



ANNUAL MEETING²⁰²⁵

*State-Level Policy
Strategies for
Implementing
Pharmacist-Initiated
PrEP & Protecting
Access to Preventive
Care Under the
Affordable Care Act*



AGENDA

- 1) Introductions
- 2) Need for Pharmacist-Initiated PrEP
- 3) Rx EACH Initiative
- 4) Public Health Collaboration
- 5) State Case Studies
- 6) Kennedy v. Braidwood
- 7) Q&A

Speakers



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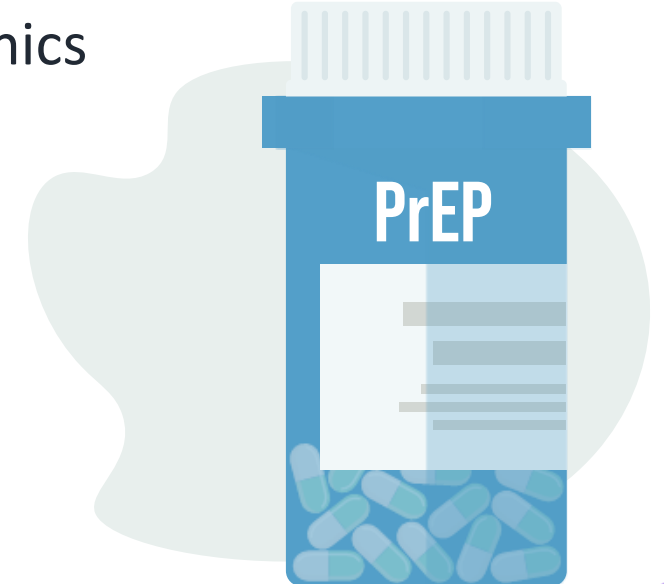


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Barriers to PrEP

- Only approximately 30% of individuals who would benefit from PrEP use the medication
- Uptake lowest among groups with greatest need – including rural Americans in the South, Black and Latinx individuals, Black and Latinx GBM, and serodiscordant couples
- Barriers to accessing PrEP:
 - Reduced access to primary care and sexual health clinics
 - Lack of knowledge about the medications
 - Stigma around HIV; bias from healthcare providers
 - Distrust of the medical establishment
 - Systemic racism



