

# Promoting PrEP & Ensuring Its Coverage & Affordability

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*2022 Biomedical HIV Prevention Summit*  
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**HIV+HEP**  

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**POLICY INSTITUTE**

# Why Uptake Hasn't Been Better

- ▶ Should not be the cost of the drug
  - Low-cost generics & available for free
- ▶ Insufficient federal government outreach program to community & providers
- ▶ No payer for lab services for the uninsured
- ▶ CDC just beginning to allow state grantees to pay for PrEP services
  - Limited level & not for the Rx
  - Has been available for EHE grants (not Rx)
  - Need grantee accountability



[Thank you again for your letter signed by 67 community-based organizations, providers, community health centers, and advocacy organizations, regarding increasing pre-exposure prophylaxis (PrEP) access and uptake in the United States.

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*Recipients may provide assistance, no more than 15 percent (15%) of the overall award amount, to support PrEP ancillary support services. Recipients are required to notify CDC, if coverage demands exceed the allotted percentage, to secure permission to redirect additional resources to meet the projected demand. •*

*This guidance allows flexibility to utilize CDC's flagship health department funding for program recipients to pay for CDC-recommended clinical care costs related to PrEP as payor of last resort. Further, this guidance allows flexibility for recipients to provide immediate, transitional support while seeking alternative, long term support for individuals as other eligible resources are secured for clients.*

# Why Uptake Hasn't Been Better

- ▶ Zero cost sharing for private insurance recently went into effect
  - Federal Government slow to issue guidance
  - Insurers aren't in compliance
  - People still being charged
- ▶ Daily pill w/ follow-up visits (up until now)
- ▶ Stigma
  - Including by providers

# What Can be Done to Scale Up PrEP

- ▶ National PrEP Grant Program
  - To meet current and future needs
- ▶ CDC Must allow grantees to Spend more on PrEP
- ▶ Continued Community Health Center Funding
  - \$102 million to 271 Centers
    - ▶ Must expand to all 1,400
  - 389,000 PrEP Patients at 925 Centers
  - Need better data
- New CDC Grant Program?

# Health Center Progress

925 Health Centers - of which 195 were PCHP-funded health centers - delivered critical primary care and HIV prevention services in CY 2020.



## 925 Health Centers

- Served over 23M Patients:
  - 65% Racial Ethnic Minorities
  - Nearly 2.5M HIV Tests
  - Provided PrEP to 389,000 Patients
  - Linked 81% of newly diagnosed patients to care within 30 days

## 195 PCHP-Funded Health Centers

- Served nearly 7M patients:
  - 80% Racial Ethnic Minorities
  - Conducted over 1.1 Million HIV Tests
  - Provided PrEP to 151,000 Patients
  - Linked 86% of newly diagnosed patients to care within 30 days



Source: 2020 Uniform Data System (UDS)



# Private Insurance

- ▶ Current Requirements Must be Enforced
  - Drug Formularies Checked
  - Improved Transparency for Prevention Drugs
  - People still being charged for Rx & other services
  - State Insurance Commissioner's must take action
- ▶ New Drugs Quickly Reviewed by USPSTF
  - CCIIO Guidance Updated
- ▶ Continued Publicity & Enforcement

Draft Research Plan

# Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis

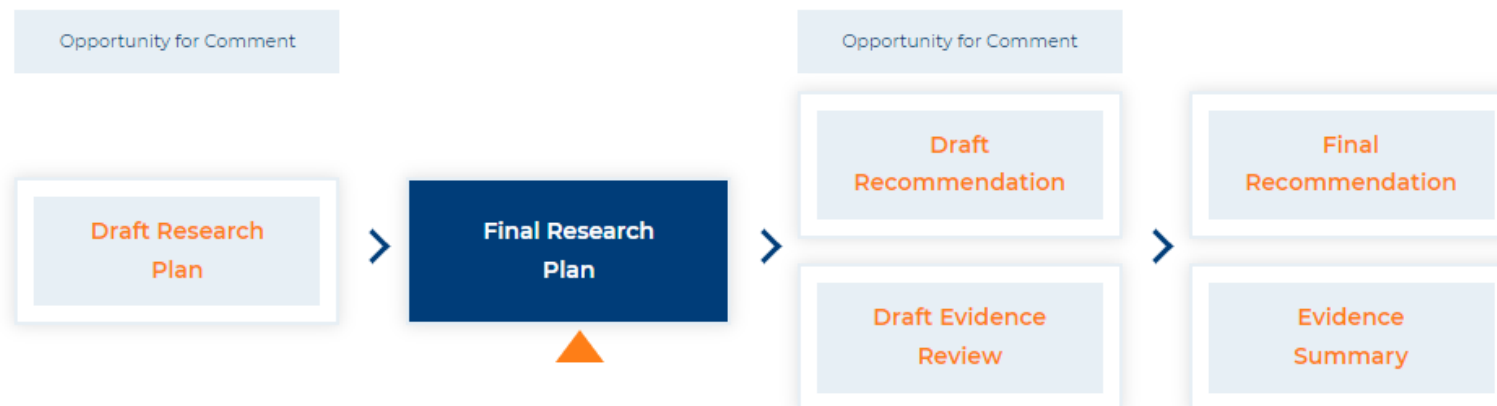
November 04, 2021

*Recommendations made by the USPSTF are independent of the U.S. government. They should not be construed as an official position of the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.*

