

Policy Advocacy for PrEP Access: Lessons from the Field <u>Moderator</u>: Damián Cabrera-Candelaria <u>Presenters</u>: Jeremiah Johnson, PrEP4All Noelle Esquire, Elton John AIDS Foundation

Continuum 2024 · June 9-11, 2024 · Puerto Rico



#### + •

### Overview of Current PrEP Policy Priorities







M2024



SIGN ON: An Appeal to the Biden Administration Regarding Mpox Preparedness



## About PrEP4All

 Mission: We ignite political action to put lifesaving medication into the hands of everyone who needs it. <u>www.PrEP4All.org</u>

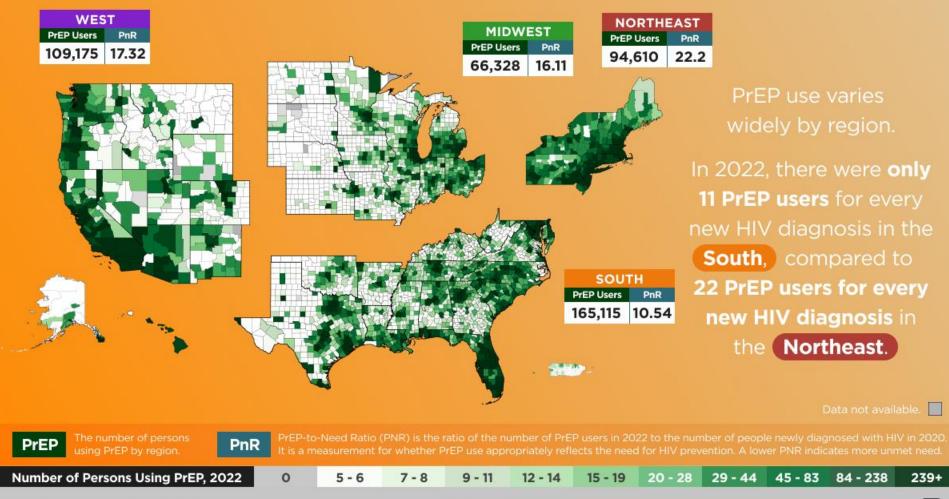
Jeremiah Johnson (He/Him), MPH, Executive Director.
 Jeremiah@PrEP4All.org





# Some Current PrEP Policy Priorities

- A National PrEP Program for un- and underinsured
  Protecting our existing infrastructure
  - (#SaveHIVFunding)
- *Braidwood v. Becerra:* Protecting PrEP coverage for the insured
- Improving coverage compliance among insurers
   Expanding access points through pharmacist-provided PrEP



AIDSVu.ORG | y @AIDSVu

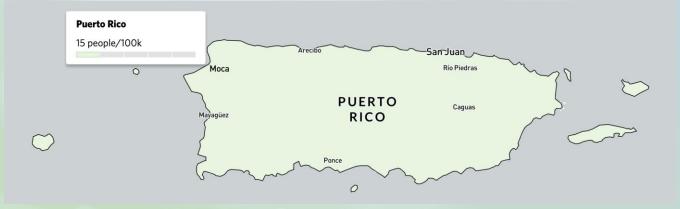
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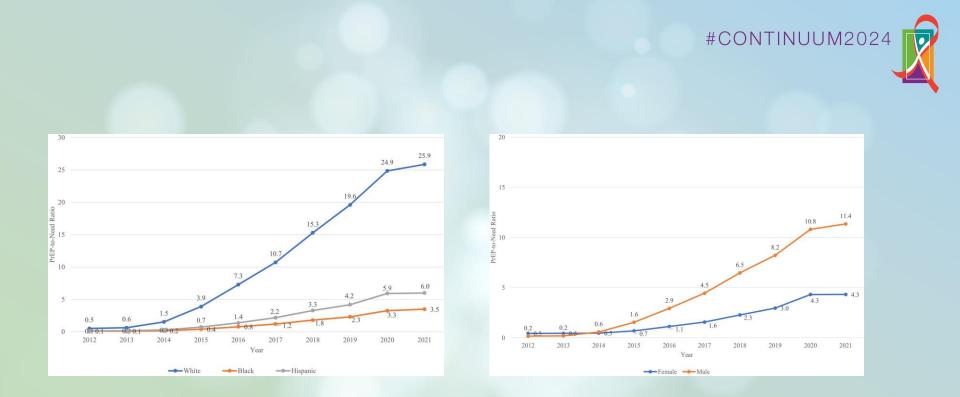
#### Jurisdictions with lowest PrEP uptake in the U.S. (AIDSVu 2022)

