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Testimony Before the United States House of Representatives

Committee on Energy and Commerce:

Subcommittee on Oversight and Investigations

Examining How Covered Entities Utilize the 340B Drug Pricing Program

Testimony of:

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Good morning Chairman Murphy, Ranking Member DeGette and Members of the Subcommittee. I am Michael Gifford and I am the President and Chief Executive Officer of the AIDS Resource Center of Wisconsin, also known as ARCW. I appreciate the opportunity to provide written testimony in conjunction with appearing before you today to discuss the critically important role the 340B Drug Pricing Program plays in contributing to the success of ARCW and many other Ryan White funded organizations in meeting the evolving demands of the AIDS epidemic in the United States.

The AIDS Resource Center of Wisconsin (ARCW):

ARCW is a nationally recognized leader in delivering high quality, patient centered health care and social services that are driving some of the best patient outcomes in the United States. As founding member of the National Center for Innovation in HIV Care along with our partners at Fenway Health and AIDS United, our success has resulted in leaders from 26 states and organizations contacting ARCW about replicating program delivery models in their communities as a way to enhance patient and community health.

ARCW envisions a world without AIDS and strives to assure that everyone with HIV disease will live a long and healthy life. Our mission is to be at the forefront of HIV prevention, care and treatment and ARCW is dedicated to providing quality medical, dental, mental health and social services for all people with HIV.

ARCW is a not-for-profit, 501(c)3 designated organization governed by a volunteer national board of directors. ARCW has thirteen (13) locations in Wisconsin and has recently merged with, and is doing business as, Rocky Mountain CARES in Denver, Colorado to expand access to care and improve clinical outcomes. In all of these setting we are truly the safety net provider for people with HIV and AIDS.

Through the past 34 years, ARCW has grown to become the largest provider of health care to people living with HIV in the state of Wisconsin. Because of our integrated, coordinated and co-located services, more than 3,500 people living with HIV in Wisconsin are receiving the health care and support needed to live healthy with HIV. We are also one of the state's leading HIV prevention providers, reaching tens of thousands of people every year who are at-risk for contracting HIV.

The ARCW HIV Medical Home is intentionally designed to ensure our patients receive the right care, at the right time, in the right setting and from the right provider. In doing so, we are able to ensure optimal patient outcomes and reduce inefficiencies in care delivery that would otherwise result in higher costs and poorer patient outcomes.

Following the merger of ARCW with Rocky Mountain CARES, ARCW is now developing Denver's first community-based safety net HIV Medical Home and is currently providing care and treatment to more than 500 people.

The HIV continuum of care:

The importance of 340B program generated savings to support patients served by organizations that are providing HIV prevention, care and treatment services cannot be overstated, and must be examined using the backdrop of the continuum of care.

The HIV care continuum is the series of steps that a person with HIV would take in order to achieve optimal health with HIV, clinically indicated as achieving viral suppression.

Viral suppression is critically important to ending the HIV epidemic for two reasons. First, people with HIV who are achieving viral suppression experience less adverse health episodes related to their HIV disease. Second, people with HIV who achieve viral suppression have a negligible risk of transmitting HIV

to someone else. The CDC announced Sept. 27, 2017 in a Dear Colleague letter that "people who take ART [anti-retroviral therapy for HIV] daily as prescribed and achieve and maintain an undetectable viral load have effectively no risk of sexually transmitting the virus to an HIV-negative partner."[1] Conversely, research conducted by the CDC and published in the *Journal of the American Medical Association* (JAMA) has demonstrated that more than 91% of HIV transmissions in the United States are attributed to people with HIV who were not regularly in medical care, inclusive of individuals who had HIV but were unaware of their status.[2] When individuals fall out of care, they can lose the ability to achieve or maintain viral suppression, making retention to care a critical component of HIV care. Not only is viral suppression an important individual health metric, it is public health imperative as well.

Within each step there are several opportunities for people living with HIV to confront barriers that prevent their successful movement along the continuum. Additionally, it is important to recognize that once a person is aware of their diagnosis, it is possible for them to move backwards along the continuum and that viral suppression must be maintained even though patients continue to face significant barriers.

