



2016 National Ryan White Conference on HIV Care and Treatment

**Prioritizing Pre-Exposure Prophylaxis within the HRSA
Panel Discussion**

Thursday, August 25, 2016
1:30 -3:30 p.m.



Disclosures

The presenters have no financial interest to disclose.

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NHAS 2020 Supports PrEP

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.

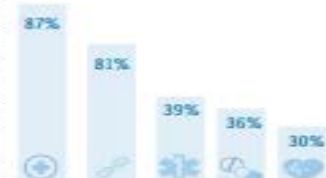
Federal HIV treatment guidelines now recommend **antiretroviral therapy** for all people living with HIV.



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.





What is HRSA 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
 - HRSA Financing Opportunities



Selected HRSA Accomplishments regarding PrEP

- Prepared and disseminated multiple PrEP messages using HRSA social media, e-newsletters and listservs
- HIV Testing Day webinar and HRSA staff trainings
- Updated SF-424 Application Guide to include PrEP and HIV Care Continuum information (see section 2.2)
- Assessing which HRSA programs funds may be used to support treatment, medication, and support services associated with PrEP
- Lessons learned from IAS conference, Durban, SA



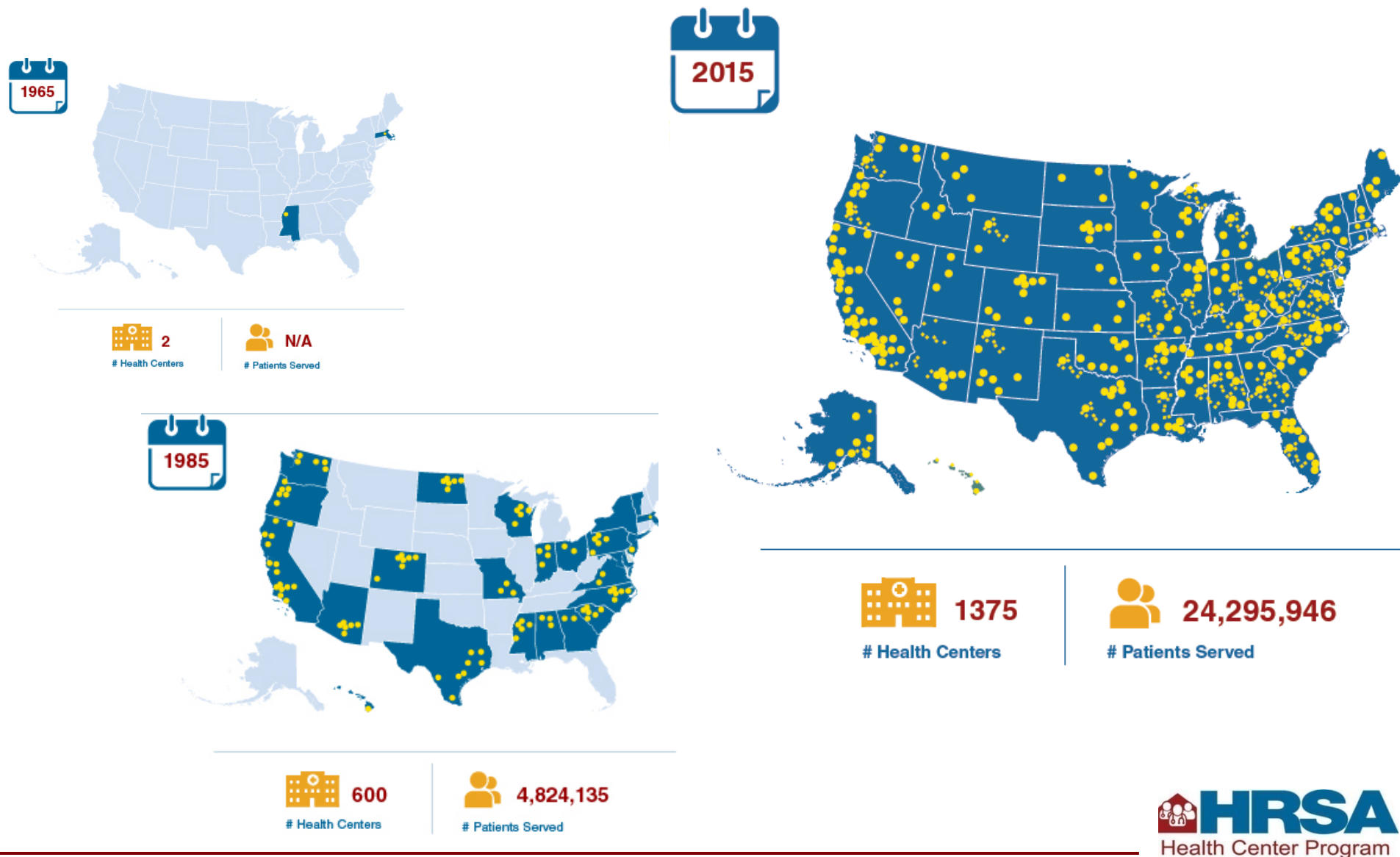
HEALTH CENTER PROGRAM



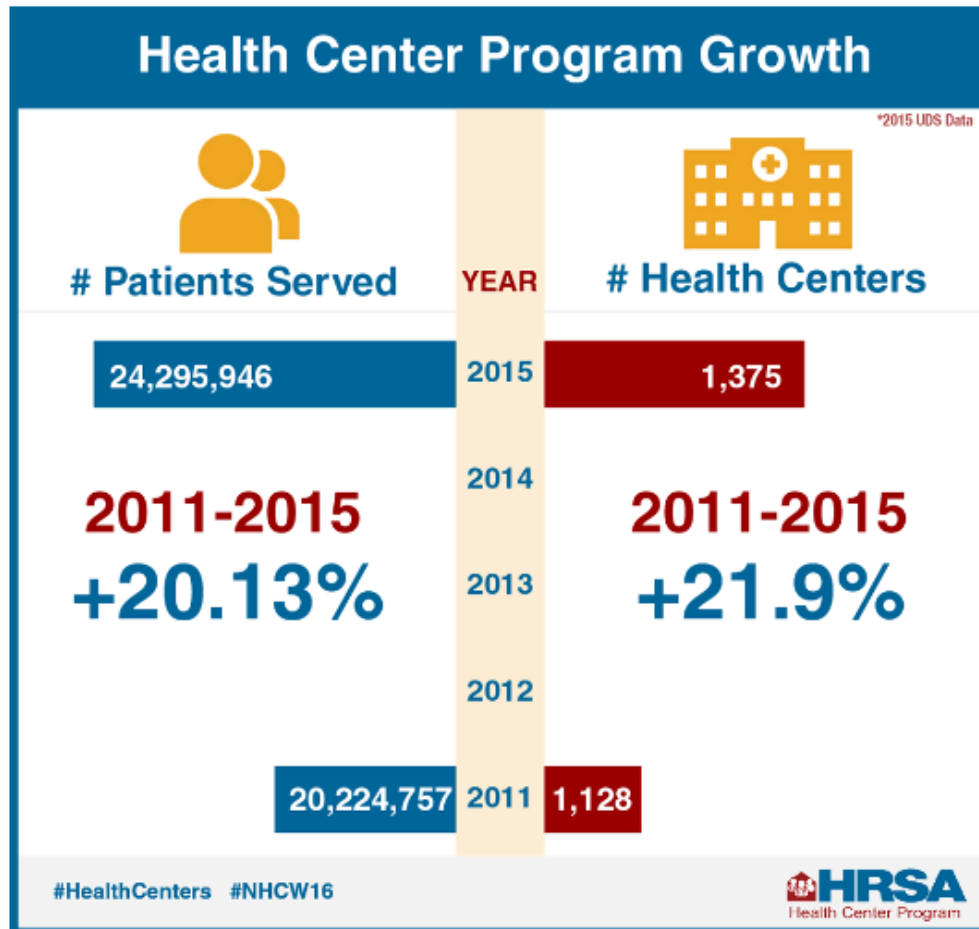
Bureau of Primary Health Care

Improving the health of the Nation's underserved communities and vulnerable populations by assuring access to comprehensive, culturally competent, quality primary health care services

