

# Federal Funding Needed for a National PrEP Program

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# Goal: Increase PrEP Uptake & Reduce Disparities

- ▶ **People are taking PrEP**

- Rely on various payers: private insurance, Medicaid & Medicare
- Rely on mix of providers, including new ones
- Uninsured also benefiting, thanks to free drug programs & 340B

- ▶ **But not enough people on PrEP**

- Particularly Black & Latino gay men & women
- People in the South
- Falling short of reaching national goals

# Current Environment

## ▶ PrEP is not Just the Drug

- People must be aware of PrEP
- Providers must prescribe it
- PrEP requires prescription, follow-up visits, periodic labs & adherence

## ▶ Drug Costs should not be the Problem

- Zero cost-sharing as a preventive service
  - Includes medical visits & labs
  - Recognize ongoing issues & Medicare gap
- Free drug programs by companies & Ready, Set, PrEP
- Generic oral
- Pending USPSTF finalized recommendation & Medicare coverage determination for long-acting PrEP

# Current Environment

## ▶ **Additional issues**

- Ryan White Program, by law, cares for people living with HIV, not those at risk of HIV
- High number of people eligible for PrEP are uninsured
- No National PrEP Program to support PrEP outreach & pay for Rx's, medical visits & labs

## ▶ **Some states have set up PrEP Drug Assistance Programs**

# Current Federal Government Activities

- ▶ PrEP is a central pillar of *Ending HIV Epidemic* initiative & National HIV/AIDS Strategy
- ▶ CDC
  - Highlights PrEP in communications & grant programs
  - Section 318 STD clinic grants
    - Can utilize 340B
  - Allows states to pay for ancillary services but not drugs
    - Little reporting & data
- ▶ SAMHSA, Indian Health Service, others
- ▶ Community Health Centers

# Ending the HIV Epidemic in the U.S. (EHE) Primary Care HIV Prevention (PCHP) Funding

## Purpose & Award History

To expand prevention services that decrease the risk of HIV transmission - including use of PrEP, testing, outreach, and care coordination – to health centers in the 57 EHE geographic jurisdictions.

**FY 2020\***: \$54 million to support **195 health centers**

**FY 2021**: \$38 million to support **107 health centers**

**FY 2022**: \$20 million to support **64 health centers**

**FY 2023**: \$35 million to support **≈100 health centers**

**TOTAL: \$147 MILLION TO SUPPORT ≈466 HEALTH CENTERS**

## Funding Objectives



Increase the number of patients counseled and tested for HIV.



Increase the number of patients prescribed PrEP.



Increase the percentage of patients newly diagnosed with HIV who are linked to care and treatment within 30 days of diagnosis.

# Health Centers and HIV Prevention

## HRSA's Health Center Program's Primary Focus in the EHE-PCHP Initiative includes:



Expanding HIV prevention services, including outreach, care coordination and;



Access to Pre-Exposure Prophylaxis (PrEP)-related services to people at high risk for HIV transmission through selected health centers in the identified jurisdictions.

- Conducted over **1.7 million** HIV tests
- Provided PrEP to **52,477** patients through more than **123,000** clinic visits
- Linked **86%** of newly diagnosed patients to care within **30** days

