Exploring critical issues in state and territorial public health.



# **Expanding Pharmacist-Prescribed HIV PrEP**

When taken as prescribed, Preexposure Prophylaxis (PrEP) <u>reduces the risk of HIV transmission</u> among people who are at risk of exposure to HIV. It can be taken as a daily pill or <u>regular injection</u>. <u>Access to PrEP</u> can be challenging—especially for <u>Black and Hispanic people</u> and people <u>living in the southern United States</u>. <u>Stigma</u> associated with HIV/AIDS, lack of <u>provider education</u>, lack of access to healthcare providers, and <u>drug pricing</u> can all act as <u>barriers to accessing PrEP</u>.

PrEP is a powerful tool to reduce new infections; expanding access to PrEP is a priority within the federal Ending the HIV Epidemic in the U.S. initiative and National HIV/AIDS Strategy. One way to increase access to PrEP is by allowing pharmacists to prescribe and dispense it. Nine out of ten people in the United States <u>live within five miles of a community pharmacy</u>. Patients visit their pharmacist significantly more often than primary care provider, making pharmacists a highly visible access point for PrEP.

Pharmacists' patient care is defined through their <u>scope of practice</u>, which can be based in legislation or regulated by a state's board of pharmacy (or other appropriate state agency). Scope of practice can be expanded through several different mechanisms, including legislation or <u>collaborative practice</u> <u>agreements</u> (CPAs)—formal agreements allowing licensed pharmacists to perform specific patient care functions under the supervision and authority of another licensed healthcare provider.

As of May 2023, at least ten states (<u>AR</u>, <u>CA</u>, <u>CO</u>, <u>IL</u>, <u>ME</u>, <u>NM</u>, <u>NV</u>, <u>OR</u>, <u>UT</u>, and <u>VA</u>) have enacted legislation to allow pharmacists to prescribe a 30- to 90-day supply of PrEP.<sup>1</sup> To accomplish this goal, these states have done one or more of the following:

- Modified scope of practice laws to expand prescriptive authority statewide.
- Adopted statewide standing orders that allow pharmacists to prescribe.
- Enabled the medical director of a local health department to grant standing orders to allow prescribing by pharmacists in their jurisdiction.

At least six more states (MA, MD, MN, MO, NJ, and RI) have proposed bills in the 2023 legislative session that would expand pharmacists' ability to prescribe PrEP. These are the major points of consideration.

#### **Pharmacist Training**

State legislation may define the components of pharmacists' training, or it may leave the specifics to a licensing authority. At least eight states (AR, CA, CO, IL, ME, NV, OR, VA) specify formal training for pharmacists to be authorized to prescribe PrEP and PEP. The statute-based standard is 1.5 hours of PrEP- and PEP-specific education followed by an assessment, and continuing education credits often serve as incentive. Training may be held by higher education institutions, the state board of pharmacy, or another entity. The <a href="AIDS Education & Training Center Program">AIDS Education & Training Center Program</a> also offers further information for pharmacists and pharmacies initiating services.

<sup>&</sup>lt;sup>1</sup> This legislation allows pharmacists to prescribe PEP, an emergency 28-day course daily medication for people potentially exposed to HIV. New York legislation allows pharmacists to prescribe emergency PEP; New Mexico recently expanded their rules to include emergency PrEP.



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#### **Prescription Duration Limits**

CDC guidelines specify that patients taking oral PrEP should be tested to confirm they are HIV-negative when beginning PrEP and get tested at least every three months to ensure HIV-negative status and check for any medication side effects. Nevada, Oregon, and Virginia allow pharmacists to prescribe a 90-day supply and refills if the pharmacist receives confirmation that a patient has followed through on testing beyond the initial HIV screen. This method allows the client to continue care with the same practitioner. Arkansas, California, and Maine cap the number of 30- to 60-day prescriptions by a pharmacist at two per year, which is intended to prompt clients to connect with a primary care practitioner. Illinois and Utah have not yet published duration limits, which are to be determined by licensing authorities.

