Toward PrEP Access for All:

An analysis of policies, approaches, and strategies in the Southern United States

March 2024

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Introduction

The success of the US Ending the HIV Epidemic (EHE) strategy depends on delivering PrEP to 50 percent of individuals who need it by 2025[1]. Yet the most recent official coverage data from 2020 stands at 25%, and this aggregate conceals significant disparities in access and uptake. Access is frequently determined by location and policy environment: the presence of PrEP providers within 30 minutes' drive; whether or not the number of providers in a specific geographical area is commensurate with the number of new HIV transmissions per year (a useful proxy for PrEP eligible people); enabling policies and programs including Medicaid expansion, PrEP drug assistance programs; insurer compliance with Federally mandated coverage of PrEP. Uptake—the number of people seeking and using PrEP—is shaped by awareness of, and confidence in, PrEP services as non-judgmental, confidential, affordable to un- and under-insured individuals, and many other factors.

In 2023, the Center for Disease Control and Prevention (CDC) published a report highlighting the progress in PrEP prescriptions in 2021, rising to 36% from 23% in 2019, the year the Ending the HIV Epidemic plan was announced.[2] That same report highlighted how disproportionate those prescriptions were among Black and Latinx communities, with drastically less prescriptions than their white counterparts. These disparities were and continue to be driven by deeply entrenched social and political determinants of health. Notably, these racial and ethnic disparities can be seen in transmission rates, as the CDC found in 2021, new transmission rates were seven times higher for Black people and four times higher for Latinx people than they are for their White counterparts[3]. These outcomes could have been adverted if prescriptions of PrEP would have yielded more equity in its distribution. In 2022, 11% of Black and 20% of Latinx people who were eligible for PrEP were prescribed it, compared to 78% of their White counterparts. PrEP uptake among women most in need of PrEP was estimated at 12% compared to 34% of males. Another study found that 32% of transgender women not living wth HIV, reported using PrEP[4]. Ending the HIV epidemic will require a focus on equitable access to HIV treatment and prevention, including PrEP.

Current efforts to achieve the goals of the US campaign to End the HIV Epidemic (EHE[5]) are undercut by the fragmented system of PrEP access, which requires uninsured and underinsured consumers to navigate

Reference 1: PrEP Access Under Threat: *Braidwood Management v Becerra*

Braidwood Management v. Becerra is an ongoing lawsuit challenging the ACA requirement that most health plans cover preventive services, including PrEP at low or no cost, per the recommendations of the US Preventive Services Task Force (USPSTF). The lawsuit specifically cites provision of PrEP as a preventive service that insurers should be allowed to opt out of on the grounds of religious beliefs. The initial ruling found the requirement to provide PrEP violated the Religious Freedom Restoration Act and struck down the requirement for insurers to cover (without cost sharing) all of the services recommended by the USPSTF on or after March 23, 2010. The court issued a nationwide injunction barring enforcement of these requirements. However, in mid-May 2023, the Fifth Circuit Court of Appeals issued an administrative stay of the injunction, meaning all of the ACA preventive services protections will remain in place as the appeal proceeds. As this report was finalized, the case was still underway. If the ruling were to be upheld, insurers will be allowed to opt out of provision of many preventive health services recommended by USPSTF, including PrEP, and the present patchwork of coverage will be further shredded, with some of the greatest losses of coverage likely in the Deep South.

To learn more and sign up for updates please visit PrEP4All's page on the fight for PrEP coverage: https://www.prep4all.org/paying-for-prep

[1] Ending the HIV Epidemic in the US: Progress. 2023. (https://www.cdc.gov/endhiv/ehe-progress/index.html, accessed 27 February 2024).
[2] "Expanding PrEP Coverage in the US to Achieve EHE Goals." October 17, 2023. (https://www.cdc.gov/nchhstp/dear_colleague/2023/dcl-101723-prep-coverage.html, accessed February 27, 2024).
[3] Estimated HIV Incidence and Prevalence in the United States, 2017–2021: National Profile. https://www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-28-no-3/content/national-profile.html. Last Reviewed, May 2023. Accessed Feb. 8, 2024
[4] Centers for Disease Control and Prevention. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 dependent areas, 2021. HIV Surveillance Supplemental Report, 2023; 28(No. 4). http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html. Published May 2023. Accessed Feb. 8, 2024
[5] https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview/

multiple programs with differing eligibility and application rules. This fragmented approach disproportionately harms people in communities that already face a range of barriers to preventive services, including low levels of health insurance coverage, long travel distances to medical facilities including PrEP providers, high levels of anti-HIV and anti-gay stigma, poverty, racism, gender bias, homophobia and transphobia.

The ongoing legal case, *Braidwood Management v. Becerra* poses an additional threat to equitable access to PrEP and other preventive services (See Reference 1). The plaintiffs in the case claim that the Affordable Care Act requirement that private insurers cover preventive services recommended by the US Preventive Services Task Force (USPSTF) like PrEP is unconstitutional. The plaintiffs also challenge PrEP in particular because they argue it violates their religious freedom rights under federal law. The case has implications far beyond PrEP; however, this intervention is at the crux of the case's stigmatizing, homophobic and HIV-phobic arguments about which human beings have the right to health. As advocates fight for PrEP and health justice in Texas, work is also ongoing in neighboring Southern states.

Issues of equity, dignity and non-discrimination are in play, every day, for members of the Southern AIDS Coalition (SAC) and allies working on the HIV/AIDS response in the Southern region of the United States. SAC's work is dedicated to analyzing and changing conditions so that people vulnerable to HIV and eligible for PrEP and other prevention services have access to the resources they need, from providers they trust, with supportive community-embedded partners shaping the environment in which people make health-related decisions.

Today, HIV advocates around the country are engaged in a concerted, coordinated campaign to secure US federal financing for, and political leadership on, a national PrEP program. Such a program would fill in gaps in access to, and coverage of, labs, drugs, and clinic visits; expand provider networks to ensure sufficient coverage; and resource community partners whose contributions are essential to public health, including the HIV response. At present, champions for a National PrEP Program in the Biden Administration and Congress are working closely with community partners to transform this vision into a reality, however significant advocacy will be needed to keep PrEP access a priority during a time of deeply divided government. As this campaign moves forward, there are also several issues, policies, approaches, and frameworks in play at state and jurisdictional levels that can be influenced in the short- and mid-term by SAC and its members. This report is designed to facilitate this analysis and to serve as the basis for a learning and action collaborative including SAC and its allies.

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Statement of Scope and Purpose

This is a resource to support shared learning and coordinated action by organizations and individuals working in southern EHE jurisdictions to increase utilization of biomedical interventions. This document looks specifically at pre-exposure prophylaxis, or PrEP, for HIV prevention, with a particular emphasis on oral tenofovir-based PrEP, which is the most widely used and readily available PrEP formulation, and additional considerations of long-acting injectable cabotegravir (CAB-LA). This resource is designed as a tool for stakeholders involved in expanding PrEP coverage to identify opportunities and challenges relevant to their local contexts and communities. The information collected in this report is drawn from research, publications and programs across the United States, key-informant interviews, and from a survey developed as part of the formative research for this project. The authors are indebted to the providers, PrEP users, researchers, health officials and activists whose work and insights informed this document. A list of the publications reviewed, and individuals consulted for this report can be found in the Appendix, which also provides detailed information on the survey respondents by state and professional role.