i. South Dakota – 41 in 100k
ii. Wyoming – 47 in 100k
iii. West Virginia – 61 in 100k
iv. Mississippi – 67 in 100k
v. Wisconsin- 67 in 100k

vi. Kentucky – 78 in 100k vii.Alabama – 80 in 100K viii.Michigan – 85 in 100k ix. South Carolina – 86 in 100k x. Maine – 89 in 100k

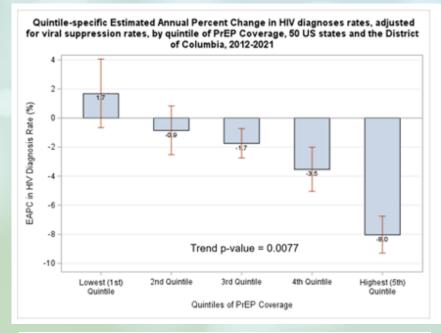


#CONTINUUM2024



Sullivan, Patrick S., et al. "Equity of PrEP uptake by race, ethnicity, sex and region in the United States in the first decade of PrEP: a population-based analysis." The Lancet Regional Health–Americas 33 (2024).

### Increasing Urgency to Address Inequitable PrEP Uptake



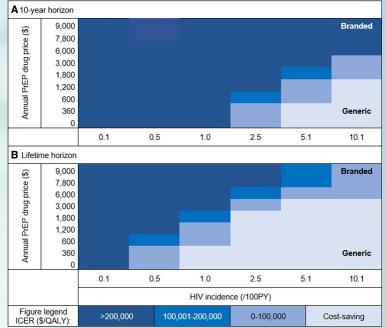
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Sullivan P et al. *Association of State-Level PrEP Coverage and State-Level HIV Diagnoses, US, 2012-2021.* Conference on Retroviruses and Opportunistic Infections, Denver, abstract 165, 2024.



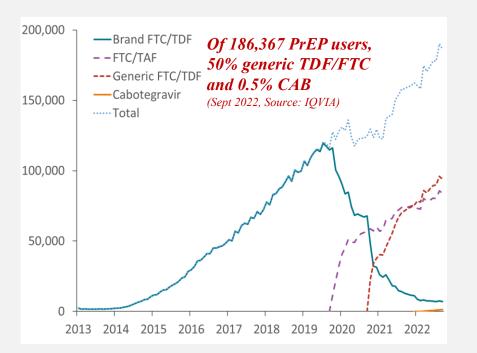
# A Cost Saving Intervention

- PrEP can be prescribed for as little as \$26/month/per person averting an HIV infection with a lifetime cost of at least \$500,000 per person
- In our 2022 proposal, we estimate that six thousand monthly prescriptions would cost less than \$500,000.
- At 35,000 new infections per year, we add approx \$17.5B in healthcare costs annually
- A <u>recent analysis</u> out of Mass General Hospital looking at costs of PrEP for young MSM found that "generic oral PrEP and every-3-month screening would be cost-saving compared with annual screening alone, even with high discontinuation and low adherence, over a range of HIV incidences."



Amick AK, et al. Daily Oral HIV Pre-exposure Prophylaxis Among Young Men Who Have Sex With Men in the United States: Costsaving at Generic Drug Price. Clin Infect Dis. 2024 Feb 17;78(2):402-410. doi: 10.1093/cid/ciad566. PMID: 37823865; PMCID: PMC10874274.

