Diversifying PrEP Financing:

Strategies to Leverage Funding across the PrEP Care Continuum

FEBRUARY 2022

Introduction

Recent changes to the pre-exposure prophylaxis (PrEP) medication landscape have impacted the way that 340B covered entities are able to generate program income from PrEP medications. These changes have led to declining revenues resulting in the potential destabilization of program and client support systems aimed at increasing PrEP access. While access to PrEP medications has been addressed through federal programs and payor policies, strategies to fund the ancillary services necessary to recruit PrEP candidates, initiate therapy, and support retention are crucial. This tool provides an overview of landscape changes, discusses the impacts of these changes, and explores opportunities to meet the funding needs of PrEP ancillary services.

Background

Since the initial approval of PrEP as a biomedical HIV prevention strategy, service organizations who are engaged in contractual relationships (and other agreements) with jurisdictional health departments receiving federal funds have had the ability to utilize public health pricing for prevention drugs via the 340B Drug Pricing Program\(^1\) to generate program income and support financing strategies for PrEP programs. This source of program income allows organizations to offer low or no-cost care to individuals in need without having to pass these costs on to them or engage in burdensome negotiating and contracting processes with health plan administrators. The robust level of program income generated within the PrEP space during the first decade of the intervention’s availability were the direct result of a single-manufacturer drug market where Truvada\(^3\), and later Descovy\(^3\), were the only approved options available for use as PrEP in the United States. In the absence of generic competition, drug prices increased and remained stably high for a period of time, resulting in significant cost-savings and program income for covered entities.

Overview of the 340B Drug Pricing Program

Created by Congress in 1992, the 340B Drug Pricing Program requires pharmaceutical manufacturers to sell drugs at a discount to eligible safety net clinics and hospitals. This allows uninsured and underinsured patients to purchase drugs at reduced prices; it also allows agencies to retain any revenue associated with discounted purchasing. While manufacturer participation in the 340B program is voluntary, it is required if manufacturers wish to sell their products under Medicaid and Medicare Part B. This revenue, or “program income,” is generated when clinics purchase the drug at a discounted rate but are reimbursed by insured clients’ plan at a higher usual and customary payment rate. These savings can then be used to “stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” The program is available to HIV, STD, and viral hepatitis prevention programs, Family Planning Clinics, community health centers, and several other safety-net clinics and hospitals listed in the program’s statute.

For expensive brand-name drugs such as Truvada\(^3\) or Descovy\(^3\), the 340B spread can be quite a substantial sum. By contrast, when clinics prescribe a cheaper generic medication, the difference between the price they pay and the price at which they are reimbursed is often relatively minimal; so the prescription generates little revenue.

\(^1\)https://www.hrsa.gov/opa/index.html
PrEP Financing Landscape Changes

In October 2020 the drug market began a shift to include generic versions of TDF/FTC (generic Truvada®) with Teva Pharmaceuticals deploying the initial generic under a six-month exclusivity agreement with Gilead Sciences. At the conclusion of that exclusivity period an additional set of manufacturers brought bioequivalent generic versions of TDF/FTC to market causing dramatic price declines that have been deeply felt by organizations who were previously reliant on cost-savings associated with branded Truvada® and Descovy®.

Concurrently, Gilead Sciences announced plans to modify an existing program (Advancing Access®) that provides no-cost drug access to uninsured individuals by limiting reimbursement to cover only acquisition cost plus dispensing fees. This policy modification2, which was implemented in January 2022, is anticipated to eliminate all program income potential that has historically been derived from the provision of PrEP care to uninsured individuals who obtained medications through this program, greatly impacting programs’ generation of revenue.

In addition to these changes, Gilead Sciences reduced its voluntary supplemental discounts for Descovy® in 2021. In addition to the statutorily required 340B discount, manufacturers may provide an additional supplemental discount at their sole discretion. These voluntary supplemental discounts were extended to 340B covered entities, via their wholesaler purchase prices, for several years. During the second half of 2021, 340B covered entities noted a significant increase in the price of Descovy®, consequently decreasing 340B revenue generation on prescription fills subject to insurance payments. The introduction of multiple low-cost generic TDF/FTC products has required the company to increase rebates to payers to compete for formulary placement. As per Gilead Sciences, the reduction of voluntary discounts aims “to ensure that providers continue to have the ability to choose Descovy if it is the most clinically appropriate option.”

Problem Statement and Clarification

Jurisdictions and PrEP service organizations became reliant on the program income generated from 340B program participation during a limited brand-drug market in the absence of generic competition. While the introduction of generic TDF/FTC has greatly reduced drug prices for patients and payors, this same drop in pricing has also driven down the potential for organizational revenue generation related to PrEP drug cost savings.