How the Document is Organized

The report is organized around three domains identified by the National PrEP Program Working Group (NPPWG), a coalition working to ensure funding for, and implementation of, a National PrEP Program for un- and under-insured individuals in the United States[3]. These domains are:

1. **Medication and Medical Coverage**
   Affordability is key to uptake. For any PrEP service, this includes medication and labs, as well as staff time for adherence support, health system navigation and provider visits. Coverage strategies could include insurance company compliance with the US Preventive Service Task Force "A" grade and ACA mandated coverage of PrEP without cost sharing (this mandate is currently under legal challenge in the *Braidwood Management v Becerra* case, see page 3 for information). Additional components include a centralized reimbursement mechanism to cover the costs of generic TDF/FTC PrEP and labs specifically for uninsured and underinsured individuals, and alternative mechanisms that allow smaller clinics or programs, that cannot afford to purchase drugs up front, to access PrEP medications in a timely manner. A reimbursement mechanism could be done by contracting with billing administrators, such as a contracted pharmacy benefit manager and medical benefit manager.
2. **Expanding Provider Networks**
   One of the challenges of expanding PrEP access in general and in Southern states and jurisdictions in particular is that there are too few providers knowledgeable about PrEP or willing to prescribe it to their patients. Dramatic increases in the number of clinical and non-clinical PrEP touchpoints in communities are needed and can be achieved via a range of approaches including state and local "hub and spoke" networks, telePrEP, and pharmacist provided PrEP.
3. **Communications, Marketing & Demand Creation**
   Research continues to show that many communities that are most in need of PrEP still have relatively low knowledge of PrEP. There is a need for resources to better research the narrative and messaging shifts needed for people most impacted to want to consider and take PrEP, as well as implement novel and innovative messaging at the national level, local levels, and tailored to different demographics.

This report lists and reviews the status of enabling policies, guidelines, cooperative agreements, and other approaches in each of these three domains. The approaches explored, such as legislation to allow pharmacist provision of PrEP, telePrEP and others, are not exhaustive across the domains. Instead, we hope that this analysis will serve as a starting point for community groups and members to develop local agendas, identify precedents and approaches in neighboring geographies, and build even stronger coalition work to expand PrEP coverage in the South.

[6]These domains complement other frameworks for conceptualizing and identifying action areas to expand PrEP access, for example the expanded chronic care model, which has been adapted to guide incorporation of prevention practices into public health systems and used by researchers to understand and advance recommendations on PrEP services. See: Siegler, A.J., Steehler, K., Sales, J.M. et al. A Review of HIV Pre-exposure Prophylaxis Streamlining Strategies. Curr HIV/AIDS Rep 17, 643–653 (2020). https://doi.org/10.1007/s11904-020-00528-9

Medication and Medical Coverage

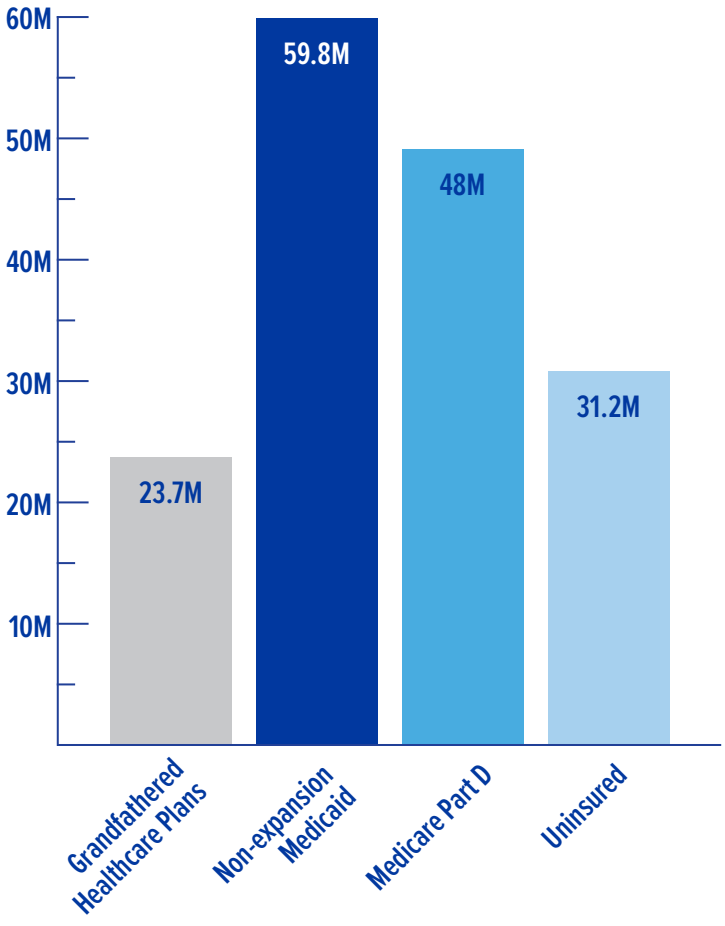
Overview: Policies Impacting Medication and laboratory cost coverage

Since 1984, the US Preventive Services Task Force has served as an independent panel that reviews and grades evidence for clinical prevention services. Oral tenofovir-based PrEP has received the highest grade (A) from this panel, which has issued the same grade, for long-acting injectable cabotegravir (CAB-LA). The Affordable Care Act requires prevention services with the A grade be covered with no cost-sharing (e.g., co-payments, co-insurance, and deductibles)) by most group health plans and health insurance issuers[7]. This same guidance on coverage is also implemented for Medicaid expansion programs. Critically, guidance issued by the Centers for Medicare and Medicaid Services (CMS) issued in 2021 clarified that coverage of PrEP services not only include the cost of medication, but also the cost of ongoing services requisite to care including quarterly clinician visits, required laboratory testing including for HIV and STD, and medication adherence counseling.

Because the ACA preventive services coverage and cost-sharing requirements only apply to private insurance and Medicaid expansion benefits, they do not affect the nearly 50% of the US population, who are either uninsured or insured by plans and products to whom the protections do not apply. Plans not subject to the ACA's preventive services requirements include grandfathered healthcare plans (23.7 million persons), traditional, non-expansion Medicaid (59.8 million), Medicare Part D (48.0 million) and uninsured persons (31.2 million)[8]. State Medicaid plans must cover PrEP medication, but states may impose utilization management[9] on medication coverage and coverage of ancillary laboratory and clinician services vary considerably across states and Medicaid managed care plans.

An enabling policy environment for PrEP coverage includes Medicaid expansion and/or a PrEP Drug Assistance Program (PrEP DAP). In one study, states with both Medicaid expansion and PREP DAPs had 99% higher PrEP prevalence compared to those states that did not have both of those programs. The National PrEP Program calls for other mechanisms and approaches that would, if implemented, afford comparable coverage to PrEP DAPs on a federal level. The takeaway from the analysis to date is that policies and programs supporting affordable PrEP and access health care lead to dramatic increases in PrEP coverage.

Number of Patients on Plans not subject to the ACA's preventive services requirements



[7]It is important to note that preventive services requirements from the USPSTF remain the law of the land, even though plaintiffs in *Braidwood Management v. Becerra* have questioned them in their suit.
[8]Siegler A, Sullivan P. The PrEP Laboratory Service Gap: Applying Implementation Science Strategies to Bring PrEP Coverage to Scale in the United States. J Law Med Ethics. 2022;50(S1):40-46. doi: 10.1017/jme.2022.34. PMID: 35902081; PMCID: PMC9341189.
[9]Utilization management or review is the use of managed care techniques such as prior authorization that allows payers, particularly health insurance, particularly health insurance companies, to manage the cost of health care benefits. Ideally, utilization management is an assessment of the appropriateness of a benefit that uses evidence-based criteria or guidelines to inform decisions about whether a service is provided. In practice, utilization management can function as a barrier to access, including to PrEP.

Overview: Policies that Shape an Enabling Environment

In addition to insurance coverage and reimbursement policies that have a direct impact on PrEP prevalence, several policies, laws and guidance areas shape coverage and uptake. These include policies that directly limit, or by virtue of creating confusion, defacto limit access for adolescents and minors, and policies that impact and exacerbate HIV stigma and discrimination and which may deter people at risk of HIV transmission from self-identifying and seeking PrEP. The former category includes allowance for minor consent to confidential care including PrEP, HIV testing, HIV treatment, STD and STI testing and treatment; the latter includes HIV-specific statutes such as those that criminalize non-disclosure of HIV status to a sexual partner as well as laws and statutes regarding trans, homosexual or gender non-conforming identities, behaviors, and expressions.