Accessibility of Pharmacies

90% of Americans live within 5 miles of a pharmacy

Extended hours, some up to 24 hours a day

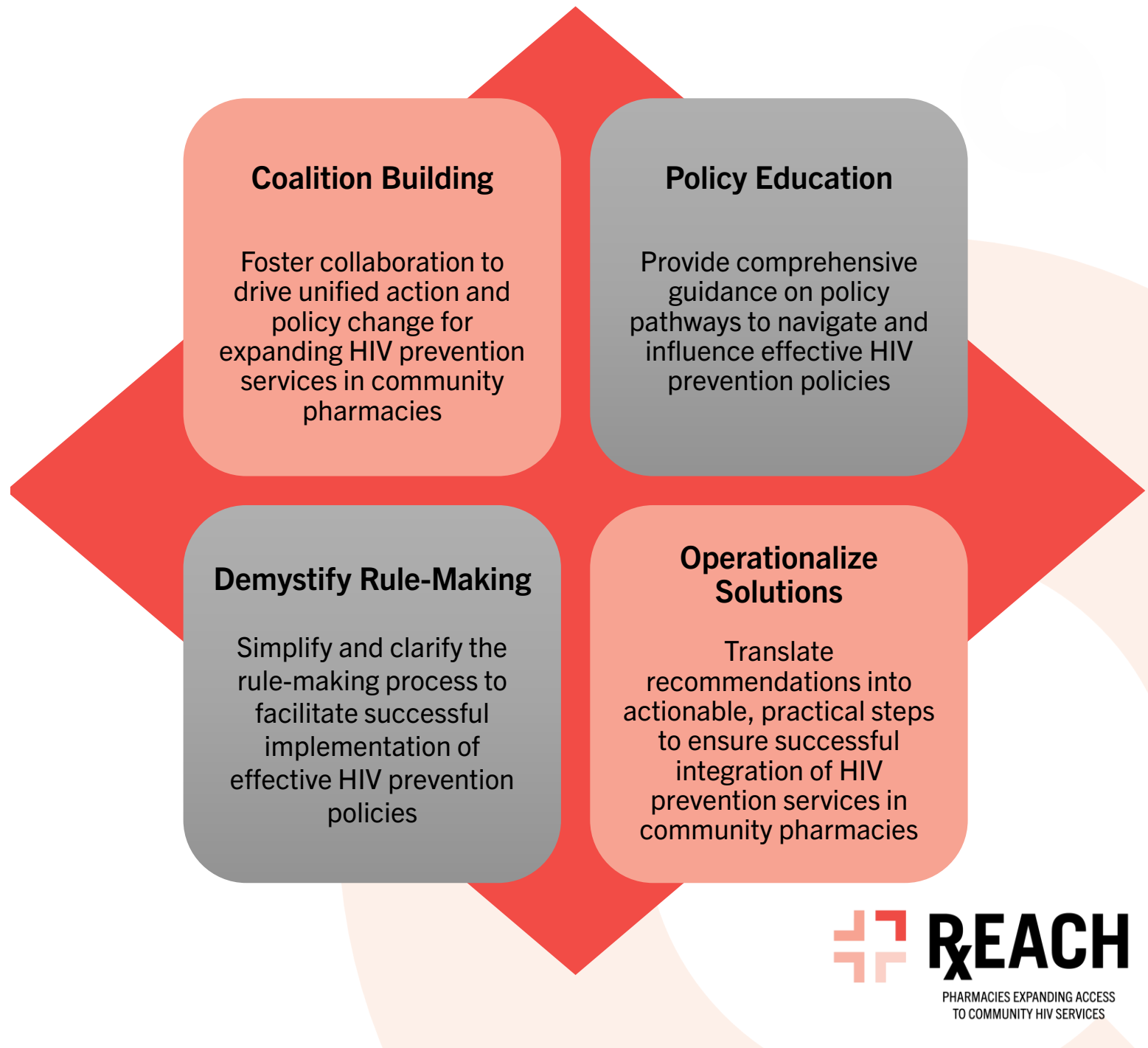
Can receive care without an appointment

Referrals and linkage to mainstream healthcare



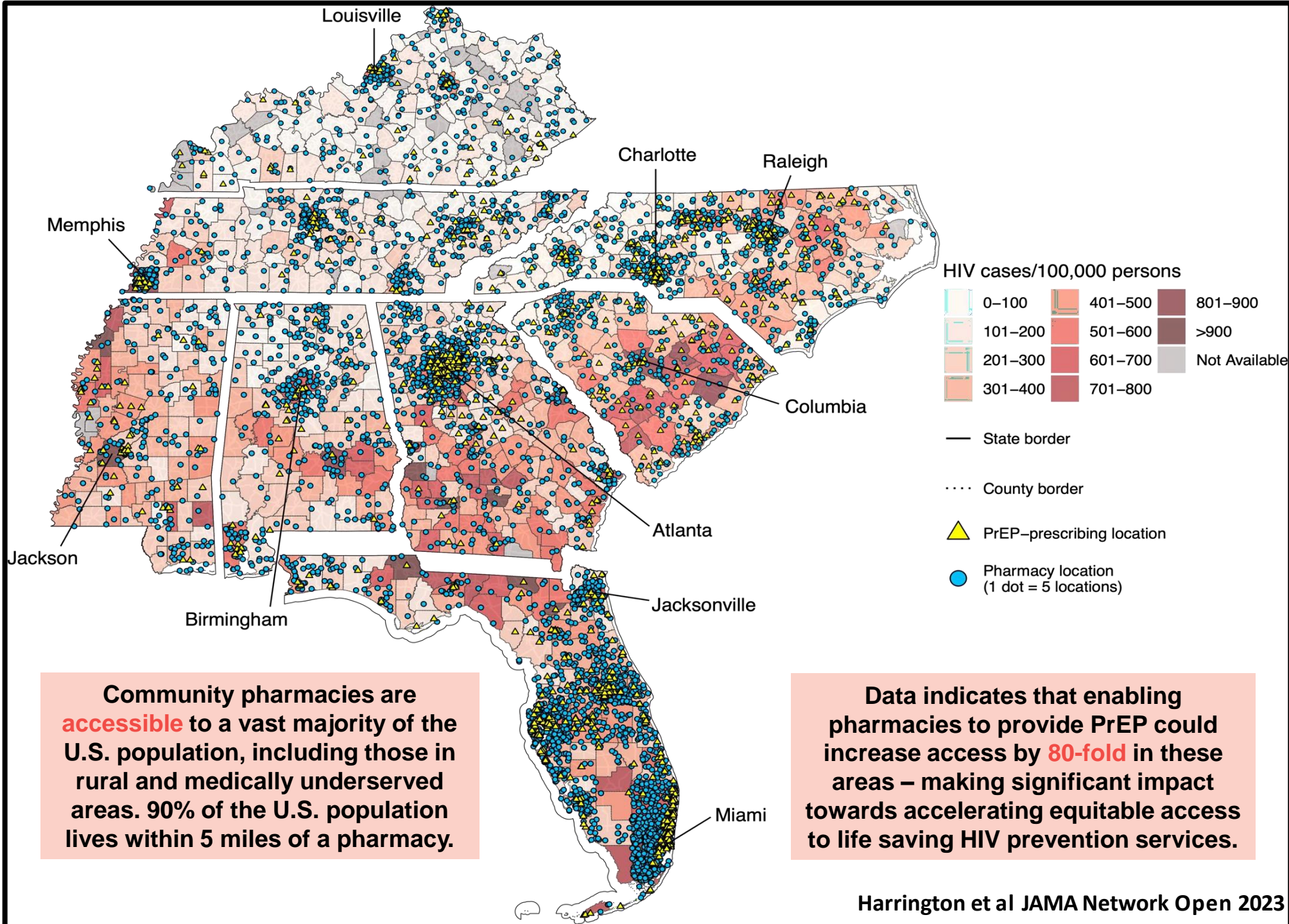
Goal

Accelerate Efforts to End the HIV Epidemic in the United States by 2030 by expanding access to HIV prevention services nationwide – through community pharmacies



Pharmacy-Based HIV Prevention Services

- **HIV Screening:** Ordering & administering HIV screening & patient consultation
- **PrEP/PEP:** Perform patient assessment and independent prescribing
- **Linkage to Care:** Pharmacies as an entry point
- **Medication Administration and Adherence:** Identify and re-engage patients who have stopped filling ARVs
- **Harm Reduction Services:** Distribution of sterile injection equipment, naloxone, and safe disposal services



Community pharmacies are **accessible** to a vast majority of the U.S. population, including those in rural and medically underserved areas. 90% of the U.S. population lives within 5 miles of a pharmacy.

Data indicates that enabling pharmacies to provide PrEP could increase access by **80-fold** in these areas – making significant impact towards accelerating equitable access to life saving HIV prevention services.

RxEACH State Resources

BRIDGING GAPS

Community pharmacies can play a crucial role in addressing geographic disparities in PrEP* access, particularly in underserved areas where access to HIV prevention services may be limited.

BOOSTING EQUITABLE ACCESSIBILITY

