Value of Ryan White Providers and Impacts Associated with Resource Reduction



Ryan White Clinics for 340B Access (RWC-340B) is a national organization of HIV/AIDS health care clinics and service providers receiving support under the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act that was organized in 2013 by a group of providers with one common goal—to preserve the benefits of the 340B program for themselves and for all private non-profit 340B program participants that provide primary care, case management, and other support services with a particular focus on persons living with HIV/AIDS (PLWHA). All members of RWC-340B provide primary care, case management, and other support services to PLWHA; the 340B Drug Pricing Program allows RWC-340B members to leverage their 340B savings to support the full HIV/AIDS care continuum, from diagnosis, to linkage to care, to medication adherence and viral suppression. RWC-340B engaged Avalere Health to review relevant literature about Ryan White clinics and examine policies to review the potential impact of reduced resources.

Background

Access to HIV care and treatment

An estimated 1.2 million people are living with HIV/AIDS in the US. Roughly 1 out of 7 of those infected are unaware of their infection and could be unknowingly transmitting the virus. In 2018, the number of new HIV infections was approximately 36,400. Non-white populations are disproportionately affected, with the highest rate of infections in Black/African Americans (45.4 per 100,000) and Hispanic/Latinos (22.4 per 100,000). The projected total annual healthcare cost for PLWHA is estimated to be about \$30,000 per person, with projected total healthcare expenditures for PLWHA in the US over a 10-year period approximately \$10.7 billion higher than for those without the disease, after controlling for socio-demographic factors and comorbidities. ²

HIV/AIDS incidence and prevalence falls disproportionately on populations with lower socioeconomic status, including those with lower income and less education. Living in disenfranchised communities often limits access to prescription drugs, reduces frequency of medical care, fragments patient engagement with HIV clinical and non-clinical care, and leads to worse health outcomes. PLWHA are likely to have comorbid psychological and physical health conditions. Lack of access to and retention in care can make it less likely a PLWHA will have access to or be adherent to antiretroviral treatment (ART) to suppress the virus. Individuals who are not virally suppressed are more likely to transmit the infection.³ Over 80% of new HIV transmissions in the US are by people unaware of their diagnosis or were diagnosed and not in care. Continuous patient engagement in HIV medical care is associated with better health outcomes and preventing HIV transmission.⁴

Ryan White HIV/AIDS Program

In 1990, Congress passed the Ryan White CARE Act to provide grants to state and local governments to provide testing and treatment for HIV/AIDS.⁵ The legislation has been reauthorized and expanded to become the Ryan White HIV/AIDS Program (RWHAP) and now provides grants through the Health Resources and Services Administration (HRSA) to government and community-based organizations to provide HIV primary medical care,

¹ HIV.gov "HIV Basics: Overview: Data & Trends: U.S. Statistics." https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics. Accessed August 19, 2020.

² Richwood, T.D., Bishu, K.G. & Egede, L.E. Trends in healthcare expenditure among people living with HIV/AIDS in the United States: evidence from 10 Years of nationally representative data. Int J Equity Health 16, 188 (2017). https://doi.org/10.1186/s12939-017-0683-y. ³ Pellowski, Jennifer A et al. "A pandemic of the poor: social disadvantage and the U.S. HIV epidemic." The American psychologist vol. 68,4 (2013): 197-209. doi:10.1037/a0032694.

⁴ US Centers for Disease Control and Prevention. "Ending the HIV Epidemic." https://www.cdc.gov/vitalsigns/end-hiv/index.html, accessed August 19, 2020.