Reference 2: SAC's Southern Geographic Regions

Deep South:

- Alabama
- Florida
- Georgia
- Louisiana
- Mississippi
- North Carolina
- South Carolina
- Tennessee
- Texas

Additional Jurisdictions:

- Arkansas
- Delaware
- Maryland
- Kentucky
- Oklahoma
- Washington, DC
- West Virginia
- Virginia

Context and Considerations in the South

As Table 1 shows, two thirds of states in the deep South (see Reference 2 for definitions of geographic regions) have not adopted Medicaid expansion and also lack PrEP drug assistance programs (DAP). Florida is the only state with both programs; Louisiana and North Carolina have adopted Medicaid expansion but does not have a PrEP DAP. Table 2 reviews statutes affecting the ability of minors to consent to confidential medical services with the assurance that parents or guardians will not be notified by provider and/or by insurance plan explanation of benefits notices sent to parents or guardians as the policy holders. The table considers the policy environment for PrEP, HIV testing and treatment and STI testing and treatment. No Southern state has statutory language specific to PrEP and minors' ability to access it confidentially. Providers may infer that the statutes that apply to HIV and STI services may also apply to PrEP, but in the absence of that statutory clarity, providers may also choose to avoid prescribing PrEP to minors altogether.

The results received from the SAC-PrEP4All survey of individuals working on PrEP services in a variety of capacities (see Figures 1 and 2) corroborate this policy landscape. As shown in Figure 3, when presented with an array of policies and approaches that could be barriers to PrEP coverage, many respondents selected responses that centered on the complexities of obtaining coverage for medication and laboratory costs, for un- and underinsured individuals (7 respondents, or 43.8) via insurance reimbursement to providers (6 respondents or 37.5 percent) or CDC funds (9 respondents, or 56.3 percent), were identified as major barriers to PrEP access. The sample size is small and the differences in percent responses should not be over-interpreted, however the emphasis on insufficient or confusing coverage by providers and health workers on the frontlines in Southern states should be taken seriously. The costs of a first year set of laboratory tests for PrEP are roughly USD $1,000, according to one analysis that used the CMS and CDC guidance for requisite labs among gay men and other men who have sex with men as the source of indicative costs[10]. Adding the recommended four annual visits brings the costs of PrEP even higher—as is discussed in the next section.

[10]Aaron Siegler and Patrick Sullivan. "The PrEP Laboratory Service Gap: Applying Implementation Science Strategies to Bring PrEP to Scale in the United States." *The Journal of Law, Medicine & Ethics*, 50 S1 (2022): 40-46.

Figure 1: PrEP4All-SAC Survey Respondents by Geography

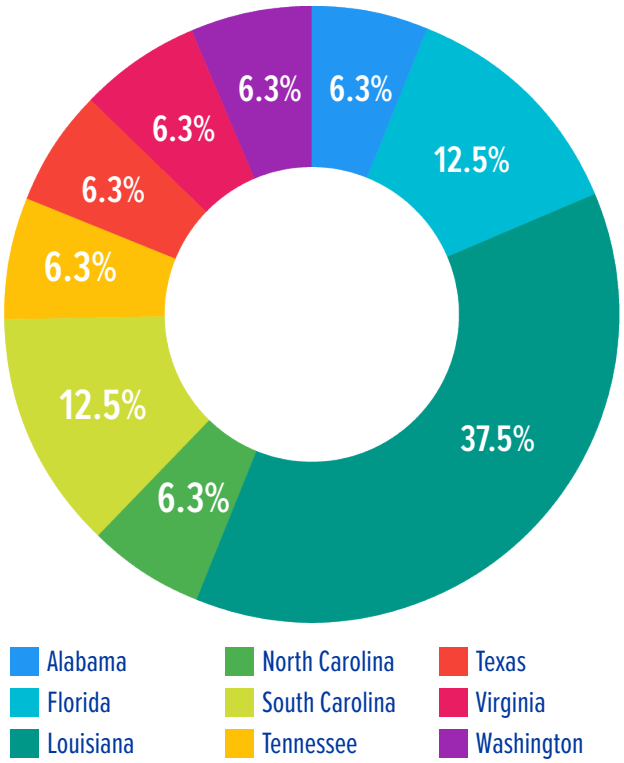
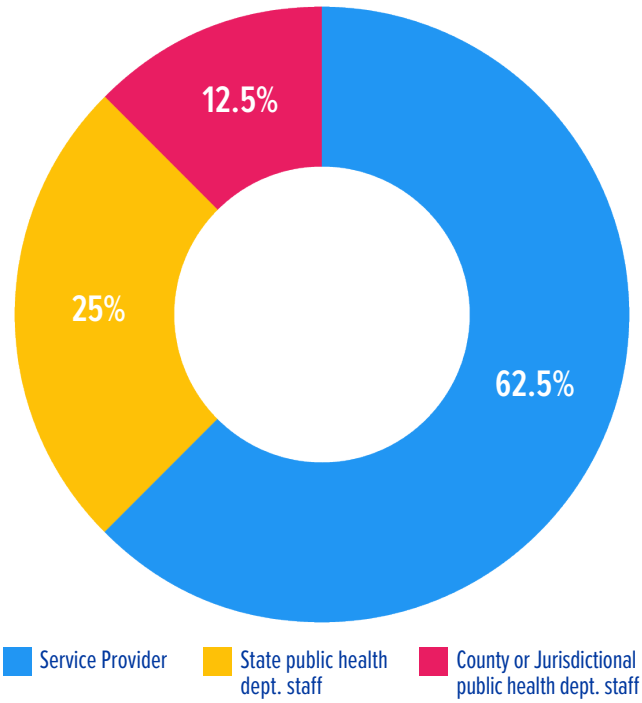


Figure 2: PrEP4All-SAC Survey Respondents by Role vis a vis PrEP



A comparatively high percentage of survey respondents also identified barriers created by age of consent and confidentiality statutes. "Policies are vague with teens," one respondent noted. Another wrote that, "Many of the issues with the stated priorities stem from providers being unsure of what policies exist (some of which could help them more than hurt them) and instead of inquiring they simply take a step back." In New York state, the team responsible for PrEP programming invests heavily in communications resources and channels to reach providers, paying particular attention to primary care physicians who may have less familiarity with PrEP as compared to STD/STI or infectious disease specialists.

Of interest, relatively few respondents reported as a barrier the absence of confidentiality protections for minors accessing services on their parent or guardian's insurance, including explanations of benefits that, when delivered to the policy holder, can disclose information about services obtained confidentially. A further survey assessing the role of EOB policies among providers and/or young people who are, and are not, accessing PrEP could yield insights into whether the absence of confidentiality provisions is a barrier to minors seeking PrEP services to begin with. A National PrEP Program or equivalent that provided PrEP to uninsured and under-insured individuals could also support access for individuals who are not able to use their insurance because of privacy concerns (e.g., minors who cannot or do not want to obtain this medication on an adult's policy).

In addition to the policies described above, it will be crucial to monitor the case. The threat Braidwood poses to PrEP coverage is another rationale for moving towards a Federally resourced National PrEP Program.

"Many of the issues with the stated priorities stem from providers being unsure of what policies exist (some of which could help them more than hurt them) and instead of inquiring they simply take a step back."