[1] US Centers for Disease Control and Prevention website; https://www.cdc.gov/hiv/library/dcl/dcl/092717.html; accessed Oct. 2, 2017
[2] JAMA Intern Med. 2015;175(4):588-596. doi:10.1001/jamainternmed.2014.8180

Fig. 1. The HIV Care Continuum[3]

At each step in the continuum individuals face a multitude of challenges that prevent them from achieving and maintaining the ultimate goal of viral suppression. The HIV epidemic in the United States is firmly entwined with both individual and community barriers to health. Regarding personal health, many patients today confront comorbidities including mental health concerns such as anxiety, depression, neuropsychological impairments and substance abuse as well as chronic diseases including hypertension, hyperlipidemia, hepatitis and other liver impairments, and issues related to aging. Socioeconomic and/or community barriers to health – also known as social determinants of health – can include combinations of any other following such as hunger, homelessness, high rates of poverty, stigma and discrimination, lack of health insurance coverage, inadequate numbers of health care providers (both urban and rural), inadequate educational opportunities, lack of access to employment, and lack of community support in achieving health.

Overcoming these barriers often times takes precedence over managing their HIV. A person newly diagnosed with HIV who is confronting homelessness may seek housing before they seek health care. A

[3] Health Resources Services Administration HIV AIDS Bureau; https://hab.hrsa.gov/about-ryan-white-hivaids-program/hiv-care-continuum; accessed Sept. 21, 2017.

person living with HIV who is living in poverty may use their limited financial resources to purchase food instead of medicine. A person without access to transportation may not be able to make several different appointments at multiple organizations or health care providers. Someone struggling with mental health issues may be challenged to take their medications on a daily basis.

Addressing these barriers is made more difficult for people living with HIV when they are receiving their care in a system of fragmented health and social service providers. Health care providers in these environments often cannot readily communicate and patients often find them to be confusing and difficult to navigate.

Helping patients overcome these barriers usually requires the provision of services that are not reimbursable under public or private insurance. Given limited and uncertain grant resources, many organizations are cannot rely solely on grants when building service delivery models. Furthermore, many Ryan White funded grantees have identified the following challenges to expanding and providing the kinds of services patients need to be successful[4]:

- 75% of HIV/AIDS-serving community based organizations reported an operating loss in one of the last three years;
- 38% of the above agencies reported an operating loss in two of the last three years;
- 15% reported an operating loss in three of the last three years;
- >90% identified a lack of financial resources as the most significant barrier to providing and/or linking to medical services; and

[4] Capacity for Health Project at the Asian & Pacific Islander American Health Forum; HIV/AIDS ASO and CBO Stability and Sustainability Assessment Report; http://www.apiahf.org/resources/resources-database/hivaids-aso-and-cbo-stability-and-sustainability-assessment-report; Accessed October 5, 2017

- 37.5% identified concerns about sustainability.

The financial challenges of providing care to people with HIV must be addressed to assure they have access to health and social services. 340B savings play a crucial role in assuring services for HIV patients are available and sustainable so they can achieve and maintain an undetectable viral load.

In order to help patients overcome these challenges and achieve health 340B savings have been critical as ARCW has developed one of the nation's most innovative care delivery systems for our patients and clients. The ARCW HIV Medical Home ensures patients have access to coordinated, co-located and fully integrated health and social services including: medical and dental care, mental health therapy and drug treatment, housing services including rent and utility assistance, food pantries, and nutrition services, legal services, and medical and social work case management.

The goal of the ARCW HIV Medical Home is to ensure patients receive the right care, at the right time, in the right setting, from the right provider, at the right cost – that being the lowest one possible. To accomplish this goal, it is imperative that all health care and social service professionals work together as a team to address all the challenges our patients face. To this end, every patient at ARCW receives an in-depth annual assessment by a care coordinator who then works with the patient to identify a care and treatment plan. The patient's care team including their doctor, dentist, clinical pharmacist, mental health professional, nurse and case manager then work together with the patient to achieve the patient's goals. Documentation of the patient's care plan, needs and challenges as well as their medical records are all housed within the ARCW electronic health record making for easy access of the information across disciplines within ARCW.

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Figure 2. ARCW HIV Medical Home

ARCW Patient Demographic Data:

Much like people living with HIV in other parts of the United States, the overwhelming majority of people we provide care and treatment to are living in poverty, are people of color and experience high rates of uninsurance, underinsurance or enrollment in public insurance programs. More than 90% of people served by ARCW programs and services are living below 200% of the FPL.