It is important to note that programs and policies outside of the 340B program have been recently enacted or expanded to ensure PrEP drugs and associated services remain accessible to individuals:

- The Gilead Advancing Access® program continues to directly provide no-cost medications to uninsured individuals under 500% of the federal poverty level.3
- The Ready, Set, PrEP program provides no-cost medications to qualified individuals who lack prescription drug coverage.4

3 https://www.gileadadvancingaccess.com/
4 https://www.getyourprep.com/
Diversifying PrEP Financing: Strategies to Leverage Funding across the PrEP Care Continuum

The United States Preventive Services Task Force (USPSTF) Grade A recommendation of PrEP as a preventive service now requires qualified health plans to provide at least one PrEP option and associated PrEP initiation and monitoring services without cost-sharing by the individual. U.S. approval and commercialization of Apretude™, cabotegravir extended-release injectable suspension, not only provides a new biomedical option for PrEP, but possible cost saving opportunities for covered entities. However, potential cost savings associated with Apretude™ will depend on availability; client acceptance, demand, and utilization of the product; as well as insurance coverage determinations in a competitive market involving safe, effective, and low-cost generic oral options.

Limitations

While access to PrEP medications appears to be relatively stable, it is the ancillary services necessary to obtain a PrEP prescription and persist in PrEP care that are most likely to be impacted by the decline in cost savings. This is most true for individuals who are uninsured, reside in states that have not expanded Medicaid programs, and those who are covered by insurance plans that do not benefit from the cost-sharing protections associated with USPSTF grading, such as pre-Affordable Care Act (ACA) individual health plans. These services include (but are not limited to):

- HIV Testing;
- HCV Testing;
- HBV Testing and Immunization;
- Syphilis Testing;
- Chlamydia and Gonorrhea Testing;
- Pregnancy Testing;
- Serum Creatinine Screening; and
- Provider Consultations/Office Visits.

In order to best address these barriers, without passing direct costs on to patients in such a way that may be prohibitive, health departments and organizations that provide PrEP services must work collaboratively and strategically to stabilize the system of PrEP care delivery in the era of declining drug pricing.

Service Organization Strategies

The best first step that can be taken by organizations, independent of available grants and cooperative agreements, is to maximize potential reimbursements. With the expansion of many state Medicaid programs and the availability of health plans through state and federal healthcare

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7 https://nastad.org/resources/nastad-prep-coverage-brief-prep-services-covered-no-cost-sharing
marketplaces, organizations that provide PrEP care can and should seek reimbursement for services through payors when individuals have health insurance. In doing so, available cost savings may result by providing co-payment or co-insurance support, but may not offset the complete cost of care. NASTAD has developed a billing coding guide for HIV prevention that may assist organizations in planning for and implementing these practices. Appropriate coding of services provided as a part of PrEP care is an essential strategy in ensuring appropriate coverage. Modifier 33, which is a CPT code addition that indicates the service provided was preventive and should exclude copayment, coinsurance, or other out of pocket costs, can be particularly helpful in reducing cost burdens to patients for whom services are being billed to an external payer.

Finally, organizations may consider provider type when assessing strategies to constrain costs. Physician Assistants and Advanced Registered Nurse Practitioners are capable of initiating and managing PrEP care independently. In some cases, Pharmacists and Registered Nurses may also initiate, prescribe, and monitor therapy under standing orders or through collaborative practice agreements with physicians. Staffing adjustments such as these may present opportunities to reduce the cost of PrEP care management and extend the life of available resources to be strategically prioritized in other program areas.

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Jurisdictional Health Department Strategies

As the recipients of federal dollars, health departments are uniquely positioned to layer federal funds at the program design and contracting levels to support the increased reach and efficiency of programs and projects that aim to increase PrEP awareness, identify and recruit potential patients, provide linkage to care and navigation services, and support PrEP retention. Federal funding streams directed towards HIV prevention, HIV core medical and support services, hepatitis prevention, sexually transmitted disease (STD) prevention and control, family planning, and (in limited jurisdictions) Ending the Epidemic all have the potential to offset specific program implementation costs and contribute to a more sustainable care delivery environment.

