

# Ryan White HIV/AIDS Program and Pre-Exposure Prophylaxis

**Health Resources and Services Administration  
HIV/AIDS Bureau  
August 2, 2016**

# Outline

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- 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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Captain, USPHS

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# Purpose of RWHAP

**RYAN WHITE  
HIV/AIDS PROGRAM  
MOVING FORWARD  
FRAMEWORK**



- 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.

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- 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

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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%

#### Treatment as Prevention

The risk of transmitting HIV is reduced by

96%

in those who start treatment early.

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



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



There is **no denial of coverage for pre-existing conditions, like HIV.**

**Preventive services**, including HIV testing, are covered without co-pays.



**Protections** against sex or disability discrimination in health care.

### HIV testing and treatment are recommended.

Federal Guidelines now recommend **routine HIV screening** for people aged

15 TO 65



CDC updated recommendations for HIV testing to help labs detect infections earlier.

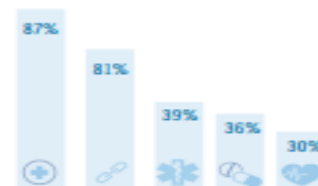
Federal HIV treatment guidelines now recommend **antiretroviral therapy for all people living with HIV.**



### 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.



# 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%**

<http://www.cdc.gov/hiv/risk/prep/index.html>

**ARE YOU READY FOR PrEP?**

PrEP 101

**PrEP Basics**

PrEP stands for **Pre-Exposure Prophylaxis**. The word "prophylaxis" means to prevent or control the spread of an infection or disease.

PrEP can help prevent you from getting HIV if you are exposed to the virus.

PrEP is an HIV prevention option that works by taking **one pill every day**.

**1 PILL DAILY**

The infographic features a man's face in the bottom right corner, a large number '1' in a circle, and icons of pills and viruses.

# Guidelines for PrEP Use

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**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.**

[\\*http://www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf](http://www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf)

# Medications Used for PrEP

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- **Truvada<sup>®</sup> 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

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## 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**



# **HIV/AIDS Program PrEP Letter Released on June 23, 2016**

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- **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

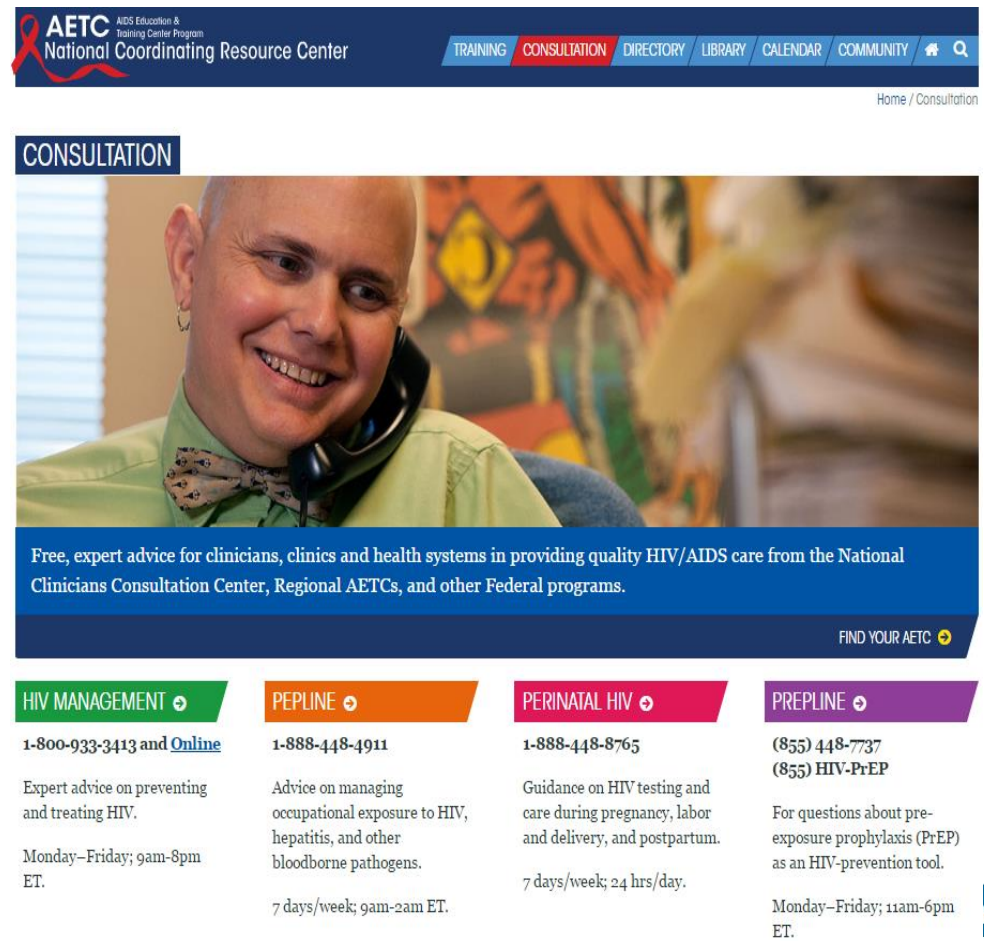
# Examples of RWHAP Existing Systems

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- **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)



The screenshot shows the AETC National Coordinating Resource Center website. The header includes the AETC logo and navigation links for TRAINING, CONSULTATION, DIRECTORY, LIBRARY, CALENDAR, and COMMUNITY. Below the header is a 'CONSULTATION' section featuring a photo of a smiling man on a phone. Text below the photo states: 'Free, expert advice for clinicians, clinics and health systems in providing quality HIV/AIDS care from the National Clinicians Consultation Center, Regional AETCs, and other Federal programs.' Below this is a 'FIND YOUR AETC' button. At the bottom, there are four colored boxes representing different services: HIV MANAGEMENT (green), PEPLINE (orange), PERINATAL HIV (pink), and PREPLINE (purple). Each box lists a phone number, a brief description of the service, and the hours of operation.