#### **PrEP Counseling**

At least nine states (AR, CA, CO, IL, ME, NV, OR, UT, and VA) required pharmacists to counsel patients.<sup>2</sup> The content of counseling sessions varies but generally includes obtaining a sexual history, information on how to take PrEP, the possible side effects, and referrals to a doctor or clinic for continued care. If the patient tests positive for HIV or STIs or has any other contraindications, they are immediately referred to a healthcare provider or clinic.

#### **Testing Requirements**

At least nine states (AR, CA, CO, IL, ME, NV, OR, UT, and VA) require a negative HIV test result from the patient. Pharmacists can perform a point-of-care finger stick test, order their own tests, or accept results of an antigen/antibody test from another provider that is less than seven days old. Testing is followed by consultation and screening for risk factors and signs and symptoms of acute HIV infection.

In states that allow a pharmacist to prescribe a full 90-day supply of PrEP, the patient must be tested for HIV, Hepatitis B, renal function, and sexually transmitted infections and take a pregnancy test when applicable. Both Colorado and Oregon have stipulations in their provider protocols that allow for the patient to receive a 30-day supply after a negative HIV test while waiting to receive other test results.

#### Conclusion

Since 2019, ten states have passed legislation that allows pharmacists to prescribe PrEP in their jurisdictions. Pharmacist-prescribed PrEP is a powerful tool to end the HIV epidemic in the United States; jurisdictions have several options to design policies to meet the needs of their communities.

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<sup>&</sup>lt;sup>2</sup> New Mexico does not require counseling or testing in statute but instead directs the Medical Board to develop regulations based on CDC guidelines.



# **Appendix A: Enacted State Legislation**

#### **Arkansas**

State Legislation	AR <u>HB1007</u> (2023)
Law/ Regulation/ Protocol	Statewide protocols pending.
Mechanism	Pharmacists may prescribe pursuant to a statewide protocol.
PrEP Duration Limits	Allows for a minimum 30-day supply up to a 60-day supply after which clients are directed to a primary care provider.
Pharmacist Training	Pharmacists must complete a training program approved by the board that must include information about financial assistance programs for PrEP, relevant federal guidelines on dispensing, and that the patient consultation may not be waived.

## California

State Legislation	CA <u>SB159</u> (2019)
Law/ Regulation/ Protocol	Section 4052 of the Business and Professional Code
Mechanism	Directly changes California law regarding pharmacist scope of practice.
PrEP Duration Limits	Up to a 60-day supply of PrEP once every two years. No limits on PEP.
Pharmacist Training	Required 1.5 hour training program

#### Colorado

State Legislation	CO <u>HB1061</u> (2020)
Law/ Regulation/ Protocol	Code of Colorado Regulations State Board of Pharmacy 3 CCR-719-1 (page 203).
	Pharmacists may prescribe pursuant to a statewide standing order.
Mechanism	The legislation authorizes the department of health to develop a standing order for pharmacists based on CDC guidelines. These protocols have since been developed by the state board of pharmacy, medical board, and state board of nursing in collaboration with the department of public health and environment.
PrEP Duration Limits	Up to a 30-day supply of PrEP. Refills are not authorized past the initial supply if the recommended baseline testing is not completed.
Pharmacist Training	Required 1.5-hour training program.

#### Illinois

State Legislation	IL <u>HB4430</u> (2022)
Law/ Regulation/ Protocol	This bill allows for a standing order to be issued by a physician or the medical director of a local health department.
Mechanism	Amends the Illinois Pharmacy Practice Act to allow the initiation, dispensing, or administration of drugs, laboratory tests, assessments, referrals, and consultations for HIV preventative drugs. Requires the pharmacist to have a standing order issued by a licensed physician or a county or local health department.



PrEP Duration Limits	No duration set. Pharmacist is acting under standing orders and is prescribing under the order of a physician or health department.
Pharmacist Training	Requires the completion of an accredited educational training program.

## Maine

State Legislation	ME <u>LD1115</u> (2021)
Law/ Regulation/ Protocol	Pursuant to a board approved protocol by the Maine Board of Pharmacy.
Mechanism	Requires the Maine Board of Pharmacy to develop a standing order or other protocols for prescribing PrEP/PEP and ordering testing.
PrEP Duration Limits	Up to a 60-day supply of PrEP to a single patient in a two-year period unless otherwise directed by a practitioner.
Pharmacist Training	Pharmacists must complete a training program approved by the Board of Pharmacy.