With over half of the 70,000 pharmacies in the U.S. in medically underserved areas, community pharmacies can serve as vital entry points for essential HIV prevention and linkage to care services.

EMPOWERING CHOICE

Individuals can choose to receive PrEP* and other prevention services in a location that best suits their needs.

SAVES LIVES AND MONEY

Early intervention through PrEP offered by community pharmacies can significantly decrease HIV transmission rates, reducing lifetime healthcare costs.

*PrEP (Pre-Exposure Prophylaxis) is a medicine that greatly reduces the chances of getting HIV from sex or injection drug use.

LEVERAGING COMMUNITY PHARMACIES FOR HIV PREVENTION MATTERS

Pharmacies can improve access to HIV prevention services in communities that need it most.

NORTH CAROLINA

HIV cases/100,000 persons

- Very Low
- Low
- Medium
- High
- Very High
- Not Available

County border

PrEP-prescribing location

Pharmacy location (1 dot = 5 locations)

The map shows that in communities where HIV prevention services are needed most, there are many more pharmacies than PrEP-prescribing locations.

Harrington, K. R. V., C. Chandra, D. I. Aohan, D. Cruz, H. N. Young, A. J. Siegler, and N. D. Crawford. "Examination of HIV Preexposure Prophylaxis Need, Availability, and Potential Pharmacy Integration in the Southeastern U.S." JAMA Netw Open 6, no. 7 (Jul 3 2023): e2326028. <https://dx.doi.org/10.1001/jamanetworkopen.2023.26028>.

REACH

PHARMACIES EXPANDING ACCESS TO COMMUNITY HIV SERVICES

- 57% of the 70,000 U.S. pharmacies are in medically underserved areas.
- 85% of adults identify pharmacies as easy to access.
- Over 70% of adults support pharmacies administering HIV tests and 65% support pharmacies prescribing PrEP.