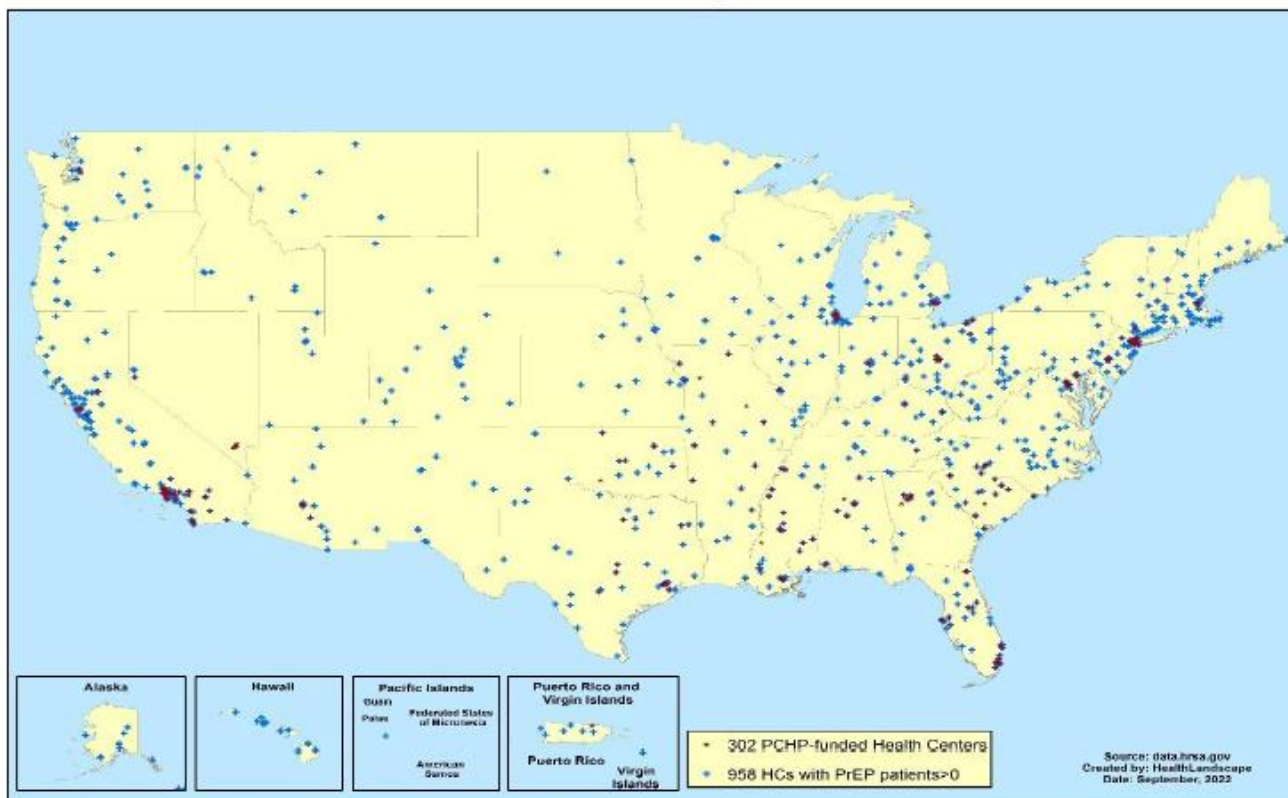
Source: 2021 Uniformed Data System (UDS)

Source: 2021 Uniform Data System (UDS).



# Ending the HIV Epidemic – Health Center Progress

*Health centers deliver critical primary care and HIV prevention services. In 2021, 958 of the overall health centers provided PrEP, including 302 that were PCHP-funded.\**



## The overall 958 Health Centers

- Served over **25 million** total patients
- **65%** racial or ethnic minorities
- Conducted nearly **3 million** HIV tests
- Provided PrEP to **79,163** patients
- Linked **83%** of newly diagnosed patients to care within 30 days

## 302\*\* PCHP-Funded Health Centers

- Served nearly **9 million** patients
- **79%** racial or ethnic minorities
- Conducted over **1.7 million** HIV tests
- Provided PrEP to **52,477** patients
- Linked **86%** of newly diagnosed patients to care within 30 days

Source: 2021 Uniform Data System (UDS).

\*Pre-exposure prophylaxis (PrEP), Ending the HIV Epidemic - Primary Care HIV-Prevention (PCHP) funding.

\*\*FY 2020-21 PCHP-funded Health Centers (HCs) only (FY 2020 = 195 HCs awarded, FY 2021 = 107 HCs). An additional 64 HCs received PCHP funding in FY 2022.





