



November 5, 2019

VIA ELECTRONIC SUBMISSION: CHACAdvisoryComm@hrsa.gov

Health Resources and Services Administration
HIV/AIDS Bureau
5600 Fishers Lane
Rockville, MD 20857
Attn: CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHAC) Fall Meeting

RE: CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHAC) Fall Meeting

RWC-340B appreciates the opportunity to submit comments in anticipation of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHAC) Fall Meeting announced in the Federal Register on September 12, 2019 (84 Fed. Reg. 48154). As requested in the announcement, these comments will include a discussion of issues related to the President's initiative on "Ending the HIV Epidemic: A Plan for America."

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.

We applaud the purpose and goals of the President's Initiative and CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHAC) and stand ready to work with CHAC to achieve these goals. RWC-340B is especially eager to respond to CHAC's request for comments on building community capacity, models of clinical care, and pre-exposure prophylaxis services and ask that the CHAC consider our requests, which are:

- 1. Support the 340B program and Ryan White Clinics (RWCs) participating in the program because the 340B program empowers RWCs to build community capacity and models of care in order to help eradicate the HIV/AIDS epidemic in the United States;**

2. **Work with RWCs to prevent lower, discriminatory reimbursement of 340B drugs, which results in insurers or pharmaceutical benefit managers usurping the 340B benefit from RWCs; and**
3. **Support efforts to allow RWCs to use grant funding and program income to provide Pre-Exposure Prophylaxis (PrEP) medications and related medical services to individuals at risk of contracting HIV.**

The following is RWC-340B's detailed explanation of why the three initiatives listed above are so crucial to the fight against the HIV/AIDS epidemic.

- **Support the 340B program and Ryan White Clinics (RWCs) participating in the program because the 340B program empowers RWCs to build community capacity and models of care in order to help eradicate the HIV/AIDS epidemic in the United States.**

We ask that CHAC recognize the critical role that the 340B program plays in helping RWCs to support the complex array of health care and social services needed by the vulnerable patient population that RWCs serve. We also ask that CHAC support both the Ryan White grant program and 340B program because doing so will improve the efficiency, effectiveness, accountability, and impact of the President's initiative and further the goal of ending the HIV epidemic in America.

RWCs are efficient, effective, accountable and impactful. RWCs are on the front lines of caring for low-income and vulnerable patients in their communities and eradicating the HIV/AIDS epidemic. In 2017, RWCs served over 500,000 clients, reaching more than 50 percent of people living with HIV in the U.S.¹ Approximately 63% of individuals served by the Ryan White program live at or below 100% of the federal poverty level. In addition, 73.3% of individuals in the Ryan White program are racial minorities.

RWC-340B applauds recent comments from HHS Assistant Secretary for Health ADM Brett P. Giroir, M.D. who said, "We are committed to enabling communities to best use the resources they need to plan and engage stakeholders."² RWC-340B also strongly agrees with the key goals identified by HHS from feedback received through recent community input efforts:

- "design and direct approaches that best meet their (local communities) needs";
- "supporting bold, innovative efforts that overcome barriers to HIV prevention, testing, and treatment"; and
- "building upon community experience that is already in the field."³

¹ Health Resources and Services Administration, *Ryan White HIV/AIDS Program Annual Client-Level Data Report 2017*, <http://hab.hrsa.gov/data/data-reports>

² *HHS Awards \$13.5 Million to Accelerate State and Local Planning Efforts for Ending the HIV Epidemic: A Plan for America*, HHS.gov (October 2, 2019), <https://www.hhs.gov/about/news/2019/10/02/hhs-awards-13.5-million-dollars-to-accelerate-state-and-local-planning-efforts.html> (last reviewed Oct 31, 2019).

³ *Id.*

RWCs participating in the 340B program are well versed in designing and directing programs to meet community needs, having built successful and appropriate models of care that focus on providing comprehensive health services to HIV/AIDS patients. RWCs also engage in innovative efforts to overcome barriers to care, and are relied upon as community leaders with extensive experience in the treatment of HIV/AIDS. Significantly, the 340B program is integral to enabling RWC to assist local communities in each of these areas.

The 340B program is also integral to effectively treating HIV/AIDS. Viral suppression can best be achieved through provision of comprehensive services to link HIV-positive individuals to care, to retain them in care, and to ensure that they are adherent to a medication regimen – case management services that private payers do not cover. Not only does proper HIV treatment benefit the individual with HIV/AIDS, individuals who achieve viral suppression do not infect others, resulting in overall healthcare savings. The 340B program allows RWCs to stretch their resources to support the full continuum of care that their patients need, from diagnosis, to linkage to care, to medication adherence and viral suppression.

RWCs in the 340B program have impressive rates of viral suppression. According to the Ryan White HIV/AIDS Program Services Report, RWCs achieved a record level viral suppression rate of almost 86% in 2017, which exceeds the average rate national viral suppression by over 26%.⁴ 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. Just as it was designed to do, the 340B program is allowing safety net HIV/AIDS providers to serve more patients, provide more services, and generate better health outcomes.