10 https://www.ahrq.gov/evidencenow/tools/standing-orders.html
12 https://www.bls.gov/ooh/healthcare/mobile/home.htm
Federal Grants Overview

Table of contents for grants overview:

- PS18-1802: CDC Integrated HIV Surveillance and Prevention
- PS19-1901: CDC STD Prevention and Control
- PS20-2010: Integrated HIV Programs for Health Departments to Support Ending the HIV Epidemic
- PS21-2102: Comprehensive High-Impact HIV Prevention Programs for Community-Based Organizations
- PS21-2103: CDC Integrated Viral Hepatitis Surveillance and Prevention
- HRSA-21-091; HRSA-21-092; HRSA-22-104: Ending the HIV Epidemic-Primary Care HIV Prevention (PCHP) Funding
- HRSA Ryan White HIV/AIDS Program

**PS18-1802: CDC Integrated HIV Surveillance and Prevention**

This award integrates HIV surveillance and prevention activities. Strategy 5 (p.29) is specifically intended to increase referral, linkage, and access to prescriptions for individuals who are PrEP eligible. This award also funds traditional HIV testing activities and community level awareness activities, both of which can be used to pave pathways into PrEP services. Found within the resource document "CDC PrEP Program Guidance for HIV Prevention Health Department Grantees, May 2014", the Division of HIV Prevention (DHP) specifically states the following:

- PrEP-related activities to support prevention services for MSM and heterosexually-active men and women must be implemented as part of a comprehensive HIV prevention program that includes, as appropriate, linkage and referral to prevention and treatment services for STDs and viral hepatitis, substance abuse and mental health, and other prevention support services;
- To minimize duplication of effort, DHP health department recipients should coordinate and collaborate with other agencies, organizations, and providers involved in PrEP-related activities, STD, viral hepatitis, and substance abuse prevention and treatment, and HIV prevention activities; and
- Funds for PrEP-related activities should ensure that referral and linkage to existing HIV prevention and treatment services are maintained.

The guidance further specifies that funds may be used to support PrEP integration planning efforts, the development of PrEP educational materials, the development and delivery of HIV risk-reduction counseling and behavioral interventions that must be provided with PrEP, communications activities related to disseminating information about PrEP, evaluation activities for PrEP-related activities, and personnel conducting allowable PrEP-related activities.

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In December of 2021, the CDC released updated guidance for recipients of the "CDC PrEP Program Ancillary Support Services Guidance for HIV Prevention Health Department Recipients, December 2021" which updates the previous guidance to include the following additional ancillary support services:

- Laboratory costs associated with screening for and monitoring PrEP in accordance with CDC guidelines for uninsured or underinsured persons accessing PrEP in non-profit or governmental settings;
- Services provided utilizing mobile units or other novel strategies where PrEP candidates may need assistance with transportation or communication; and
- Limited personnel costs related to the provision of medication if services are delivered in conjunction with other supportive services such as eligibility assessments, risk reduction education, referral, and navigation to other essential services.

The updated guidance further clarifies that when personnel costs related to the provision of PrEP medications are supported, the following conditions must also be met:

- Activities must be a well-defined set of duties that are in addition to writing prescriptions and providing clinical care;
- Funding may not exceed 75% of the total cost of the FTE; and
- Other sources of funding must be utilized to support any duties that are specifically and exclusively related to providing clinical care.

Total ancillary service support is capped at 15% of the overall award amount without advance permissions from the funder.

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**PS19-1901: CDC STD Prevention and Control**

The purpose of this award is to implement and strengthen STD prevention and control programs with a primary focus on three major STDs (chlamydia, gonorrhea, and syphilis). Support strategies and activities that will eliminate congenital syphilis, prevent antibiotic resistant gonorrhea, reduce...

primary and secondary syphilis, prevent STD-related pelvic inflammatory disease/ectopic pregnancy/infertility, address STD-related outbreaks, reduce STD-related health disparities, and strengthen STD-related HIV prevention.

The guidance for this award specifically notes that STD-related HIV prevention work (p. 8-9):

- Is part of all HIV work;
- Can involve up to 10% of total budget; and
- Is not a separate strategy, but critical to include within all five strategy areas of the program.

Strategy Area II (p.11-14), further states that recipients will conduct disease investigation and intervention activities linkage to HIV testing, HIV medical care, or PrEP and that these services are specifically included in the disease investigation and intervention framework.

In terms of providing safety-net STD screening services the following guidance is provided (p.15):

- No more than 10% of the overall budget amount may be used to support safety net services at governmental or not-for-profit clinics without written approval from the CDC; and
- Services should be focused on the highest priority populations (persons with childbearing potential, adolescents and young adults, and MSM) with prioritization based on local data.

### Marketing & Awareness

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**PS20-2010: Integrated HIV Programs for Health Departments to Support Ending the HIV Epidemic**

This award is intended to support the development and implementation of programs tailored to ending the HIV epidemic in the United States by building upon ongoing activities funded under the Integrated HIV Surveillance and Prevention funding opportunity (PS18-1802) and to complement other existing programs.

