

Board Officers

January 24, 2024

Shannon Burger, President
Cempa Community Care

Via Email

Rob Renzi, Vice President
Big Bend Cares

Andy J. Mao
Deputy Director, Civil Division, Fraud Section
United States Department of Justice

Mark Malahosky, Treasurer
Trillium Health

145 N Street, NE
Washington, D.C. 20002

Mike Lee, Secretary
Evergreen Health Services

Re: Letter of Support for Adventist West False Claims Act Case

Emily Blaiklock, At-Large
Positive Impact Health Centers

Dear Mr. Mao:

Tony Mills, At-Large
Men's Health Foundation

Max Wilson, At-Large
CAN Community Health

Sean DeYoung, At-Large
Allies for Health + Wellbeing

Ryan White Clinics for 340B Access (RWC-340B) is submitting this letter of support in connection with a False Claims Act case that was filed by a California health care system called Adventist West. Specifically, RWC-340B writes to ask that the Department of Justice exercise its veto authority, under 31 U.S.C. 3730(e)(4)(A), over the public disclosure defense raised by the defendant manufacturers named in the Adventist West complaint. Adventist West, like each member

of RWC-340B, qualifies for and participates in the federal 340B drug pricing program (340B program). Adventist West has made serious and credible allegations of 340B program overcharges by the defendant manufacturers that, if upheld by the court, have far reaching implications for both Ryan White clinics (RWCs) and people living with HIV/AIDS.

As background, 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. RWCs are dedicated to caring for low-income and vulnerable patients living with HIV/AIDS and are serving on the frontlines of the AIDS epidemic, supporting high risk clients and communities. RWC-340B members provide primary care, case management, and other support services for persons living with HIV/AIDS. For many of these services, RWCs receive no insurance payments and, for that reason, are highly dependent on the 340B program to underwrite the cost of providing comprehensive care to their patients. Consistent with the purpose of the 340B program, RWCs use 340B savings and revenue to allow them to “stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”¹ The 340B program has a 30-year record of successfully expanding services and increasing access to low-cost drugs for low income and other vulnerable patients served by 340B covered entities. Many RWCs depend on 340B savings and revenue to keep their doors open.

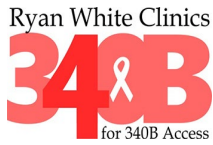
¹ H.R. Rep. No. 102-384(II), at 12 (1992).

Manufacturers have only one responsibility under the 340B program, namely, to ensure they do not charge more than a statutory ceiling price for 340B drugs. Adventist West claims in its lawsuit that four manufacturers—AbbVie, AstraZeneca, Novartis, and Sanofi—have circumvented this obligation by charging more than a penny for drugs when the statutory formula yields a ceiling price of less than a penny. Penny price overcharges are the most serious type of 340B program violation because they deprive 340B providers, including RWCs, of almost the entire financial benefit of the 340B program. Such losses undermine their efforts in adequately meeting the health care needs of their patients and communities.

The adverse public health consequences of overcharging RWCs is especially troubling. Controlling the AIDS epidemic in this country requires testing and identifying individuals who carry the virus, treating them in accordance with accepted standards of care and making sure they adhere to their daily regimen of anti-retroviral medications so that they achieve viral suppression. Viral suppression reduces the risk of HIV-positive individuals transmitting HIV to HIV-negative individuals because the level of HIV in their blood is undetectable. Studies show that people living with HIV/AIDS are much more likely to achieve viral suppression when they receive their care from an RWC than a non-RWC provider.² RWCs attribute their high rate of success on the savings and revenue they receive through the 340B program. Manufacturer overcharges deprive RWCs of such savings and revenue which, in turn, undermines their efforts to keep HIV-positive patients non-infectious.

It would be a setback for RWCs, and our country's fight against the AIDS epidemic, if Adventist West's complaint is dismissed on what is essentially a procedural argument. The merits of Adventist West's case should be addressed because the stakes are so high. Although Medicaid would directly benefit from the case, RWCs and their patients would indirectly benefit because the case would provide a pathway for 340B providers to recoup overpayments for their non-Medicaid penny-priced drugs using the 340B program's administrative dispute resolution process. A recovery of this magnitude would provide greater resources for RWCs to continue and expand their successful fight against the AIDS epidemic. It is therefore imperative that Adventist West have "its day in court."

² See, e.g., HRSA, Clients Served by the Ryan White HIV/AIDS Program 2021 – HIV Care Outcomes: Viral Suppression (Feb. 2023) available at <https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/data/hiv-care-outcomes-viral-suppression-2021.pdf>; HRSA, Ryan White HIV/AIDS Program Annual Client-Level Data Report 2021 (2021) available at <https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/data/rwhap-annual-client-level-data-report-2021.pdf>.



Andy J. Mao
Deputy Director, Civil Division, Fraud Section
Department of Justice
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RWC-340B appreciates the opportunity to voice its support for the Adventist West case and to urge the Department of Justice to exercise its veto authority over the defendants' public disclosure argument. If you have any questions, please do not hesitate to contact us.

Sincerely,

A handwritten signature in cursive script that reads "Shannon Burger".

Shannon Burger
President
RWC-340B

cc: Will Olson, Trial Attorney, US Department of Justice, Comm'l Lit., Civil Fraud
Ross Cuff, Chief, Civil Fraud Section, US Attorney's Office, C.D. California
Nick Paul, Senior Assistant Attorney General at California Department of Justice