# President Biden Proposal

- ▶ **Proposed National PrEP Delivery Program FY23 & FY24**
  - 10-year \$9.8 billion mandatory spending program (FY24: \$237 million)
  - Provide no-cost Rx & associated services
  - Capped reimbursement for Rx & associated services
  - Generic & non-generic when medically authorized
  - Expand network of providers, including Ryan White Program
  - Provide grants to wide range of clinics
  - Fund provider and community outreach
  - Eliminate PrEP barriers in Medicaid (savings of \$10.2 billion)
  - Must be authorized by Congress, set up & implemented

# Congressional Response – 117<sup>th</sup> Congress

- ▶ **PrEP Assistance Program Act ([HR 5605](#))**
  - ▶ Rep. Bonnie Watson Coleman (D-NJ)
  - ▶ Establishes \$400 million/year grant program for:
    - Community & provider outreach
    - PrEP & associated services for uninsured & underinsured
- ▶ **PrEP Access and Coverage Act ([S 3295](#), [HR 6117](#))**
  - ▶ Sen. Tina Smith (D-MN) & Rep. Adam Schiff (D-CA)
  - ▶ Zero cost-sharing coverage by all payers
  - ▶ Grant programs for clinics, community & provider outreach

# Budget & Appropriations

## ▶ FY23

- ▶ **Community Health Centers:** +\$35 million
- ▶ **CDC EHE:** +\$25 million
- ▶ **CDC Report Language:** Recognizes importance of PrEP & addressing inequities

## ▶ President's FY24 Budget

- ▶ **Community Health Centers:** +\$15 million
- ▶ **CDC EHE:** +\$90 million

# Federal Funding Needed for National PrEP Program

- ▶ **HIV+Hep** wished to model the federal funding needed to build a national PrEP Program that builds on current system & meets goals of the National HIV Strategic Plan for all racial and ethnic groups
- ▶ Contracted **RTI International**
- ▶ Model is not perfect: used one set of assumptions, which can be altered



# U.S. PrEP Cost Analysis

# Purpose

- Estimate the costs of expanding access to pre-exposure prophylaxis (PrEP) medications and services in the United States
  - Focus on costs for individuals whose PrEP medications and related services are not covered by third party payers (e.g., private health insurers, Medicaid, and Medicare) or by federal and drug manufacturer cost assistance programs
- Include outreach costs to reach PrEP-eligible populations and navigation costs for patient initiation in and adherence to PrEP
  - Approach for assessing PrEP-related costs accounts for practical realities of how clinics are currently supporting and expanding PrEP use and builds on existing systems to provide support for missing elements

# Existing funding sources for PrEP

Funding Source	Eligibility Criteria	PrEP Drugs	Outreach	Ancillary Services
<b>Ready, Set, PrEP (federal PrEP programs)</b>	Patients must lack prescription drug coverage, test negative for HIV, and have a prescription for PrEP.	Truvada or Descovy are free eligible individuals.	No	No
<b>Gilead Advancing Access Program (manufacturer assistance program)</b>	Serves the uninsured and commercially insured. The household income limit is 500% of the Federal Poverty Level (FPL)	Truvada and Descovy are free for the uninsured. A rebate of up to \$4,800 per year is available for commercially insured patients at 340B sites.	No	No
<b>ViiV Healthcare Patient Assistance Program (manufacturer assistance program)</b>	Serves uninsured and some patients with Medicare or commercial insurance depending on their prescription drug coverage. Patients must be ineligible for Medicaid. The household income limit is 500% of the FPL.	Apretude is free for eligible patients. The manufacturer also offers an Apretude savings program for some commercially insured patients for up to \$7,500 per calendar year.	No	No
<b>340B PrEP programs</b>	Individuals receiving 340B drugs must be a patient of a covered entity under the 340B Drug Program as defined by HRSA.	Covered entities purchase drugs at a 340B discount with a financial incentive to prescribe brand name oral PrEP over generic versions.	Most 340B providers cover outreach and linkage to care services using 340B revenue.	Most 340B providers cover lab services and clinic visits using 340B revenue.
<b>CDC HIV prevention funding</b>	None/based on project	No. CDC policy prohibits the use of most HIV prevention funding for PrEP drugs.	CDC funds a wide range of HIV prevention providers to conduct outreach and education services.	Up to 15% of CDC funding can be used for ancillary services
<b>State PrEP Assistance Programs</b>	Patients must live in the state and there are some restrictions based on income level and insurance status. Programs serve the uninsured and under-insured.	States with PrEP assistance programs cover PrEP drug costs.	No	Most state programs cover lab services and clinic visits.