Component A of this award allows for recipients to utilize campaigns to increase knowledge about PrEP availability and effectiveness and promote PrEP uptake. This includes increased screening for PrEP indications among HIV-negative individuals and increased referral and rapid linkage of persons found to have indications for PrEP (p. 15-17). Component C of this award allows for increased screening for PrEP and non-occupational post-exposure prophylaxis (nPEP) need among clients served in STD specialty clinics and the offering of PrEP initiation within these settings, when appropriate (p. 25-26).
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**Limited**  **Allowable**  **Unallowable**

PS21-2102: Comprehensive High-Impact HIV Prevention Programs for Community-Based Organizations

This funding opportunity is intended to support the implementation of comprehensive HIV prevention programs that will reduce morbidity, mortality, and health disparities by working within the framework set by the Ending the HIV Epidemic initiative. Strategies supported by this award address reducing new infections, increasing access to care, and promoting health equity. PrEP is identified as a key component of this award and the following PrEP-related activities are defined as allowable (p. 16-17):

- Deliver strategic, culturally competent, community-based marketing campaigns;
- Implement targeted HIV testing including onsite, venue-based, mobile, and self-testing;
- Support awareness and uptake of PrEP services;
- Provide referrals to PrEP services; and
- Develop client navigation capacities.

The NOFO notes that up to 5% of requested funding may be used to implement and/or strengthen integrated screenings (when offered concurrently with HIV screening) including those for syphilis and extra-genital gonorrhea and chlamydia with an emphasis on self-collected samples to facilitate implementation and reduce costs (p.11). It is important to note that recipients are not allowed to use funds received from this award to support treatment of sexually transmitted infections and that, when feasible, all available mechanisms to bill third-party payers for these screening services must be pursued (p. 12-13).

Recipients are also restricted from using this award to purchase or supply medications and may not use funds to provide clinical services related to PrEP prescribing and monitoring (p.48).

PS21-2103: CDC Integrated Viral Hepatitis Surveillance and Prevention

This award integrates viral hepatitis surveillance and prevention activities. Component 2 (core viral hepatitis prevention activities) calls for grantees to increase access to HCV and HBV testing and referral to care in high-impact settings such as syringe service programs, substance use disorder

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treatment facilities, medically assisted treatment providers, emergency departments, hospital systems, and correctional facilities (p. 14-16). Test kits to support HCV, HBV, and HCV RNA detection are allowable under this award, and recipients are allowed to propose building state laboratory capacity for HCV and HBV testing up to and including the purchase of necessary equipment and the performance of validation testing and quality assurance, which could contribute to reduced laboratory costs for PrEP initiation and monitoring over time (p. 19).

Patient or peer navigators may also be supported through this award and be based in clinics, hospitals, or high-impact community settings. Services may include preparing clients for medical appointments, scheduling appointments, care coordination, linkage or referral for treatment of HBV or HCV, and linkage or referral to other necessary prevention services for persons who inject drugs (PWID), including PrEP services (p. 19). Support of patient or peer navigators in high-impact settings may act as novel entry points into the system of PrEP care for individuals most at-risk for HIV acquisition.

Finally, this award designates a bundle of services for PWID who are defined as a group in need of services to prevent or mitigate health effects from injection drug use. This includes the provision of sufficient sterile injection equipment to cover all injections; disposal of used injection paraphernalia; naloxone provision and training; assessment for opioid use disorder; linkage to medically assisted treatment; screening and linkage to treatment for infectious diseases such as HCV, HBV, HIV, and STDs; condoms; vaccination for HBV and HCV; and PrEP for HIV. The bundle can also include patient-centered reproductive care including access to long-acting reversible contraceptives (p.22-25, 81).

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**HRSA-21-091; HRSA-21-092; HRSA-22-104: Ending the HIV Epidemic—Primary Care HIV Prevention (PCHP) Funding**

These opportunities are available to Health Center Program Operations (H80) recipients located within *Ending the HIV Epidemic in the U.S. geographic locations*. Funds are intended to support the expansion of HIV prevention services that decrease the risk of transmission in priority areas. Given that health centers provide comprehensive primary care to individuals, these awards offer a robust pathway to meet needs that are related to the entire PrEP continuum within a single organizational structure.

Allowable activities related to PrEP recruitment, prescribing, and persistence fall into four categories specifically outlined in the funding opportunities:

1. Workforce Development (p. 34-36):
   - Training for providers and staff including professional development related to PrEP; and
   - Hiring primary care providers and clinical pharmacists who are capable of delivering PrEP and other HIV prevention services.

