Ryan White HIV/AIDS Program and Pre-Exposure Prophylaxis

Health Resources and Services Administration
HIV/AIDS Bureau
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Outline

• Review the purpose of the Ryan White HIV/AIDS Program (RWHAP)
• Discuss why pre-exposure prophylaxis (PrEP) is an important tool
• Describe PrEP
• Illustrate how the RWHAP can support PrEP services
Speakers

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Purpose of RWHAP

- Public health approach to providing a comprehensive system of care
- Ensure low-income people living with HIV (PLWH) receive optimal care and treatment
Purpose of RWHAP, cont.

- Increase access to care and treatment for PLWH
- Only disease-specific discretionary grant program for care and treatment of PLWH
- Payor of last resort – safety net for uninsured and low-income PLWH

Funding to support:
- Medical services, including medications
- Support services
- Provider training
- Technical assistance
- Demonstration projects
NATIONAL HIV/AIDS STRATEGY: UPDATED TO 2020 AND PrEP

Why PrEP Is an Important Tool
THE VISION

The United States will become a place where new HIV infections are rare, and when they do occur, every person, regardless of age, gender, race/ethnicity, sexual orientation, gender identity, or socio-economic circumstance will have unfettered access to high-quality, life-extending care, free from stigma and discrimination.
THE GOALS

Reducing new HIV infections

Improving access to care and health outcomes

Reducing HIV-related health disparities

Achieving a more coordinated national response
NHAS 2020

### NATIONAL HIV/AIDS STRATEGY: UPDATED TO 2020

#### 5 MAJOR CHANGES SINCE 2010

Since the first National HIV/AIDS Strategy was released in 2010, major advances have transformed how we respond to HIV, provided new tools to prevent new infections, and improved access to care. With a vision for the next five years, our National HIV/AIDS Strategy has been updated to leverage these achievements and look ahead to 2020.

**Our prevention toolkit has expanded.**

- **Pre-Exposure Prophylaxis (PrEP):** A daily pill to prevent HIV. When taken consistently, can reduce the risk of HIV by up to 92%.

**The Affordable Care Act has transformed health care access.**

- Millions more individuals now have affordable, quality health coverage.

**HIV testing and treatment are recommended.**

- Federal Guidelines now recommend routine HIV screening for people aged 15 to 65.

**Improving HIV Care Continuum outcomes is a priority.**

- President Obama’s HIV Care Continuum Initiative directed Federal departments to increase the number of people with HIV who are diagnosed with HIV linked to HIV care retained in HIV care prescribed HIV treatment virally suppressed (having very low levels of HIV in their body).

**Research is unlocking new knowledge and tools.**

- Evidence that starting HIV treatment early lowers the risk of developing AIDS or other serious illnesses.
- New HIV testing technologies, including new diagnostic tests.
- New HIV medications with fewer side effects, less frequent dosing, and a lower risk of drug resistance.
- Continued investigation of long-acting drugs for HIV treatment and prevention, an HIV vaccine, and, ultimately, a cure.

Learn more about the National HIV/AIDS Strategy: Updated to 2020 at AIDS.gov/2020 #HIV2020
OVERVIEW OF PrEP
Overview of PrEP

• Pre-exposure prophylaxis, or PrEP, is a way for people who do not have HIV but who are at **substantial risk** of getting it to *prevent* HIV infection by taking a pill every day

• When taken consistently, PrEP has been shown to **reduce the risk of HIV infection in people who are at substantial risk by up to 92%**

Guidelines for PrEP Use

Federal guidelines* for health care providers categorize those at substantial risk by mode of transmission for individuals who do not use condoms, and/or people who inject drugs. Refer to the PrEP guidelines for the detailed information.