# Methods



# Determining PrEP-eligible by transmission group and insurance status

- No single source had data on the number of people eligible for PrEP by transmission group and insurance status; we started with AHEAD numbers by age group & sex
- **PrEP-eligible population by transmission group**
  - PrEP-eligible population by transmission group was calculated in 2015 (Smith et al., 2017)
  - Used the current PrEP-eligible population (AHEAD, 2019) and applied transmission group percentages from Smith et al. (2017)
- **Determining PrEP by insurance status and transmission group (from the prior step)**
  - **Medicare:** assumed that all 65+ had Medicare coverage; used surveillance data by age at diagnosis to determine percentage of 55+ years that were 65+
  - **Medicaid:** determined the percentage of each transmission group that was below the Federal Poverty Level from three separate CDC reports. Then used the Smith et al. data by state and transmission group and included the eligible population for each state that had expanded Medicaid
  - **Uninsured:** determined the percentage of each transmission group that had no health insurance from the same three separate CDC reports as for Medicaid
  - **Privately Insured:** subtracted out the Medicare, Medicaid, and uninsured populations from the PrEP-eligible population

## Results for number of PrEP-eligible individuals in 2019, adjusted to match AHEAD estimates

Insurance status	MSM	HET	PWID	Total
Medicare (65+ only)	20,452	6,484	1,822	28,759
Medicaid	95,836	140,769	43,566	280,171
Uninsured	156,552	64,989	20,268	241,809
Privately insured	592,090	61,973	11,408	665,472
<b>Total</b>	<b>864,931</b>	<b>274,216</b>	<b>77,063</b>	<b>1,216,210</b>

# Number of PrEP-eligible people by risk, race/ethnicity, and insurance status

- Started with surveillance estimates of the number of people eligible for PrEP by race and ethnicity in 2019
- Estimated the percentage of each race/ethnicity subgroup in each of the 4 insurance categories using data from the Kaiser Family Foundation
- Compared with representation in the U.S. adult population to estimate percentages of each race and ethnic group in each insurance category so that the total closely matched our estimated numbers eligible for PrEP by insurance category
- Our estimated allocations across insurance category vary by race and ethnicity, but are assumed not to change over the analysis period
  - For example, the percentage of the PrEP-eligible population covered by Medicaid is 30% for Black, 22% for Hispanic, 15% for White, and 20% for other races.

# Number of People Using PrEP

- Started with surveillance estimates from AIDS Vu of the number of people using PrEP by race and ethnicity in 2021
- Allocated individuals across transmission groups and insurance categories using data from AHEAD and Chan et al. (2020)

# Annual PrEP drug and ancillary services cost

- **PrEP drug costs:**
  - Brand name oral PrEP: based on April 2022 FSS daily drug acquisition cost for Truvada and Descovy, adjusted to 2021\$
  - Generic oral PrEP: based on the monthly wholesale acquisition price of \$30/month for FTC/TDF
  - Injectable PrEP: based on initial December 2021 list price of \$3,700/dose, or about \$22,200 per year
- **Ancillary costs:** from Shrestha et al. (2022); include PrEP-related clinic visits and laboratory testing
- **Gradual uptake of PrEP:** model default achieves the 50% EHE goal by 2027 and maintains this level of PrEP coverage through 10 years
  - Increase in use of long-acting PrEP from 20% of all users by year 5 up to 80% by year 10
  - For users of oral PrEP, shift to generic so that 75% of oral PrEP use is generic by year 10.