Table 1: Medicaid expansion (and implementation status), and PrEP DAP programs in the Southern jurisdictions[11]

	PrEP DAP						Medicaid Expansion		
	Has a PrEP DAP		Drug Assistance		Clinical Visits and Lab Test Assistance	Patient Income Limit	Adopted and implemented	Adopted but not implemented	Not Adopted
State	No	Yes	Copay Assistance	Medication Assistance					
Alabama	X								X
Arkansas	X						X		
Florida		X	No	Yes	Local health department clinics	No threshold			X
Georgia	X								X
Louisiana	X						X		
Mississippi	X								X
North Carolina	X						X		
South Carolina	X								X
Texas	X								X
Tennessee	X								X

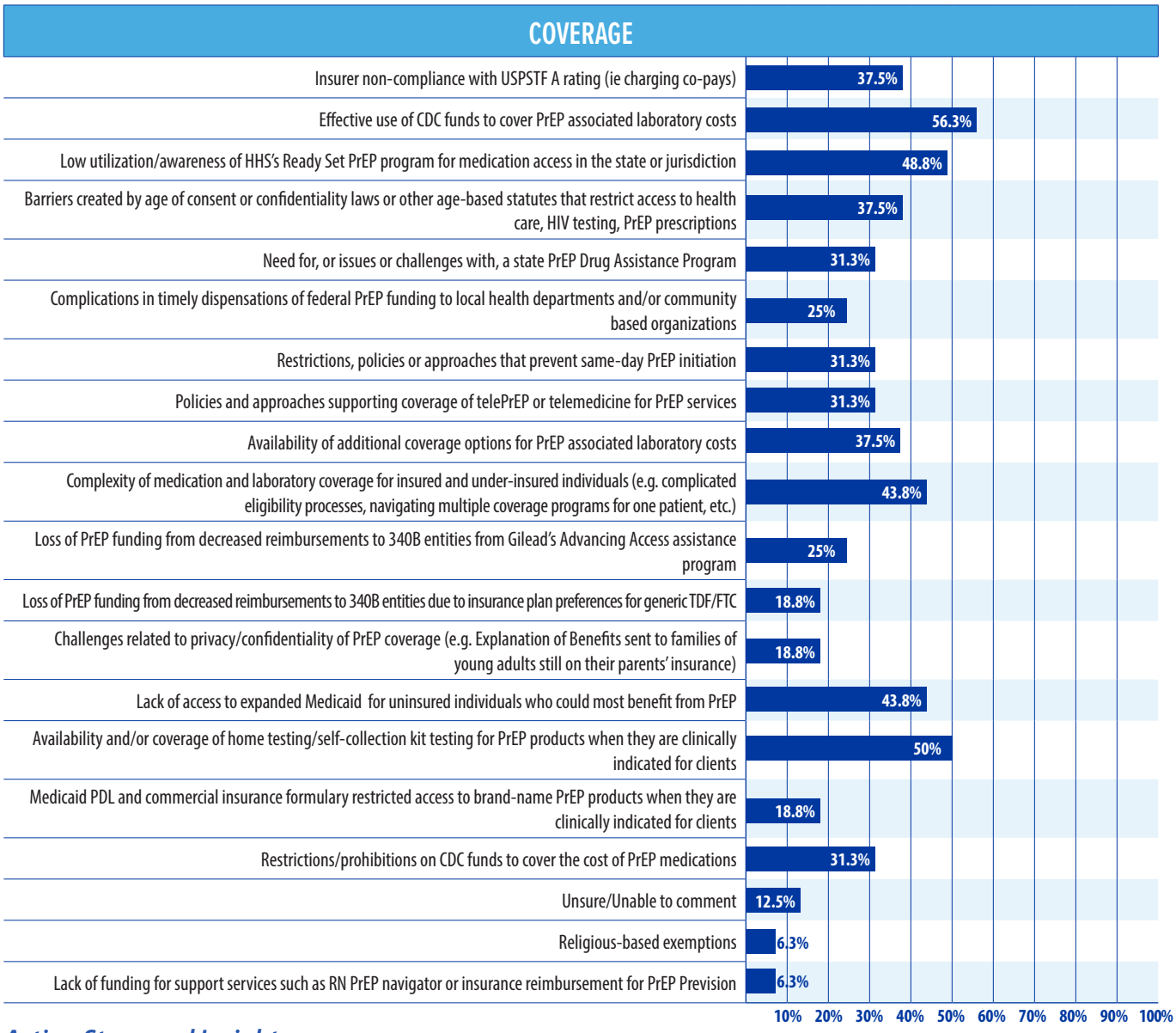
Do not have PrEP DAP Have PrEP DAP Passed and/or implemented Medicaid expansion

Table 2: Minor consent and confidentiality laws in Southern States – adapted from NASTAD (Feb 2022)[12]

	Minor Consent for Confidential Care					Parent/Guardian Consent Required					Parent/Guardian Notification Required/ Allowed					Insurance EOBs/Confidentiality Protections				
	PrEP	HIV test	HIV tx	STI test	STI tx	PrEP	HIV test	HIV tx	STI test	STI tx	PrEP	HIV test	HIV tx	STI test	STI tx	PrEP	HIV test	HIV tx	STI tst	STI tx
AK	Not in stat lang	Yes, for minors of any age				Not in stat lang	No				Not in stat lang	Provider may, but is not required, to notify parents				Not in stat lang	No confidentiality protection			
AL	Not in stat lang	Yes >12	Yes any age			Not in stat lang	No				Not in stat lang	Provider may, but is not required to, notify parents				Does not address confidentiality protections				
FL	Not in stat lang	Yes, for minors of any age				Not in stat lang	No				Not in stat lang	Notification not permitted				Not in stat lang	No confidentiality protection			
GA	Not in stat lang	Yes, for minors of any age				Not in stat lang	No				Not in stat lang	Provider may, but is not required to, notify parents or guardians				Not in stat lang	No confidentiality protection			
LA	Not in stat lang	Yes, for minors of any age				Not in stat lang	No				Not in stat lang	Provider may, but is not required to, notify parents or guardians				Not in stat lang	No confidentiality protections			
MS	Not in stat lang	Yes, for minors of any age except for HIV treatment which is not specified under statute				Not in stat lang	No for all except HIV treatment, which is not specified under statute				Not in stat lang	No obligation to disclose for STD/STI testing and treatment; not specified for HIV testing and tx				Not in stat lang	No confidentiality protections for HIV testing, STI testing and tx and not addressed for HIV tx			
NC	Not in stat lang	Yes, for minors of any age				Not in stat lang	No				Not in stat lang	Notification is not explicitly required				Not in stat lang	No confidentiality protections			
SC	Not in stat lang	Ye,s for minors 16 and older				Not in stat lang	No				Not in stat lang	Allowed under some circumstances			Not in stat lang	Not in stat lang	No confidentiality protections			
TX																				
TN	Not in stat lang	Yes, for minors of any age				Not in stat lang	No				Not in stat lang	Not specified under statute				Not in stat lang	No confidentiality protections			

[11]Adapted from: NASTAD: PrEP/PEP Access: State PrEP Assistance Programs. https://nastad.org/prepcost-resources/prep-assistance-programs (Accessed on 3.28.2023), and Kaiser Family Foundation/KFF. Status of State Medicaid Expansion Decisions: Interactive Map. https://www.kff.org/medicaid/issue-brief/status-of-state-medicaid-expansion-decisions-interactive-map/ (Accessed 3.28.2023)
[12]https://nastad.org/sites/default/files/2022-02/PDF_Minor_Consent_and_Confidentiality_Laws.pdf

Figure 3: Feedback on Policies and Approaches Impacting PrEP Coverage – Results from the SAC-PrEP4All Survey (Percentage of Respondents)



Action Steps and Insights

There are local, regional and national steps that can help close the coverage gaps for PrEP.

Locally and regionally:

Dispel confusion and raise awareness

- Develop communications materials and channels to build provider awareness about PrEP coverage under USPSTF guidance. One crucial issue that is not addressed at length in this report is the need to reinforce that generic TDF/FTC is wholly equivalent to branded Truvada and can be used interchangeably and preferentially. The National PrEP Plan Working Group has addressed ongoing confusion and misinformation which drives prescribers and PrEP users to opt for more costly branded medications. Provider outreach and awareness is key.)