⁵ S.2240 Ryan White Comprehensive AIDS Resources Emergency Act of 1990, 101st Congress (1989-1990).

medications, and support services for underserved and uninsured PLWHA. RWHAP serves over half a million clients each year through over 2,000 RWHAP grant recipients. The program is organized in 5 parts, with Congressional appropriations totaling nearly \$2.4 billion specific to each area:

Program Part ⁶	Grantees and Services	FY2019 Appropriation ⁷
Part A: Grants to Eligible Metropolitan and Transitional Areas	Awarded to counties for medical and support services for PLWHA	\$655.9M
Part B: Grants to States & Territories	Awarded to states/territories for medical and support services for PLWHA, including AIDS Drug Assistance Programs (ADAP)	\$1.3B
Part C: Early Intervention Services and Capacity Development Program Grants	Awarded to clinics and other community-based organizations to fund comprehensive primary care for PLWHA	\$201M
Part D: Services for Women, Infants, Children, and Youth	Awarded to public or private nonprofit clinics to fund comprehensive primary care for women, infants, children, and youth who are HIV-positive	\$75M
Part F: Specific Initiatives	 Special Projects of National Significance AIDS Education and Training Centers Dental Programs Minority AIDS Initiative 	\$141.7M

340B Drug Pricing Program

In 1992, as a measure to address the unintended consequence of the Medicaid Drug Rebate Program that resulted in certain providers experiencing increases in their drug costs, Congress enacted Section 340B of the Public Health Service Act (PHSA) requiring pharmaceutical manufacturers to provide discounts on outpatient drugs to specific safety net health providers and select clinics as a condition of participating in Medicaid.⁸

Section 340B of the PHSA specifies types of organizations, or "covered entities," that are eligible to purchase discounted drugs through the 340B Drug Pricing Program, including federally qualified health centers (FQHC) and FQHC look-alikes, specific types of hospitals (e.g., disproportionate share hospitals and critical access hospitals), specialized clinics (e.g., comprehensive hemophilia diagnostic treatment centers and Title X family planning clinics), and RWHAP grantees. Covered entities may purchase drugs through the 340B Drug Pricing Program for their eligible patients at a discounted rate and bill the patients' third-party insurers; any difference

⁶ US Health Resources & Services Administration. "About the Ryan White HIV/AIDS Program." https://hab.hrsa.gov/about-ryan-white-hivaids-program, accessed August 19, 2020.

⁷ US Health Resources & Services Administration. "Ryan White HIV/AIDS Program Funding: FY 2011-FY2020 Appropriations by Program." https://hab.hrsa.gov/program-grants-management/ryan-white-hivaids-program-funding, accessed August 19, 2020.

⁸ H.R.5193 - Veterans Health Care Act of 1992, 102nd Congress (1991-1992), title VI, §602(a).

⁹ US Health Resources & Services Administration. "340B Drug Pricing Program: 340B Eligibility." https://www.hrsa.gov/opa/eligibility-and-registration/index.html, accessed August 21, 2020.

between the discounted purchase and third-party reimbursement adds to the resources available for Ryan White clinics to provide additional services. ¹⁰ Recently, the 340B Drug Pricing Program has grown as additional covered entities have entered the program and existing covered entities have expanded their reach. Critics of the 340B Drug Pricing Program have questioned whether covered entities are using savings obtained through the 340B Program to provide care to uninsured and underserved populations. ¹¹ Unlike hospitals, RWHAP grantees are eligible as 340B covered entities by virtue of being grant recipients and are subject to federal regulations restricting use of their grant funds and related income, including income from services and goods provided. This grant related income is referred to as "program income." RWHAP grantees must add program income to funds committed to the grant and use it to further eligible project or program objectives. Program income may not be used for costs that are otherwise unallowable under the grant. In the case of RWHAP clinics, "allowable costs are limited to core medical and support services, clinical quality management, and administrative expenses (including planning and evaluation) as part of a comprehensive system of care for low-income individuals living with HIV." The HRSA HIV/AIDS Bureau oversees the RWHAP and the HRSA Office of Pharmacy Affairs oversees the 340B Drug Pricing Program. RWHAP Clinics

Clients

RWHAP serves over 500,000 clients annually, about half of all individuals diagnosed with HIV/AIDS in the US. In 2018, approximately 61.3% of all RWHAP clients were living at or below 100% of the federal poverty level (FPL). Female (70.5%) and transgender (75.6%) patients were more likely than male clients to be below the FPL, although the majority of male clients (57.6%) were also living in poverty. Poverty is typically associated with food insecurity and people living in poverty tend to be in worse health than people with even slightly higher incomes. 14

Program Efficacy

The RWHAP has evolved and expanded since its inception, both in program scope and types of services offered, and has shown improvements, as detailed below, in clinical (viral suppression and retention in HIV care) and non-clinical outcomes.