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Table 1 - ARCW Patient and Client Demographics

Race and Ethnicity		Age	
African American/Black	42.6%	24 and under	4.1%
White	39.8%	25-44	36.3%
Hispanic	11.2%	45-54	54.2%
Other	6.4%	55 and older	5.3%
Gender		**Insurance Status**	
Men	75.6%	Private Insurance	13.5%
Women	23.1%	Public Insurance	67.2%
Transgender	1.3%	Uninsured	19.2%

ARCW patient outcomes:

The primary goal at ARCW is for every patient to achieve optimal health. For people living with HIV, this is most commonly associated with achieving viral suppression. Viral suppression is critically important to both individual patient health and ending the HIV epidemic for two reasons. First, people with HIV who are achieving viral suppression experience less adverse health episodes related to their HIV disease, such as opportunistic infections. Second, people with HIV who achieve viral suppression have a negligible risk of transmitting HIV to someone else.

The ARCW patient-centered, team-based approach is ensuring some of the best clinical outcomes for HIV patients in the country. These outcomes are being achieved among patients who are some of the most vulnerable and who face significant challenges in succeeding in their treatment, such as poverty, mental health and substance abuse disorders, hunger, homelessness, discrimination and other social determinants of health. While not a cure for HIV, viral suppression means that the individual is managing their HIV disease as well as possible and copies of the virus in their body are undetectable.

Table 2 – ARCW patient outcomes and quality of care indicators

Patients	National Standard amongst Ryan White Program Clinics	ARCW
With an Undetectable Viral Load	81%	89%
Prescribed Anti-HIV Medications	91%	95%
Prescribed preventative PCP treatment	86%	95%
With diabetes that is well managed	56%	83%
With controlled hypertension	56%	59%

Unfortunately, the patient outcomes achieved at ARCW are not being achieved for all people with HIV in the United States. In fact, according to the US Centers for Disease Control and Prevention (CDC), only 49% of people living with HIV in the United States are achieving viral suppression. [5] ***Moreover, only 48% of people living with HIV are regularly engaged in care, only 62% are receiving any care and only 85% of people living with HIV are aware they have HIV*** [6]***.***

Research and the experience of ARCW both indicate that the biggest barriers to treatment success for people living with HIV in the United States are not solely access to medical care. In fact, untreated or undiagnosed mental health issues, lack of stable housing, food insecurity, lack of transportation, lack

[5] US Centers for Disease Control and Prevention:https://www.cdc.gov/hiv/images/library/infographics/continuum-infographic.png; accessed Sept. 22, 2017.
[6] Ibid.

of insurance coverage, and inability to pay for medications are all barriers that prevent HIV patients from staying adherent to their treatment regimens and achieving viral suppression.

The 340B program allows ARCW and other Ryan White funded organizations to make strategic investments in services for people with HIV that address these barriers to care. These services are often not covered or reimbursed by public or private insurance programs.

Financial Impact of the ARCW HIV Medical Home:

In 2010, the Wisconsin Legislature adopted legislation directing the Wisconsin Department of Health Services to develop a proposal to the US Centers for Medicare and Medicaid Services (CMS) to increase Medicaid reimbursement to ARCW to support care coordination services to people with HIV. CMS approved Wisconsin's Medicaid State Plan Amendment, submitted by Wisconsin Governor Scott Walker's administration, effective October 1, 2012.

Two significant aspects of the approval and implementation of the SPA are requirements that enhanced patient outcomes are coupled with cost savings. The ARCW HIV Medical Home is accomplishing both goals. According to independent analysis of the ARCW HIV Medical Home by the University of Wisconsin Center for Health Systems Research and Analysis (CHSRA), "[i]t is an important study revelation that an ongoing primary care relationship with the ARCW is the most influential factor in reducing costs, hospital stays / admits and the diagnostic incidence of chronic disease."[7]

In fact, the CHSRA report goes on to detail additional financial and health benefits of the ARCW HIV Medical Home.

