

Pharmacist Prescribed PrEP and PEP in Oregon

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Background

HIV continues to have a disproportionate impact on certain populations, particularly racial and ethnic minorities, People Who Inject Drugs (PWID), transgender women, and gay, bisexual, and other men who have sex with men. Currently, more than 1.1 million Americans are living with HIV and many more are at risk of HIV infection. Since the FDA first approved the use of TDF/FTC for HIV Pre-Exposure Prophylaxis (PrEP) in 2012, PrEP has become one of our best tools to prevent new HIV infections.

HIV Pre-Exposure Prophylaxis (PrEP) is a medication individuals take to prevent HIV infection before exposure occurs. The Centers for Disease Control and Prevention (CDC) estimates that 44% of those who could benefit from PrEP are Black, and 25% are Latinx, but less than 1% of those prescribed PrEP are from these communities. In the state of Oregon, Black and Latinx communities account for about 15% of the population, but account for about 30% of all people with new diagnoses of HIV.

Post-Exposure Prophylaxis (PEP) is a medication that individuals can take up to 72 hours after an exposure to HIV to prevent seroconversion. Because of the timeframe in which PEP is effective, streamlined access is imperative. Oftentimes few, if any, timely access options are available to individuals in rural or frontier settings.

CDC estimates that approximately 1.2 million people are at high-risk for HIV exposure and could benefit from comprehensive HIV prevention strategies, including PrEP. Pharmacist-prescribed PrEP and PEP could expand the availability of HIV prevention medication to populations that the traditional healthcare system is not reaching and reduce barriers to access for life-saving medications.

Oregon Board of Pharmacy PEP & PrEP Protocols and House Bill 2958

In 2017, the Oregon Legislature passed House Bill 2397, which granted the Oregon Board of Pharmacy the authority to allow pharmacists licensed in Oregon to prescribe, dispense, and administer board-approved drugs and devices according to a standard protocol. The Board recently approved pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) for prescribing by pharmacists who complete continuing education on HIV prevention medications. The full PrEP and PEP protocols can be viewed on the [Oregon Board of Pharmacy website](#).

In June 2021, Oregon Gov. Kate Brown signed into law House Bill 2958. The primary effect of the bill will be to require insurers to reimburse pharmacists for their time prescribing PrEP and PEP (and in fact all Board of Pharmacy-approved drugs or devices) at the same rate they would

reimburse any other healthcare provider. This requirement will provide pharmacists a critical financial incentive to offer PrEP and PEP prescriptions.

HB 2958 also mandates that insurers cover PEP and at least one form of PrEP without prior authorization and regardless of whether the prescribing pharmacist is in-network. Health maintenance organizations such as Kaiser Permanente are exempt from the prohibition on network restrictions.

Finally, the bill directs the Board of Pharmacy to adopt rules allowing pharmacists to prescribe a 30-day supply of PrEP based solely on a negative HIV test result. However, Board of Pharmacy adopted such rules on its own in June 2021, rendering that portion of the legislation moot.

Timeline & Pharmacist Requirements

The Oregon Board of Pharmacy PrEP and PEP protocols are currently in effect. HB2958 takes effect on the 91st day after the close of the 2021 legislative session, which falls in late September of 2021.

In order to start prescribing PrEP and PEP, the Oregon Board of Pharmacy requires that pharmacists complete “a comprehensive training program related to the prescribing and dispensing of HIV prevention medications, to include related trauma informed care.” It is up to pharmacists to determine if a training program meets these criteria prior to participating. The Oregon State University College of Pharmacy is in the process of creating a 2-hour, online, ACPE accredited course designed to meet the Oregon Board of Pharmacy’s training program criteria. The training modules are expected to be ready in January 2022. The registration fee for the training is not yet known. The OSU College of Pharmacy is currently exploring the viability of sponsorship options for the training. To view a detailed breakdown of the OSU College of Pharmacy’s training modules, see the Pharmacist Education and Support section below.

Pharmacy Participation

The Oregon Board of Pharmacy PrEP and PEP protocols and HB2958 create a pathway for any pharmacist licensed and practicing in Oregon to prescribe PrEP and PEP. The decision to prescribe, however, is an opt-in decision. Pharmacists and/or pharmacies will have to decide if prescribing is a good fit on a case-by-case basis. Decisions to prescribe may take into account factors such as staffing, financial viability, and the capacity of physical space to honor patient confidentiality. HB2958 made counseling for and prescribing PrEP and PEP billable services for pharmacists, which may inform any decision-making processes to opt-in.

Once community pharmacies begin prescribing PrEP and PEP, the Oregon AETC will collaborate with partners to maintain a list of pharmacies offering the service on the Oregon AETC website.

Implementation

Pharmacists that complete a training program that meets the Oregon Board of Pharmacy criteria will have the authority to prescribe PrEP (up to a 90-day prescription) and PEP (30-day prescription).

The Board of Pharmacy PrEP protocol provides guidance on prescribing TDF/FTC (Truvada®) and TAF/FTC (Descovy®), but does not provide guidance on administering injectable forms of PrEP as no forms of injectable PrEP have been approved by the FDA at this time. It is unknown if the Board of Pharmacy will incorporate guidance on administering injectable PrEP once an injectable form of PrEP is FDA approved. Pharmacists in Oregon currently have the authority to administer vaccines and prescribe and administer injectable contraceptives.