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## The Recommendation Development Process

The Task Force follows a multistep process when developing each of its recommendations. Use the graphic below to see where this recommendation is in the development process. [Learn about our full development process.](#)







U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control  
and Prevention (CDC)  
Atlanta GA 30329-4027

March 30, 2022

The Honorable Mondaire Jones  
U.S. House of Representatives  
Washington, DC 20515

The Honorable Ritchie Torres  
U.S. House of Representatives  
Washington, DC 20515

Dear Representatives Jones and Torres:

CDC supports efforts to ensure no cost-sharing extends to all PrEP medications approved by the FDA, including Apretude, and looks forward to continued collaboration with CMS to advance this effort.

Sincerely,

Rochelle P. Walensky, MD, MPH  
Director, CDC

# Medicaid & Medicare

- ▶ State Medicaid Programs cover PrEP & labs
  - Very low cost-sharing, if any
  - But many states not expanded Medicaid to all low-income individuals
- ▶ PrEP Covered under Medicare
  - All ARV's must be covered in Part D
  - Need Coverage Determination for Part B
  - Beneficiary cost-sharing applies

# National PrEP Grant Program Legislation

- ▶ **PrEP Assistance Program Act ([HR 5605](#))**
- ▶ Rep. Bonnie Watson Coleman (D-NJ)
- ▶ 55 co-sponsors
- ▶ Establishes \$400 million/year for:
  - Community & Provider Outreach
  - PrEP & associated services for uninsured & underinsured
- ▶ Eligible entities:
  - States, tribes, cities, FQHCs, family planning centers, rural health clinics, CBOs, Ryan White Program Clinics

# National PrEP Grant Program Legislation

- ▶ **PrEP Access and Coverage Act ([S 3295](#), [HR 6117](#))**
- ▶ Sen. Tina Smith (D-MN) & Rep. Adam Schiff (D-CA)
- ▶ 52 cosponsors
- ▶ Establishes Separate Grant Programs for Community & Provider Outreach
  - No specified dollar amount
- ▶ PrEP & associated services for uninsured & underinsured
- ▶ Same list of eligible entities

# PrEP Access and Coverage Act: Additional Components

- ▶ No cost-sharing for all PrEP Rx's & associated services by all payers (Private Insurance, Medicare, Medicaid, Indian Health, TriCare)
  - No prior authorizations
- ▶ No discrimination in disability, long-term care, life insurance for PrEP users
- ▶ Education campaign by HHS Secretary
- ▶ Protects privacy of PrEP users on family plan

# Appropriations

- ▶ Whatever is authorized still must be funded
- ▶ Can establish grant program through appropriations, especially if build on existing programs
- ▶ 111 HIV & LGBTQ orgs. sent [letter](#) to President Biden in support of \$400 million national PrEP grant program in FY23 budget

February 7, 2022

President Joseph R. Biden  
The White House  
1600 Pennsylvania Avenue  
Washington, DC 20500

Re: National PrEP Grant Program to Prevent HIV

Dear President Biden,

The undersigned 111 public health, HIV, hepatitis, and STD community-based organizations, along with providers, community health centers, and advocacy organizations are writing to **urge you to support the creation of a national PrEP grant program to prevent HIV in the United States.**

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**We ask that you include at least \$400 million in your FY2023 budget to establish and fund a national PrEP grant program to increase awareness and access to PrEP and related services.** This program should provide funding to community-based organizations including state and city public health departments, Indian tribal communities, rural health clinic, community health centers, Ryan White clinics, sexual health and family-planning clinics, community-based organizations providing HIV prevention services, and others to ensure that PrEP reaches the communities most in need. The program should also be designed to allow for the low-cost purchase of PrEP medications via the 340B drug pricing program and utilization of generic PrEP. It should also work with people's existing health care coverage and take advantage of zero dollar cost-sharing for PrEP and associated ancillary services for those who have private insurance.