[7] Newsom, R., Exploration of Evaluative Analyses & Methods: Claims-Based Options for the AIDS/HIV – Medicaid Health Home SPA, Center for Health Systems Research and Analysis, UW-Madison. *Not a published document*

Table 3. ARCW Medical Home Delivers Results[8]

Indicators	Non ARCW Patients	ARCW Patients
Average annual cost per patient	$22,993	$16,192
Average number of days in hospital	2.22 days	2.01 days

In addition, patients receiving care at ARCW had an overall 52% lower hospitalization rate and had 48% lower utilization of emergency department care than did patients who were not engaged in care at ARCW.[9]

In total, the ARCW HIV Medical Home is resulting in savings to the Wisconsin Medicaid program of more $3.9 million per year.[10]

340B Drug Pricing Program and the Fight Against AIDS:

When Congress established the 340B Program in 1992, it intended to create a way to strengthen the health care safety net without increasing taxpayer costs and "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[11] The clearly stated legislative intent with bipartisan support that created the 340B program never intended to ensure patients received drug discounts from manufacturers, nor was it intended to be a way to address

[8] Newsom, R., Exploration of Evaluative Analyses & Methods: Claims-Based Options for the AIDS/HIV – Medicaid Health Home SPA, Center for Health Systems Research and Analysis, UW-Madison. *Not a published document*.
[9] Ibid.
[10] Ibid.
[11] US Department of Health and Human Services; 340B Drug Pricing Program & Pharmacy Affairs Office of Pharmacy Affairs http://hrsa.gov/opa/; Accessed October 4, 2017

concerns related to drug prices overall. As the legislative history of the law makes clear, the explicitly stated purpose of the 340B program is to help stretch scarce federal resources for safety net providers

It is within this context that the implementation and successful use of the 340B program by ARCW and other Ryan White safety net providers should be considered in responding to the AIDS epidemic.

Ryan White funded organizations that are eligible to participate in the 340B program are able to purchase certain medications at a price lower than what these medications are normally purchased for. Savings that are generated off the reimbursement for the medication purchased using 340B pricing are then reinvested into programs and services that directly benefit the individuals the covered entity serves.

At ARCW, these savings are directed into programs and services that directly and positively impact the ability of our patients to achieve the single most important factor in their health – achieving viral suppression.

340B at ARCW:

ARCW is eligible for participation in the 340B Drug Pricing Program as a Health Resources Services Administration (HRSA) grantee via the Parts B (sub recipient) and C (direct recipient) of the Ryan White Program. ARCW is also a recipient, via subcontract, of US Centers for Disease Control and Prevention sexually transmitted disease prevention grant funding. This subcontract makes ARCW eligible for the 340B program as an STD clinic.

At ARCW, Ryan White grant funding is directed into discreet service areas based on HRSA's implementation of the Ryan White Program statutes and contracts between ARCW and HRSA (Part C) or

ARCW and the State of Wisconsin Department of Health Services (Part B) once ARCW grant applications have been approved.

Our innovative HIV Medical Home model of care builds upon critical investments made in our organization through Parts B and C of the Ryan White Program. This funding, combined with our ability to leverage other private and public resources, allows us to ensure access to health care, medications and wrap around programs that address the socioeconomic barriers to health our patients face such as hunger, homelessness, and discrimination. We also support patients in navigating a complex health care system that often struggles to fully address the holistic needs of individuals who are living in poverty, have limited education and are living with a complex, expensive and communicable chronic disease.

While bipartisan Congressional support for the Ryan White program remains strong, funding for this critical program has lagged behind need, especially considering the United States still experiences more than 35,000 new cases of HIV every year and people with HIV disease are living longer. It is the ability of ARCW to leverage additional resources through the 340B program, pursue reimbursement for services, access state and local grants and engage in private fundraising that together allow us to serve a growing number of patients who face a tremendous amount of health and socioeconomic challenges.

ARCW utilizes 340B savings to fill-in the programmatic area deficits incurred in the delivery of our services to people living with HIV. This is carrying out the original intent of Congress when the 340B program was created – namely to stretch scarce federal resources as far as possible. It is also consistent with mandates from HRSA regarding how 340B savings must be utilized.

