



July 7, 2020

The Honorable Rosa DeLauro
Chairwoman
House Appropriations Subcommittee on
Labor, Health and Human Services,
Education, and Related Agencies
U.S. House of Representatives
Washington, DC 20515

The Honorable Tom Cole
Ranking Member
House Appropriations Subcommittee on
Labor, Health and Human Services,
Education, and Related Agencies
U.S. House of Representatives
Washington, DC 20515

RE: Request Regarding President's 2021 Budget Proposal, 340B Drug Discount Program

Chairwoman DeLauro and Ranking Member Cole:

Ryan White Clinics for 340B Access (RWC-340B) is a coalition of HIV/AIDS health care providers and related organizations that receive funding under the Ryan White CARE Act and participate as "covered entities" in the federal 340B drug discount program (340B Program). We are writing to express our opposition to certain provisions in the President's budget proposal for Fiscal Year 2021 (the "Budget Proposal") that would have a tremendously negative impact on the 340B Program. We ask that you not include these provisions in legislation being advanced by the House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies.

As you know, the 340B Program allows safety net providers, including HIV/AIDS clinics and service providers receiving funding through the Ryan White CARE Act, to obtain prescription drugs at discounted prices. The 340B Program is vitally important to Ryan White clinics and other safety net providers that use the program because it helps them maintain existing services or provide new services that are needed by low income and other vulnerable populations. Many of these services are not reimbursed by any payer, though these services directly enable people living with HIV/AIDS to access and remain in care and, most importantly, to become virally suppressed so they cannot transmit the virus to others. The program generates both savings and revenue that help underwrite these services at no cost to taxpayers and at relatively low cost to pharmaceutical manufacturers.

Summary

Given the limited resources of Ryan White clinics, we view any budgetary proposals that would undermine the 340B Program as a threat to RWC-340B members and the health and wellbeing of our patients. The President's 2021 Budget Proposal would negatively impact the 340B Program in three substantial ways: (1) it would impose user fees, constituting a tax on Ryan White clinics and other safety net providers participating in the 340B Program; (2) it would grant broad regulatory authority to the Health Resources and Services Administration ("HRSA") in direct contradiction to views expressed by the Chairs and Ranking members of the committees of jurisdiction for the 340B Program; and (3) it would impose financially burdensome accounting requirements at a time when Ryan White clinics are fighting to protect their communities.

User Fees Represent a Tax on the Safety Net

The Budget Proposal includes a user fee of 0.1% of the amount of each 340B drug purchase by participating covered entities.¹ This fee is effectively a tax on covered entities that will reduce the benefit of participating in the 340B Program and consequently threaten access to HIV care for vulnerable populations. Safety net providers in the 340B Program have never been subject to user fees as a condition of their participation in the program. When Congress enacted the 340B Program in 1992 and amended it in 2010, Congress could have established a user fee program, but it chose to focus instead on the important goal of securing discounts for the health care providers that serve vulnerable patients. Several Administrations have included 340B user fees in their proposed budgets, but Congress has never adopted this proposal. According to HRSA, the proposed user fee would generate \$24 million in revenue to HRSA – \$24 million of funding directly stripped away from cash-strapped entities, including Ryan White clinics, many of which are now fully engaged in helping their patient communities address the COVID-19 pandemic.

Committees of Jurisdiction Have Already Rejected HRSA's Request for Additional Regulatory Authority

The Budget Proposal requests that Congress grant HRSA broad regulatory authority over all aspects of the 340B Program.² HRSA has repeatedly requested broader regulatory authority from Congress to oversee the 340B Program following a 2014 federal court ruling that recognized that HRSA has regulatory authority only in three specific areas.³ It is also important to note that in 2018, the Chairs and Ranking members of the Senate and House committees with jurisdiction over the 340B Program (Senate Health, Education, Labor and Pensions and House Energy and Commerce) sent a letter to HRSA's Director of the Office of Pharmacy Affairs (OPA) rejecting OPA's request for additional regulatory oversight because HRSA had not yet exercised the regulatory authority that Congress had already given OPA.⁴ Although OPA has adopted regulations in two of the three areas for which it has regulatory authority, it still has not adopted regulations in a third area.

¹ Office of Mgmt. & Budget, Exec. Office of the President, Appendix, Budget of the United States Government Fiscal Year 2021, 436 (2020), https://www.whitehouse.gov/wp-content/uploads/2020/02/appendix_fy21.pdf.

² *Id.* at 502.

³ *Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 43 F. Supp. 3d 28, 42–45 (D.D.C. 2014).

⁴ See Letter from Sens. Lamar Alexander and Patty Murray and Reps. Greg Walden and Frank Pallone to Krista Pedley, August 27, 2018, available at <https://republicans-energycommerce.house.gov/wp-content/uploads/2018/08/20180827HRSA.pdf> (since that letter, Congress has not acted to provide HRSA with additional rulemaking authority).

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Burdensome Accounting Requirements Undermine Covered Entity Efforts to End the HIV/AIDS Epidemic

The Budget Proposal would allow HRSA to audit covered entities to determine how the net income that the covered entity receives through the 340B Program is used and would require covered entities to provide records and reports to HHS “as deemed necessary”.⁵ RWC-340B fully supports transparency in government programs. However, Ryan White clinics, like all federal grantees, are already subject to reporting requirements and audits with respect to their “program income”, which is the income that is generated through their grant activities.⁶ Moreover, Ryan White clinics are required to use income generated through the grant “for the purposes and under the conditions of the Federal award”.⁷ Ryan White clinics are audited on uses of their program income as part of their grant audits. In addition, the division of HRSA that oversees the Ryan White program requires Ryan White HIV/AIDS clinics to collect financial information related to Ryan White HIV/AIDS Program grant funds and report this data to HRSA at the beginning and end of the grant budget period. In fact, HRSA has recently proposed to add more detailed information about program income to the report.⁸ As such, Ryan White clinics are already subject to auditing and reporting requirements as federal grantees and collection of this data would be unduly burdensome at a time when Ryan White clinics are facing serious time and budget constraints.

For these reasons, RWC-340B strongly urges the Committee not to include these 340B-related provisions of the Budget Proposal in your legislation. Thank you for your continued support and promotion of the lifesaving services that our members provide.

For further information, please contact Peggy Tighe at Peggy.Tighe@PowersLaw.com or see RWC340B.org.

Sincerely,



Shannon Stephenson
President, RWC-340B

cc: The Honorable Nita Lowey
Chairwoman, Committee on Appropriations
The Honorable Kay Granger
Ranking Member, Committee on Appropriations

⁵ Office of Mgmt. & Budget, Exec. Office of the President, Appendix, Budget of the United States Government Fiscal Year 2021, 502 (2020), https://www.whitehouse.gov/wp-content/uploads/2020/02/appendix_fy21.pdf.

⁶ 45 C.F.R. § 75.2.

⁷ 45 C.F.R. 75.307(e)(2).

⁸ Information Collection Request (ICR), issued by HRSA, entitled Ryan White HIV/AIDS Program: Allocation and Expenditure Forms and published in the Federal Register on Tuesday, February 11, 2020 (85 Fed. Reg. 7653, 7763). {D0895121.DOCX / 8 }