- Identify and share strategies for assessing the strategic risks and benefits to pursuing statutory clarification regarding confidentiality of services for minors – considering whether raising the need for clarification will draw attention to PrEP as configured in the context of the ongoing Braidwood case, for example,

- Share and connect providers and clients with PrEP4All's team that is tracking and reacting to instances of insurance refusing to cover some or all costs associated with PrEP

Demand additional resources for labs and medications

- Join and/or amplify relevant demands of the National PrEP Program Working Group. These include supporting White House efforts to advance the vision of a fully funded, 10-year National PrEP Program, and to ensure that existing resources, , including CDC/HHS funds are used to advance the conversation of a National PrEP Program. (See Table 3 for an example of how $25M in funds could theoretically be invested for a few initial priority jurisdictions). The advocacy related to such a program is continually evolving; to follow the conversation please sign up for the NPPWG listserv at bit.ly/natlprepgroup.

- Identify capacity to develop local or state access mechanisms, such as PrEP-DAPs, that defragment lab and medication coverage for un- and under-insured individuals and eliminate cost as a barrier. Note that NPPWG is currently pressing for CDC to increase flexibility of federal funds for just such a purpose while also advocating for a strong federal mechanism for access.

Table 3: National PrEP Program: $25M "Down Payment"

Program component	FY23 EHE funding	Justification	Mechanism
Generic TDF/FTC purchase	$2M	Assuming 5,000 individuals served in two to three high need jurisdictions.	Federal negotiated rate, distributed via a pharmacy network, and paid through federal reimbursement
Lab purchase	$4M	Assuming 5,000 individuals served in high need jurisdictions	Federal negotiated rate, implemented via a lab network, and paid through federal reimbursement
PrEP clinical and non-clinical services, including provider capacity building	$6M	Grant allocation to establish 15-20 "hub and spokes" administrators in initial jurisdictions to connect clinical hubs to non-clinical provider spokes via telehealth and referrals	Competitive grant process open to health departments, clinical organizations, or other entities with demonstrated capacity to build a network and provide PrEP to marginalized communities
Federal reimbursement vendor	$4M	To achieve administrative efficiencies, CDC will contract with a vendor to administer the claims submission and	CDC will issue a competitive bid for a vendor via an initial contract based on anticipated volume
CDC Administrative Costs	$5M	CDC costs to negotiate fair public health prices for generic TDF/FTC and PrEP labs, administer a competitive bid for a reimbursement vendor, and oversee the National PrEP Program	
Demand Creation Activities	$4M	Activities to ensure knowledge of PrEP across communities most at risk for HIV acquisition.	Competitive grant process open to community organizations and other entities with demonstrated capacity to increase knowledge of and demand for PrEP in marginalized communities.

Expanding Provider Networks

Overview: Defining Network Sufficiency, Supportive Policies and Approaches

Expanding provider networks to achieve 'network sufficiency' is crucial to equitable and impactful use of PrEP as an HIV prevention strategy. The first step towards this goal is defining sufficiency and identifying metrics that can be used to make meaningful comparisons across different contexts. Researchers focused on determinants of PrEP access use the term "PrEP desert" to describe locations where PrEP access is more than a thirty-minute drive away. Whether or not you live in a PrEP desert determines the likelihood of PrEP use—even if you are eligible. In one study of nearly 4800 PrEP-eligible nonurban men who have sex with men, suburban men who lived in PrEP deserts were less likely to use PrEP than suburban men not living in PrEP deserts; the same was true for nonurban men in the same categories[13].

The presence or absence of PrEP clinics across the country is uneven and diverges from the burden of HIV found in varying regions. The researchers who developed the PrEP Locator database, a repository of information on PrEP provision services nationwide, looked at PrEP clinic prevalence (the number of clinics per 1,000 PrEP eligible individuals) and looked at clinic prevalence compared to the number of new HIV diagnoses per year in each state. Southern census divisions had lower ratios of PrEP-providing clinics compared to new HIV diagnoses than any other regions in the nation[14].

Data on PrEP clinic prevalence and PrEP prevalence among PrEP eligible individuals in each state or jurisdiction can be used together to illustrate the connection between clinic availability, PrEP deserts and PrEP use by eligible individuals. It is estimated that achieving 40 percent coverage among PrEP eligible people would lead to a 33 percent reduction in new HIV transmissions in that community[15].

Increasing PrEP clinic prevalence, PrEP prevalence in eligible people, and reducing the number of people who live in PrEP deserts (and the number of PrEP deserts overall) are metrics for network sufficiency. There are multiple approaches that can be used to support network expansion—many of which require support from state or jurisdictional health departments and, in some cases, legislatures, in the form of statutes, guidance, training, policies and funding. These approaches include pharmacy-provided PrEP, telemedicine-provided PrEP, PrEP integration into general health services (with attention to provider training to address issues of stigma, bias, and skill gaps in taking and discussing sexual histories). Pharmacy-provided and/or telemedicine-provided PrEP programs have supported network expansion in several states including California, New York, Seattle, and Iowa.

Pharmacy-based network expansion

The potential for increasing network coverage via pharmacy-based PrEP is undeniable. As a NASTAD brief on this topic notes, "Nearly nine in 10 Americans live within five miles of a pharmacy. 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.[16]" However there are also key considerations at the level of policies, regulations, and collaborative practice agreements (see Table 4) and at the level of provider training. Effective pharmacy-based PrEP depends on pharmacists who are trained in sexual risk assessment, counseling on PrEP adherence, continuation and discontinuation, and review of relevant medical records and laboratory results required prior to PrEP initiation. Pharmacists will need to be reimbursed for the time invested in receiving and refreshing this training and relevant certifications.

[13]Sharpe, JD, Sanchez, TH, Siegler, AJ, Guest, JL, Sullivan, PS, Association between the geographic accessibility of PrEP and PrEP use among MSM in nonurban areas. J Rural Health. 2022; 38: 948– 959. https://doi.org/10.1111/jrh.12645

[14]Siegler, A, Bratcher A, et al. Location, Location, Location: an exploration of disparities in access to publicly listed pre-exposure prophylaxis clinics in the United. Annals of Epidemiology. 28 (2018) 858-864.

[15]Samuel M. Jenness, Steven M. Goodreau, Eli Rosenberg, Emily N. Beylerian, Karen W. Hoover, Dawn K. Smith, Patrick Sullivan, Impact of the Centers for Disease Control's HIV Preexposure Prophylaxis Guidelines for Men Who Have Sex With Men in the United States, The Journal of Infectious Diseases, Volume 214, Issue 12, 15 December 2016, Pages 1800–1807, https://doi.org/10.1093/infdis/jiw223

[16]https://nastad.org/sites/default/files/2021-11/PDF-Pharmacist-Initiated-PrEP-PEP.pdf

Tele-PrEP network expansion

The range of approaches to tele-PrEP services includes synchronous (real time) and asynchronous counseling and assessment, services that are affiliated with brick-and-mortar clinics and services that are entirely virtual. The pathways to profit and reimbursement for these different service types are complex. A 2022 report from the Kaiser Family Foundation (KFF) describes, in detail, the state of tele-PrEP in the United States including the multiple configurations of for-profit providers and their pathways to reimbursement[17]. Only five states in the United States have state-run tele-PrEP services, and in the recent KFF report, many state health officials said that the complexities of a state-run service were such that they preferred partnership-based models.