In addition to filling-in the programmatic area deficits at ARCW, 340B savings have been critical to ensuring patients have access to life-saving programs for which funding has ended. Three critical

examples of this illustrate the power of 340B savings in fulfilling the intent of the 340B program to stretch scarce federal resources:

1.) Dental Services in Green Bay, Wisconsin:

ARCW offers its entire cadre of services – medical, dental, and mental health care with integrated social services including medical and social work case management, legal services, rent and utility assistance and a food pantry – in Green Bay. While Green Bay is Wisconsin's third largest city, the city and its surrounding areas suffer from a dearth of dental providers. The ARCW dental clinic in Green Bay provides dental care to people living with HIV from more than 40 Wisconsin counties, almost all of which are rural. Estimates from the State of Wisconsin Department of Health Services Primary Care Program indicate that the area served by the ARCW dental clinic in Green Bay needs between 34 and 112 Dentist FTE to reduce shortages in access to dental care for Medicaid Members. [12]

In order to address this shortage in access to dental care for HIV patients, ARCW applied for and received funding from HRSA through the Special Projects of National Significance (SPNS) program. This funding helped ARCW establish the only HIV dental clinic in Wisconsin outside of Milwaukee and eliminated the need for many HIV patients residing in the rural northern half of Wisconsin to travel up to eight hours in one direction to receive oral health care. Today, hundreds of HIV patients receive oral health care through the ARCW dental clinic in Green Bay.

In August 2011, the HRSA grant ARCW received to establish this clinic ended, putting patients at risk of losing access to dental care that had a direct role in improving their overall health. In

[12] Wisconsin Department of Health Services Primary Care Program, https://www.dhs.wisconsin.gov/primarycare/maps.htm; Accessed October 3, 2017

order to ensure the sustainability of the dental clinic, ARCW has invested the savings it is realizing from participation in the 340B program into its Green Bay dental clinic.

2.) Expansion of Access to Mental Health Services Statewide

The National Institutes of Mental Health estimate that approximately 18% of adults have had a mental illness, and that the rates of mental health conditions among people living with HIV are higher.[13] At ARCW, as many as 50% of our patients at any given time are experiencing a mental health condition such as anxiety, depression, substance abuse, post-traumatic stress disorder, insomnia or thoughts of suicide.

ARCW has long recognized the important role of good mental health in achieving overall health. People living with HIV who are experiencing poor mental health are not as likely to stay adherent to their HIV treatment regimens, making viral suppression significantly harder for them to attain.

As with the dental provider shortage in Wisconsin, there is a significant shortage of psychiatrists in the state as well. The State of Wisconsin Department of Health Services Primary Care Program indicates that more than 260 Psychiatrist FTE are needed to reduce significant shortage of this professional statewide. [14] This shortage directly impacts the ability of people living with HIV who are also experiencing mental health illness to get the care they need.

[13] US Department of Health and Human Services, National Institutes of Health, https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/27/92/hiv-and-mental-health, Accessed October 3, 2017
[14] Wisconsin Department of Health Services Primary Care Program, https://www.dhs.wisconsin.gov/primarycare/maps.htm; Accessed October 3, 2017x

In response, ARCW has dedicated 340B program savings into hiring additional mental health professionals, including a full time psychiatrist, and is in the process of initiating telepsychiatry. Combined, these two critical approaches will help make sure that ARCW can carry out more than 7,000 mental health appointments in the coming year.

3.) Addressing Food Security Throughout Wisconsin

More than 90% of the people ARCW serves annually are living below 200% of the federal poverty limit. With limited income, people living with HIV are often forced to choose between purchasing medications, paying for doctors' visits, making rent and utility payments or purchasing food.

For people living with HIV, studies have shown that food is medicine.[15] Researchers at the University of California – San Francisco found that people with HIV who regularly eat and receive healthy meals are more likely to adhere to their medication regimens, which translates into better health outcomes.

To ensure the nutritional health needs of people living with HIV are met, ARCW operates a network of food pantries that span the entire state of Wisconsin in each of the 10 cities in which we operate. Using savings from the 340B program, ARCW is able to ensure that each of these pantries is always fully stocked with nutritious food that supports the health of the patients we serve. 340B program savings also allow ARCW case managers to do home delivery of food for patients who are too ill to travel or are otherwise home bound. In 2016, ARCW made more than 502,000 meals available to our patients and their families, with roughly 1/3 of this total

[15] Kalar, P, et al; Comprehensive and Medically Appropriate Food Support Is Associated with Improved HIV and Diabetes Health; Journal of Urban Health; https://doi.org/10.1007/s11524-016-0129-7; accessed October 4, 2017

delivered. Such a robust food program would not be possible without the savings ARCW realizes through the 340B program.