**AETC** AIDS Education & Training Center Program  
National Coordinating Resource Center

TRAINING CONSULTATION DIRECTORY LIBRARY CALENDAR COMMUNITY

Home / Consultation

**CONSULTATION**

Free, expert advice for clinicians, clinics and health systems in providing quality HIV/AIDS care from the National Clinicians Consultation Center, Regional AETCs, and other Federal programs.

FIND YOUR AETC

HIV MANAGEMENT	PEPLINE	PERINATAL HIV	PREPLINE
1-800-933-3413 and <a href="#">Online</a>	1-888-448-4911	1-888-448-8765	(855) 448-7737 (855) HIV-PrEP
Expert advice on preventing and treating HIV.	Advice on managing occupational exposure to HIV, hepatitis, and other bloodborne pathogens.	Guidance on HIV testing and care during pregnancy, labor and delivery, and postpartum.	For questions about pre-exposure prophylaxis (PrEP) as an HIV-prevention tool.
Monday–Friday; 9am–8pm ET.	7 days/week; 9am–2am ET.	7 days/week; 24 hrs/day.	Monday–Friday; 11am–6pm ET.

# RYAN WHITE HIV/AIDS PROGRAM AND PREP

## Case Scenarios

# RWHAP Part A Recipient: Local Health Department Example

- 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

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- 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.

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- **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

## ***Ryan White HIV/AIDS Program Services: Eligible Individuals & Allowable Uses of Funds***

*Policy Clarification Notice (PCN) #16-02  
Replaces Policy #10-02*

**Scope of Coverage:** Ryan White HIV/AIDS Program (RWHAP) Parts A, B, C, and D, and Part F where funding supports direct care and treatment services.

### **Purpose of PCN**

This policy clarification notice replaces the Health Resources and Services Administration (HRSA) PCN 10-02: Eligible Individuals & Allowable Uses of Funds for Discretely Defined Categories of Services regarding eligible individuals and the description of allowable service categories for Ryan White HIV/AIDS Program and program guidance for implementation.

### **Background**

The Office of Management and Budget (OMB) has consolidated, in 2 CFR Part 200, the uniform grants administrative requirements, cost principles, and audit requirements for all organization types (state and local governments, non-profit and educational institutions, and hospitals) receiving federal awards. These requirements, known as the "Uniform Guidance," are applicable to recipients and subrecipients of federal funds. The OMB Uniform Guidance has been codified by the Department of Health and Human Services (HHS) in [45 CFR Part 75—Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards](#). RWHAP grant and cooperative agreement recipients and subrecipients should be thoroughly familiar with 45 CFR Part 75. Recipients are required to monitor the activities of the subrecipient to ensure the subaward is used for authorized purposes in compliance with applicable statute, regulations, policies and the terms and conditions of the award (see [45 CFR §§ 75.351-352](#)).

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

[http://hab.hrsa.gov/affordablecareact/service\\_category\\_pcn\\_16-02\\_final.pdf](http://hab.hrsa.gov/affordablecareact/service_category_pcn_16-02_final.pdf)

# Overview of RWHAP Service Categories that Support PrEP

Service Category	Part A	Part B	Part C	Part D
Early Intervention Services	Targeted HIV testing  Outreach Services and Health Education/Risk Reduction related to HIV diagnosis	Targeted HIV testing  Outreach Services and Health Education/Risk Reduction related to HIV diagnosis	High risk targeted HIV testing  Counseling with respect to HIV	
Health Education/ Risk Reduction	Health Education/ Risk Reduction services for <b><u>HIV positive clients</u></b> including strategies to reduce transmission such as PrEP for exposed partners	Health Education/ Risk Reduction services for <b><u>HIV positive clients</u></b> including strategies to reduce transmission such as PrEP for exposed partners	Health Education/ Risk Reduction services for <b><u>HIV positive clients</u></b> including strategies to reduce transmission such as PrEP for exposed partners	Health Education/ Risk Reduction services for <b><u>HIV positive clients</u></b> including strategies to reduce transmission such as PrEP for exposed partners
Psychosocial Support Services				Counseling services , as part of family-centered care

# 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.

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- 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

# RWHAP Part D: Psychosocial Support Services

- **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](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:**  
<http://hab.hrsa.gov/manageyourgrant/prepletter062216.pdf>
- **16-02 Ryan White HIV/AIDS Program Services:**  
[http://hab.hrsa.gov/affordablecareact/service\\_category\\_pcn\\_16-02\\_final.pdf](http://hab.hrsa.gov/affordablecareact/service_category_pcn_16-02_final.pdf)
  - **Frequently Asked Questions for Policy Clarification Notice: 16-02**  
[http://hab.hrsa.gov/affordablecareact/faq\\_service\\_definitions\\_pcn\\_final.pdf](http://hab.hrsa.gov/affordablecareact/faq_service_definitions_pcn_final.pdf)

# Resources: PrEP

- AETC National Coordinating Resource Center: <http://aidsetc.org/>
- PrEPline: <http://nccc.ucsf.edu/clinician-consultation/prep-pre-exposure-prophylaxis/>
- CDC PrEP Guidelines:  
<http://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf>
- CDC PrEP Resources:  
<http://www.cdc.gov/hiv/basics/prep.html>
- AIDS.gov: <https://www.aids.gov/hiv-aids-basics/prevention/reduce-your-risk/pre-exposure-prophylaxis/>

# Question and Answer

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**THANK YOU!**