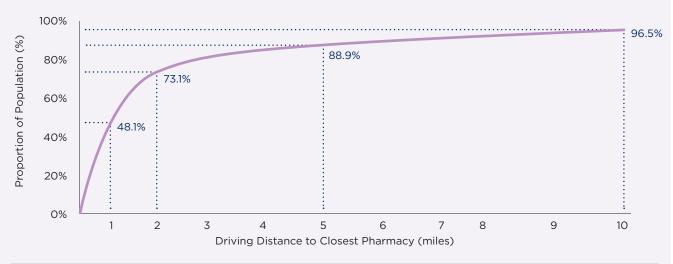
QUICK TAKE

BARRIERS TO PHARMACIST-ADMINISTERED LONGER-ACTING INJECTABLE PREP

ANTIRETROVIRAL THERAPY (ART) FOR THE TREATMENT OF HIV has allowed for improved health and quality of life, and reduced HIV-related mortality along with reduced transmission of HIV. Since 2012, antiretrovirals also have been available as pre-exposure prophylaxis (PrEP). HIV treatment and prevention regimens, however, have depended on adherence to daily oral pills. While highly effective, some people struggle with daily pill taking. Further, uptake and persistence of oral PrEP has been suboptimal to achieve public health impact. In 2021, the Food and Drug Administration (FDA) approved a longer-acting (LA) injectable form of ART and PrEP. Numerous additional forms of LA products for HIV treatment and PrEP are in the research pipeline.

While not intending to replace oral regimens, the existence of alternative forms of administration can give users more options that may support adherence and persistence to PrEP. Too few people with a clinical indication for PrEP ever begin using it, and for those who do, taking medication as prescribed or consistently using PrEP over time can prove challenging. A recent study found that half of individuals discontinued PrEP within the first year. (McCormick C et al. Adherence and persistence of HIV pre-exposure prophylaxis use in the United States. 2024). If users are able to obtain financial access to LA injectable medication through insurance or other programs, it could help make PrEP use more consistent and sustainable. LA injectables could prove especially beneficial to some individuals experiencing homelessness, individuals who use drugs, young people, and others who may find it difficult to adhere to a daily oral medication regimen.

The only LA PrEP medication currently approved by the FDA (cabotegravir), is administered through a gluteal intramuscular injection, and is administered every two months after initial doses. Currently, this product is primarily administered in clinical settings, typically by a nurse or physician. Beyond financing barriers, uptake of LA PrEP often has been limited, due in some cases, to constrained clinical capacity and workflow challenges. Introducing LA



NEARLY 9 IN 10 AMERICANS LIVE WITHIN 5 MILES OF A PHARMACY

Source: NASTAD, Pharmacist Initiated PrEP and PEP, available at https://nastad.org/sites/default/files/2021-11/PDF-Pharmacist-Initiated-PrEP.pdf Source: https://www.japha.org/article/S1544-3191(22)00233-3/fulltext ADEQUATE ACCESS TO LONGER-ACTING PRODUCTS FOR HIV PREVENTION IS A PROBLEM. WHILE COVERAGE BY INSURANCE AND GOVERNMENTAL HEALTH CARE PROGRAMS FOR LA PRODUCTS IS A SIGNIFICANT BARRIER, EXPANDING THE ROLE OF PHARMACIES IN ADMINISTERING THESE PRODUCTS OFFERS AN IMPORTANT PARTIAL SOLUTION TO IMPROVE ACCESS

PrEP in new settings and expanding scope of practice to allow a broader range of health professionals to administer it could help to address current gaps and barriers to access.

PHARMACIST SCOPE OF PRACTICE

Pharmacies are an important venue that can narrow gaps in access to PrEP. Patients visit pharmacies more often than their primary care providers, and nearly 90% of Americans live within 5 miles of a pharmacy. For pharmacies to administer PrEP, this must be authorized under state law. State laws, however, are not always clear on pharmacists' authority to administer LA injectable medications, or on authority to administer PrEP more broadly. In several states the practice of pharmacy includes the authority to administer injections. Some states explicitly authorize pharmacists to administer LA medication, but limit which medication can be administered (i.e., only antipsychotic medications). Where states are clear on authority to administer PrEP, they remain unclear on authority to administer LA PrEP. In recent years, however, many states have extended pharmacists' scope of practice through legislation or collaborative practice agreements.

As it stands, at least ten states have enacted legislation that either:

- modifies scope of practice laws to expand pharmacist authority to prescribe PrEP
- 2) implements statewide standing orders allowing pharmacists to prescribe PrEP, or
- gives authority to medical directors of local health departments to grant standing orders allowing pharmacists to prescribe in their jurisdiction.

These states offer a pathway for expanding on the ability of pharmacies and pharmacists to fulfill this critical role.

PHARMACIST REIMBURSEMENT

State and federal laws that determine how health services are billed state that "healthcare providers" can be reimbursed for services they perform, but tend to exclude pharmacists from the definition of "healthcare providers." Because of this, in most states pharmacists are not assured of reimbursement for services provided that would otherwise be reimbursed to other health providers. In some cases, pharmacists are not being paid for services that already fall within their scope of practice. This uncertainty around reimbursement poses a significant barrier to utilizing pharmacies to increase access to HIV prevention. Pharmacist administered LA would allow additional points of contact through which individuals could access HIV prevention. This, however, would require pharmacists to engage in additional services, such as testing and counseling, for which they would not be assured of reimbursement. Additionally, providing HIV prevention services requires training and education, and pharmacists may be hesitant to invest in such training when reimbursement is uncertain.

Several states, including Kentucky, New Mexico, Ohio, Oklahoma, Texas, Washington, and West Virginia, have passed legislation calling for payment parity for pharmacists. The various bills require insurers to reimburse pharmacists no less than other healthcare professionals providing similar services, as long as the services are within the pharmacist's scope of practice. Ensuring pharmacist payment parity would encourage pharmacists to engage in HIV prevention, potentially making LA products more accessible. Adequate access to longer-acting products for HIV prevention is a problem. While coverage by insurance and governmental health care programs for LA products is a significant barrier, expanding the role of pharmacies in administering these products offers an important partial solution to improve access. Building on the work of these initial states, policymakers should consider updates to laws and policies to seize the opportunity that pharmacies offer.

TO LEARN MORE

See Big Ideas Brief: Effective Implementation of Longer-Acting HIV Treatment and PrEP Requires Delivery System Innovation, May 2023, available at the link below.

NASTAD, Pharmacist Initiated PrEP and PEP, available at https://nastad.org/sites/default/files/2021-11/PDF-Pharmacist-Initiated-PrEP-PEP.pdf.



GEORGETOWN LAW

APRIL 2024

This Quick Take is a product of the Longer-Acting HIV Treatment and Prevention Policy Project of the **O'Neill Institute for National and Global Health Law** and was developed with support from *Gilead Sciences*, *Merck*, and *ViiV Healthcare*. It was authored by **Aiseosa Osaghae** with input from community stakeholders. The views expressed are solely those of the author.

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