### **PrEP Prescribing in the United States**



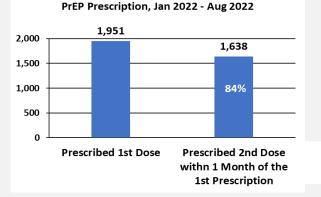
 <u>186,367 persons were prescribed</u>

 <u>PrEP (Sept 2022):</u>

 Generic FTC/TDF: 93,808

 Zhu W, et al. Or (50,3 e ) b u e in the U.S., 2013-2022. CROI 2023 Abstract #980

	Oral PrEP		Injectable PrEP		
	N	%	N	%	
Total	381,883		2,695		
Sex					
Male	355,087	93.0	2,359	87	
Female	26,697	7.0	336	12	
Unknown	99	0.0	0	0	
Age					
13-24	46,814	12.3	369	13	
25-34	150,864	39.5	1,111	41	
35-44	96,243	25.2	698	25	
45-54	47,668	12.5	297	11	
55-64	31,427	8.2	149	5	
65+	8.867	2.3	71	2	



Number of People Who Received a CAB-LA

# A National PrEP Program: What are 24 we asking for?

#### **PrEP** Pass

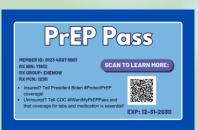
- Build simplified federal reimbursement mechanisms that leverage existing pharmacy supply and payment mechanisms and laboratory networks.
- The system needs to cover labs, medications, and provider visits related to PrEP.
- Help to save time for providers, pharmacies, and patients in navigating reimbursement for un- and under-insured individuals

#### **Provider Network Expansion**

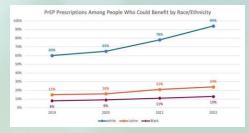
- Need for additional prescribing sites: pharmacies, STD clinics, etc.
- Grant program that could establish "hub & spokes administrators"
- An expanded nonclinical network can leverage telePrEP in a way that allows immediate virtual access to a prescribing provider as well as act as a traditional referral system for patients who prefer in person clinical visits.

#### **Demand Creation**

- A need for several novel approaches to awareness and demand creation. Pharmacies can do a lot here.
- For community-led messaging, contract with an experienced PR/marketing firm that specializes in deep partnership with communities most in need of PrEP
- National and locally-tailored campaigns







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## **Progress Towards National Access**



### July 2018- PrEP4All releases white paper

Dec 2021- JHU releases policy proposal

Mar 2022- Biden FY23 Budget Request released (includes \$9.8B mandatory spending "PrEP for All" program)

June 2022- NPP Working Group sends letter for \$400M discretionary ask

Sept 2022- PrEP in Black America summit

**Dec 2022**- \$25M increase for CDC/DHP Ending the HIV Epidemic funding secured + report language **Feb 2023**- PIBA releases the Roadmap

Feb 2023- follow up call with CDC, and letter on additional specificity sent Mar 2023- FY24 Budget Request released

May 2023- WH surprises us with a hard push for a revised "NP3" proposal, first publicly presented at PIBA Summit N.O. June 2023- We receive slides and a handout on revised proposal; work with coalition to coordinate discretionary request

July 2023- Major FY24 HIV cuts proposed in the House, Senate reverses and mentions NPP

**Sept 2023**-PrEP4All, AVAC, HIVMA, and PrEP In Black America meet with Neera Tanden at White House

### Recent Work with the Biden Administration

- September meeting with Neera Tanden
  - Emphasis on existing resources
- November meeting with OMB
  - Inclusion of \$9.8B, 10-year NPP in FY25
- December meeting with Dr. Cohen
- February and April meetings with CDC
  - Commitment to an NPP pilot in two jurisdictions
  - Data transparency
  - Additional meetings to be had, incl with other HHS agencies
    - What to do about *Ready*, *Set*, *PrEP*?



#CONTINUUM2024

### Sign on to our FY25 Funding #CONTINUUM2024 Request Letter [For Organizations]

Calling for \$100M in FY25 discretionary funding to continue to develop a National PrEP Program

#### bit.ly/npp-orgs2024



### **#SaveHIVFunding Campaign**

- PrEP4All initiated campaign, close coordination with AVAC, HIVMA, and PrEP in Black America
- Funding from Elton John AIDS Foundation
- Expanded by Federal AIDS Policy Partnership, further funding from BC/EFA
- Sept Press Conference
- <sup>o</sup> World AIDS Day Ad Buys/Campaign
- February/March Ad Buys

TELL OUR LEADERS THIS WORLD AIDS DAY #SAVEHIVFUNDING

Our leaders in the House are calling for \$767 million in cuts to HIV funding in the U.S.

Make your voice heard by telling your representatives to #SaveHIVFunding!