EXPANDING HIV PREVENTION SERVICES THROUGH COMMUNITY PHARMACIES STATE MODEL POLICY CHECKLIST

Prescriptive Authority for Pharmacists

Expanding pharmacist prescribing authority to include HIV PrEP and PEP allows pharmacists to provide PrEP and PEP directly to patients, in accordance with CDC Guidelines, including the support for PrEP care management.

These legislative components enhance and streamline patient access to critical HIV prevention services and promote timely intervention. These changes often require amending the state's pharmacy practice act or corresponding pharmacy regulations.

- ☐ **Independent Prescriptive Authority:** Pharmacists will have independent prescriptive authority for all forms of Pre-Exposure Prophylaxis (PrEP), Post-Exposure Prophylaxis (PEP), in alignment with current clinical guidelines, without time or quantity limits.
- ☐ **Authority to Order and Administer Tests:** Pharmacists will have the authority to order and administer HIV tests and the laboratory panel required for PrEP initiation and monitoring, including sexually transmitted infection tests.
- ☐ **Authority to Administer Medication:** Pharmacists will have the authority to administer HIV prevention and treatment medications through any route of administration, as appropriate.
- ☐ **Remove referral requirements:** Pharmacists will not be required to have an initial referral from a physician for patients to access HIV prevention services.
- ☐ **Pharmacy Technician Support:** If not already allowed, pharmacy technicians should be authorized to perform any duties that do not require the clinical judgement/discretion of a licensed pharmacist. For example, pharmacy technicians should be eligible to perform CLIA-waived tests, administer medications, and collect information from the patient for the pharmacist to assess and evaluate.

State Action Playbook



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

State Action Playbook



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Download the Playbook:



State Action Playbook: Exploring Policy Components

ADDITIONAL POLICY COMPONENTS

Policies that promote training, education, and public awareness can also be powerful tools in HIV prevention.

COMPONENT	ACTION ✨	IMPACT
Invest in Training and Education	<div><input type="checkbox"/> Allocate funding for training and education programs for pharmacists.</div> <div><input type="checkbox"/> Allow for flexibility in training standards without prescribing detailed training programs.</div>	<div>✨ Equips pharmacists with the skills and knowledge necessary to provide effective HIV prevention services.</div> <div>✨ Ensures that pharmacists are well-prepared to deliver high-quality care.</div> <div>✨ Contributes to better patient outcomes and the overall success of HIV prevention programs.</div> <div>✨ Prevents legislation that may become out of date or cumbersome to implement.</div>
Public Awareness Campaigns	<div><input type="checkbox"/> Develop public awareness campaigns to educate patients about the crucial role pharmacists play in providing HIV prevention services, reducing stigma, and increasing awareness.</div>	<div>✨ Increases patient knowledge about the role of pharmacists in HIV prevention.</div> <div>✨ Encourages individuals to access essential care.</div> <div>✨ Contributes to a more informed and healthier community</div> <div>✨ Reduces stigma.</div>

Coming Soon: RxEACH Technical Package

Experts

- ✓ Lived experience navigating HIV prevention and treatment services
- ✓ Academia in pharmacy, nursing, and other allied health professions
- ✓ Health and program service delivery experience in HIV/STI and LGBTQIA+ care services
- ✓ Representatives of associations critical to the successful implementation of services, such as medical associations
- ✓ Federal, state, and local public health officials
- ✓ Industry representatives aligned with laboratory testing, pharmacy retail business operations

Evidence

- ✓ Collaborated with Dr. Natalie Crawford, Emory University CORE Lab for literature review and summary
- ✓ Key Question: How can community pharmacies effectively operationalize HIV prevention and linkage to care services?
- ✓ Key words: HIV screening, PrEP, PEP, referral protocols, pharmacy setting, HIV testing privacy, pharmacy practices, confidentiality, stigma-free healthcare, patient privacy
- ✓ 3-phase review process
- ✓ Acknowledgements: Alexis Hudson, Chante Hamilton, Daniel Alohan, Seth Zissette, Kristin Harrington

Experience

- ✓ Working groups will draw upon their professional and personal experiences
- ✓ Charge is to develop practical recommendations that can be used by pharmacy, healthcare and public health organizations
- ✓ **Scope of Technical Package:** Overall Strategy, specific approaches to implement noted strategies, and practical tips, examples and resources
- ✓ Working Groups will be asked to identify practical “real-world” examples to include in technical package

