

## Financing and Delivering Pre-Exposure Prophylaxis (PrEP) to End the HIV Epidemic in the United States

Q & A document, December 2021

### Why is a national PrEP program needed?

While many factors make PrEP difficult to access, at least part of the problem is that we don't have a functioning safety net system for PrEP access that includes BOTH the PrEP medications and labs. We've seen some significant progress for people with private insurance (you can read more on recent progress [here](#), but for others – particularly the uninsured or those on Medicaid – getting PrEP can be very complicated.

In other countries like Australia and England, a comprehensive program that eliminates cost and coverage barriers has opened access to PrEP. It's time for us to apply these lessons to PrEP for uninsured and Medicaid covered individuals in the US.

### Why are we putting this proposal together now?

A radical simplification of cost and coverage for PrEP is long overdue. When the first product for PrEP was approved in 2012 by the US Food and Drug Administration (FDA), the extremely high price of TDF/FTC (brand name Truvada) set by Gilead Sciences, combined with America's complex healthcare system, immediately limited access. The federal government played no role in securing a fair price for PrEP, and instead, access was built around complex manufacturer assistance programs.

In nine years, not much has changed. However, as of April 2021 multiple generic manufacturers are marketing TDF/FTC. That competition has driven the price down to just \$40 a bottle, opening the door to innovative new ideas for access, but only if we reform the broken financing and delivery system for PrEP.

### How will this proposal help people who need access to PrEP?

Right now, the system is too complicated for many patients to navigate. Problems include:

1. **Fragmented coverage:** For people without insurance, paying for PrEP medications and labs gets very complicated. Even where assistance programs exist, someone using PrEP may need to apply and reapply to more than one program to pay for everything. A lot of burden is put on patients to find these programs and prove their eligibility.
2. **Limited access points:** Uninsured and Medicaid covered individuals often have limited community-based provider options for PrEP access, meaning that they have to go out of their way to get their PrEP rather than get it in a way that works best for them.

Our proposal will make it so that **patients have easy access to both medications and laboratory studies**. They would be able to access PrEP at multiple points in and near their community.

How would you make that happen?

A national PrEP program will dramatically change PrEP access in three steps:

Part A: Streamline access to PrEP medications.	The federal government will purchase PrEP medications to secure fair public health prices and guarantee availability for people on Medicaid and the uninsured. Access will be simple for health care providers and patients alike.
Part B: Enhance clinical care for PrEP.	Clinicians will have new options to provide on-site, same-day PrEP and to refer patients to needed laboratory testing.
Part C: Create a new network of PrEP access points in the community	People without regular sources of health care will be able to get PrEP through telehealth at trusted neighborhood locations, such as domestic violence centers and street outreach programs.

What do you mean by a new network of PrEP access points?

When we say “providers” we don’t mean traditional doctors. We need to think outside of the box and meet people where they are already connected to services through telehealth arrangements with prescribers. Many of the people who most need PrEP in America already receive services, such as at mobile outreach units, syringe service programs, and domestic violence programs. We should be trying to involve these existing networks whenever possible.

What would it be like to be in the program?

People who need PrEP deserve a program that is very simple and totally free. Some people would be enrolled automatically. Others would let their providers know their insurance status at the time they are discussing PrEP. So long as they still need PrEP and don’t have private insurance coverage that can be used, they would continue to be eligible for the program. Their provider would then either hand them a bottle of TDF/FTC PrEP (for clinical providers only; this could be a 30 or 90 day supply), or provide the patient with a prescription for a participating pharmacy.

People who need lab access would be referred to a provider contracted with the federal government. Those with existing lab access through Medicaid could use their existing provider. Those accessing PrEP in nontraditional community sites would work with a telehealth provider for medication access and laboratory testing.

What about people who aren't connected to a place to get PrEP? How will they get connected?  
Not everyone who needs PrEP is connected to social or healthcare services. We are advocating for the CDC to also provide funds for a community-designed campaign to help raise awareness of a national PrEP access program.

Will the proposal help address other social and structural barriers to PrEP?

Yes. The proposal addresses some common structural and social barriers to PrEP:

1. **Meet people where they already feel comfortable:** Provider-related stigma is a major barrier to PrEP. We also know that access to a limited number of quality access points can be difficult depending on community stigma and transportation. By enrolling a large network of both traditional and nontraditional providers, including programs and services where people are already connected and feel comfortable, we can meet people where they're already at. We've seen how well this works with STD clinics in New York.
2. **Create a foundation for public communications and provider training:** The complexity of the current system undermines the chance to communicate coherently about PrEP access. The new program would sync well with an outreach program to the public and a national provider training program.
3. **Partnership with key communities:** Positions created by this proposal at the CDC and in state and city health departments should be filled by individuals with meaningful history and connection with the communities most in need of PrEP. Health departments must also establish meaningful partnerships with community representation for the formation and implementation of the program.

Will people be able to access all PrEP medications?

Because of its inexpensive cost, a national PrEP program would initially focus on generic TDF/FTC. The mechanism of global purchase of medications, however, can be easily applied to second-line and newer PrEP formulations. Instead of recapitulating access challenges and inequities that occurred in the first decade of PrEP medications, a national PrEP access program can eliminate unnecessary barriers to innovative treatments at the outset.

The full proposal is online at <http://publichealth.jhu.edu/PrEP>. Send questions to [prepproposal@jhu.edu](mailto:prepproposal@jhu.edu).