

Pharmacist Authority to Initiate PrEP & PEP and Participate in Collaborative Practice Agreements

Grace Lee Parr
Manager, Legal Research

EHE Implementation Technical Assistance Meeting
October 11, 2023



Barriers to PrEP

- Fewer than 25% of individuals who would benefit from PrEP use the medication
- Uptake lowest among groups with the greatest need – including rural Americans in the South, Black and Latinx individuals, Black and Latinx GBM, and serodiscordant couples
- Barriers to accessing PrEP:
 - Lack of knowledge about the medications
 - Stigma around HIV; bias from healthcare providers
 - Distrust of the medical establishment
 - Inability to afford the medications
 - Systemic racism
 - Reduced access to primary care and sexual health clinics



A close-up photograph of various pills and capsules on a white surface. The image shows several white round tablets, two blue and white capsules, and one white and blue capsule. The background is a soft, out-of-focus light blue.

Accessibility of Pharmacies

- Pharmacists consistently rated as one of the most trusted healthcare professionals, making them ideal providers of PrEP and PEP
- Pharmacies offer a more accessible option for many people seeking care
 - 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
 - Can provide referrals and linkage to mainstream healthcare

Expanding Pharmacists' Scope of Practice

- 1) Statute
- 2) Statewide Protocol
- 3) Statewide Standing Order
- 4) Standing Order from Primary Care Provider (PCP)
- 5) Collaborative Practice Agreement (CPA)

Definition: Statute

- Written law enacted by a state's legislature
- Statute may:
 - a) Directly grant pharmacists the authority to independently initiate PrEP or PEP

OR

- b) Indirectly grant pharmacists the authority to do so through a standing order (either a statewide standing order or a standing order from a PCP) or a statewide protocol



Definition: **Statewide Protocol**

- State Board of Pharmacy establishes guidelines that pharmacists must follow to independently distribute a specified drug (e.g., PrEP or PEP)
- Authority for State Board of Pharmacy to establish a statewide protocol would be granted by statute
 - Statutory authority may be granted under a statute generally authorizing Board to establish binding regulations regarding practice of pharmacy



Definition: Standing Order

Serves as a prescription for either:

- Specified patient (patient-specific standing order)
- Specified population (non-patient specific standing order)

Two forms:

- Statewide standing order
- Standing order from a PCP

Definition: **Statewide Standing Order**

- State government official, often State Health Director with a Doctor of Medicine (MD), issues written authorization for specified drug (e.g., PrEP or PEP) that any pharmacist licensed to practice in state may utilize
- Authority granted by statute
- Non-patient specific
 - Ex: non-patient specific standing order for PrEP allows pharmacists to distribute PrEP to any persons at risk of contracting HIV

Definition: Standing Order from a PCP

- Blanket prescription to distribute a specified drug (e.g., PrEP or PEP)
- May be patient-specific or non-patient specific
- Legislation permitting pharmacists to initiate PrEP or PEP may require a standing order from a primary care provider.



Definition: Collaborative Practice Agreement

- Purpose:
 - Establish formal relationship between PCP and pharmacist
 - Broaden pharmacist's scope of practice through PCP's supervision
 - Define patient care services pharmacist may provide under certain situations and conditions.
 - Delegate to pharmacist patient care service(s) within PCP's scope of practice
- Each PCP/pharmacist relationship requires unique CPA
- May be patient-specific or non-patient specific, as dictated by statute or regulation
- Authority to participate in CPAs must come from either statute or regulation



Pharmacist-Initiated PrEP: Key Considerations



Training and Education



Quantity and Frequency Limitations



Insurance Requirements

Prior Authorization

Step Therapy

Reimbursement – Pharmacists Not Legal
“Providers”

PrEP-Specific Legislation: Utah

PROS:

- Pharmacist does not need standing order from PCP
- Does not impose quantity or frequency limitations
- Pharmacist does not have to undergo additional training

CONS:

- Does not address pharmacist's reimbursement or other insurance provisions regarding PrEP and PEP-related services

Statute:
Utah Code Ann. § 58-17b-627
and UT ADCR156-17b-627

PrEP-Specific Legislation: Colorado

PROS:

- Insurers prohibited from requiring step therapy or prior authorization
- Private insurance plans required to cover PrEP and PEP prescribed by pharmacist and pay consultative fee
- Does not impose quantity or frequency limitations
- Pharmacist does not have to undergo additional training

CONS:

- Pharmacist must have non-patient specific standing order from PCP

Standing Order:

Colo. Rev. Stat. Ann. § 10-16-102(27.5), (38.5), (50.5), and (50.7);
Colo. Rev. Stat. Ann. § 10-16-104 (18)(e);
Colo. Rev. Stat. Ann. § 10-16-152;
Colo. Rev. Stat. Ann. § 12-280-103(39)(c)(II)(C), (39)(d), and (39)(e);
Colo. Rev. Stat. Ann. § 12-280-125.7; and Colo. Rev. Stat. Ann. § 25-1-130

PrEP-Specific Legislation: Nevada

PROS:

- Pharmacist does not need standing order from PCP
- Does not impose quantity or frequency limitations
- Insurers required to provide coverage and reimbursement for PrEP and PEP-related services at rate equal to rate of reimbursement provided to PCP for similar services

CONS:

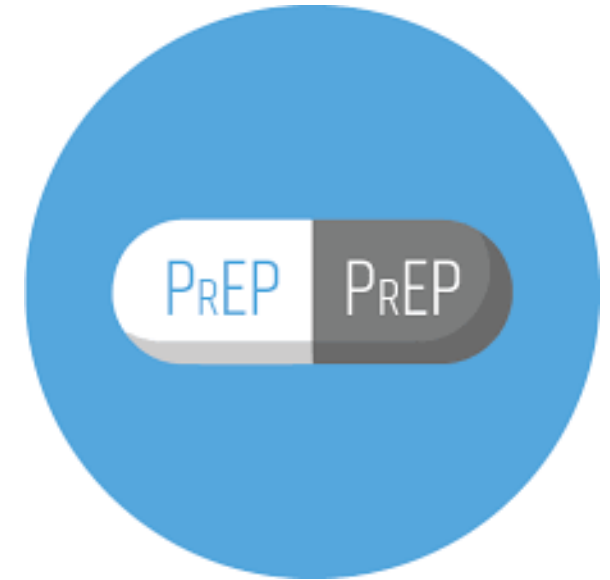
- Pharmacist must complete a two-hour course regarding treatment for PrEP and PEP for HIV-negative persons
- Pharmacist must have professional liability insurance coverage of at least \$1,000,000

Statewide Protocol:

Nev. Rev. Stat. Ann. § 639.0124;
Nev. Rev. Stat. Ann. § 639.28085;
Nev. Rev. Stat. Ann. § 689B.0312; and
Nev. Admin. Code R039-21

“Ideal” PrEP-Specific Legislation


- Direct statutory authority
- No quantity or frequency limitations
- Standing order from PCP not needed
- No prior authorization or step therapy requirements
- No/minimal additional training requirements
- Reimbursement clause:
 - a) Pharmacist defined as legal “provider”OR
 - b) Insurers required to provide coverage and reimbursement for PrEP and PEP-related services at rate equal to rate of reimbursement provided to PCP for similar services



CPAs as an Alternative



- Useful for:
 1. States without PrEP-specific legislation
 2. States with inaccessible PrEP-specific legislation
- Inaccessible PrEP-specific legislation:
 - Pharmacists may find it easier to utilize a CPA than navigate additional training requirements or insurance reimbursement
- CPA reimbursement:
 - PCP healthcare “provider” for insurance purposes
 - PCP compensates pharmacist based on mutually-agreed payment structure



Using CPAs to Initiate PrEP: Idaho

Idaho admin. Code r. 24.36.01.351

- Does not need to be patient-specific
- No filing requirements
- Must identify parties to agreement, pharmacist's scope of practice under agreement, and if necessary, any monitoring parameters
- No time period limit
- Pharmacist not required to undergo additional training

Recap:



Pharmacist
Accessibility



Need PrEP-specific
legislation that addresses:

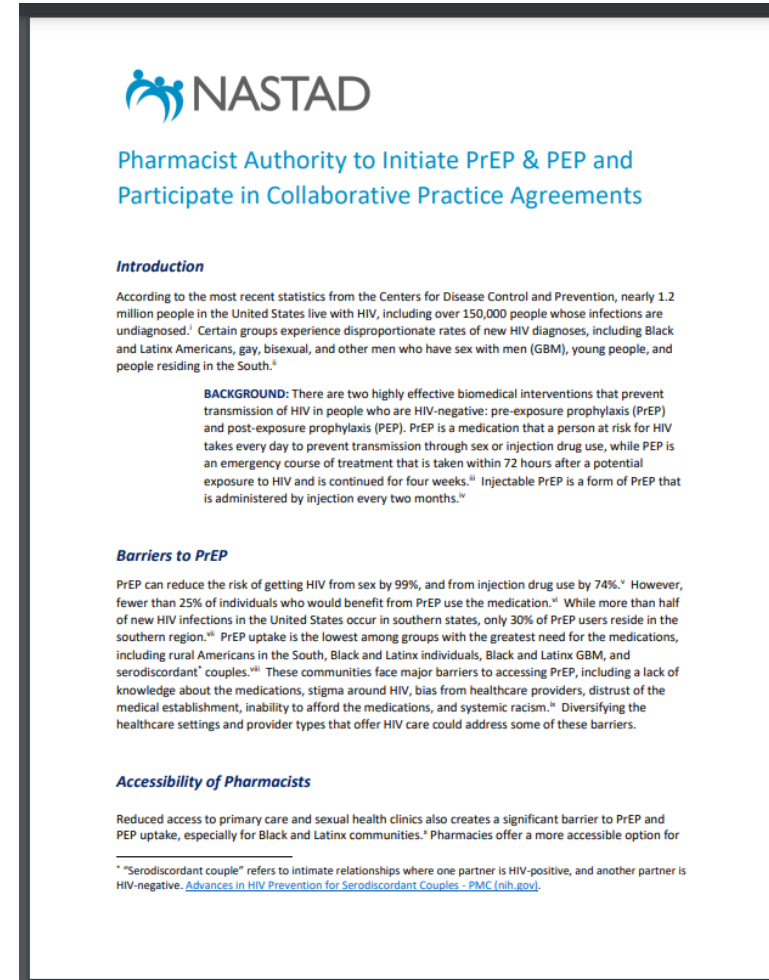
- 1) Training and Education
- 2) Quantity and Frequency
Limitations
- 3) Insurance Requirements
 - a) Prior Authorization
 - b) Step Therapy
 - c) Reimbursement



CPAs as alternatives to
PrEP-specific legislation

NASTAD Resources

2. Issue Brief: *Pharmacist Authority to Initiate PrEP & PEP and Participate in Collaborative Practice Agreements*



The thumbnail shows the cover of the NASTAD issue brief. At the top left is the NASTAD logo, which consists of three stylized human figures in blue and green. To the right of the logo is the word "NASTAD" in a bold, blue, sans-serif font. Below the logo and name is the title of the issue brief, "Pharmacist Authority to Initiate PrEP & PEP and Participate in Collaborative Practice Agreements", in a smaller blue font. Underneath the title is the word "Introduction" in a bold, italicized blue font. The main body of text is in a small, black, sans-serif font. It starts with a paragraph about HIV statistics from the CDC. This is followed by a "BACKGROUND" section in bold, italicized blue font, which describes PrEP and PEP. Next is a "Barriers to PrEP" section in bold, italicized blue font, which discusses uptake and access issues. Finally, there is an "Accessibility of Pharmacists" section in bold, italicized blue font, which mentions barriers to access. At the bottom, there is a footnote in a small black font explaining the term "serodiscordant couple".

NASTAD

Pharmacist Authority to Initiate PrEP & PEP and Participate in Collaborative Practice Agreements

Introduction

According to the most recent statistics from the Centers for Disease Control and Prevention, nearly 1.2 million people in the United States live with HIV, including over 150,000 people whose infections are undiagnosed.¹ Certain groups experience disproportionate rates of new HIV diagnoses, including Black and Latinx Americans, gay, bisexual, and other men who have sex with men (GBM), young people, and people residing in the South.²