Serving America's Communities for 50 Years



Who We Serve



188,852
HEALTH CENTER EMPLOYEES

1 IN 13
PEOPLE IN THE US



1 IN 10
CHILDREN IN THE US



SERVING SPECIAL POPULATIONS.*



1,191,772
HOMELESS



910,172
AGRICULTURAL WORKERS



649,132
SCHOOL-BASED



1,510,842
PUBLIC HOUSING



305,520
VETERANS



Health Center Program Fundamentals

- Provide **high quality, culturally competent, comprehensive primary care**, as well as **supportive services** such as education, translation, and transportation that promote access to health care
- Community-based organizations with autonomous, **patient-majority** governing boards
- Focus on **underserved** populations and communities
- Respond to individual **needs of community**
- **Diverse** in size, capacity, populations served, and staff

PrEP Service Delivery by Health Centers

- **BPHC supports adopting PrEP into clinical practice for at risk patients as part of routine primary care**
 - Health Center Program/ Section 330 funding can be used for PrEP, including medication and health center visits for follow-up and related services
 - Offered services must be provided in accordance with applicable clinical guidelines (CDC 2014), regardless of insurance status and/or ability to pay
- **BPHC is working with partners to support PrEP training and technical assistance**



The National LGBT Health Education Center provides educational programs, resources, and consultation to health care organizations with the goal of optimizing quality, cost-effective health care for lesbian, gay, bisexual, and transgender (LGBT) people.

The Education Center is a part of [The Fenway Institute](#), the research, training, and health policy division of [Fenway Health](#), a Federally Qualified Health Center, and one of the world's largest LGBT-focused health centers.



Providing adequate education to medical students as well as continuing education for clinicians and other healthcare providers is critical to addressing the needs of LGBT patients. Georgetown University School of Medicine starts the conversation about LGBT health early for their students and is leading the way ...

FEBRUARY 5, 2015



SEP 23 Advancing Excellence in Transgender Health: A Two-day Conference for the Whole Care Team

Our Publications and Training Materials

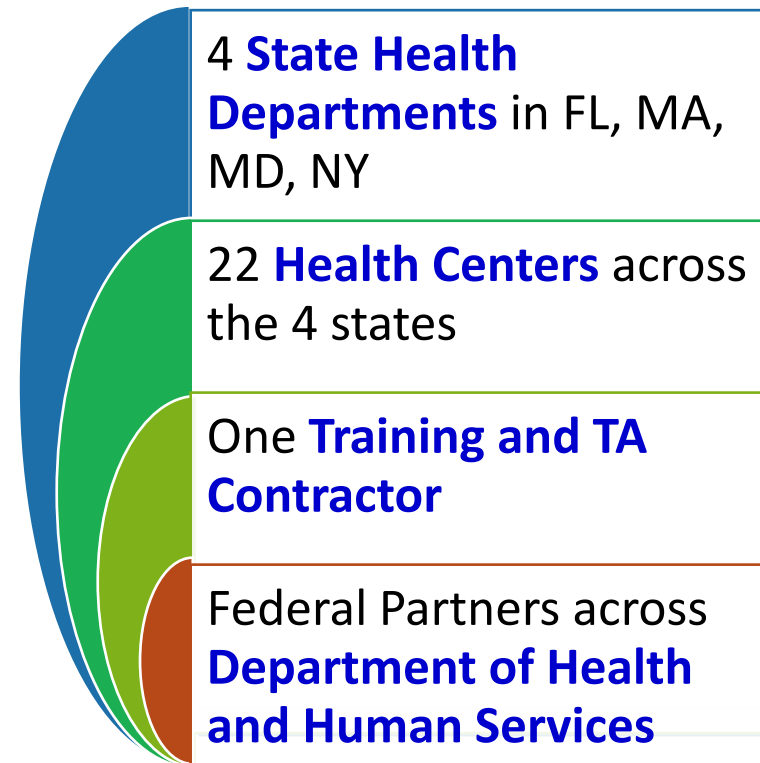
[See All Publications](#)