Viral Suppression

RWHAP patients are more likely to achieve viral suppression than PLWHA who seek treatment elsewhere. Achieving viral load suppression, or an "undetectable" level of HIV in a person's blood, requires adherence to antiretroviral drugs. Viral suppression reduces the risk of sexually transmitting HIV to HIV-negative individuals. The RWHAP Service Report shows the percentage of clients who were

¹⁰ Medicare Payment Advisory Commission. "Report to the Congress: Overview of the 340B Drug Pricing Program." May 2015.

¹¹ "Proposed Reforms to the 340B Drug Discount Program," Health Affairs Blog, March 7, 2018. DOI: 10.1377/hblog20180306.70004.

¹² HRSA, "Clarifications Regarding the Ryan White HIV/AIDS Program and Program Income," Policy Clarification Notice (PCN) #15-03, 2015, https://hab.hrsa.gov/sites/default/files/hab/Global/pcn 15-03 program income.pdf.

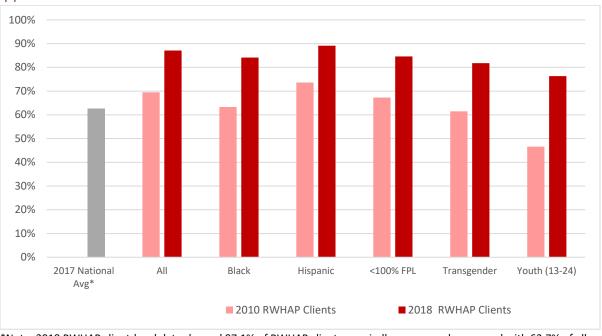
¹³ US Health Resources & Services Administration. December 2019. "Ryan White HIV/AIDS Program Annual Client-Level Data Report 2018." https://hab.hrsa.gov/sites/default/files/hab/data/datareports/RWHAP-annual-client-level-data-report-2018.pdf.

¹⁴ Braveman, P. A., Cubbin, C., Egerter, S., Williams, D. R., & Pamuk, E. (2010). Socioeconomic disparities in health in the United States: what the patterns tell us. American journal of public health, 100 Suppl 1(Suppl 1), S186–S196. https://doi.org/10.2105/AJPH.2009.166082.

viral suppressed improved from 69.5% in 2010 to 87.1% in 2018,¹³ while the Centers for Disease Control and Prevention (CDC) statistics estimate only 62.7% of all PLWHA were virally suppressed in 2017.¹⁵

RWHAP clinics have also shown a reduction in disparities in viral suppression rates between demographic groups. A study of HRSA RWHAP clinic data comparing 2010 to 2014 found that disparities in viral suppression rates improved between PLWHA ages 13-24 compared with patients older than age 45, and Black/African Americans compared with Whites. Disparities persisted for transgender patients compared with cisgender males or females, but all gender identities experienced an increase in viral suppression rates.¹⁶

Percent of RWHAP Clients Virally Suppressed, 2010 and 2018, Compared to National Average of Viral Suppression in 2017^{13,15,17}



*Note: 2018 RWHAP client-level data showed 87.1% of RWHAP clients are virally suppressed compared with 62.7% of all PLWHA in 2017, and over 80% of RWHAP clients are retained in care.

Retention in HIV care

Client-level data from 2011 shows that 82.2% of patients receiving care from RWHAP-funded HIV medical facilities were retained in care. Retention in care typically refers to a patient's regular engagement with medical care at a healthcare facility after initial entry into the system.¹⁸

¹⁵ Harris NS, Johnson AS, Huang YA, et al. Vital Signs: Status of Human Immunodeficiency Virus Testing, Viral Suppression, and HIV Preexposure Prophylaxis — United States,2013–2018. MMWR Morb Mortal Wkly Rep 2019; 68:1117–1123. DOI: http://dx.doi.org/10.15585/mmwr.mm6848e1.