Medications Used for PrEP

- Truvada® is a combination of two HIV medications (tenofovir and emtricitabine)
- Other medications are in development
How PrEP is Administered

• Clinical providers determine if a client is clinically eligible by:
  • Identifying an individual as an appropriate candidate
  • Screening for HIV
  • Checking renal function and medications that may be contraindicated
  • Documenting vaccination and hepatitis B negative status
  • Prescribing PrEP medication
  • Conducting follow up visits every three months
Paying for PrEP

PrEP coverage is variable but it may be covered by:

• Health care insurance plans (variability with co-payments or co-insurance)
• Medicaid
• Pharmaceutical assistance programs
RYAN WHITE HIV/AIDS PROGRAM
How RWHAP Can Support PrEP

• Recognizes the importance of PrEP

• Acknowledges role of RWHAP system of care and services

• Confirms HIV/AIDS Bureau support of RWHAP recipients’ exploring ways to use expertise and infrastructure to support PrEP
RWHAP Unallowable Costs Related to PrEP

• RWHAP funding cannot be used to pay for PrEP medications or the related medical services for HIV-negative clients who are at substantial risk for HIV
  • These unallowable costs also apply to program income and rebates
How the RWHAP can Support PrEP

• Building PrEP services or programs on existing RWHAP systems, services, programs, personnel, and expertise (leveraging what has been built over the past 25 years)

• Using components of a few service categories specifically related to:
  • HIV testing and referral
  • Psychosocial support for affected family members
  • Risk reduction education for partners of people living with HIV
Examples of RWHAP Existing Systems

- RWHAP AIDS Drug Assistance Program
- Clinical systems
- Case management systems
- HIV program support systems
- Clinical expertise and training
RWHAP AIDS Education and Training Centers and PrEP

• Provide training to primary care providers on PrEP
• Provide a *PrEPline for providers (funded by CDC)
RYAN WHITE HIV/AIDS PROGRAM AND PrEP

Case Scenarios
A local health department wants to establish a PrEP program in its service area

- AETC funds are used for clinical provider training and outreach
- PrEP medications are funded through:
  - Clients’ insurance
  - Pharmaceutical assistance program
- RWHAP expertise is leveraged in implementation:
  - RWHAP-funded medical providers are using local funding for a proportion of their time to implement PrEP with partners of PLWH clients
  - Adherence models for PrEP based on RWHAP medical case management models are being developed
RWHAP Parts A, B and C Recipient: Health Center Example

• The health center has medical providers that are partially funded by RWHAP funds to provide HIV primary care to PLWH

• The medical providers also provide primary care to HIV-negative individuals through health center funds

• One of the expert medical providers is seeing clients that are referred for PrEP with health center resources

• PrEP medications for those without insurance are obtained through pharmaceutical assistance programs
RWHAP Part B ADAP Recipient: State Example

- State health department is establishing a PrEP program
- Leveraging RWHAP ADAP infrastructure for implementation:
  - RWHAP ADAP data system used to enroll PrEP clients and track utilization (alterations to the data system for PrEP client information was paid for with non-RWHAP Part B related funding)
  - RWHAP ADAP’s contracted pharmacy network utilized to fill prescriptions for PrEP (medication cost and dispensing fee paid for with non-RWHAP funding)
  - RWHAP ADAP’s contracted Pharmacy Benefits Manager utilized to process claims for PrEP (any claim charge paid for with non-RWHAP funding)
  - RWHAP ADAP’s eligibility staff process PrEP applications, the same staff process ADAP and PrEP applications, but PrEP related time is allocated to non-RWHAP Part B funding
RWHAP Part B ADAP Recipient: State Example, cont.

• Using available reimbursement/health care coverage options:
  • Clients’ insurance
  • State general funds
  • Pharmaceutical assistance program
RWHAP SERVICE CATEGORIES

Defining Parameters for RWHAP Service Categories and PrEP
Ryan White HIV/AIDS Program Services: Eligible Individuals & Allowable Uses of Funds Policy Clarification Notice (PCN) #16-02

Please reference PCN #16-02 in its entirety here:

http://hab.hrsa.gov/affordablecareact/service_category_pcn_16-02_final.pdf
## Overview of RWHAP Service Categories that Support PrEP