Partnerships for Care (P4C)

<https://p4chivtac.com/>

- Build **public health – primary care partnerships** through
 - Data Sharing
 - Case conferencing
 - Training/TA
- Support **workforce** and **infrastructure** development within health centers
- Utilize **multi-disciplinary care teams**
- Identify and disseminate **promising practices**
- Improve **HIV outcomes**, especially for racial/ethnic minorities



HIV Training, TA and Collaboration Center

<https://p4chivtac.com/content/archived-webinars>



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FEATURED RESOURCES



[The Centers for Disease Control and Prevention's HIV Risk Reduction Tool](#)

[Updated Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents](#)

PARTNERSHIPS FOR CARE (P4C): HEALTH DEPARTMENTS AND HEALTH CENTERS COLLABORATING TO IMPROVE HIV HEALTH OUTCOMES

Partnerships for Care (P4C): Health Departments and Health Centers Collaborating to Improve HIV Health Outcomes is a three-year, multi-agency project funded by the Secretary's Minority AIDS Initiative Fund and the Affordable Care Act. The goals of the project are to: (1) expand provision of HIV testing, prevention, care and treatment in health centers serving communities highly impacted by HIV, (2) build sustainable partnerships between health centers and their state health department, and (3) improve health outcomes among people living with HIV, especially among racial/ethnic minorities. The project is supported by the HIV Training, Technical Assistance, and Collaboration Center (HIV TAC). [READ MORE](#)

HIV TAC

The HIV TAC supports health centers and health departments in meeting the P4C project goals through providing training and technical assistance, and tracking health center activities and progress.

[READ MORE](#)

HEALTH DEPARTMENTS

CDC-funded state health departments support health centers by providing training and technical assistance to advance workforce and infrastructure development; and, expand partner notification.

[READ MORE](#)

HEALTH CENTERS

HRSA-funded health centers collaborate with P4C partners to provide HIV services such as routine HIV testing and prevention; basic HIV care and treatment; patient self-care management planning; and, care coordination.

[READ MORE](#)



RYAN WHITE HIV/AIDS PROGRAM

How RWHAP Can Support PrEP



HIV/AIDS Bureau Vision and Mission

Vision

Optimal HIV/AIDS care and treatment for all.

Mission

Provide leadership and resources to assure access to and retention in high quality, integrated care, and treatment services for vulnerable people living with HIV/AIDS and their families.



HIV/AIDS Bureau Priorities

- **NHAS 2020/PEPFAR 3.0** - Maximize HRSA HAB expertise and resources to operationalize NHAS 2020 and PEPFAR 3.0
- **Leadership** - Enhance and lead national and international HIV care and treatment through evidence-informed innovations, policy development, health workforce development, and program implementation
- **Partnerships** - Enhance and develop strategic domestic and international partnerships internally and externally
- **Integration** - Integrate HIV prevention, care, and treatment in an evolving healthcare environment
- **Data Utilization** - Use data from program reporting systems, surveillance, modeling, and other programs, as well as results from evaluation and special projects efforts to target, prioritize, and improve policies, programs, and service delivery
- **Operations** - Strengthen HAB administrative and programmatic processes through Bureau-wide knowledge management, innovation, and collaboration

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.