Table 4: Select policies, agreements and policies impacting telePrEP

Network Expansion Approach	Agreements and collaborations	State laws and regulations	Reimbursement opportunities
Pharmacy provided PrEP	**Collaborative practice agreements (CPAs)** create formal relationships between pharmacists and health providers including health departments that allow the pharmacist to perform duties usually outside their scope of practice. The health provider formally delegates some responsibilities to the pharmacist. This has been used to expand PrEP provider networks in San Francisco and Seattle.	**Pharmacy "scope of practice" considerations:** A growing number of states permit pharmacists to prescribe some medications (versus filling prescriptions from a provider.) There are restrictions on these medications; some states also restrict pharmacists from interpreting lab results, which could be a barrier to an expanded scope of practice for PrEP. State scope of practice laws also vary on the extent to which pharmacists can provide point-of-care testing and other clinical services associated with PrEP, in addition to the medication.	**Reimbursement policies**, particularly for state Medicaid programs, can expand the scope of services pharmacists can seek payment for through Medicaid. While it is common for Medicaid to reimburse for dispensing medication, more programs are moving to allow pharmacists to seek reimbursement for clinical services, including point-of-care testing and counseling.
Telemedicine	Tele-PrEP programs rely on a range of contracts and agreements between various actors including state health departments, telemedicine providers, insurance companies, laboratories, brick and mortar clinics; they are also impacted by the terms of Gilead's PrEP Assistance Program which has, of 2022, instituted terms such that uninsured patients no longer generate 340b savings[18].	▶ Laws (proposed and passed) that require insurance coverage of at-home tests (proposed in California) and/or prohibit or restrict self-collection of samples to a set of diagnostics meeting specific state-mandated criteria (New York); ▶ CDC's newest HIV screening recommendation for HIV RNA testing which can be costly and cannot presently be done at home ▶ State regulations with regard to asynchronous telehealth (12 states do not allow it); ▶ State approaches to credentialing for tele-PrEP including for physician assistants and/or multi-state licensing for physicians	Policy responses to the COVID-19 pandemic expanded reimbursement opportunities for telehealth, particularly through Medicare policy changes. State Medicaid programs and commercial payers, however, vary in the extent to which they reimburse for services provided via telehealth and whether payment parity is required with in-person services.

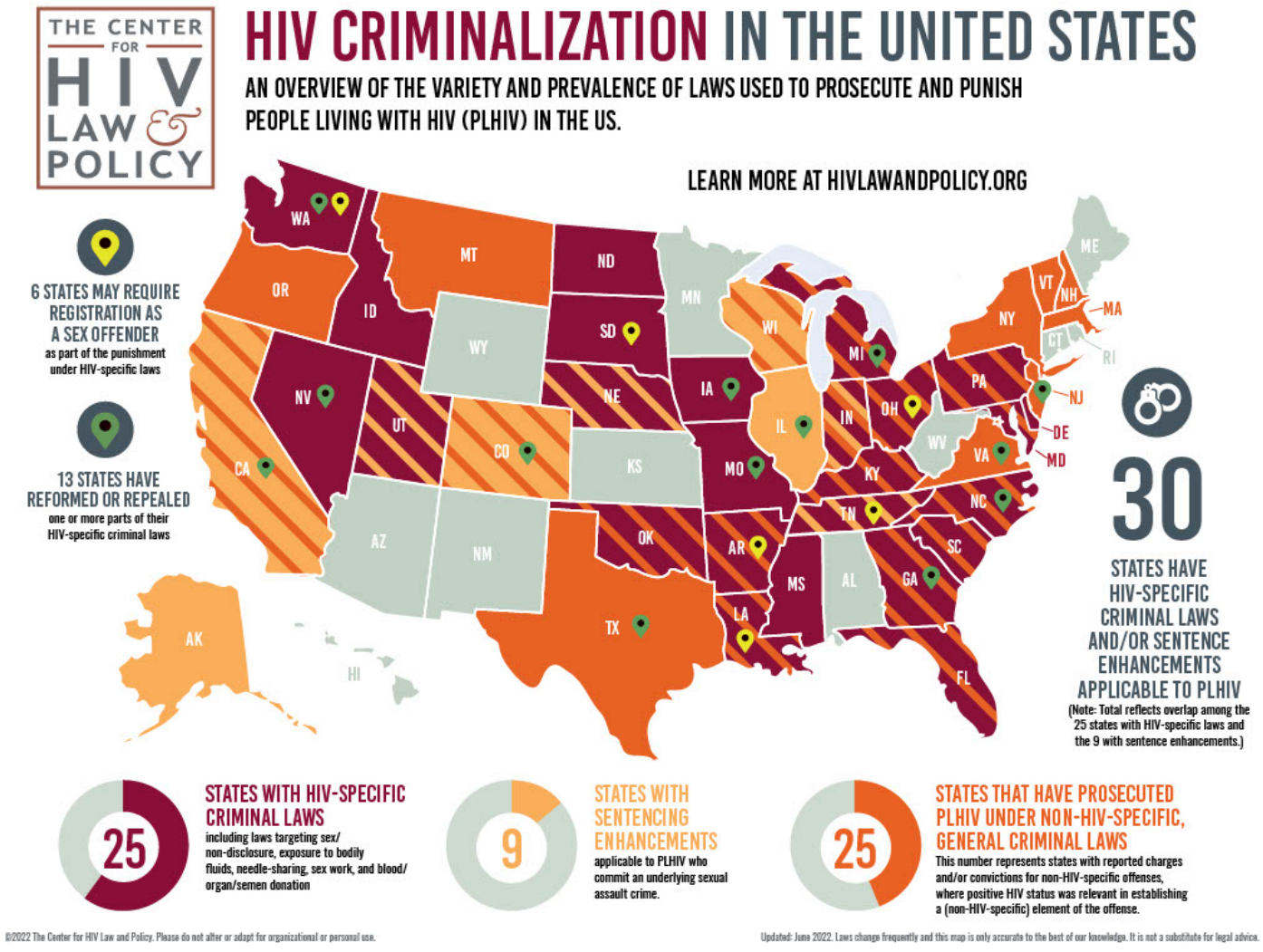
[17] https://www.kff.org/report-section/prep-access-in-the-united-states-the-role-of-telehealth-issue-brief/

[18] In order to participate in Medicaid and Medicare, drug manufacturers have to offer their medications at a significant discount for specific types of clinics including safety net providers that meet the needs of under-served communities. This category, which includes Ryan White clinics and community health centers, is collectively known as 340b providers. After purchasing a medication at a discount, 340b entities can charge higher amounts to payers such as insurance companies. The funds remaining after the cost of purchase–340b savings–are then available to the facility for other purposes and can be a crucial source of revenue for community-based providers. Gilead Sciences's reimbursement practices have undermined and/or eliminated 340b savings.

Overview: Enabling Environment Considerations

When it comes to PrEP providers, quality, and quantity both matters. The efforts to expand PrEP provider networks must happen in the context of professional training and community-based and -led activities aimed at addressing anti-HIV- and anti-LGBTQI+ stigma, and stigma regarding sex that can serve as major barriers to individual's willingness to seek or stay on PrEP. PrEP use is higher among white people, even as HIV disproportionately impacts BIPOC communities. It is crucial to deliver PrEP in contexts that are anti-racist and actively seeking to build trust with individuals and communities that have experienced bias, neglect, mis- and under-treatment from the health system. Policies and laws that impact stigma include criminalization of HIV, which can take a range of forms (see Figure 4 for a summary), laws and statutes that prohibit or curtail the provision of health care services for trans or gender-non conforming individuals, and/or prohibit trans or gender-non conforming expression (i.e. via statutes prohibiting drag performances), as well as public statements by elected officials and community leaders that embolden public expression of hate speech or, alternatively, that encourage supportive, rights-based and non-discriminatory community norms.

Figure 4: HIV Criminalization in the United States



Context and Considerations in the South

The Southern region has the highest proportion of its population living in rural areas, and has higher rates of new HIV transmissions, which are a proxy for need for PrEP) compared to non-urban areas in other region; the South as a region also has the highest proportion of people who are eligible for PrEP who live an hour away from the nearest provider. High rates of un- and under-insured individuals, small numbers of doctors and health providers and a regional lack of Medicaid expansion puts the region at the center of any meaningful effort to expand PrEP access and impact.