Visit: <u>bit.ly/savehivfundingnow</u>



#### **Basic Facts (From Lambda Legal)**

- The plaintiffs are Braidwood Management, a for-profit closely held organization, owned by a trust, with Dr. Hotze, a religious Christian, as the sole trustee and beneficiary.
  - Braidwood is self-insured and provides health insurance it its 70 employees.
- The other plaintiff is Kelley Orthodontics, a Christian professional association owned by plaintiff John Kelley
- 6 private individuals who purchase insurance some with religious objections, some who don't have religious objections
- The plaintiffs claim that requiring them to purchase insurance the covers preventative health services violates various rights.
- The US Dept of Health and Human Services and Health Secretary are the defendants.

### RECAP FROM CHLPI: KEY RULINGS IN THE DISTRICT COURT

- ACA § 2713 requires full coverage of preventive services recommended by USPSTF, ACIP, and HRSA.
- Plaintiffs challenged mandate to cover all services.
- District Court held:
  - 1) Requirement to cover services recommended by USPSTF on or after March 23, 2010, violates the Appointments Clause
  - 2) Requirement to cover PrEP violates religious plaintiffs' rights under the Religious Freedom Restoration Act (RFRA).

### WHAT'S HAPPENING NOW: FIFTH CIRCUIT APPEAL024

- Both sides appealed to the Fifth Circuit.
  - Defendants want to reverse the lower court's two main rulings—but the Plaintiffs want a decision that does *more* damage to the ACA.
  - Bottom line: appeal could impact coverage of USPSTF, ACIP, and HRSA recommended services.
- Next steps: Waiting to see outcomes from briefing and March 2024 oral arguments at the Fifth Circuit, possibly followed by appeal to Supreme Court.

# **Insurer** Compliance

The AIDS Institute examined insurance plan documents for insurance plans available on the 2024 Health Insurance Marketplace to determine how insurance plans are communicating their coverage of PrEP and its related services.

- 13% of marketplace health insurance plans in 2024 do not clearly indicate on their formulary that at least one PrEP drug is available without a copayment;
  30% of plans do not include PrEP on a preventive service list;
  66% of plans do not include any information about the availability of cost-free PrEP-related provider visits, labs, and
- screenings; and
- 71% of plans have no detail about which labs, screenings, or provider visits are covered without cost.

Read the full report here: https://bit.ly/3UCBCpv





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#### Pre-Exposure Prophylaxis

Coverage, Compliance, and Ending the HIV Epidemic

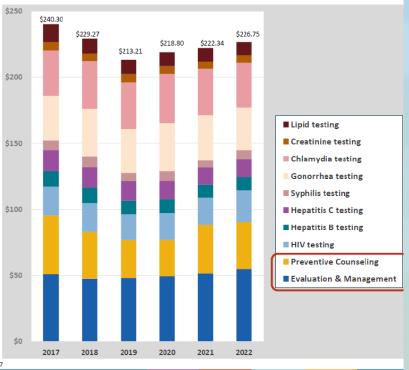
2024

#### **Out-of-Pocket Payments**

Payments have decreased over time

1 out of 3 commercially-insured persons were charged cost sharing for PrEP services despite ACA financial protections (2022)

~50% of service costs were for the provider visit (see red box)



Huang YA, et al. Out-of-pocket payments for PrEP ancillary services 2017-2022. CROI 2024 Abstract #1117

Slide provided by Rupa Patel, MD, MPH

RESEARCH ARTICLE HIV/AIDS

HEALTH AFFAIRS > VOL. 43, NO. 1: PHARMACEUTICALS, OPIOID USE, HEALTH SPENDING & MORE

DNTINUUM2024

Estimating The Impact Of Out-Of-Pocket Cost Changes On Abandonment Of HIV Pre-Exposure Prophylaxis

<u>Lorraine T. Dean, Amy Stewart Nunn, Hsien-Yen Chang, Shivani Bakre, William C. Goedel, Rahel Dawit,</u> <u>Parya Saberi, Philip A. Chan, and Jalpa A. Doshi</u>

AFFILIATIONS V

- PrEP "abandonment rates" 5.5% at \$0
- Increase in cost from \$0 to \$10 doubled the rate of "abandonment"
- HIV diagnoses 2 to 3 times higher among people who did not pick up their PrEP prescriptions than among those who filled them