- 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



HIV/AIDS Program PrEP Letter Released on June 22, 2016

- **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

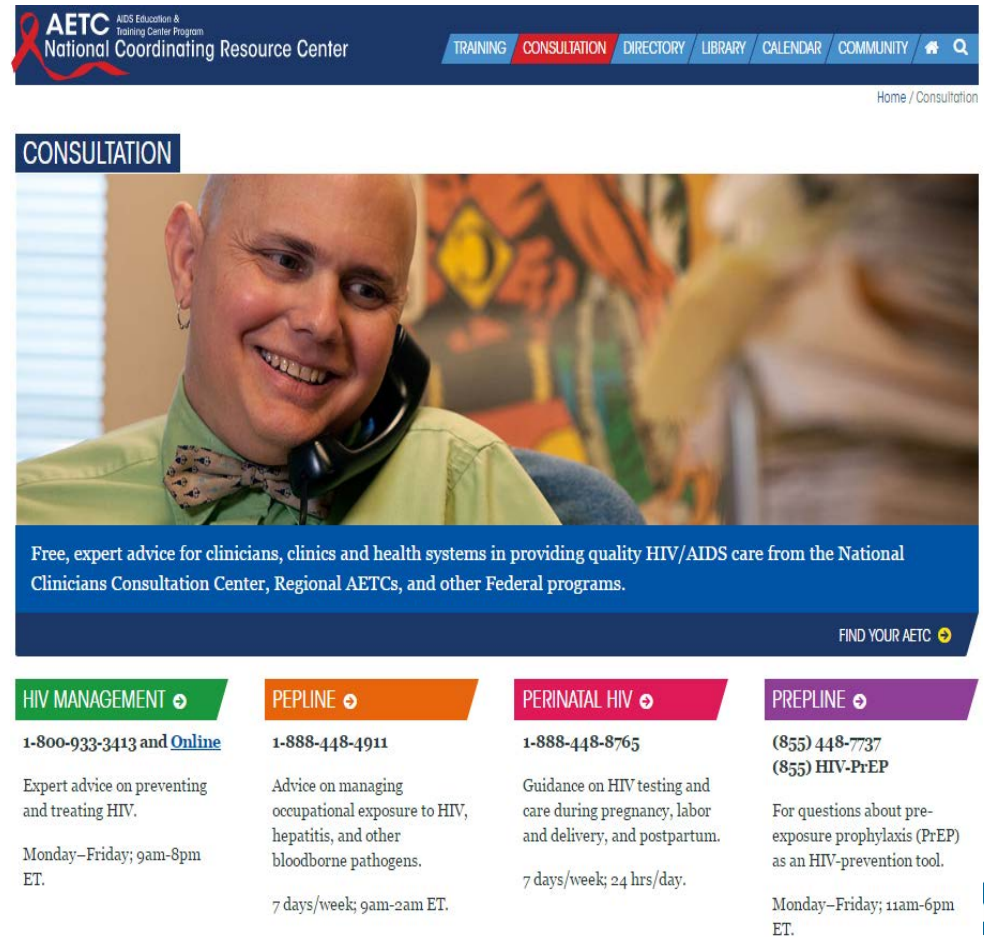


Examples of RWHAP Existing Systems

- **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)



The screenshot displays the AETC National Coordinating Resource Center website. The header includes the AETC logo and navigation links: TRAINING, CONSULTATION, DIRECTORY, LIBRARY, CALENDAR, and COMMUNITY. A 'CONSULTATION' banner features a photo of a smiling man on a phone. Below the banner, text describes free expert advice for clinicians. A table at the bottom lists four services: HIV MANAGEMENT, PEPLINE, PERINATAL HIV, and PRELINE, each with contact information and descriptions.

HIV MANAGEMENT	PEPLINE	PERINATAL HIV	PRELINE
1-800-933-3413 and Online	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

- **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

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_pc_n_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 <u>HIV positive clients</u> including strategies to reduce transmission such as PrEP for exposed partners	Health Education/ Risk Reduction services for <u>HIV positive clients</u> including strategies to reduce transmission such as PrEP for exposed partners	Health Education/ Risk Reduction services for <u>HIV positive clients</u> including strategies to reduce transmission such as PrEP for exposed partners	Health Education/ Risk Reduction services for <u>HIV positive clients</u> including strategies to reduce transmission such as PrEP for exposed partners
Psychosocial Support Services				Counseling services , as part of family-centered care



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
 - **Frequently Asked Questions for Policy Clarification Notice: 16-02**
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

- Please discuss the strategies you have employed to support PrEP services within your organization
- Please share what is working particularly well or not within your organization
- Please describe major barriers that you've faced in your organization

THANK YOU!