



March 11, 2019

VIA ELECTRONIC SUBMISSION: HepHIVStrategies@hhs.gov

U.S. Department of Health and Human Services
Room L001
330 C Street, SW
Washington, D.C. 20024
Attn: HIV/Viral Hepatitis RFI

RE: Request for Information: Improving Efficiency, Effectiveness, Coordination, and Accountability of HIV and Viral Hepatitis Prevention, Care, and Treatment Programs

RWC-340B appreciates the opportunity to submit the following comments in response to the Request for Information (“RFI”), issued by the U.S. Department of Health and Human Services (“HHS”), entitled Improving Efficiency, Effectiveness, Coordination, and Accountability of HIV and Viral Hepatitis Prevention, Care, and Treatment Programs and published in the Federal Register on February 8, 2019. (84 Fed. Reg. 2883).

RWC-340B is a national association of HIV/AIDS health care providers that receive funding under the Ryan White CARE Act and participate as “covered entities” in the federal 340B drug discount program. The 340B program generates savings for Ryan White Clinics (RWCs), allowing them to stretch their scarce resources to support the full continuum of care that their patients need including testing, linkage to care, treatment, retention, case management, and medication adherence.

RWC-340B applauds your efforts in seeking comments, recommendations, and ideas for updating the National HIV/AIDS Strategy (“NHAS”) and provide our suggestions below.

- 1. Recognize the critical role that RWCs participating in the 340B program play in helping to eradicate the HIV/AIDS epidemic in the United States, consistent with the goals of the NHAS.**
- 2. Conclude that any attempts to alter the 340B program in ways that harm efforts to stop the spread of HIV/AIDS or create new taxpayer burdens would not be consistent with the NHAS.**
- 3. Acknowledge that discriminatory reimbursement against 340B covered entities is a serious impediment to advancing the NHAS.**

- **Recognize the critical role that RWCs participating in the 340B program play in helping to eradicate the HIV/AIDS epidemic in the United States, consistent with the goals of the NHAS.**

RWC-340B supports the current NHAS goal of reducing the rate of new HIV infections, especially in communities with high concentrations of individuals living with HIV/AIDS. RWC-340B also supports the broad goal of increasing access to care and improving health outcomes. The current NHAS recognizes the importance of the Ryan White Program and the work that RWCs do to achieve these goals.¹ We ask that the NHAS also acknowledge the important role that the 340B program plays in helping RWCs to support the complex array of health care and social services needed by this vulnerable population.

As you know, RWCs are on the front lines of caring for low-income and vulnerable patients in their communities. In 2017, RWCs served over 500,000 clients, reaching more than 50 percent of people living with HIV in the U.S.² Approximately 63% of individuals served by the Ryan White program live at or below 100% of the federal poverty level.³ In addition, 73.3% of individuals in the Ryan White program are racial minorities.⁴ To support this vulnerable population, it is important to reduce any barriers that may impede access to needed services. RWCs are able to break these barriers by using 340B savings to stretch scarce resources to provide testing, linkage to care, treatment, retention, case management, and medication adherence.

Experts recognize that HIV is a lifelong condition that requires constant adherence to medications and persons living with HIV/AIDS often need not only medical care, but also a wide array of social support services. The work of RWCs allows the vast majority of their patients to achieve viral suppression, which prevents the HIV virus from spreading to others, resulting in lower overall health care costs. According to the Ryan White HIV/AIDS Program Services Report, RWCs achieved a record level viral suppression rate of 85.9% in 2017, which exceeds the average rate national viral suppression by over 26%.⁵ When an HIV/AIDS patient achieves viral suppression, the disease cannot be transmitted to another individual, thereby avoiding the increased health care spending that would be needed to treat that individual.

These positive, demonstrable results are due in large part to the 340B program, which allows RWCs to close the gaps in the continuum of care that would otherwise hinder HIV/AIDS patients from achieving viral suppression. Given the success of RWCs in this arena, we are pleased to support President Trump's recently announced goal, in the context of his National HIV/AIDS Strategy, to end the HIV epidemic within the next 10 years. We know that support of both the Ryan White and 340B programs will improve the efficiency, effectiveness, accountability, and impact of the national response to HIV.

¹ National HIV/AIDS Strategy: Updated to 2020, HIV.gov (July 2015) available at <https://files.hiv.gov/s3fs-public/nhas-update.pdf>.

² Health Resources & Services Administration, Ryan White HIV/AIDS Program: Annual Client-Level Data Report, 6 (2017), available at <https://hab.hrsa.gov/sites/default/files/hab/data/datareports/RWHAP-annual-client-level-data-report-2017.pdf> (hereinafter *Annual Client-Level Data Report*).