Equitable Access Will Be Foundational to All Deliberations

Implementation Strategies: Public Health Collaboration

Impact in Action: Virginia

- Statewide Protocols; Est. 2021 – Amended 2024
- No standing order required
- Covers PrEP and PEP
 - No quantity limitations
 - 2024 amendment added injectable PrEP
- Coverage of pharmacists' services:
 - Medicaid – Fee For Service and Managed Care
 - Commercial health plans

HIV ORAL Pre-Exposure Prophylaxis (PrEP) Assessment & Treatment Care Pathway
(CONFIDENTIAL-Protected Health Information)

ALGORITHM A: PrEP INITIATION (Review Relevant Questions on Patient In-Take Form)

1) PrEP INDICATION AND ELIGIBILITY
- Review Patient Intake Form #1a
- Review Patient Intake Form #1b or #1c

If NO to both, proceed. Refer

2a) CURRENT HIV STATUS
- Review Patient Intake Form #2a and HIV test results from Section 4.

If NO history of HIV, proceed. Refer

HIV TEST
- HIV Ag/Ab Test result: ☐ reactive ☐ indeterminate ☐ non-reactive
*HIV Ag/Ab blood test must be RESULTED within 7 days prior to prescribing and dispensing
- HIV RNA test result: ☐ detected ☐ indeterminate ☐ not detected ☐ result pending ☐ none
May order HIV RNA at initial intake (preferred) and as appropriate thereafter

If NO current HIV
HIV Ag/Ab Test non-reactive HIV
RNA Test not detected, proceed. Refer & Report

If YES possibly living with HIV
HIV Ag/Ab Test result reactive or indeterminate or
HIV RNA Test result detected or indeterminate, refer & report.
*A positive or indeterminate HIV test either indicates HIV infection, a false positive, or a result requiring specialist interpretation.
(See Communication Example A)

3) ASSESS FOR POSSIBLE HIV ACQUISITION WITHIN THE PAST 4 WEEKS
- Review Patient Intake Form #2b, 2c, 2d, and 2e
*Acute HIV symptoms: Fever, tiredness, muscle or joint aches pain, rash, sore throat, headache, night sweats, swollen lymph nodes, diarrhea, or general flu-like symptoms.
*Could have acute HIV with negative screening HIV Ag/Ab result
- Consider calling the HIV Warmline (888) 448-4911 for guidance if unclear

Time of last potential exposure:	<input type="checkbox"/> ≤ 72 hours	<input type="checkbox"/> >72 hours to ≤ 4 weeks	<input type="checkbox"/> > 4 weeks
Symptoms of possible acute HIV infection:	HIV Post-Exposure Prophylaxis (PEP) PEP Protocol	If NO symptoms: - Eligible for up to a 30-day supply of PrEP - Order HIV RNA test now - Counsel on acute retroviral syndrome symptoms	If YES to symptoms, refer (Communication Example B) Refer

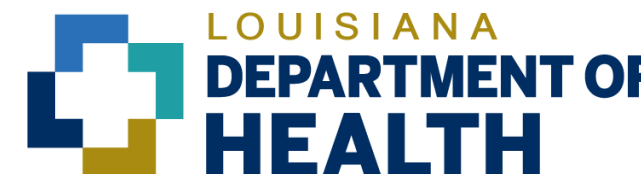
4) MEDICAL AND MEDICATION HISTORY
- Review Patient Intake Form #3a, 3b, 3c, 3d, 3e and 3f

Kidney Disease	Bone Mineral Density	Hepatitis B Status	Pregnancy	Medication
- Review Patient Intake form #3a	- Review Patient Intake form #3b	- Review Patient Intake Form #3c - Tenofovir disoproxil fumarate 300mg/Emtricitabine 250mg (Truvada®) and Tenofovir alafenamide 25mg/Emtricitabine 200mg (Descovy®) are treatments for Hepatitis B. In patients with Hepatitis B who stop PrEP, this may cause a Hep B disease flare. * People with Hep B infection must have their PrEP managed by a gastroenterologist or infectious disease specialist.	- Review Patient Intake form #3d	- Review Patient Intake form # 3e, 3f
<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	Hepatitis B History <input type="checkbox"/> YES <input type="checkbox"/> NO Hepatitis B Vaccine Confirmation of being fully vaccinated for hepatitis B via VHS	Pregnancy and breastfeeding are not contraindications for PrEP.	Evaluate for additional medications that can be nephrotoxic or decrease bone mineral density. * Tenofovir use in conjunction with NSAIDs may increase the risk of kidney damage. * Concurrent use is not contraindicated, but patient should be counseled on limiting NSAID use.
Refer	Refer	Refer	Refer PRN	