BACKGROUND: There are two highly effective biomedical interventions that prevent transmission of HIV in people who are HIV-negative: pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP). PrEP is a medication that a person at risk for HIV takes every day to prevent transmission through sex or injection drug use, while PEP is an emergency course of treatment that is taken within 72 hours after a potential exposure to HIV and is continued for four weeks.³ Injectable PrEP is a form of PrEP that is administered by injection every two months.⁴

Barriers to PrEP

PrEP can reduce the risk of getting HIV from sex by 99%, and from injection drug use by 74%.⁵ However, fewer than 25% of individuals who would benefit from PrEP use the medication.⁶ While more than half of new HIV infections in the United States occur in southern states, only 30% of PrEP users reside in the southern region.⁶ PrEP uptake is the lowest among groups with the greatest need for the medications, including rural Americans in the South, Black and Latinx individuals, Black and Latinx GBM, and serodiscordant* couples.^{6,7} These communities face major barriers to accessing PrEP, including a lack of knowledge about the medications, stigma around HIV, bias from healthcare providers, distrust of the medical establishment, inability to afford the medications, and systemic racism.⁸ Diversifying the healthcare settings and provider types that offer HIV care could address some of these barriers.

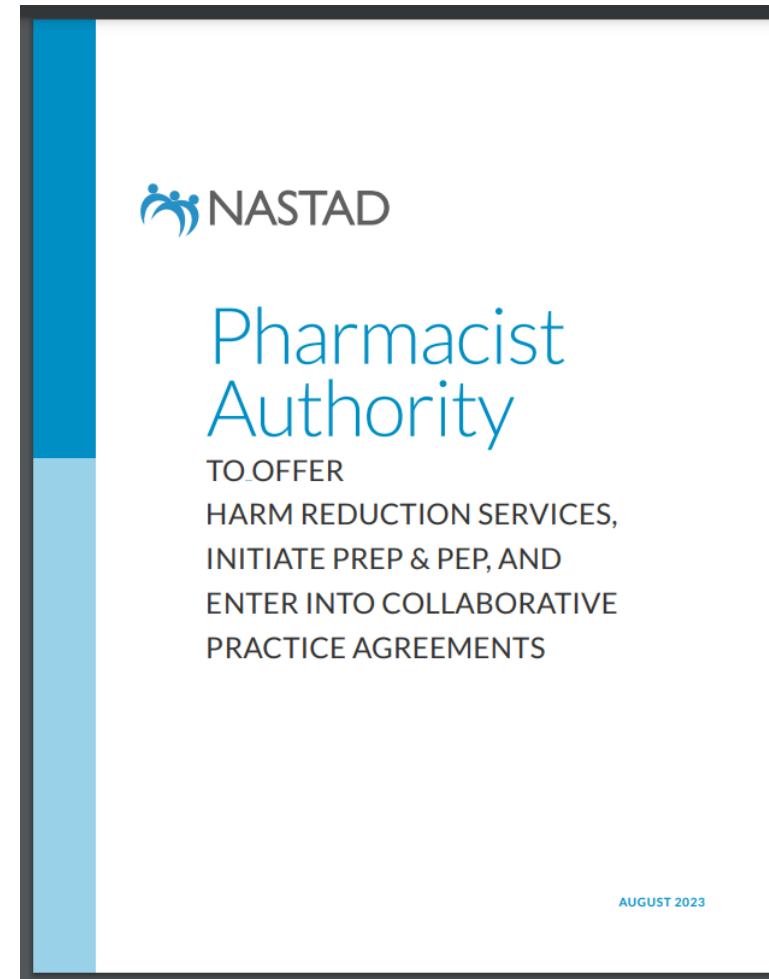
Accessibility of Pharmacists

Reduced access to primary care and sexual health clinics also creates a significant barrier to PrEP and PEP uptake, especially for Black and Latinx communities.⁹ Pharmacies offer a more accessible option for

* "Serodiscordant couple" refers to intimate relationships where one partner is HIV-positive, and another partner is HIV-negative. [Advances in HIV Prevention for Serodiscordant Couples - PMC \(nih.gov\)](#).

NASTAD Resources

3. [Database](#): *Pharmacist Authority to Offer Harm Reduction Services, Initiate Prep & Pep, and Enter into Collaborative Practice Agreements*



Contact

Grace Lee Parr

Manager, Legal Research

NASTAD

gparr@nastad.org