<table>
<thead>
<tr>
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<th>Part A</th>
<th>Part B</th>
<th>Part C</th>
<th>Part D</th>
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<tbody>
<tr>
<td>Early Intervention Services</td>
<td>Targeted HIV testing</td>
<td>Targeted HIV testing</td>
<td>High risk targeted HIV testing</td>
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<td></td>
<td>Outreach Services and Health Education/Risk Reduction related to HIV diagnosis</td>
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<td>Counseling with respect to HIV</td>
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<tr>
<td>Health Education/ Risk Reduction</td>
<td>Health Education/ Risk Reduction services for <strong>HIV positive clients</strong> including strategies to reduce transmission such as PrEP for exposed partners</td>
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<td>Psychosocial Support Services</td>
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<td>Counseling services , as part of family-centered care</td>
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RWHAP Part A and B Early Intervention Services that can Support PrEP

- RWHAP Parts A and B EIS services must include the following four components:
  - Targeted HIV testing to help the unaware learn of their HIV status and receive referral to HIV care and treatment services if found to be HIV-infected
  - Referral services to improve HIV care and treatment services at key points of entry
  - Access and linkage to HIV care and treatment services such as HIV Outpatient/Ambulatory Health Services, Medical Case Management, and Substance Abuse Care
  - Outreach Services and Health Education/Risk Reduction related to HIV diagnosis
RWHAP Part C Early Intervention Services that can Support PrEP

• RWHAP Part C Early Intervention Services (EIS) must include the following four components:
  • Counseling individuals with respect to HIV
  • High risk targeted HIV testing (confirmation and diagnosis of the extent of immune deficiency)
  • Referral and linkage to care of HIV-infected clients to Outpatient/Ambulatory Health Services, Medical Case Management, Substance Abuse Care, and other services as part of a comprehensive care system including a system for tracking and monitoring referrals
  • Other clinical and diagnostic services related to HIV diagnosis
RWHAP Part C Early Intervention Services that can Support PrEP, cont.

• RWHAP Part C Early Intervention Services (EIS) component, Counseling individuals with respect to HIV, parameters in legislation (section 2662):

  • Service includes counseling for individuals with HIV negative test results by providing information including measures for prevention of, exposure to and transmission of HIV, hepatitis B, hepatitis C, and other sexually transmitted diseases
RWHAP Parts A, B, C and D: Health Education/Risk Reduction

• Health Education/Risk Reduction is the provision of education to clients living with HIV about HIV transmission and how to reduce the risk of HIV transmission. It includes sharing information about medical and psychosocial support services and counseling with clients to improve their health status. Topics covered may include:

  • Education on risk reduction strategies to reduce transmission such as pre-exposure prophylaxis (PrEP) for the PLWH partner and treatment as prevention
• Psychosocial Support Services provide group or individual support and counseling services to assist eligible people living with HIV to address behavioral and physical health concerns.

• Counseling services, as part of family-centered care can be provided to affected/family members, under RWHAP Part D
Program Income (PCN #15-03) and PrEP

• Program income must be used for the purposes for which the award was made, and may only be used for allowable costs under the award.
  • For RWHAP Parts A, B, and C, 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.

• Please refer to PCN #15-03 for further reference: http://hab.hrsa.gov/affordablecareact/pcn_15-03_program_income.pdf
Next Steps and What is HRSA is Doing to Support PrEP

• HRSA established an agency-wide PrEP Workgroup in November 2015 to better understand PrEP resources across the bureaus and offices in order to leverage these resources.

• Communications to all HRSA programs, providers, recipients and stakeholders
• Technical assistance activities with external stakeholders
• HRSA Funding Opportunity Announcements
• 2016 National Ryan White Conference on HIV Care and Treatment
Resources: RWHAP Program Letter and Policy Clarification Notices

• The Ryan White HIV/AIDS Program and Pre-Exposure Prophylaxis (PrEP) Letter:

• 16-02 Ryan White HIV/AIDS Program Services:
  http://hab.hrsa.gov/affordablecareact/service_category_pcn_16-02_final.pdf
  • Frequently Asked Questions for Policy Clarification Notice: 16-02
Resources: PrEP

Question and Answer
THANK YOU!