Virginia Board of Pharmacy
Page 1 of 6 ORAL Standardized Assessment and Treatment Care Pathway
Revised: 9/24/2024

Impact in Action: Louisiana

- Statewide Protocol
 - To be developed by LA Department of Health
- No standing order required
- Covers PrEP and PEP
 - Full course of PEP
 - 30-day supply of PrEP
- Required reimbursement at a rate equal to PCP
- Additional training required



Impact in Action: Oregon

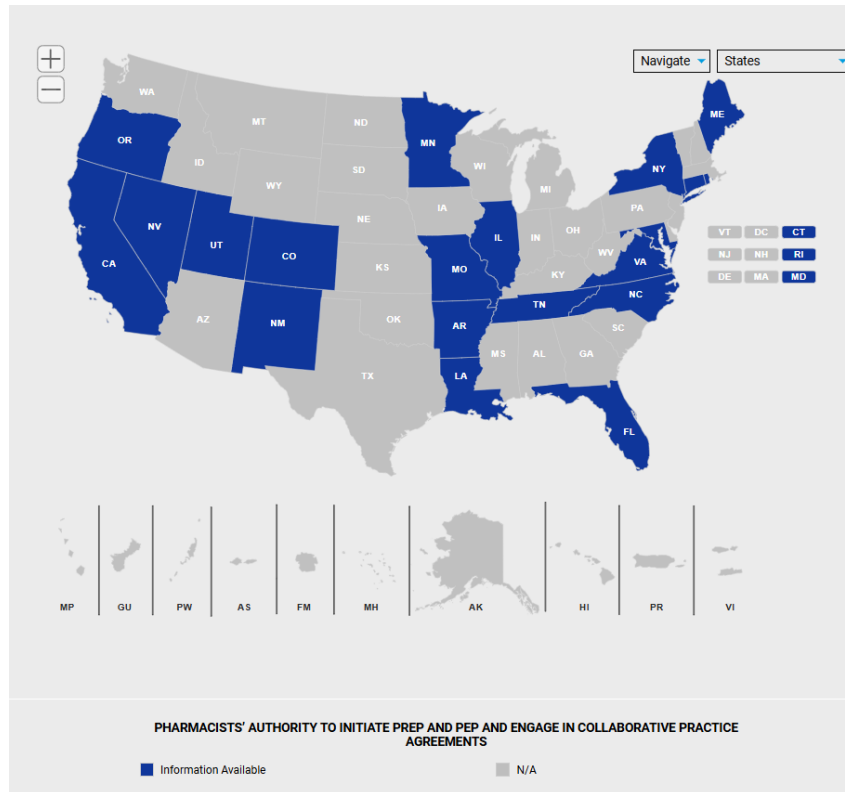
- Statewide Protocol; Est. 2023
- No standing order required
- Covers PrEP and PEP
 - Full course of PEP
 - 90-day supply of PrEP
- Required reimbursement at a rate equal to PCP
- No additional training required

HIV ORAL Pre-Exposure Prophylaxis (PrEP) Assessment & Treatment Care Pathway
(CONFIDENTIAL-Protected Health Information)