Table 4 – ARCW funding from the Ryan White Program, expenses and programmatic deficit

	FY 2015	FY 2016
Savings		
340B Program Savings	**$6,659,664**	**$7,429,666**
Investments		
Medical, Dental, Mental Health, and Drug Treatment Services	$1,717,871	$2,128,262
Case Management, Food Services, and Legal Assistance	$1,167,499	$1,135,366
Housing Services	$108,892	$86,730
Pharmacy Services	$1,948,943	$1,967,918
Health Information Technology, Quality Assurance, & Other Federally Allowable Costs	$1,716,459	$2,111,390
TOTAL	**$6,659,664**	**$7,429,666**

340B Program Integrity at ARCW:

ARCW takes very seriously its role in ensuring 340B Program integrity in its role as a covered entity. 340B program integrity and compliance guidelines are outlined in the ARCW 340B Policies and Audit Procedures. It is the stated policy of ARCW that it will *"comply with all applicable laws and regulations related to the 340B program. The 340B program has a substantial impact on ARCW's ability to sustain and enhance needed treatment and care services that would otherwise not be addressed by other providers."*

Implementation and oversight of these policies and procedures start with the ARCW President and Chief Executive Officer. Additionally, several senior management staff at ARCW including the ARCW Vice President of Compliance and General Counsel, the ARCW Vice President and Chief Financial Officer, the ARCW Vice President of Pharmacy Services, the ARCW Director of Health Care Revenue and the ARCW 340B Coordinator.

In addition to strict adherence to stated policies, ARCW also conducts monthly audits of its 340B program to ensure 340B program activities. These monthly audits are in place to ensure ARCW does not inadvertently engage in diversion of 340B medications to ineligible patients and make sure that information supplied to the State of Wisconsin Medicaid program is accurate to avoid duplicate discounts. Since ARCW initiated monthly audits, it has achieved more than 99% adherence with 340B program requirements. ARCW is dedicated to achieving 100% compliance in this area.

Additionally, every year, ARCW has an independent audit conducted by external auditors. These audits have not identified any significant deficiencies related to 340B program internal controls at ARCW, and have found 99.57% adherence to HRSA drug eligibility requirements. ARCW continues to refine the

program integrity of its 340B program and the most recent 9 months of operation show 99.9996% compliance with program requirements.

All staff at ARCW who are involved in implementation of the 340B program at ARCW are required to complete Apexus' 340B University on Demand within 90 days of hire and again every two years subsequent to that.

340B and HRSA's *Policy Clarification Notice 15-03* – limitations on the use of 340B income at ARCW*:*

According to HRSA's claims, as a Ryan White Program grantee, ARCW and other Ryan White funded clinics participating in the 340B program **are** limited in how 340B savings can be used. The limitations on the use of 340B revenue by Ryan White grantees are outlined by HRSA in *Policy Clarification Notice 15-03: Clarifications Regarding the Ryan White HIV/AIDS Program and Program Income*[16] and the corresponding Frequently Asked Questions document issued by HRSA: *Frequently Asked Questions, March 21, 2016, Policy Clarification Notices (PCNs) 15-03 and 15-04*[17] as well as PCN 16-02: *Ryan White HIV/AIDS Program Services: Eligible Individuals & Allowable Uses of Funds*. [18]This appears to run contrary to the testimony of HRSA before the Subcommittee during the July 18, 2017 hearing in which HRSA stated that it does not have the authority to regulate how covered entities utilize their 340B program savings.

The ability of HRSA to regulate 340B savings stems from its conclusion (which we dispute) that 340B savings fall under the definition of "program income" as defined by 45 C.F.R. Section 75.2. According to

[16] HRSA PCN 15-03; https://hab.hrsa.gov/sites/default/files/hab/Global/pcn_15-03_program_income.pdf; accessed Sept. 25, 2017
[17] HRSA,; https://hab.hrsa.gov/sites/default/files/hab/Global/faq15031504.pdf; accessed Sept. 25, 2017
[18] HRSA; https://hab.hrsa.gov/sites/default/files/hab/program-grants-management/ServiceCategoryPCN_16-02Final.pdf; accessed Sept. 25, 2017

HRSA's issued guidance, "program income is gross incomed earned by the non-Federal entity that is directly generated by a supported activity or earned as a result of the Federal award during the period of performance (or grant year) except as provided in 45 C.F.R. Section 75.307(f)."[19]

Under HRSA's guidance:

> "program income must be used for the purposes and under the conditions of the Federal award. For Parts A, B, and C, program income must be used for core medical and support services, clinical quality management (CQM), and administrative expenses (including planning and evaluation) as part of a comprehensive system of care for low-income individuals living with HIV."