### **Specific Challenges for Puerto Rico**

#### Background

- 1 in 2 enrolled in Plan Vital
- Chaotic underfunding and reduced services
- Mandatory spending reductions implemented in 2018
- 72 of 78 municipalities "medically underserved areas"
- 32 "primary care shortage areas"



#### Gustavo Adolfo Morales Correa | Deputy Director of Programs

Latino Commission on AIDS E: gmorales@latinoaids.org | W: www.oasiscenter.nyc M: +1 646-238-4578 | W: +1 917-438-0698



### #CONTINUUM2024 Draft Policy Priorities for Puerto Rico (courtesy of Latino Commission on AIDS)

- Provider Education: Require CME credits on PrEP for providers.
- <u>PrEP Access</u>: Eliminate cosignatory requirements to PrEP access.
- PrEP Access: Extend access to PrEP to the existing exclusion of parental consent for diagnosis and treatment of STI in minors.
- PrEP Coverage: Achieve Medicaid parity in Puerto Rico compared to U.S. States by eliminating funding caps
- Prevention Focused Approach: Expand the availability of evidencebased proven practices in HIV prevention.

#CONTINUUM2024



## **#PrEPSaves PrEP Users' Union**

- *#PrEPSaves Storybank* to collect stories of members for use in future campaigns and news media to influence policymakers.
- *Direct Advocacy* to put members directly in communication with key stakeholders to discuss HIV policy issues.
- Level-Setting Discussions to ensure that PrEP4All and all P2U members are on the same page when it comes to the policy landscape for PrEP access and the barriers being faced by PrEP users around the nation.

#### **#PrEP**Saves PREP USERS' UNION

#### Join Today!

PrEP4All is recruiting a diverse group of current and former PrEP users to join our #PrEPSaves PrEP Users' Union to engage media and impact key HIV policy discussions!

Find out how to become a member at: prep4all.org/prepsaves Contact: michael@prep4all.org

🏅 PrEP4All



# **JP REACH**

PHARMACIES EXPANDING ACCESS TO COMMUNITY HIV SERVICES

#### Funding Partner:



Managing Partner:



#### Core Partners:

Appha American Pharmacists Association For Every Pharmacist, For All of Pharmacy.





#### Allied Partners:

- AIDS United
- The AIDS Institute
- Avita Care Solutions
- Frannie Peabody Center
- NASTAD
- NMAC
- Southern AIDS Coalition
- U.S. Business Action to End HIV





### **Elton John AIDS Foundation: U.S. Strategy Objectives**

Enhance health workforce capabilities to provide compassionate care and support for people with HIV and people who want to prevent HIV infection

**Increase accessibility** of and **demand for** commodities related to HIV prevention, care and treatment, sexual and reproductive health, and harm reduction.

**Reduce stigma** around HIV and discrimination against people with HIV, LGBTQ+ and people who use drugs.

Participate in opportunities for **policy change** to create a more supportive and enabling environment for priority populations to safely access the HIV prevention, care and treatment, sexual and reproductive health, and harm reduction services they need.

#### #CONTINUUM2024



# **Our Goal: Accelerate Efforts** to End the HIV **Epidemic** in the **United States by** 2030

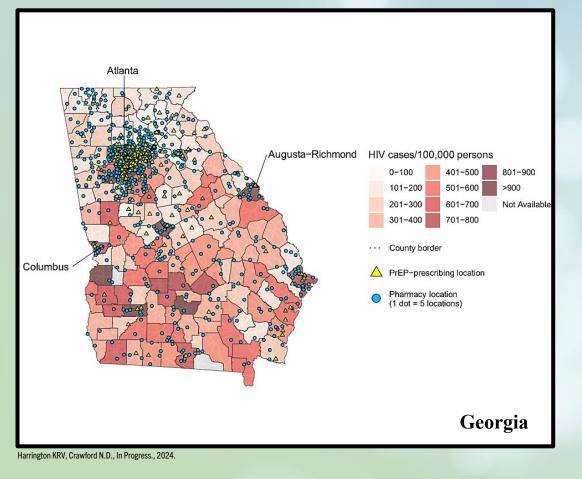
1.2 million people in the US have HIV

~32,000 new HIV infections in 2021

Health Inequities Persist: Stigma, Access to Care, Racism, anti-LGBTQIA+ bias, Education 13% of people do not know their status and need testing