## Data sources for outreach and navigation costs

- No estimates were available in the literature for costs of outreach to providers and the community or for navigation that were specific to PrEP
- Interviewed representatives from 2 health centers, 3 clinics, and 1 jurisdiction across the U.S. through video calls during July and August 2022
- Participants were informed at the start of interviews that their names and organizations would not be identified
- Purpose was to fill gaps in the literature on PrEP costs and barriers to PrEP uptake
- Used this information to guide our assumptions around how much assistance entities that provide PrEP may need to expand PrEP outreach and navigation services and to develop assumptions around which types of health centers, clinics, and other entities may need support

# Assumptions related to outreach and patient navigation for PrEP

- Assumed to build on existing funding for clinics, health centers, clinics, CBOs, and other entities, including a variety of 340B providers
- HRSA grants of \$325,000 to cover PrEP medications, ancillary services, and strengthen community partnerships will be expanded to 500 Ryan White HIV/AIDS Program city, state, clinic, and CBO awardees
  - Current funding of about \$325,000 per health center has been awarded to 366 health centers in fiscal years 2020, 2021, and 2022
- 75% of U.S. Community Health Centers will require funding levels of \$325,000 per year to expand and sustain PrEP for under-reached populations
- 1,200 STI, family planning, Indian Health Service clinics and CBOs will require funding of \$125,000 per year to expand and sustain PrEP to populations that might otherwise not be reached
- Total outreach cost estimates anticipate annual allocations of \$172 million per year to support the Health Center Program at HRSA; this anticipated annual allocation is subtracted from the estimates of annual PrEP assistance needs

# HIV incidence—Impact of PrEP

- Estimated HIV incidence among people who use PrEP was based on calculations reported in Davis et al., 2022
- We used estimates of HIV incidence of 3 per 100 person-years for people who do not use PrEP and 1.72 per 100 person years for people who use PrEP
  - HIV incidence estimates do not vary by transmission group, PrEP formulation, or other observable characteristics





# Results

# Summary of interview takeaways

PrEP-Eligible Patient Population	PrEP Drugs	PrEP Ancillary Services	PrEP Outreach to Providers and Community, Patient Navigation, Adherence Services
<ul style="list-style-type: none"> <li>• Health centers and clinics in Medicaid expansion states usually had a smaller proportion of uninsured patients than clinics in non-Medicaid expansion states</li> <li>• Clinics may purchase Affordable Care Act health insurance plans for uninsured patients</li> <li>• Stigma may prevent patients from using PrEP and some insured pay for PrEP out-of-pocket due to privacy concerns</li> <li>• Cultural and linguistic barriers may limit PrEP access</li> </ul>	<ul style="list-style-type: none"> <li>• Health centers and clinics primarily prescribe generic and branded oral PrEP, though the share between generic and branded drug varied considerably</li> <li>• The interviewed health centers and clinics do not prescribe long-acting PrEP because it may not be covered by insurance</li> <li>• Eligible health centers, clinics, and jurisdictions rely to some degree on 340B revenue to purchase PrEP drugs</li> <li>• Many health centers and clinics do not routinely enroll clients in Ready, Set, PrEP or manufacturer drug assistance programs because they do not receive funding for the resource and staff time required</li> </ul>	<ul style="list-style-type: none"> <li>• Most state PrEP drug assistance programs cover ancillary services for uninsured patients</li> <li>• Health centers and clinics tended to rely on 340B revenue to provide ancillary services or insurance plans that cover these services to uninsured patients</li> <li>• Clinics that are not federally qualified health centers have fewer existing funding options</li> <li>• Health centers and clinics differ in how much they are impacted by reduced 340B revenue</li> <li>• Health centers and clinics are resourceful with combining existing funding sources to provide ancillary services to uninsured patients</li> <li>• One jurisdiction described a safety net telehealth program to provide ancillary services at no cost to uninsured patients</li> </ul>	<ul style="list-style-type: none"> <li>• Health centers, clinics, and jurisdictions pay for outreach, patient navigation, and adherence services using grants from HRSA, the CDC, states, and cities</li> <li>• One jurisdiction described the state health department's centralized navigation services for PrEP</li> <li>• One health center noted that outreach efforts need to be actionable and sustainable</li> <li>• Health centers and clinics emphasized the importance of funding to invest in hiring and training staff</li> <li>• One clinic uses a mobile van for outreach to PrEP-eligible people</li> </ul>

