources that can be tapped to address these efforts, which means no additional federal resources are needed. RWCs typically receive reimbursements from third party payers for the care that they provide to HIV/AIDS patients, but are restricted in how they can use these funds. As discussed below, with appropriate waivers from the Secretary, RWCs will be able to use these funds to address the opioid crisis.

Barriers to RWCs' Response to the Opioid Crisis

RWCs are currently unable to fully address the opioid epidemic in their communities due to regulations that restrict the use of the funds that they generate from treating HIV/AIDS patients. As stated above, RWCs typically receive reimbursements from third party payers for the care that they provide to HIV/AIDS patients. These revenues are referred to as "program income."[16] Federal regulations restrict the use of program income by federal grantees and subgrantees. Specifically, these program income restrictions prevent RWCs from using program income to provide care to individuals who do not have HIV/AIDS, even when those individuals may be at very high risk of contracting HIV and prevent RWCs from using program income to obtain health care facilities.[17] RWCs cannot treat persons without HIV/AIDS for preventative measures

[14] Robin Williams, Edward Nunes, & Mark Olfson, *To Battle the Opioid Overdose Epidemic, Deploy The 'Cascade of Care' Model*, Health Affairs (Mar. 13, 2017) https://www.healthaffairs.org/do/10.1377/hblog20170313.059163/full/.

[15] *Id.*

[16] 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. 42 C.F.R. § 75.2.

[17] HIV/AIDS Bureau, Clarifications Regarding the Ryan White HIV/AIDS Program and Program Income, PCN # 15-03 https://hab.hrsa.gov/sites/default/files/hab/Global/pcn_15-03_program_income.pdf (Ryan White program income may only be used to provide services to individuals with HIV/AIDS or "women, children, infants or youth affected by or living with HIV"; HIV/AIDS Bureau, Frequently Asked Questions, PCNs # 15-03 & 15-04 (Mar. 21,

or for any other purpose. With respect to the opioid crisis, this restriction means that RWCs cannot use program income to treat those with an opioid addiction if they do not have HIV/AIDS, even though these individuals may be at high risk of contracting HIV and the treatment would likely prevent the spread of HIV infections. RWCs are also restricted from using program income to obtain facilities in which to provide counseling and treatment, even for HIV/AIDS patients.

Program income restrictions significantly limit how RWCs may deploy their program income to address the opioid crisis. If the Secretary exercised his waiver authority as described below, RWCs could play a greater, critical role in prevention, detection, and treatment of both opioid use disorder and HIV, averting the kind of outbreaks like the one that occurred in Scott County and providing comprehensive care to opioid users to overcome addiction.

Solution: The Secretary Should Exercise His Waiver Authority to Waive Program Income Limitations

In a public health emergency, the Secretary may waive grant requirements 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.[18] The Secretary's waiver authority is broad, but is limited to the time period for which the public health emergency declaration exists.

The Secretary should exercise his authority under the public health emergency declaration to allow RWCs to deploy their full resources to address this national crisis. Specifically, the Secretary should waive: 1) the requirement that program income generated through grant programs can only be used for individuals with HIV/AIDS and allow RWCs to use program income to treat individuals without HIV/AIDS if that individual is an opioid abuser; and 2) that prohibit use of program income to obtain facilities for counseling and treatment. Waiver of program income restrictions would allow RWCs to address the opioid crisis, a task to which they are uniquely suited. As demonstrated above, waiving program income requirements would allow RWCs to use their capacity and knowledge to respond to the opioid epidemic that would clearly "improve the health and safety of those receiving care…and the general public."

This waiver could be accomplished through a guidance document published on HAB's website. The waiver should permit Ryan White grant recipients to *provide the full range of services that are provided to HIV patients to non-HIV patients who have opioid use disorder*. In addition, the waiver should allow Ryan White grant recipients to *provide other appropriate care and services to address the nexus between HIV and opioid addiction, such as treatment and interventions for HIV prevention*. Finally, the waiver would allow Ryan White grant recipients *to obtain facilities to provide counseling and treatment for individuals with opioid use disorder.*

2016) https://hab.hrsa.gov/sites/default/files/hab/Global/faq15031504.pdf (Q. 4, p. 2. Program income may not be used for "construction and/or major alternation or renovation.);

[18] 42 U.S.C. § 300ff-83.

Conclusion

The opioid epidemic is a daunting and urgent national crisis that requires an immediate coordinated, comprehensive response. RWCs have the unique expertise and capacity to address the opioid crisis and the intersection of HIV and opioid use disorder. However, regulatory restrictions currently limit the ability to fully leverage their resources to this end. A targeted waiver of program income restrictions would allow RWCs to tap their unique capacity and knowledge to address the opioid epidemic and prevent the spread of HIV without additional federal spending. By expanding access to integrated services through RWCs for communities at the intersection of the opioid and HIV epidemics, the waiver of program income restrictions can have a major impact on the opioid epidemic in the United States.

The Secretary has the authority to waive program income limitations for RWCs to address the opioid crisis. Current regulations and HAB's policy state that program income may only be used to treat individuals with HIV/AIDS and that program income may not be used to obtain health care facilities.[19] The Secretary should waive regulatory restrictions that prevent RWCs from providing treatment and other services to address the needs of those with an opioid addition and who do not have HIV/AIDS as well as restrictions that prevent RWCs from contrasting facilities to provide this treatment.[20]

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[19] 45 C.F.R. § 75.307(e)(2). Clarifications Regarding the Ryan White HIV/AIDS Program and Program Income, PCN # 15-03, https://hab hrsa.gov/sites/default/files/hab/Global/pcn_15-03_program_income.pdf.

[20] For Parts A, B, and C, allowable costs are limited by Sections 2604(a)(2), 2612(a), and 2651(b)(1) of the Public Health Service Act ("the Act"). For Part D, allowable costs are limited by Sections 2671(a), (b), and (f) of the Act. For Part F, allowable costs are limited by Sections 2691-2693 of the Act.