Lifetime medical costs for HIV range from the mid-\$300,000 to \$500,000

1.2 million people recommended for PrEP; ~250,000 people lack insurance, stark disparities



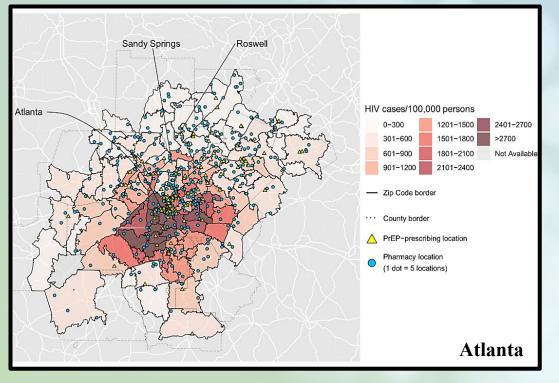
### #CONTINUUM2024



### **Opportunity**

Address structural barriers to accessing HIV prevention and linkage to care services in communities that face highest risk.





Harrington KRV, Chandra C, Alohan DI, Cruz D, Young HN, Siegler AJ, **Crawford ND.** Examination of HIV Preexposure Prophylaxis Need, Availability, and Potential Pharmacy Integration in the Southeastern US. JAMA Network Open. 2023;6(7).

### **Increase access to PrEP**

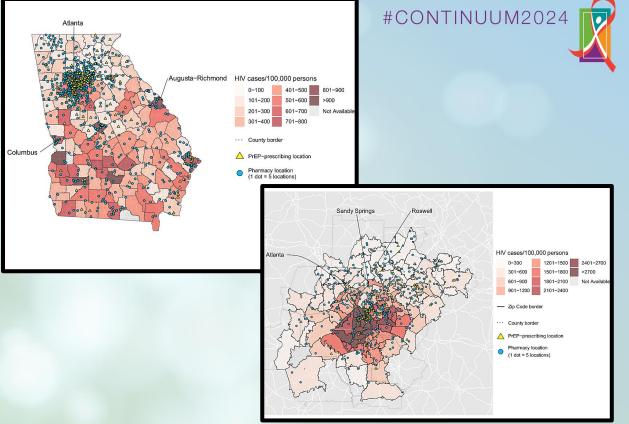
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- Access to PrEP providers is limited in areas of high need for prevention services.
- Proxy for understanding limitations for people to access HIV screening, PrEP, linkage to care, and more health services.



### Through community pharmacies\*

- Over 70,000 community pharmacies in the U.S.
- 56% of community pharmacies are in Medically Underserved Areas/Populations
- 80% of U.S. counties lack an infectious disease doctor
- Majority of U.S. population lives within 5 miles of a pharmacy
- Many pharmacies have extended hours and are open on weekends



\*Health Care Provider Taxonomy Code: A pharmacy where pharmacists store, prepare, and dispense medicinal preparations and/or prescriptions for a local patient population in accordance with federal and state law; counsel patients and caregivers (sometimes independent of the dispensing process); administer vaccinations; and provide other professional services associated with pharmaceutical care such as health screenings, consultative services with other health care providers, collaborative practice, disease state management, and education classes.

### **Opportunity: Mitigating stigma**





- Mistrust of the medical community
  - U.S. history of medical mistreatment of people of color
  - Key populations disproportionately affected by HIV often experience discrimination from health care providers
- Pharmacies may offer a less-stigmatizing entry point for HIV prevention, and a neutral environment compared to traditional medical settings
- Pharmacies can also offer anonymity and discretion, compared to providers or clinics that are known in the community for HIV services
- Collaboration with medical providers is needed to ensure continuity of care beyond an initial HIV test or PrEP prescription from a pharmacist.