Pharmacist-provided PrEP

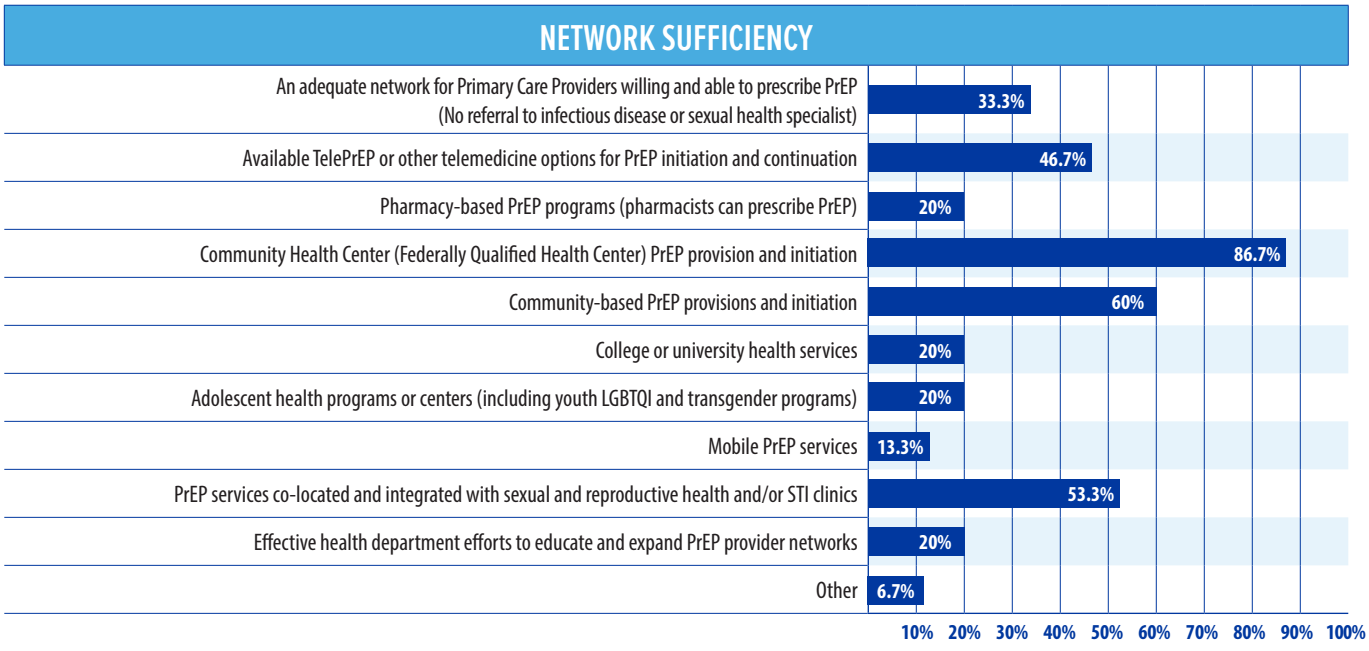
In a 2021 analysis from NASTAD, out of fourteen states with proposed or passed legislation addressing pharmacist provided PrEP or PEP, two (Florida and North Carolina) are in the Deep South. The Florida bill, which would have allowed pharmacists to dispense up to 60 days of PrEP died in committee in 2021 and again in 2023. The North Carolina bill would allow immunizing pharmacists and clinical pharmacist practitioners to prescribe PrEP and PEP, after certification by programs implemented by the medical board and pharmacist certification board. This bill remains in committee as of mid-2023[19] [20]. There is significant advocacy in this space, and just last year Arkansas passed its own law allowing pharmacists to prescribe PrEP, PEP, and other preventive therapies.

Tele-PrEP

In the Deep South, telePrEP options for un- and under-insured individuals remain complicated as existing options are geared toward individuals with private and/or public coverage. However, many of these programs do specify that they will work with individuals to navigate coverage options. Notable programs are available from the University of Arkansas (https://uamshealth.com/healthnow/) and the Louisiana HealthHub (https://www.louisianahealthhub.org/teleprep/). Additionally, for profit companies like mistr.com and qcareplus.com have expanded operations across the US and state an offer of support for navigation of cost and reimbursement challenges for the uninsured.

Figure 5 shows the results from the SAC-PrEP4All survey regarding the presence of approaches supporting network sufficiency in respondents' states and jurisdictions. Just one quarter of respondents felt that there was an adequate network of primary care providers who had the training and knowledge to prescribe PrEP; the same proportion (25%), also reported adolescent-friendly services. Even fewer participants reported the presence of tele-PrEP or pharmacy-based programs. These frontline reports reinforce the need for targeted work to expand awareness of PrEP as a strategy among general practitioners and in adolescent health clinics, and to expand provider networks through innovative approaches including tele-health and pharmacy-based care.

Figure 5: Strategies in Place to Support Network Sufficiency for PrEP – Results from the SAC-PrEP4All Survey (Percentage of Respondents)



[19] https://nastad.org/sites/default/files/2021-11/PDF-Pharmacist-Initiated-PrEP-PEP.pdf
[20] https://www.ncleg.gov/BillLookUp/2021/S575

Action Steps

There are local, regional, and national steps that can help expand provider networks for PrEP.

Locally and regionally:

Pursue cooperative practice agreements

- At a state and jurisdictional level, advocates and PrEP stakeholders can work with providers, health departments and pharmacies to map the potential for cooperative practice agreements (where they are allowed under scope of practice laws and regulations) to facilitate pharmacy provided PrEP. Sample legislation and legislative pathways can be reviewed; groups from Florida and North Carolina, where relevant legislation was developed can provide insights into the challenges and pathways to change.

Make tele-PrEP work for uninsured and underinsured individuals

- There is limited information about the barriers and facilitators to use of this service among under-served populations in the South. Efforts to identify strategies that can support use of tele-PrEP such as linkages with community-based organizations and brick-and-mortar clinics, use of community health workers and peer navigators should be resourced, implemented and acted on.

Nationally:

Amplify (and adapt to local context) Core Demands from the National PrEP Program Working Group

- Launch of a federal grant program that could go to health departments and/or CBOs well positioned to intentionally reach out and expand the network by creating a "hub & spokes administrator"
- 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. The CDC should set standards and/or programming for mail-order telePrEP labs and pharmacy-initiated labs to simplify patient care & expand PrEP to rural communities.
- Funding flexibility through CDC that allows hybrid pathway into jurisdictions – e.g., through health departments *and* directly to CBOs or clinical hubs
- State and jurisdictional support to map existing providers and expansion to new and non-traditional providers, such as harm reduction centers, homeless services, intimate partner violence clinics, LGBT centers, etc.
- Funding for capacity building assistance to develop infrastructure & train staff on issues such as how to use and order labs and to support the coordination of lab orders and lab results between community partners.
- Innovative strategies to increase interest and support for PrEP in non-HIV providers including primary care physicians (PCPs), and support current PrEP providers in HIV organizations

Communications, Marketing and Demand Creation

Overview: Policies and Approaches that Support Communications and Community Engagement Needs for Expanded PrEP Coverage

Communications and community engagement needs with regard to PrEP span every stage of the continuum from awareness (knowing about the strategy) to action (obtaining and using PrEP). Along the way, individuals need information in various forms (communication campaigns, community outreach, peer to peer learning) to support decision-making (is this strategy right for me?), health system navigation to access PrEP, and to use it continuously or discontinue if it is no longer the preferred HIV prevention option.