Labs for PrEP & PEP Initiation and Management

Although Oregon pharmacists do not have independent statutory authority to order, perform, and receive the results of clinical laboratory tests, authority can be granted as part of a statewide drug therapy management protocol. Both the PrEP and PEP protocols give pharmacists explicit authority to perform 4th generation point of care HIV tests. It should be noted that community pharmacies must have a CLIA waiver in order to perform CLIA waived 4th generation point of care HIV tests on-site.

Labs for Prescribing PEP

Pharmacists have the option of performing a 4th generation point of care HIV finger stick test when prescribing PEP. However, the PEP protocol does not require that an HIV test be performed by a pharmacist in order to prescribe. The prescribing pharmacist is, however, required to a) identify a provider for patient follow-up and communicate appropriate follow-up instructions to that provider and b) contact the patient one month after prescribing to advocate for appropriate provider follow-up. If an HIV test is not performed by the prescribing pharmacist, one should be conducted by the provider to which the patient is referred along with all other labs associated with PEP follow-up.

Labs for Prescribing PrEP

In order to write a prescription for and dispense a 90-day supply of PrEP, a pharmacist must verify that all required laboratory tests associated with PrEP initiation or ongoing management have been conducted and that all test results are negative or within range. Results from HIV tests performed elsewhere must have been performed within a 14-day period prior to prescribing and dispensing. The Oregon Board of Pharmacy protocol stipulates that the required laboratory tests for PrEP initiation and/or management include:

- HIV ag/ab (4th gen) - every 90 days
- Syphilis/Treponemal antibody - at least every 6 months
- Chlamydia/Gonorrhea (urinalysis, pharyngeal, and/or rectal dependent on patient sexual behaviors) - at least every 6 months
- Hepatitis B surface antigen - frequency not specified by protocol
- Creatinine Clearance - frequency not specified by protocol

The PrEP protocol does not currently require Hepatitis C or pregnancy testing for PrEP initiation or management.

Prescribing PrEP with an HIV Test Result Only

If only an HIV test result is available and the result is negative, the PrEP protocol grants pharmacists the authority to still prescribe PrEP, however, the patient must complete and bring in the results of all required labs within 30 days.

Positive Test Results

Pharmacists are subject to state reporting laws for positive results on any test they order and/or perform, including point of care HIV tests. Positive test results for chlamydia, gonorrhea, HIV, hepatitis B, and syphilis are required by Oregon law to be reported to a patient's local health department or the Oregon Health Authority within one business day. In addition, Oregon Board of Pharmacy PrEP and PEP protocols require pharmacists to refer a patient to their primary care provider or local health department for follow-up care and treatment in instances of a positive or indeterminate HIV, chlamydia, gonorrhea, hepatitis B, or syphilis test result.

Pharmacist Education & Support

OSU College of Pharmacy PrEP/PEP Pharmacist Education

Oregon State University College of Pharmacy has led the creation of a 2-hour ACPE course with subject matter experts. The course is designed to educate the Oregon pharmacist on assessing and prescribing HIV-1 Post-Exposure Prophylaxis (PEP) and Pre-Exposure Prophylaxis (PrEP), based on the Oregon Board's guidelines of Pharmacy's Public Health and Pharmacy Formulary Advisory Committee in conjunction with statewide experts and subject matter experts.

Module 1: HIV, PEP, and Medications

- *HIV statistics and disease state basics*

Module 2: Trauma-Informed Care

- *Specifically, as it relates to PEP and PrEP care in Oregon and pharmacists*

Module 3: Practical Application of The Oregon PEP Protocol

- *Inclusion/Exclusion criteria*
- *PEP Self-Screening Patient Intake Form*
- *PEP Assessment by pharmacist and Treatment Care Pathway*
- *Medications*
- *Dosing, contraindications counseling, adherence*
- *Payment for medication*
- *Sample Workflow in a Community Pharmacy Setting*
- *Patient Case Examples*
- *Filmed cases, Quiz throughout the module*
- *Documentation of visit*
- *Referral: to other providers if excluded, and/or to follow up care*
- *Provider Notification*
- *Medical Billing at the outpatient pharmacy for provided services*
- *Follow-up care*

Module 4: Practical Application of the Oregon PrEP Protocol

- *Screening Tests*
- *Ordering, interpretation*
- *Guidance for delivering HIV Screening test results and supporting clients who test positive.*

Module 5: Barriers to care

Ongoing Pharmacist Support

The following resources are available to provide ongoing support to pharmacists prescribing PrEP and PEP in Oregon:

- [Oregon AIDS Education & Training Center \(AETC\)](#) - Local resource available to provide free clinical consultation, customized trainings, and capacity building assistance to pharmacists and pharmacy teams in group settings or one-on-one
- [National Clinical Consultation Center \(NCCC\)](#) - National consultation resource staffed by clinical experts available to provide clinical guidance on PrEP, PEP, and HIV
- **PrEP Navigation Services offered by [Cascade AIDS Project](#) and [HIV Alliance](#)** - Local patient resource supporting PrEP and PEP prescribers by helping patients secure funding to cover the cost of PrEP and PEP and connecting patients with ancillary resources
- [Resource List for Patients Accessing PEP through Pharmacies](#) - This list includes county specific resources relevant to patients accessing PEP, such as syringe exchange sites, sexual assault advocacy and support organizations, and low cost STI/HIV testing locations. The list was created and is maintained by the Oregon Statewide PrEP/PEP Workgroup, which is facilitated by the Oregon AETC.