### U.S. adults support expanding access to services

- 71% support pharmacists administering simple HIV tests at pharmacies.
- 65% support pharmacists prescribing PrEP
- 67% support pharmacists prescribing PEP

85% say pharmacists are easy to access

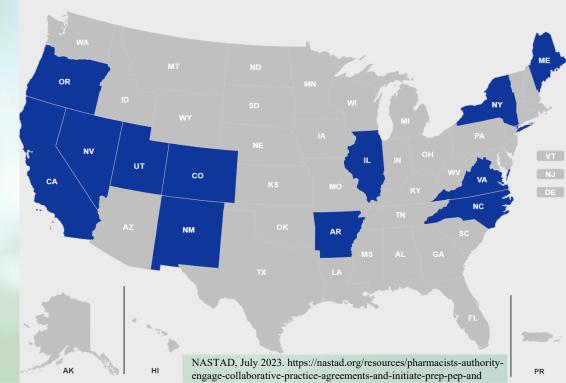
Pharmacist Actions	% Support (Strongly + Somewhat)
Helping patients prevent chronic disease such as heart disease and diabetes	73%
Helping patients to understand their nutritional choices	76%
Testing for and treating common illnesses (i.e. flu, COVID-19, etc.)	74%
Testing for and treating common minor conditions such as strep throat and urinary tract infections (UTIs)	70%
Screening for diabetes	72%
Initiating treatment for diabetes (if screening is positive)	65%
Screening for high cholesterol	73%
Testing for sexually transmitted infections	64%

Data reflects results of a nationwide poll conducted online from October 25-30, 2023 among a sample of 10,031 adults. The poll was conducted by Morning Consult and commissioned by NACDS. State-level results are estimated by a multi-level regression and post-stratification (MRP) model weighted by age, race/ethnicity, gender, and educational attainment within each state. Results from the full survey have a margin of error of plus or minus 1 percentage points.



# Why is HIV prevention not currently available in most U.S. pharmacies?

- In most U.S. states, pharmacists do not have the legal authority to conduct HIV testing or independently prescribe PrEP or PEP
- In the U.S. states that do provide authority to pharmacists, very few state policies include the ability for pharmacists to get reimbursed by insurance for the service



### **Dual Strategies: federal and state policy**



**Federal:** Seeking modifications to expand coverage of HIV Prevention services to include community pharmacies **Possible pathways:** Revising ACA Implementation Guidance and Medicare Benefit Policy Manual, National Coverage Determination for PrEP



**State:** State scope of practice policies through legislation, Board of Pharmacies, or other policy mechanism

Authority: Providing services (ordering, administering, consultation & management) and **payment** mechanism for services



#### #CONTINUUM2024

Some people who may want access to services through community pharmacies do not have insurance access Ensuring no cost-sharing for USPSTF Grade A and B services: HIV screening and HIV PrEP

# Anticipated Challenges

Determining availability of and reimbursement for point of care lab tests for PrEP recommended routine testing

Complicated and diverse state policies guide pharmacy practice

Ensuring effective collaborations across medical care disciplines Incentivizing participation across commercial and public payors for community pharmacists as 'providers'



The following checklist outlines key components for successfully launching an effective advocacy effort.