# Cost calculator output

- **PrEP costs**

- Total PrEP program costs/year and cumulatively for up to 10 years
- PrEP costs by payer type and race/ethnicity by year and cumulatively for up to 10 years
- PrEP costs by category of spending for up to 10 years (e.g., drug costs, ancillary costs, outreach and navigation costs)

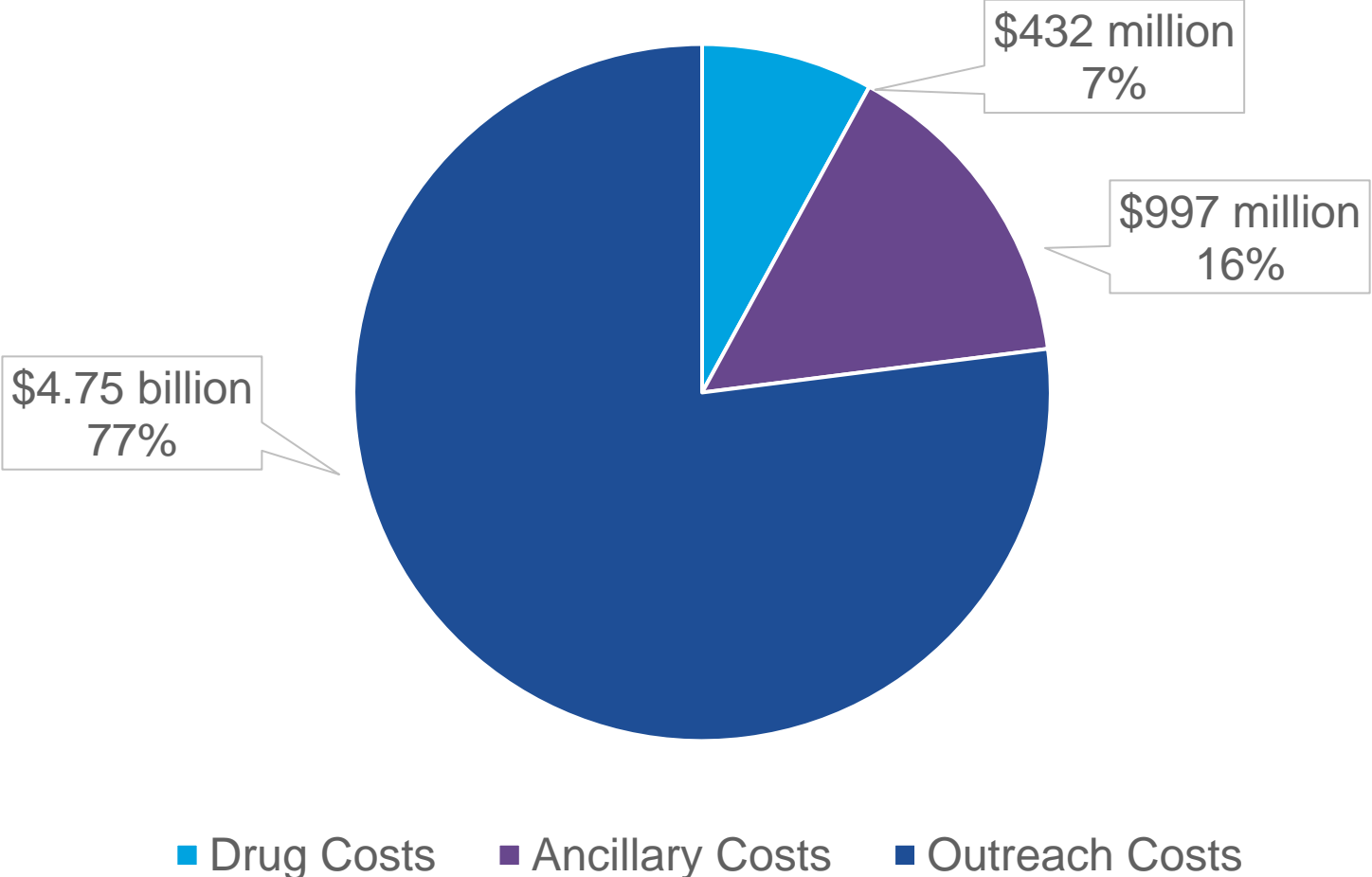
## Estimated number of people using PrEP by payer type and race/ethnicity, 2022