¹⁶ Mandsager P, et al, 2018: Reducing HIV-Related Health Disparities in the Health Resources and Services Administration's Ryan White HIV/AIDS Program, American Journal of Public Health 108, S246 S250, https://doi.org/10.2105/AJPH.2018.304689.

¹⁷ US Health Resources and Services Administration. "Ryan White HIV/AIDS Program Annual Client-Level Data Report 2014." http://hab.hrsa.gov/data/servicesdelivered/2014RWHAPDataReport.pdf. Published December 2015.

¹⁸ Doshi RK, et al. (2015). High rates of retention and viral suppression in the US HIV safety net system: HIV care continuum in the Ryan White HIV/AIDS Program, 2011. Clinical infectious diseases: an official publication of the Infectious Diseases Society of America, 60(1), 117–125. https://doi.org/10.1093/cid/ciu722.

In 2017, one Ryan White clinic piloted a mobile health intervention for retention in HIV care and clinical outcomes called PositiveLinks, which assessed impact on retention in care and viral suppression. The intervention used a mobile application that connected users with clinical staff, education resources, stress tests, medication adherence and appointment reminders, and a support group. The results of the piloted intervention showed participants' retention in care rose from 51% to 88% in as little as 6 months and stayed above 80% over a 12-month period.¹⁹

Non-Clinical Outcomes

In a study of the Medical Monitoring Project at the CDC, researchers found about one-third of outpatient HIV care facilities received RWHAP funding and, compared with non-RWHAP-funded clinics, were more likely to provide care coordination and management services. RWHAP clients are more likely to have less than a high school education, live in poverty, and be homeless. About 1 in 3 clients received food assistance, and almost 1 in 5 received housing assistance. RWHAP-funded clinics were also more likely to provide mental health and substance abuse treatment on site. The authors concluded these services are more likely to result in improved health outcomes for clients of RWHAP-funded clinics than non-RWHAP-funded clinics.²⁰

HRSA has identified PLWHA with unstable or temporary housing as an especially vulnerable group, with disparity in viral suppression more than 5 percentage points below other RWHAP clients. HRSA has conducted a Special Project of National Significance initiative to increase engagement in care for unstably housed PLWHA using a patient-centered medical home model that includes access to treatment for mental health and/or substance use disorders along with HIV treatment. While the disparity in viral suppression persists between stably housed and unstably/temporary housed PLWHA, overall viral suppression in these groups of clients has increased year over year. HRSA has partnered with the US Department of Housing and Urban Development (HUD) to provide policy information to RWHAP grantees on appropriate use of grant funds for housing assistance and programs available through HUD. 22

Funding

RWHAP clinics under Parts C and D receive grants from HRSA to serve uninsured and underinsured patients, but these funds are to be used only when no insurance or other coverage is available. Congressional appropriations have remained relatively flat since fiscal year 2011. Additional sources of funding include third-party payments for insured patients, savings from the 340B Drug Pricing Program, and donations. The implementation of the Affordable Care Act in 2010 opened up new coverage avenues for many low-income patients, including the state option to expand Medicaid to all adults with income up to 138% of the federal poverty level and the creation of the health insurance marketplace (exchanges) with subsidies for people with incomes too high to qualify for

¹⁹ Dillingham R, et al. (2018). PositiveLinks: A Mobile Health Intervention for Retention in HIV Care and Clinical Outcomes with 12-Month Follow-Up. AIDS patient care and STDs, 32(6), 241–250. https://doi.org/10.1089/apc.2017.0303.

²⁰ Weiser J, Beer L, Frazier EL, et al. Service Delivery and Patient Outcomes in Ryan White HIV/AIDS Program-Funded and -Nonfunded Health Care Facilities in the United States. JAMA Intern Med. 2015;175(10):1650-1659. doi:10.1001/jamainternmed.2015.4095.

²¹ Doshi RK et al. "For many served by the Ryan White HIV/AIDS program, disparities in viral suppression decreased, 2010-14." *Health Affairs*. 36, no. 1 (2017), 166-123. https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.0655.

²² Griffin A, Dempsey A, Cousino W, Avery L, Phillips H, Egwim E, et al. (2020) Addressing disparities in the health of persons with HIV attributable to unstable housing in the United States: The role of the Ryan White HIV/AIDS Program. PLoS Med 17(3): e1003057. https://doi.org/10.1371/journal.pmed.1003057.