³ Health Resources & Services Administration, Ryan White HIV/AIDS Program Overview, 2018; available at <https://hab.hrsa.gov/sites/default/files/hab/Publications/factsheets/program-factsheet-program-overview.pdf>

⁴ *Id.*

⁵ Annual Client-Level Data Report, *supra* note 2.

- **Conclude that any attempts to alter the 340B program in ways that harm efforts to stop the spread of HIV/AIDS or create new taxpayer burdens would not be consistent with the NHAS.**

The 340B program generates savings that helps to underwrite necessary services for patients living with HIV/AIDS – all at no cost to taxpayers and at relatively low cost to pharmaceutical manufacturers. RWCs have been very successful in their mission to increase viral suppression and help eradicate HIV/AIDS because of the inherent flexibility of the 340B program. The program allows RWCs and other 340B covered entities the ability to determine how best to use their 340B savings to meet community needs. Many of the services that RWCs provide are not reimbursed by any payer, although these services directly enable people living with HIV/AIDS to access and remain in care.

Over the past few years, RWC-340B has seen unprecedented activity aimed at taking away RWC's ability to best address their patients' needs. Such proposals have included a moratorium on enrollment of new covered entities, narrowing of the definition of patients eligible to receive 340B drugs, and/or the imposition of additional, burdensome reporting requirements in the name of transparency – all of which would result in serious disruption or scaling back of the 340B program and diminution of their ability to increase viral suppression.

Any change to the 340B program that reduces the number of patients who can receive 340B drugs, or reduces the reimbursement paid for 340B drugs would have a direct and negative impact on the important goals of the NHAS. Without access to the 340B program – or if the size or scope of the program were significantly diminished – the burden of providing these necessary services would fall on the states or the federal government, increasing health care costs for taxpayers and thwarting the national strategy.

- **Acknowledge that discriminatory reimbursement against 340B covered entities is a serious impediment to advancing the NHAS.**

Pharmacy Benefit Managers (“PBMs”), managed care plans, and other third party payers are increasingly usurping the benefit of the 340B program from the safety net providers in the 340B program by reimbursing for 340B drugs well below the non-340B rates and by establishing discriminatory terms in their pharmacy participation agreements. Left unchecked, discriminatory reimbursement will greatly reduce, if not eliminate, the benefit of the 340B discount for covered entities, thereby undermining the purpose of the 340B program and harming the low income and medically vulnerable patients served by RWCs. RWCs use their 340B savings to supplement the services that they provide, resulting in high viral suppression rates.

Congress intended the benefits of the 340B program to accrue to 340B covered entities, not to for profit payers that do not have a mission to achieve high viral suppression or reduce HIV/AIDS. The Health Resources and Services Administration (“HRSA”) has expressed concerns that providers would have no reason to participate in the 340B program if insurers take the benefit of 340B savings. HRSA explains that “if covered entities were not able to access resources freed up by the drug discounts when they... bill private health insurance, their

programs would receive no assistance from the enactment of section 340B and there would be no incentive for them to become covered entities.”⁶

RWC-340B has been fighting against discriminatory reimbursement and strongly supporting legislative initiatives to prohibit discriminatory reimbursement against 340B entities at the federal and state levels. RWC-340B supported Rep. Doris Matsui’s (D-CA) legislation in the 115th Congress – H.R. 6071, the SERV Act – that included a provision to prohibit discriminatory reimbursement. We are also pleased to see that legislatures in at least two states recently passed legislation that would prohibit discriminatory reimbursement. The South Dakota legislature passed legislation to prohibit a PBM from discriminating against a pharmacy owned by a 340B covered entity.⁷ And, the West Virginia legislature passed legislation that would prohibit a PBM or third-party entity from reimbursing an entity participating in the 340B program at a lower rate than non-340B pharmacies.⁸ Several other states are also drafting such legislation to prohibit discriminatory reimbursement.

We ask that the NHAS send a strong signal that discriminatory reimbursement should not be tolerated because it harms RWCs and therefore interferes with the NHAS mission and goals. The fight to end the HIV/AIDS epidemic starts with support of those on the front lines and any “taking” of the 340B benefit away from RWCs would therefore be antithetical to the NHAS’ vision.

Thank you for the opportunity to submit a response to your RFI to update the National HIV/AIDS Strategy. RWC-340B hopes to work with members of the administration to preserve and protect the 340B program and achieve the ultimate goal of ending the HIV epidemic. For further information, contact Peggy Tighe at 202-872-6752 or Peggy.Tighe@PowersLaw.com.

⁶ Health Resources & Services Administration, Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section 340B of the Public Health Service Act (July 2005).

⁷ H.B. 1137, 94th Sess. (S.D. 2019) (as passed, Feb. 11, 2019), S.J. 501, 94th Sess. (S.D. 2019) (as passed, Feb. 25, 2019).

⁸ S.B. 489, 2019 Reg. Sess. (W. Va. 2019) (as passed, Feb. 26, 2019).