	Black	Hispanic	White	Other Race	All Race/ Ethnicities
Medicare	2,572	2,705	9,764	787	15,828
Medicaid	17,144	12,012	27,179	3,841	60,177
Private Insurance	53,414	52,857	183,523	17,923	307,718
Uninsured	9,817	11,486	15,738	2,270	39,310
All Payer Categories	82,947	79,060	236,205	24,821	<b>423,032</b>

# Number of person-years of PrEP use by payer type and race/ethnicity 2022 through 2031

Number of Person-Years among those Eligible for PrEP*	Black	Hispanic	White	Other Race	All Race/ Ethnicities
Medicare	42,309	31,210	98,173	12,045	183,739
Medicaid	570,331	290,094	273,268	108,376	1,242,069
Private Insurance	1,025,073	678,234	1,845,198	368,540	3,917,044
Uninsured	340,789	392,447	230,343	69,764	1,033,341
<b>All Payer Categories</b>	<b>1,978,502</b>	<b>1,391,984</b>	<b>2,446,982</b>	<b>558,725</b>	<b>6,376,193</b>

Estimated % of total PrEP costs over 10 years, by cost category



## Estimated PrEP costs by category and payer type, 2022 (2021\$)

By payer	PrEP drugs	Ancillary services	Outreach & PrEP navigation	Total
Medicare	\$739,582	\$153,215	N/A	
Medicaid	\$0	\$0	N/A	
Private insurance	\$0	\$0	N/A	
Uninsured	\$6,771,247	\$38,274,405	N/A	
<b>All payer categories</b>	<b>\$7,510,830</b>	<b>\$38,427,620</b>	<b>\$475,168,750</b>	<b>\$521,107,200</b>

## Cumulative estimated PrEP costs by category and payer type over 10 years (2021\$)

By payer	PrEP drugs	Ancillary services	Outreach & PrEP navigation	Total
<b>Medicare</b>	\$10,626,990	\$1,669,267	N/A	
<b>Medicaid</b>	\$0	\$0	N/A	
<b>Private insurance</b>	\$0	\$0	N/A	
<b>Uninsured</b>	\$421,628,704	\$995,028,874	N/A	
<b>All payer categories</b>	<b>\$432,255,694</b>	<b>\$996,698,141</b>	<b>\$4,751,687,500</b>	<b>\$6,180,641,335</b>