17 https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/jurisdictions/phase-one#:~:text=To%20achieve%20maximum%20impact%2C%20the,rural%20areas%2C%20bringing%20the%20total
2. Outreach (p. 32):
   • Organize and participate in community events and provide outreach to raise awareness of HIV prevention options and recruit potential patients;
   • Coordinate with health departments and other community and faith-based organizations to develop and enhance social media campaigns that are aiming to reach and engage individuals at-risk for acquiring HIV; and
   • Develop and leverage partnerships with community organizations to increase referrals for HIV prevention services.

3. Testing (p. 33-34)
   • Establish protocols to support rapid access to HIV testing;
   • Enhance protocols to support universal/routine HIV testing;
   • Purchase HIV tests, STI tests, and support serum creatinine testing; and
   • Purchase home testing products or home collection kits to support PrEP retention.

4. PrEP Prescribing (p. 31):
   • Utilize PrEP navigators to provide benefits/assistance navigation and care coordination to patients;
   • Pursue care integration and coordination support that addresses co-existing behavioral health conditions and social determinants of health to support PrEP adherence;
   • Purchase or enhance systems to assist with providing virtual care, especially tele-PrEP services;
   • Purchase PrEP drugs to support same-day initiation; and
   • Update emergency plans to ensure continuity of access to PrEP in emergencies.

There is no limit on the amount of funds that may be used to directly purchase PrEP medications as long as all available patient assistance opportunities, including the “Ready, Set, PrEP” program, are utilized as a priority method of medication access (p. 3).

### Marketing & Awareness

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#### Communication assistance, provider counseling

- **Limited**: $\leftarrow$
- **Allowable**: $\rightarrow$
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**HRSA Ryan White HIV/AIDS Program**

The primary purpose of the Ryan White HIV/AIDS Program (RWHAP) is to provide core medical and support services to individuals diagnosed and living with HIV. While the use of RWHAP funds are generally limited in scope to individuals who are living with HIV, legislation allows for Part A, Part B, and Part C grantees to fund Early Intervention Services (EIS).

HRSA RWHAP Parts A and B EIS services must include the following four components:

- Targeted HIV testing;
- Referral services;
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- Linkage to HIV medical care; and
- Health education and literacy training that would enable individuals to navigate the HIV system of care.

HRSA RWHAP Part C EIS services must include the following four components:

- HIV counseling;
- Targeted HIV testing;
- Referral and linkage to care; and
- Other clinical and diagnostic services related to HIV care

RWHAPs should work in coordination with HIV Prevention programs to coordinate efforts, avoid service duplication, and ensure that EIS program activities expand the availability of services (p. 9-10)^18.

- A presentation given by the Health Resources and Services Administration (HRSA) provides an overview of the EIS category's potential as a method of addressing unmet need and engaging unaware, out-of-care populations^19.
- Iowa provided an overview of the jurisdiction's expanded use of the EIS category during the 2018 Ryan White Conference that may assist other grantees when considering an expanded approach to the use of this funding category^20.

While Ryan White EIS funds may be used to supplement existing activities related to areas that may increase awareness of and access to PrEP, funds may not be used to provide preventive care to individuals who are not living with HIV. For example, these funds may be used to augment the front end of the continuum by increasing access to testing and referral into prevention programs.

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Recommendations

The PrEP continuum^21 relates to each of the federal funding opportunities mentioned within this document. It is incumbent upon jurisdictional health department and other federal funding recipients to work collaboratively across program areas to align efforts along this continuum in order to streamline service delivery while also reducing existing and anticipated barriers to PrEP initiation and retention. Coordination across programs has the potential to be particularly beneficial in phase 1 EHE jurisdictions where community health centers have been awarded Primary-Care HIV Prevention funds and have developed full-service PrEP capabilities.

^19 https://targethiv.org/sites/default/files/file-upload/resources/EIS.pdf
^21 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5333727/
As the availability of cost-savings derived from the 340B Drug Pricing Program continue to decline in a multi-generic drug market, federal funds and coordinated partnerships between recipient organizations should be used to supplement support that remains available. Grantees are encouraged to explore implementation of billing practices to further offset costs and stretch resources in an effort to engage and retain more individuals in need.

Federal Grants PrEP Continuum Crosswalk

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This document was developed by NASTAD’s PrEP Access team and supported with funding from CDC PS19-1906 Component A. For questions about this document please contact NASTAD’s PrEP team at PrEP@NASTAD.org.