# Letter to President Biden

- ▶ Build on existing CDC & FQHC programs
- ▶ Utilize, as appropriate
  - Existing payers
    - ▶ No cost-sharing for private insurance
  - Generic drugs
  - Free Rx programs
  - 340B program

Note: If created under “STD Clinic/Section 318” authority any grantee, including Ryan White Program clinics, can use 340B and pay for & conduct PrEP activities





**PRESIDENTIAL**  
ADVISORY COUNCIL ON HIV/AIDS

March 15, 2022

The Honorable Xavier Becerra  
Secretary  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

**Re: Recommendations to Scale-Up Uptake of PrEP Nationwide**

Dear Secretary Becerra:

As you and the Biden administration proceed with implementing the National HIV/AIDS Strategy (NHAS) for the U.S. 2022–2025 and the *Ending the HIV Epidemic in the U.S.* (EHE) initiative, we urge you to support the creation of a national PrEP program to ensure there is a concerted scale up of PrEP so that all those who need it can access and afford PrEP along with any associated services.

# PACHA Recommendations

- ▶ Addressing Racial, Ethnic and Other Inequities Must be Prioritized
- ▶ Utilize and maximize existing payer systems including private insurance, Medicaid and Medicare
- ▶ Create and fund a national PrEP Grant Program for Community and Provider outreach and pay for PrEP and associated services for those who are uninsured and underinsured

# President's FY23 Budget

## ▶ **Community Health Centers (EHE)**

- +\$50 million for PrEP
- +100 health centers in EHE jurisdictions
- Will bring to \$172 m & 400 nationwide

Note: +\$50m proposed in FY22; final +\$20m; will only be able to fund +60 centers, not +140.

## ▶ **CDC HIV Prevention (EHE)**

- +\$115 million for \$310 million total

Note: +\$100 m proposed in FY22; final +\$20 m for \$195 m total

## ▶ **CDC HIV Prevention (non-EHE)**

- Flat funded at \$756 million

**MANDATORY LEGISLATIVE PROPOSAL**  
**PrEP DELIVERY PROGRAM TO END THE HIV EPIDEMIC IN THE UNITED STATES**

**Budget Summary**  
(Dollars in Millions)

	<b>FY 2023 President's Budget</b>
<b>Mandatory Proposal – PrEP Delivery Program to End the HIV Epidemic in the United States</b>	<b>\$237</b>

Allocation Method.....Direct federal

**Program Description and Accomplishments**

The FY 2023 President's budget includes a new mandatory Pre-Exposure Prophylaxis Delivery Program to End the HIV Epidemic in the United States ("PrEP Delivery Program"). The PrEP Delivery Program is designed to expand access to PrEP and essential wraparound services for uninsured and underinsured individuals at high risk of HIV infections across the United States. This national program would create a financing and delivery system for PrEP. Currently, there is a patchwork of PrEP access programs for uninsured individuals; this comprehensive new program is a key pillar of the Administration's efforts to meet the commitments laid out in the National HIV/AIDS Strategy for the United States 2022-2025 to reduce HIV infections by 75% by 2025.

# Be Bold, But be Real

- ▶ **Mandatory Programs**
  - Do not need annual appropriations
  - Need Legislation
    - ▶ Stakeholder Agreement
    - ▶ Sponsors
    - ▶ Hearings
    - ▶ Committee & Floor Passage
      - Amendments
      - House , Senate & Conference
  - Need \$9.8 billion Offset
  - Congressional Make up

Note: Ryan White Program is not a mandatory program & hasn't been reauthorized since 2009

# Drug Purchasing Proposal

- ▶ No need to include Medicaid
  - No 340B rebates
- ▶ Clinics/Jurisdictions need grants to do outreach, provider education & other services
- ▶ Should integrate PrEP w/ existing programs
- ▶ Doesn't rely on current payers & payer of last resort
- ▶ Focus on generic; denying new long-acting Rx's
- ▶ Will take years to implement

# Proposals for Moving Forward

- ▶ Must focus on increasing funding for existing programs
  - CDC, Health Centers & others
- ▶ CDC grantees must do more
  - CDC pay for Rx's?
- ▶ Take advantage of private insurance coverage
- ▶ Ensure Medicaid & Medicare coverage

# Proposals for Moving Forward

- ▶ Take advantage of free Rx programs & patient assistance
- ▶ Leverage 340B entities
  - Negotiate w/manufactures on greater discounts
- ▶ Focus on introduced Congressional Bills
- ▶ CDC has the authority to do more if given direction & resources



# Leveraging 340B Entities

▶ Ryan White grantees:	708	
- RW & STI:	141	
- RW & CHC:	46	
▶ (STI as well)	(6)	
▶ Total Ryan White		181
▶ STI grantees:		2,061
▶ Community Health Center grantees:		1,623
▶ Title X Family Planning clinics:	1,411	
- FP & STI:	(454)	
- Total FP:		957

25% Ryan White entities can do PrEP  
4,822 entities total, plus hospitals

Source: Avita Pharmacy

# Thank you!

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