## Cumulative estimated PrEP costs by category and race/ethnicity over 10 years (2021\$)

By race/ethnicity*	PrEP drugs	Ancillary services	Outreach & PrEP navigation	Total
<b>Black</b>	\$147,898,819	\$337,287,892	N/A	
<b>Hispanic</b>	\$169,004,498	\$388,242,029	N/A	
<b>White</b>	\$97,567,666	\$228,664,080	N/A	
<b>Other</b>	\$30,301,562	\$69,080,321	N/A	
<b>All races/ethnicities</b>	\$444,772,545	\$1,023,274,321	\$4,751,687,500	<b>\$6,219,734,366</b>

# Estimated person-years of HIV infections averted over 10 years

	Men who have sex with men	Heterosexuals	People who inject drugs	All transmission groups
Person-years of infections averted	53,513	14,692	6,335	74,540



# Conclusions

# Summary of Findings: Costs for a National PrEP Assistance Program

- We calculated the costs of expanding PrEP access to achieve the EHE PrEP goals of getting half of individuals eligible for PrEP into PrEP care within 5 years and maintaining the care levels through 10 years. Our main findings are as follows:
  - To achieve the goal of moving half of eligible individuals into PrEP in 5 years, estimated costs would be **\$521 million in 2022 and \$6.18 billion over a 10-year period.**
  - Reducing racial and ethnic disparities in the percentage of eligible people who are using PrEP to achieve EHE goals by race and ethnicity will require rapid increases in the use of PrEP among Black, Hispanic, and other race subpopulations.
  - The cost of achieving racial and ethnic goals would be somewhat higher than the costs to achieve EHE goals without addressing disparities, with costs of approximately **\$6.22 billion over 10 years.**

# Limitations

- Allocated the PrEP-eligible population and the numbers using PrEP across 4 insurance categories using data from disparate sources due to limitations in what each source reports
- Limited data on PrEP outreach and navigation costs meant that we needed to talk with on-the-ground providers to assess their coverage needs for expanding PrEP, but costs vary across entities based on whether the state expanded Medicaid, whether the entity has access to federal funding that can be used for ancillary and outreach/navigation services, and whether the entity is a 340B provider
- Baseline analysis made assumptions about how the brands/formulations of PrEP used will likely change over the 10-year period of analysis and assumed that the maximum coverage achieved is 50% of those eligible for PrEP by insurance category or by race/ethnicity

# Conclusions

- Analyses suggest that a **national PrEP assistance program would cost about \$521.1 million in its first year of operation** and \$6.18 billion to \$6.22 billion over a 10-year period.
- The **largest share of costs needed for expanding PrEP to achieve EHE goals is for PrEP outreach and navigation** (77% of total estimated costs)
  - Drug and ancillary services costs account for a smaller share of total costs than outreach and navigation (7% and 16%, respectively)

# Next Steps

- ▶ **Updating model** to adjust number of HIV cases averted to correspond with projected uptake in long-acting PrEP
- ▶ **Continued outreach** to educate community, policy makers, media etc. on the need for a National PrEP program, a way to build it and funding needed
- ▶ Can **adjust assumptions** and update over time
- ▶ **Help to achieve FY24 \$200 million PrEP ask for CDC**

# Additional Immediate Steps

- ▶ **CDC FY23 spend plan:** Urge large part of \$25 million increase for PrEP community & provider outreach and targeted grants, particularly Ryan White funded clinics that are not community health centers & others
- ▶ **CDC existing funding:** Urge CDC and grantees to spend more existing dollars on PrEP services and greater accountability, data and reporting
- ▶ **Community Health Centers:** Need better data on who is on PrEP & urge Congress to increase funding in FY24 by \$50 million
- ▶ **Protect 340B & ACA preventive services**



# U.S. PrEP Cost Analysis

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[https://hivhep.org/wp-content/uploads/2022/11/PrEP\\_Cost\\_Final\\_Report\\_21November2022.pdf](https://hivhep.org/wp-content/uploads/2022/11/PrEP_Cost_Final_Report_21November2022.pdf)



# Thank you!

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