In short, the RWCs who participate in the 340B program are successful because the 340B program enables them to fight HIV/AIDS in a comprehensive fashion, allowing them the flexibility to use program savings to best suit their community needs. In this way, RWCs have been building community capacity for decades. This flexibility is entirely consistent with HHS' findings and goals. As such, we ask for support for the 340B program and Ryan White Clinics that participate in the program.

- **Work with RWCs to prevent lower, discriminatory reimbursement of 340B drugs, which results in insurers or pharmaceutical benefit managers usurping the 340B benefit from RWCs.**

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. Discriminatory reimbursement against 340B covered entities is a serious impediment to safety net providers that participate in the program and a very real threat to HHS’ goal of maintaining and expanding community

⁴ Health Resources and Services Administration, *Ryan White HIV/AIDS Program Annual Client-Level Data Report 2017*, <http://hab.hrsa.gov/data/data-reports>.

capacity. We ask that CHAC send a strong signal that discriminatory reimbursement should not be tolerated because it harms RWCs and therefore interferes with CHAC's mission and goals.

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. 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. 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."⁵

Discriminatory reimbursement ultimately harms the low income and medically vulnerable patients served by 340B providers including RWCs. The Government Accountability Office has found that providers use 340B to offset losses incurred from treating some patients, support existing pharmaceutical and clinical services, lower drug costs for low-income patients, serve more patients, and to provide additional services, such as case management, which facilitate access to appropriate care. Reducing reimbursement to 340B covered entities therefore jeopardizes the ability of RWCs to provide these important services.

In the context of the CHAC strategy, we ask that CHAC note that discriminatory reimbursement practices will not be tolerated, that they are anathema to the 340B program and RWCs and, therefore, to the Administration's goals that we support.

- **Support efforts to allow RWCs to use grant funding and program income to provide Pre-Exposure Prophylaxis (PrEP) medications and related medical services to individuals at risk of contracting HIV.**

The Ryan White HIV/AIDS Program (RWHAP) has always recognized that early intervention efforts are essential to effectively preventing and treating HIV/AIDS. We appreciate that the Administration has advanced efforts to provide increased funding for Pre-Exposure Prophylaxis (PrEP) to help eradicate HIV/AIDS. PrEP is one of the most powerful prevention tools against HIV transmission. We ask that CHAC consider supporting efforts to expand the ability of RWCs to use grant funding and 340B program income to pay for PrEP and related services for those at risk of contracting HIV/AIDS.

Currently, the Ryan White HIV/AIDS Program (RWHAP) legislation (Ryan White CARE Act) prohibits the use of RWHAP funds for PrEP medications and the related medical services such as physician visits and laboratory costs. More specifically, because the Ryan White CARE Act states that grant funds may only be used only for the care and treatment of people diagnosed with HIV, those funds cannot be used for people at risk of contracting HIV. This restriction on

⁵ Health Resources and Services Administration, *Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section 340B of the Public Health Service Act (2005)*, <http://www.hrsa.gov/hemophiliatreatment/340Bmanual.htm>.

the use of funding was in the original Ryan White legislation, which was enacted at a time when use of PrEP was unimaginable. It is time to update the Ryan White CARE Act, and allow RWCs to use grant funds to build comprehensive PrEP programs.

The Centers for Disease Control and Prevention reports that PrEP reduces the risk of HIV infection in at risk individuals by about 99%, when PrEP is taken daily.⁶ As a result of its effectiveness at preventing transmission of the virus, the 2020 National HIV/AIDS Strategy includes full access to comprehensive PrEP services as one its four critical focus areas.⁷ In a June 2016 letter to RWCs, the Health Resources and Services Administration’s HIV/AIDS Bureau (HAB) strongly encouraged RWHAP recipients and providers to “leverage the RWHAP infrastructure to support PrEP services within the parameters of the RWHAP legislation.”⁸

RWC-340B agrees with the Administration’s emphasis to encourage the use of PrEP and urges CHAC to support efforts that would allow RWCs to use grant funding to provide PrEP medications and related medical services to individuals at risk of contracting HIV. RWCs are well equipped to provide PrEP services using existing support networks and community relationships. Leveraging existing RWC networks, services, programs, and expertise that has been developed over the past two decades is the best way to ensure PrEP can be provided to those individuals who need it most and to lower HIV transmissions.

Thank you for the opportunity to submit comments in anticipation of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHAC) Fall Meeting. RWC-340B hopes to work with members of the committee 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 *Pre-Exposure Prophylaxis (PrEP)*, Centers for Disease Control and Prevention, Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, Sexual Transmitted Diseases and Tuberculosis Prevention, <https://www.cdc.gov/hiv/risk/prep/index.html> (last reviewed October 11, 2019).

⁷ *National HIV/AIDS Strategy for the United States: Updated to 2020* (July 2015) <https://files.hiv.gov/s3fs-public/nhas-update.pdf>

⁸ Health Resources and Services Administration, HIV/AIDS Bureau (HAB), *PrEP Letter* (June 22, 2016), https://hab.hrsa.gov/sites/default/files/hab/Global/prepletter062216_0.pdf