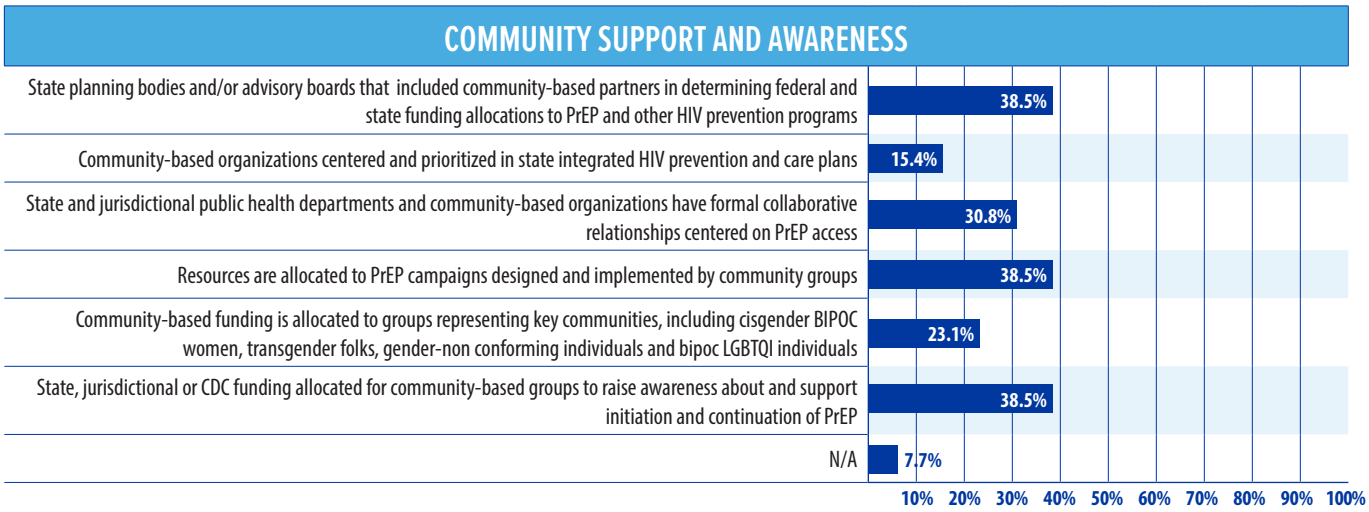
There are gaps and disparities in communications and community engagement efforts impacting PrEP. Research continues to show that many communities that are most in need of PrEP still have relatively low knowledge of PrEP, and that knowledge is lower among BIPOC individuals, particularly young gay men and other men who have sex with men, compared to non-Hispanic white people [1]. The most recent Centers for Disease Control and Prevention report on HIV trends in the United States confirms this once again. While overall incidence (annual rates of new transmissions) are estimated to have dropped 12 percent between 2017 and 2021 (although it is important to note that such an estimate must be interpreted with caution given testing disruptions due to COVID-19), BIPOC people–especially young men who have sex with men–are disproportionately represented among new cases compared to white men. 52 percent of new diagnoses were made in the American South. It is imperative to build on success–declining transmissions is a positive development–and to address inequities[21] . This extends to PrEP, where, even as demand has grown in the decade since PrEP was introduced, the gap between non-Hispanic whites and BIPOC individuals has persisted and continues to widen.

Raising awareness that PrEP exists does not automatically trigger demand and use among PrEP-eligible people. Anti-HIV and anti-gay stigma may act as deterrents from seeking PrEP, as discussed in previous sections; many people who are eligible for PrEP do not assess themselves as needing to use the strategy for HIV prevention. Communications and engagement to support accurate self-assessment—not once but across the lifecycle as people move in and out of periods of HIV risk—are also essential. To support this awareness raising, resources are needed for both national-scale media that convey clear, accurate PrEP information to everyone and more local community-informed communications campaigns that include qualitative research with the target audiences, development of tailored messages, evaluation, scaling and iteration [2].

The strategies needed for PrEP are specific to the intervention, but the skills involved are longstanding and centered in community-based organizations led by and for those most impacted by HIV and other health disparities. Yet in a bio-medicalized model of HIV treatment and prevention, many of these groups are under-funded and at the sidelines of the research and design processes that lead to the development of PrEP or other HIV campaigns—even when they receive funding to deliver these messages. Figure 6 shows the results from the PrEP4All-SAC survey of Southern providers and PrEP advocates. Just one respondent out of 13 indicated that groups led by and for those most impacted were resourced for communication and demand creation. Only two respondents felt that community-based organizations were centered in state and jurisdictional planning for HIV prevention and care activities.

[21]Centers for Disease Control and Prevention. Estimated HIV incidence and prevalence in the United States, 2017–2021. HIV Surveillance Supplemental Report, 2023; 28 (No.3). http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html. Published May 2023.

Figure 6: Community-based Partner Engagement in PrEP Services: Results from the SAC-PrEP4All Survey (Percentage of Respondents)



Funding to community-based groups led by those most impacted by HIV often flows to state and local health departments, which then grant and contract with groups to implement specific components of a program or campaign. These departments may have requirements attached to the funding which dictates the terms of these onward grants and contracts, or the scope of work may be determined based on the department's strategic assessment of needs and priorities. There are many instances where health departments and community-based organizations have worked together to develop dynamic, localized communications and demand creation activities for PrEP; but there are also instances where the funding flow through the health department limits what CBOs can do—either because the resources are insufficient, or because of requirements about what communications can and cannot say, portray or convey with regard to HIV, sexual behavior, LGBTQI or gender non-conforming identity.

There is limited published literature examining the funding flow of federal and state resources for PrEP demand creation and health literacy to identify challenges and best practices in relation to resources for local, tailored campaigns designed by CBOs and local jurisdictions. Sharing experiences between CBOs and coalition members could uncover approaches that support flexibility, innovation, and impactful messaging. The findings could then be used to shape alternative funding approaches that allow local groups and jurisdictions to retain flexibility in instances where local health department politics or preferences might interfere.

Overview: Enabling Environment Considerations

As this report was being prepared, the ACLU was actively tracking 462 anti-LGBTQ bills in the U.S. [22] As discussed in previous sections, HIV criminalization and anti-LGBTQI stigma and discrimination can deter people from accessing the health services they need. These bills, most of which have not yet become law, would not apply to public health communications but their existence—even as proposed legislation—contributes to a chilling environment for open discussions about PrEP for LGBTQI people. Likewise, communications campaigns about tele-PrEP and sexual health may be impacted by ongoing state-based struggles to secure access to medical abortion for pregnant women and other pregnant people in states where surgical abortion has been effectively banned. Exploring the opportunities for synergy between tele-PrEP, contraception and medical abortion is a fruitful area for public health advocates. Understanding if and how concerns about the privacy, confidentiality and legality of telemedicine for abortion impact the willingness of cis-women (and other groups) to use tele-PrEP is also important.

[22]Mapping Attacks on LGBTQ Rights in U.S. State Legislatures in 2024. https://www.aclu.org/legislative-attacks-on-lgbtq-rights-2024 Accessed March 1, 2024.

Action Steps

There are local, regional, and national steps that can help resources for demand creation and community mobilization for PrEP.

Locally and regionally:

- Collect and share information on campaigns and funding models that work. Local groups should be resourced to document and disseminate their practices, and coalitions like SAC can create spaces for frank discussion about how best to ensure that local communications work is resourced adequately and with flexibility.

- Partner with local research groups to design and implement formal studies to inform message development for target audiences.

- Amplify to state health departments and CDC that communications campaigns need to address localized/geographic tastes and differences, as well as demographic specificity even among racial/ethnic minorities. Always ensuring that the principles of cultural competence and humility are prioritized.

Nationally:

Amplify (and adapt to local context) Core Demands from the National PrEP Program Working Group:

- The federal government through CDC/HHS should contract with an experienced PR/marketing firm that specializes in deep partnership with communities most in need of PrEP to research new narrative frames/messages and to help implement those messages, instead of using traditional public health focused marketing agencies.

- The National PrEP Program and initial steps to expand access should be promoted through strategic rollout of a national campaign with ambassadors/spokespeople doing radio, podcasts, TV, etc, including targeted ads on different social media platforms, e.g., ads on YouTube on key influencer channels on the site.

- The federal government should support national baseline setting, e.g., guiding principles, ads, messaging, while using localized community mobilization strategies for engagement and outreach.

CONCLUSION

This is a time of opportunity and obstacles for expanding PrEP access. As this report went to press, the future of ACA-mandated PrEP coverage was uncertain, while at the same time, the US government was making progress toward a National PrEP Program, and Southern AIDS Coalition and its allies were building momentum via the PrEP in Black America coalition. This document is designed as an organizing and learning tool to support community-based work to change conditions. You can use this guide to start or strengthen concrete actions–such as finding the status of legislation related to pharmacist provision, requesting up-to-date data on PrEP coverage to identify areas of low coverage, urging Medicaid expansion and PrEP DAPS. Combining efforts and comparing approaches across states in the Deep South can help build power. Together, we can–and will–secure equitable PrEP access for all.