



Board Officers

Shannon Stephenson, President

Cempa Community Care

Rob Renzi, Vice President

Big Bend Cares

Mark Malahosky, Treasurer

Trillium Health

Mike Lee, Secretary

Evergreen Health Services

John Hassell, At-Large

AIDS Healthcare Foundation

Gilbert Kouame, At-Large

Prism Health North Texas

Tony Mills, At-Large

Men's Health Foundation

Max Wilson, At-Large

CAN Community Health

March 4, 2022

Charles Clapton - Vice President, Federal Government Affairs
Gilead Sciences
300 New Jersey Ave, NW, Suite 650
Washington, D.C. 20001

Re: Request for Exceptions to MAP/PAP Policies

Dear Mr. Clapton:

I am writing as President of RWC-340B to make two requests: 1) Gilead Science consider an exception to its Advancing Access® Medication Assistance Program (MAP) for pharmacies that dispense TRUVADA for PrEP® and DESCOVY for PrEP® (Truvada® and Descovy®, respectively) to patients of clinics that are dually enrolled in the 340B program as both a Ryan White grantee or sub-grantee and another grantee type; and 2) Gilead Science consider lowering the 340B price of Descovy®, which has risen at an unprecedented rate in recent months.

RWC-340B is a national association of HIV/AIDS health care clinics and service providers receiving support under the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act. As Gilead is aware, Ryan White clinics are dedicated to caring for low-income and vulnerable patients living with HIV/AIDS and are serving on the frontlines of the HIV/AIDS epidemic, supporting patients living with HIV/AIDS by providing primary care, case management, testing and behavioral health and other support services. Our members are dedicated to stopping the spread of HIV/AIDS and, to that end, have a proven record of helping patients to achieve viral suppression so that they cannot transmit HIV/AIDS. See HRSA, [Ryan White HIV/AIDS Program Annual Client-Level Data Report 2020](#).

Changes to MAP

Ryan White clinics are committed to controlling the HIV infection rate but are not permitted to provide PrEP or other services through their Ryan White grants to individuals without an HIV/AIDS diagnosis.¹ Ryan White clinics are required to use program income earned through their grants in accordance with the additive method, which means that earnings realized through the Ryan White grant must be used to further services and programs only for individuals with HIV/AIDS.² Because of these restrictions on use of Ryan White grant funds and program income, and to assist in the fight to control the HIV/AIDS epidemic, many Ryan White clinics have sought out other grants so that they can prescribe Truvada® and Descovy® to high risk individuals. Until the recent changes in Gilead's MAP program, Gilead's payments to pharmacies for Truvada® and Descovy® for individuals enrolled in the MAP program were sufficient to compensate clinics for the costs of providing the many healthcare and related services that are required for patients on a long-term medication regime. The current MAP payment amount for 340B drugs is simply not sufficient to cover the cost of services required to safely prescribe Truvada® and Descovy® as long-term medications. Because of restrictions on the use of program income generated through a grant, we cannot use the funds generated through services provided to individuals with HIV/AIDS to provide services to individuals who do not have HIV/AIDS.



Members of RWC-340B are familiar with Gilead's pending lawsuit against certain "bad actors" located in Florida that apparently took advantage of the MAP program by, among other questionable practices, prescribing Truvada® and Descovy® to individuals who were not at high risk and reselling the drugs to individuals that were not enrolled in the MAP program. RWC-340B respects your position that these sorts of practices defy the company's stated intent to help indigent individuals. We also note that the organizations named in Gilead's lawsuit were not registered as Ryan White clinics with the 340B program.

Ryan White clinics that receive funding under Parts C and D of the CARE Act must comply with a rigorous application process that documents their commitment to quality health care. Ryan White clinics that receive funding through Part A (for "highly impacted urban areas") or through Part B (to states) also must adhere to the compliance requirements imposed through the primary grantee. Ryan White clinics understand the level of healthcare services that are needed for individuals who are prescribed long-term medications and that commitment to quality healthcare carries over to services provided to at-risk individuals through their other grants.

RWC-340B members report that patients who are prescribed PrEP require, at a minimum, an annual physical and twice-yearly laboratory tests to ensure that they have not contracted HIV/AIDS due to noncompliance with the treatment regimen and have not contracted other STDs. Case management services are needed to ensure that PrEP patients, at a minimum, pick up the medication that they are prescribed. Many PrEP patients have never been administered an HPV vaccine or have other health care issues that need to be addressed, including behavioral health issues. Increased payment through the MAP program would help Ryan White clinics with dual 340B enrollments to provide the type of wholistic care that these patients require. We note that pharmacies that are not 340B contract pharmacies are currently being reimbursement at wholesale acquisition cost (WAC) and these pharmacies cannot provide these comprehensive services to PrEP patients.

Because Ryan White clinics have a demonstrated commitment to providing comprehensive health care to their patients, we are requesting that Gilead consider entering into a modified version of its MAP Pharmacy Participation Agreement for clinics that are dually enrolled in the 340B program as Ryan White clinics and another grantee category. Payment for 340B drugs under that Pharmacy Participation Agreement would be at a level that would compensate the clinics for providing the health care services, behavioral health services, case management, and testing services that are required to ensure that patients who are prescribed Truvada® and Descovy® remain healthy. Payment could be tied to wholesale acquisition cost (WAC), what we see as a reasonable measure, but we are amendable to further discussion this point.

We note that Gilead had announced that the changes to its MAP were to be effective on January 1, 2022. RWC-340B members have reported that they did not see any changes in reimbursement under the MAP until about January 20. At a minimum, we trust that Gilead would not attempt to recoup payments for the period between January 1 and January 20 to reflect the new MAP payment policy.

Rising Price of Descovy®

As stated on your website, "For more than a decade, Gilead Sciences has been a leader in the development of antiretroviral therapy for HIV/AIDS." Because of Gilead's leadership role in HIV/AIDS treatment, patients of Ryan White clinics are largely dependent on Gilead anti-retroviral medications. Many physicians practicing in Ryan White clinics prefer Descovy® over Truvada®, despite the cost difference, because Truvada® is more likely to have an impact on kidney function and bone density. Over the last year, the 340B price of Descovy® has increased by over 80% for many Ryan White clinics.³ One clinic reported a loss of approximately \$1,000,000 due to the jump in the price of Descovy®. The increased price obviously makes it more difficult for these safety net providers to provide the comprehensive services that their patient require. RWC-304B is requesting that Gilead lower the 340B price of Descovy® to its January 2021 price so that Ryan White clinics can continue to offer comprehensive care to their patients.



We welcome the opportunity to speak with you about our requests, provide more detail about the reasons for those requests, and work together to ensure that RWCs can be most effective in our fight to prevent HIV/AIDS.

Sincerely,

A handwritten signature in blue ink that reads "Shannon Stephenson". The signature is fluid and cursive.

Shannon Stephenson
President, RWC-340B

Cc: Peggy Tighe, Principal, Powers Law

¹See letter from Laura Cheever, M.D., Sc.M, Associate Administrator, HIV/AIDS Bureau, dated June 22, 2016.

²45 CFR § 75.307(e)(2).

³Gilead no longer offers Descovy® through the prime vendor program (PVP), and has decreased the 340B price offered outside the PVP, but the new 340B price is significantly higher than the prior PVP price.