ALGORITHM A: PrEP INITIATION				
1) PrEP INDICATION AND ELIGIBILITY - Review Patient Intake Form Questions #1a, 1b & 1c				
Is the patient < 13 years old?		<input type="checkbox"/> YES Refer		
<input type="checkbox"/> NO		<input type="checkbox"/> YES		
2a) CURRENT HIV STATUS - Review Patient Intake Form #2a and HIV test results				
<input type="checkbox"/> NO history of HIV		<input type="checkbox"/> YES has history of HIV Refer		
2b) HIV TEST - HIV Ag/Ab Test result*: <input type="checkbox"/> reactive <input type="checkbox"/> indeterminate <input type="checkbox"/> non-reactive *HIV Ag/Ab blood test must be RESULTED within 7 days prior to prescribing and dispensing - HIV RNA test result*: <input type="checkbox"/> detected <input type="checkbox"/> indeterminate <input type="checkbox"/> not detected <input type="checkbox"/> result pending <input type="checkbox"/> none May order HIV RNA at initial intake (preferred) and as appropriate thereafter				
<input type="checkbox"/> NO current HIV HIV Ag/Ab Test non-reactive HIV RNA Test not detected		<input type="checkbox"/> YES possibly living with HIV HIV Ag/Ab Test result reactive or indeterminate Refer and Report HIV RNA Test result detected or indeterminate *A positive or indeterminate HIV test either indicates HIV infection, a false positive, or a result requiring specialist interpretation. (See Communication Example A)		
3) ASSESS FOR POSSIBLE HIV ACQUISITION WITHIN THE PAST 4 WEEKS - Review Patient Intake Form #2b, 2c, 2d, and 2e *Acute retroviral syndrome symptoms: Fever, tiredness, muscle or joint aches/pain, rash, sore throat, headache, night sweats, swollen lymph nodes, diarrhea, or general flu-like symptoms. *Could have acute HIV with negative screening HIV Ag/Ab result *Consider calling the HIV Warmline (888) 448-4911 for guidance if unclear				
Time of last potential exposure:	<input type="checkbox"/> ≤ 72 hours	<input type="checkbox"/> > 72 hours to ≤ 4 weeks		<input type="checkbox"/> > 4 weeks
Symptoms of possible acute HIV infection:	PEP Protocol	<input type="checkbox"/> NO symptoms - Eligible for up to a 30-day supply of PrEP - Order HIV RNA test now - Counsel on acute retroviral syndrome symptoms	<input type="checkbox"/> YES symptoms (Communication Example B) Refer	
4) MEDICAL AND MEDICATION HISTORY - Review Patient Intake Form #3a, 3b, 3c, 3d, 3e and 3f				
Kidney Disease - Review Patient Intake form #3a	Bone Mineral Density - Review Patient Intake form #3b	Hepatitis B Status - Review Patient Intake Form #3c *Tenofovir disoproxil fumarate 300mg/emtricitabine 200mg (Truvada®) and Tenofovir alafenamide 25mg/emtricitabine 200mg (Descovy®) are treatments for Hepatitis B. In patients with Hepatitis B who stop PrEP, this may cause a Hep B disease flare. * People with Hep B infection must have their PrEP managed by a gastroenterologist or infectious disease specialist.		Pregnancy - Review Patient Intake form #3d
<input type="checkbox"/> YES Refer	<input type="checkbox"/> YES Refer	Hepatitis B History - Review Patient Intake Form #3e *Confirmation of being fully vaccinated for hepatitis B via ALERT IIS <input type="checkbox"/> YES Refer <input type="checkbox"/> NO - Offer Hep B Vaccine series. - Order Hep B Surface Antigen (see Table 1)		Medication - Review Patient Intake form #3e, 3f Pregnancy and breastfeeding are not contraindications for PrEP. Refer PRN Evaluate for additional medications that can be nephrotoxic or decrease bone mineral density. * Tenofovir use in conjunction with NSAIDs may increase the risk of kidney damage. * Concurrent use is not contraindicated, but patient should be counseled on limiting NSAID use.

Oregon Board of Pharmacy- PROPOSED v. 6/2023

[Interactive Map](#): *Pharmacists' Authority to Initiate PrEP and PEP and Engage in Collaborative Practice Agreements*



Does the state have PrEP/PEP-specific legislation?

[reset](#)

Do pharmacists have the legal authority to administer injectable PrEP?

[reset](#)

Do pharmacists have the legal authority to enter into a collaborative practice agreement (CPA) with a primary care provider (PCP)?

[reset](#)

Do pharmacists have the legal authority to independently perform CLIA-waived tests?

[reset](#)

Is there a law or regulation requiring insurers to reimburse pharmacists for the provision of clinical services?

[reset](#)

Legislative Tracker: Pharmacist-Initiated

PrEP and PEP



State Laws (or Proposed Laws) Allowing Pharmacists to Administer PrEP and PEP

Updated 9/24/24

More and more states are proposing and have enacted legislation allowing pharmacists to initiate PrEP and PEP without a prescription. States across the country have proposed legislation that would similarly allow pharmacists to initiate PrEP and PEP. Most of these proposals and enacted legislation have similar provisions. For one, most would limit pharmacy-initiated PrEP and PEP to a specified time-period and mandate pharmacists to refer patients for follow-up care. The proposed bills typically require pharmacists to complete additional training by their respective states' boards of pharmacy before self-prescribing PrEP and PEP. Also, most states have introduced limitations on prior authorization and step therapy requirements that insurers can impose for PrEP and PEP drugs and their delivery fees by mandating coverage of the pharmacist's evaluation and dispensing services.