#### CHECKLIST: LAUNCHING A SUCCESSFUL ADVOCACY EFFORT (1/2)

COMPONENT	ACTION	#CONTINUUM2024				
1 Understand the state legislative process.	Note key deadlines and timelines for introducing and passing bills. Note any specific legislative procedures. <b>* Resource:</b> National Conference of State Legislators' interactive map	What objectives do we need to accomplish to achieve our goal?	What strategies do we need t complete to achieve the object	What resources do we need tive? to be successful?	How will we know we have been successful and when do we expect to see results?	
2 Identify and understand the priorities of key decision-makers.	<ul> <li>Make a list of key stakeholders (e.g., state legislative committee leaders, healthcare officials, patient advocates, the pharmaceutical industry, members of state BOPs, pharmacy and medical associations).</li> <li>* Resource: USA.gov's Find and Contact Elected Officials Locator</li> <li>Build partnerships with members of your State BOP.</li> <li>* Resource: National Association of BOPs <u>wabsite</u></li> <li>Ask partners to describe their needs.</li> <li>Create strategies aligned with partners' goals to increase the likelihood of success.</li> </ul>	2				
3 Identify any unspoken agreements, industry-specific norms, or influential relationships between key stakeholders.	Pre encourage romanificars in the BC is, marminiputical insistence, primary associations, a marco associations, a marco associations, and a trice association association and association association and association association association and association associatin association associatin association association associ					
State-Level Advocacy Strategy Planr This document outlines the state-level	STATE-LEVEL ADVOCACY STRATEGY Plan	Partner Checklist	ocacy Partners fro nd Affiliations 2/2)	m Diverse Organizations,		
to address (Advocacy Issue)		POTENTIAL PARTNERS	GC	ALS PARTNERS CAN HELP YOU ACHIEVE		
The strategy is guided by available data, the engagement of diverse stakeholders, and the policy goal. It defines the desired outcomes of advocacy efforts, resource needs, key champions, plans for strategically		Physicians and Physician Me	edical Associations	Foster a coordinated approach between pharmacists and healthcare providers.		
engaging partners, a compelling vision	n, and assessing progress.	State BOP         State and advocate for scope of practice changes.		tice changes.		
· · · · · · · · · · · · · · · · · · ·	acal and Objectives for State Level Advocacy Strategy	Pharmacist Associations (state and national levels)	¢	Align advocacy efforts and strengthen th profession.	e collective voice of the	
overarching advocacy goal for expanding access to HIV prevention services in community pharmacies. Then, complete the table on the following page to outline specific objectives, strategies, resources, and success metrics for achieving this goal.		Labs and Diagnostic Service State Agency Contacts for C		Ensure access to necessary HIV and STI testing resources.		
	al: cy goals. What do you want to achieve to expand access to HIV prevention services in community (E.g., increase access to HIV prevention services in community pharmacies by 2025.)	Communication Experts and		Disseminate information and raise aware	,	
Break down the goal into o	objectives	Insurance Providers and Hea	lthcare Payors	Ensure adequate reimbursement for serv	ices rendered by pharmacists.	
Lentify smaller, measurable steps that will help achieve the overarching goal		Nursing Associations	¢	Promote interdisciplinary teamwork and coordination between phoresolists and wave		

#### #CONTINUUM2024



### Policy component considerations

Scope of practice: prescriptive authority, ordering and administering screening and counselling, removal of referral requirement



Payment and reimbursement: comparable pay, medical benefit billing, flexible service setting

General prevention provisions: Example – integrative health screening

Statewide protocols



Training and education campaigns

# 

#### #CONTINUUM2024

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#### PHARMACIES EXPANDING ACCESS TO COMMUNITY HIV SERVICES

### **State Advocacy Playbook**



#### EXPANDING ACCESS TO HIV PREVENTION SERVICES AND LINKAGE TO CARE IN COMMUNITY PHARMACIES

State Advocacy Playbook



#### **TABLE OF CONTENTS**

5

8

10 11

14

15

16

17

18

22

24

25

26

In	troduction
н	IV Basics
2.1	HIV Prevention & Linkage to Care Challenge
2.2	The Current State of HIV in the United State HIV Disparities

- 3 Opportunities to Prevent HIV
  - 3.1 HIV Screening

2

- 3.2 Prophylactic Medications to End HIV
- 3.3 Viral Suppression
- 3.4 Expanding Care Access Through Community Pharmacies
- 3.5 Preventing HIV Saves Lives and Money
- 4 Understanding the Policies that Guide Pharmacy Practice
- 4.1 What Policies are Necessary to Expand HIV Prevention Efforts in Pharmacies?
- 4.2 What are Federal Policy Considerations?

	4.3	State Policy Environment Considerations	27
		Impact in Action: Virginia	35
		Impact in Action: Tennessee	35
		Impact in Action: Idaho	35
	4.4	Before You Launch an Advocacy Effort	36
5	R	padmap to Success	38
	Ste	ep 1: Assess Current Political Landscapes	40
	Ste	ep 2: Identify Advocacy Partners from Diverse Organizations, Expertises, and Affiliations	41
	Step 3: Develop a State-Level Advocacy Strategy		43
	Ste	ep 4: Engage Partners Strategically: Align Partners Effectively with Advocacy Strategies	44
	Ste	ep 5: Collect and Map Data	45
	Ste	ep 6: Provide a Compelling Vision for an Effective Policy Framework	46
	Ste	ep 7: Assess and Recognize Progress	47
6	R	esources	48

#### **Access here:**





PHARMACIES EXPANDING ACCESS TO COMMUNITY HIV SERVICES

### **Get Involved**

Engage with state and local initiatives working to increase access to HIV services through community pharmacies

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Promote the value of collaborations across medical care disciplines incl. pharmacists, nurses, physicians, community health workers, patient navigators



Reach out to learn more: Noelle Esquire, noelle.esquire@eltonjohnaidsfoundation.org