Medicaid. These coverage opportunities were intended to improve access to health coverage for patients who had previously been unable to access quality care.²³ By 2018, 79.9% of RWHAP clinic patients had healthcare coverage, including Medicare (10.3%), Medicaid (31.5%), or employer coverage (10.2%).²⁴

As noted earlier, all RWHAP income must be used to provide medical and non-medical services to PLWHA. According to a survey conducted by HRSA in 2014, grant funds were used for insured patients to cover services not covered by insurance, including counseling about medication adherence and risk management, medical and non-medical case management, medical transportation, oral healthcare, medical nutrition therapy, and diagnostic testing exceeding plan utilization limits.²⁵

As eligible covered entities under the 340B Drug Pricing Program, many RWHAP clinics rely on savings from drugs prescribed to their patients as a source of funding. Clinics purchase drugs at the 340B-discounted rate and, for patients with prescription coverage, bill insurance payers, and use the savings from the program to provide additional services.²⁶

Policies Related to Program Income for RWHAP Clinic Grantees

The Affordable Care Act

After the Affordable Care Act (ACA) became law in 2010, but prior to the implementation of many aspects including Medicaid expansion, there were many discussions about whether programs such as RWHAP would be necessary in the future. The intention of the ACA was that every American would have health insurance, either through public or private means. Since the ACA's requirement for states to expand Medicaid became optional in 2012²⁷ and the individual mandate to have health insurance was repealed in 2017,²⁸ universal health coverage has not been realized.

Even if all Americans had health coverage, RWHAP clinics provide services that are not routinely covered for insured patients. In 2013, researchers surveyed HIV providers to identify concerns related to ACA implementation. Interviewers found most providers considered RWHAP case management services to be essential and not likely to be covered by Medicaid or private insurance. The provider participants identified non-medical case management services, such as housing and transportation assistance, and social services including treatment adherence counseling as essential to quality and continuity of care.²⁹

Reduction in 340B Drug Pricing Program Savings

In 2016, the Centers for Medicare & Medicaid Services (CMS) promulgated regulations in the Covered Outpatient Drug final rule that require Medicaid fee-for-service (FFS) programs to pay for drugs purchased

²³ Abara, W., & Heiman, H. J. (2014). The Affordable Care Act and low-income people living with HIV: looking forward in 2014 and beyond. The Journal of the Association of Nurses in AIDS Care: JANAC, 25(6), 476–482. https://doi.org/10.1016/j.jana.2014.05.002.

²⁴ US Health Resources & Services Administration. "Ryan White HIV/AIDS Program Annual Client-Level Data Report 2018." December 2019. https://hab.hrsa.gov/sites/default/files/hab/data/datareports/RWHAP-annual-client-level-data-report-2018.pdf.

²⁵ Matthews, Tracy. Understanding and Monitoring Funding Streams in Ryan White clinics: Survey Results, National Webcast. https://hab.hrsa.gov/sites/default/files/hab/Global/fundingstreams-presentation.pdf, accessed August 12, 2020.

²⁶ 340B Coalition. https://340bcoalition.org/about/, accessed August 19, 2020.

²⁷ Rosenbaum S & Westmoreland T. The Supreme Court's Surprising Decision on The Medicaid Expansion: How Will the Federal Government and States Proceed? Health Affairs 31, No. 8 (2012), 1663-1672. https://doi.org/10.1377/hlthaff.2012.0766. https://doi.or

²⁹ Dood N, Juday T, et al. HIV care providers emphasize the importance of the Ryan White program for access to and quality of care. Health Affairs 33, no. 3 (2014), 394-400. https://doi.org/10.1377/hlthaff.2013.1297.