This chart details the following states have either proposed or passed legislation relating to pharmacy-initiated PrEP and PEP (see Appendix 1 for a more in-depth analysis of the proposed or enacted legislation):



Pharmacist-Initiated PrEP and PEP Treatment: Opportunities and Challenges

Community Trust and Accessibility

The accessibility afforded to potential patients by community pharmacies presents a great opportunity for them to provide initial PrEP and PEP treatment without a clinician's prescription. Most patients must schedule an appointment with a nurse practitioner or primary care physician for the initial clinical visit and then continue to meet with a provider every three months for additional testing. This is a significant barrier to PrEP and PEP uptake due to reduced access to primary care and sexual health facilities in underserved communities most impacted by HIV. Black and Latinx communities are particularly burdened by lack of access to primary care in their respective communities.¹¹ Added to that challenge is

the historical marginalization facing these populations within health care systems, including lower admission rates and higher mortality in emergency departments.^{12,13}

Alternatively, with more than 60,000 community pharmacies throughout the United States, individuals with an indication for PrEP and PEP often have greater access to pharmacies than to primary care offices.¹⁴ Nearly nine in 10 Americans live within five miles of a pharmacy.¹⁵ Many pharmacies have extended hours (many have moved to 24-hour care), patients can walk in without a set appointment, and pharmacists provide more opportunities for community engagement. Community pharmacies have played a more extensive role in helping individuals manage their care over the years, and studies

State	Bill Number	Status of Legislation (In Committee, Passed, Failed, Enacted)	PrEP or PEP without Rx through pharmacist	Quantity limits for PrEP or PEP without Rx	Other Requirements for Pharmacists and Insurers Under Proposed Bill
ARKANSAS	HB 1007	Passed on March 21, 2023	PrEP and PEP	Allows pharmacists to dispense up to a 60-day supply (must dispense at least a 30-day supply) of PrEP in a two-year period or a full 28-day regimen of PEP	Pharmacists must complete training program approved by Arkansas State Board of Pharmacy Insurers prohibited from imposing prior authorization or step therapy requirements
CALIFORNIA	SB 159	Enacted October 2019	PrEP and PEP	Allows pharmacists to dispense up to a 60-day supply of PrEP in a two-year period or a full 28-day regimen of PEP	Expands Medi-Cal schedule of benefits to include PrEP and PEP; requires private insurance companies to cover PrEP and PEP. Pharmacists must complete training program approved by California State Board of Pharmacy
CALIFORNIA	SB 339	Passed January 29, 2024.	PrEP	Allows pharmacists to dispense 90-day supply of PrEP without prescription; Pharmacists may dispense beyond a 90-day supply of PrEP without a prescription if certain conditions are met	Requires all health insurers to cover pharmacist-furnished PrEP and costs for the pharmacist's services and related testing Requires state board of pharmacy to adopt emergency regulations by 7/1/23 to implement these provisions

Kennedy v. Braidwood Management, Inc.

KEY DEFINITIONS

USPSTF

- U.S. Preventive Services Task Force
- Independent, volunteer panel of experts in disease prevention and evidence-based medicine
- Makes health care recommendations, which are either issued as “A” or “B”

Appointments Clause

- Constitutional provision that lays out the appointment process for “Officers of the United States”
- Requires Principal Officers to be nominated by the President and confirmed by the Senate

KEY QUESTIONS

Why was the suit filed?

- Plaintiffs contest legality of ACA’s mandatory coverage of preventative health care services – specifically PrEP

What is the legal issue?

- Plaintiffs argue USPSTF members are Principal Officers under the Appointments Clause
- Question for Court: Whether the USPSTF violates the Appointments Clause

Supreme Court Arguments



GOVERNMENT: USPSTF members are Inferior Officers

- HHS has adequate oversight
- HHS Secretary has at-will removal power
- HHS Secretary has power to deny implementation of recommendations

Implication: Insurers would still be required to cover USPSTF recommendations BUT Kennedy would have substantial authority

BRAIDWOOD: USPSTF members are Principal Officers

- HHS has insufficient oversight
- HHS Secretary lacks removal power
- HHS Secretary lacks power to deny recommendations

Implication: Insurers would not be required to cover USPSTF recommendations

Questions?