The effect of this interpretation constricts how 340B savings could be used to support additional programs and services that can support aggressive HIV prevention, care and treatment programs across the United States.

For example, while 340B savings at a Ryan White funded clinic can support a physician dedicating additional time to working with an HIV patient doing adherence counseling to ensure a patient understand why they need to take their medications regularly (a service that may not be billable to a public or private insurer), 340B savings cannot support that same physician doing any work to support Pre-Exposure Prophylaxis (PrEP) uptake and adherence among individuals who are HIV negative, but at significantly high risk for contracting HIV.

[19] HRSA,; https://hab.hrsa.gov/sites/default/files/hab/Global/faq15031504.pdf; accessed Sept. 25, 2017

This counterproductive situation is created because Ryan White funds are limited to supporting medical care and treatment for people who are not living with HIV and because of HRSA's interpretation of 340B savings as an extension of the Ryan White grant.

Moreover, because HRSA mandates that 340B savings be classified as program income, and because program income is additive in nature, HRSA requires that these savings be 'spent' before a grantee can request additional federal awards. The potential 'death spiral' created within the logic of this program is that the very grant award that affords organizations the ability to participate in the 340B program can be taken away should an organization not spend all of its 340B savings within the identified grant period. Organizations would potentially lose their eligibility for both Ryan White funding and 340B program participation simultaneously, leading to insolvency of their operations and putting patient health and lives at risk. All of this is organizational centric regulations that is devoid of the needs of the people we serve.

Future changes in 340B program regulations:

ARCW and similar Ryan White funded grantees across the United States are using the 340B program to win the fight against the HIV epidemic. By implementing a patient-centered, continuum of care model, Ryan White clinics, with the help of 340B savings, are achieving clinical results that surpass the rest of the nation. The patient outcomes at Ryan White funded grantees are helping to reduce the number of new HIV infections, increase the number of people living with HIV who are living long, healthy lives, and drive down overall health care costs.

In order to maintain 340B program eligibility, Ryan White funded grantees are subject to extremely detailed reporting requirements, including reporting program income on the Federal Financial Report (FFR) as well as programmatic information on their Ryan White Services Report (RSR). Additionally,

when submitting applications for funding, prospective grantees are required to submit their most recently completed independent financial audit and proof of 501(c)3 non-profit status. Lastly, all Ryan White grantees are subject to periodic programmatic and financial audits by HRSA that while are not specific to the 340B program, certainly include substantial information about the use of 340B savings to support patient care and treatment.

Additional oversight of Ryan White grantees participating in the 340B program will do little in identifying misuse of the 340B program, but will create a tremendous additional compliance and reporting burden on ARCW and other similar organizations. At ARCW, more than 93% of expenses go directly into patient services and access to medications. Increasing the reporting burden on ARCW and other grantees will have the impact of reducing support for patient and client services – the exact opposite of the intent.

Statutory and regulatory changes to the 340B program that would impact the ability of Ryan White funded organizations to participate in the program should be rejected. These changes include restrictions on the definition of a patient that would result in fewer resources, worse clinical outcomes, higher overall health care costs and substantial difficulties for the people we serve.

Changes to regulations related to the use of contract pharmacies for Ryan White funded covered entities should also be rejected. It is critical to assure patient choice, easy access to medications and high levels of clinical outcomes for patients that 340B programs can be implemented in both owned and contracted pharmacies. This assures the patients do not have to overcome geographic and transportation barriers to get their medications, can access medications around work and other schedule demands, and receive integrated care as much as possible. ARCW and many Ryan White covered entities successfully implement the program in both owned and contracted pharmacies to better services patients. Any new 340B program oversight requirements that constrict or eliminate

contracted pharmacies will limit access to care and the financial benefits of the program for people with HIV.

To the contrary, changes should be made to federal law that allow Ryan White funded grantees to use 340B savings to expand services beyond those listed in PCN 16-02 including the ability to offer PrEP, expand clinical infrastructure or ensure long-term organizational sustainability. These changes are necessary in order for Ryan White funded organizations to meet the continually evolving demands of the AIDS epidemic.