through the 340B Drug Pricing Program at the 340B actual acquisition cost plus a professional dispensing fee.³⁰ Through this policy, 340B covered entities are not able to generate and use savings from the 340B program for their FFS Medicaid drugs to fund their other services. The policy does not apply to Medicaid managed care organizations (MCOs). Alongside this federal reimbursement policy, several states have chosen to carve out responsibility for pharmacy services from their Medicaid MCOs and provide pharmacy coverage through the FFS program. Through 2020, 5 states (MO, ND, TN, WI, WV) have carved pharmacy out of MCOs and 2 large state Medicaid programs (CA, NY) have announced their intention to carve out by April 2021. In addition to the pharmacy carve out initiative in NY, a 340B Advisory Group has been convened to make savings recommendations to the state on drugs eligible to be purchased through the 340B Drug Pricing Program.³¹

The California HIV/AIDS Policy Research Centers conducted interviews with providers in California serving PLWHA after the state proposed to eliminate the ability of 340B covered entities to use drugs acquired at 340B discounts for beneficiaries covered under Medi-Cal, the state's Medicaid program. The interviewees uniformly expressed concern with the proposal, noting they had pursued all available funding options and predicted the need to cut services if the policy were enacted. The services to be cut included patient engagement activities such as case management and dietician services, clinic infrastructure including quality improvement, and raising the standard of care provided, including administering vaccines and services for substance use disorders.³²

HRSA and CDC Model of Elimination of RWHAP Program

A hypothetical analysis conducted by HRSA's HIV/AIDS Bureau and CDC's Division of HIV/AIDS Prevention used theoretical modeling to assess the impact of the absence of the RWHAP. In a hypothetical state with high prevalence of HIV, the absence of RWHAP providers could result in an additional 172 HIV cases in 1 year, resulting in approximately \$82 million in additional lifetime HIV care and treatment costs.³³

Implications

If RWHAP grantee clinics were to lose any sources of funding or experience a reduction in 340B savings, these providers may be compelled to eliminate other services in order to manage costs. Losing stable access to care, medications, and services could result in a heightened risk for severe illness in PLWHA. These clinical and non-clinical outcomes suggest that program clients could have negative clinical and non-clinical effects if funding for RWHAP clinics were reduced. Reduction in resources, including 340B Drug Pricing Program savings, could have long-term consequences for patients served through RWHAP-funded clinics, including disruptions in care and treatment, adverse health outcomes, or increased healthcare expenses. In addition to the effects on clinics and patients, state and local governments could also see detrimental financial effects. The lifetime treatment cost of an HIV infection is estimated to be approximately \$380,000 and RWHAP clients are more likely than other PLWHA to be virally suppressed.³⁴ A snapshot of recent RWHAP client-level data showed 87.1% of RWHAP

 $^{^{\}rm 30}$ 81 FR 5169 - Medicaid Program; Covered Outpatient Drugs. February 1, 2016.

³¹ New York State Department of Health. "340B Advisory Group Meeting #1." August 5, 2020. https://www.health.ny.gov/health_care/medicaid/redesign/mrt2/meetings/docs/2020-08-05_340b_advisory_mtg1.pdf, accessed August 19, 2020.

³² Kirby, Valerie B., Botta, Emma Wilde, Steward, The Role of the 340B Drug Pricing Program in HIV-Related Services in California, May 2018, https://www.californiaaidsresearch.org/files/340B-HIV-Rapid-Response-Report-FINAL.pdf.

³³ Klein PW, Cohen SM, Uzun Jacobson E, Li Z, Clark G, Fanning M, et al. (2020) A mathematical model to estimate the state-specific impact of the Health Resources and Services Administration's Ryan White HIV/AIDS Program. PLoS ONE 15(6): e0234652. https://doi.org/10.1371/journal.pone.0234652.

³⁴ Centers for Disease Control and Prevention. HIV cost-effectiveness. Published May 2012, accessed August 19, 2020. https://www.cdc.gov/hiv/programresources/guidance/costeffectiveness/index.html

clients are virally suppressed compared with 62.7% of all PLWHA, and over 80% of RWHAP clients are retained in care. The services financed by 340B Drug Pricing Program savings enable PLWHA to become virally suppressed, leading to undetectable viral load thus eliminating the risk of transmission to others. Without viral suppression, an increase in infections and healthcare costs would fall to other payer sources including Medicaid and uncompensated care, ultimately being borne by the taxpayer.