## Nevada

State Legislation	NV <u>SB325</u> (2021)
Law/ Regulation/ Protocol	<u>Draft regulations</u>
Mechanism	Requires the Nevada Board of Pharmacy to develop protocols. The Board of Pharmacy has released a memo on what Pharmacists can expect.
PrEP Duration Limits	Up to a 30-day supply of PrEP available pursuant to an HIV test and assessment. There are provisions allowing longer prescriptions if the patient receives HIV test, renal function testing, and Hepatitis B testing.
Pharmacist Training	Per the bill: Pharmacist must complete an FDA approved training program.  Draft regulations state that a pharmacist must complete a two-hour ACPE education course.

## **New Mexico**

State Legislation	NM <u>SB92</u> (2023)
Law/ Regulation/ Protocol	Pursuant to a board approved protocol by the New Mexico medical board.
Mechanism	Requires the New Mexico medical board to approve protocols allowing a pharmacist to order, test, screen, treat, and provide preventative services for multiple health conditions including HIV PrEP/PEP.
PrEP Duration Limits	Not defined in statute, directed to the medical board.
Pharmacist Training	Not defined in statute, directed to the medical board.

## Oregon

State Legislation	OR <u>HB2958</u> (2021)
Law/ Regulation/ Protocol	PrEP protocols PEP protocols
Mechanism	Modifies existing laws regulating pharmacists in the state and gives the board of pharmacy the power to adopt rules based on the requirements set out in the bill.
PrEP Duration	To be adopted by the state Board of Pharmacy but must allow up to a 30-day supply. The



Limits	pharmacist can prescribe and continue prescribing a 90-day supply if the patient receives the rest of CDC's recommended testing on the proper schedule.
Pharmacist Training	Pharmacists must take a training program and are offered continuing education credits as an incentive.

## Utah

State Legislation	UT <u>HB178</u> (2021)
Law/ Regulation/ Protocol	Draft PrEP/PEP protocols
Mechanism	Allows pharmacists to prescribe drugs or devices designated by the Department of Health, including both PrEP and PEP. The enacted legislation requires the Division of Occupational and Professional Licensing to make rules in collaboration with other specified stakeholders.
PrEP Duration Limits	To be adopted by the Division of Occupational and Professional Licensing.
Pharmacist Training	Stipulates that the pharmacist may prescribe a prescription drug or device that is within the pharmacist's scope of training and experience.
	Further guidelines will be created by the Division of Occupational and Professional Licensing. (Example training PPT available online).

## Virginia

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State Legislation	VA <u>HB2079</u> (2021)
Law/ Regulation/ Protocol	Prep Protocols Pep Protocols
Mechanism	Requires the Board of Pharmacy, in collaboration with the Board of Medicine and the Department of Health, to establish protocols and adopt regulations within 280 days of enactment.
PrEP Duration Limits	Up to a 30- day supply of PrEP with negative HIV test, 90-day supply if patient has all CDC-recommended testing.
Pharmacist Training	Must participate in a comprehensive training program related to the prescribing and dispensing of HIV prevention medications, to include trauma-informed care.



# **Appendix B: Additional Resources**

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Killelea A, Johnson J, Dangerfield D, et al. "Financing and Delivering Pre-Exposure Prophylaxis (PrEP) to End the HIV Epidemic in the United States: A Policy Proposal." *Journal of Law, Medicine, and Ethics*. 2022;50(Suppl 1): 8-23. Available at <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9341207/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9341207/</a>. Accessed 3-6-2023.

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Washington State Department of Health. "Washington State HIV PrEP Pharmacy-based Pilot Program." Available at <a href="https://doh.wa.gov/you-and-your-family/illness-and-disease-z/hiv/prevention/pre-exposure-prophylaxis-prep/hiv-prep-pharmacy-based-pilot-program">https://doh.wa.gov/you-and-your-family/illness-and-disease-z/hiv/prevention/pre-exposure-prophylaxis-prep/hiv-prep-pharmacy-based-pilot-program</a>. Accessed 3-6-2023.

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