



## Ending the HIV Epidemic: A Plan for America PrEP Donation Program Q&A

### **SUMMARY OF ACTION**

Earlier this year, the Trump Administration secured a historic donation of pre-exposure prophylaxis (PrEP) medication from Gilead Sciences, Inc. (Gilead). The donation will expand access to this important preventive drug for uninsured individuals in the United States who are at substantial risk of acquiring HIV.

HHS recently granted a short-term contract to Gilead to accelerate distribution of the medication by utilizing a pre-existing network of vendors and subcontractors.

### **BACKGROUND**

In February 2019, President Trump announced the launch of *Ending the HIV Epidemic: A Plan for America* (EHE), an initiative to reduce the number of new HIV transmissions in the U.S. by 75% in five years and by 90% in ten years. A key component of the initiative is expanded patient access to PrEP medication. PrEP is the practice of prescribing drugs that prevent HIV infections in patients who are at substantial risk of acquiring HIV.

Gilead manufactures Truvada for PrEP—the only medication approved in the United States for use as PrEP against HIV—and is seeking FDA approval of Descovy for PrEP. In support of the President’s Initiative, Gilead donated its PrEP medication to the U.S. Department of Health and Human Services (HHS) to expand access for uninsured patients in the U.S. (subject to the donation agreement that Gilead and HHS had executed on May 8, 2019).

Under the donation agreement, Gilead bears the cost for the medication itself. Specifically, Gilead must reimburse pharmacies for (or back fill) PrEP medication that the pharmacies distribute to eligible patients.

HHS bears all other costs. These costs include verifying patient eligibility, enrolling eligible patients, building a network of participating pharmacies, distributing the donated medication to uninsured patients, and processing claims for the distributed medication—all in accordance with the donation agreement.

In order to distribute PrEP medication to eligible patients as quickly as possible, HHS sought a contractor to establish and administer an integrated, nationwide, medication-distribution system, which includes various vendors and subcontractors.

Gilead already has such a system and has been distributing free PrEP medication to a similar population for years. Gilead offered to establish and administer a similar system for distributing donated PrEP medication, charging HHS for only the costs that the vendors and subcontractors charge Gilead. Under this contract, Gilead will not charge HHS for any work performed by Gilead itself.

Given the urgent need to reach those at risk for HIV, HHS has awarded Gilead a six-month contract to administer the distribution of donated PrEP medication to eligible recipients.

During that six-month period, HHS will hold a full and open competition to select a longer-term contractor or contractors.

## **QUESTIONS & ANSWERS**

### **What is the purpose of the contract award to Gilead?**

HHS has been clear in its intention to distribute PrEP medication to the target population as quickly and efficiently as possible. The award allows HHS to leverage Gilead's existing Medication Assistance Program (MAP) to achieve that goal.

### **How much money is being awarded?**

HHS awarded Gilead approximately \$6 million. Gilead will charge HHS for only the costs that its vendors and subcontractors charge to Gilead. Gilead will not charge HHS for the work that it performs.

### **Why is this a sole-source contract?**

HHS requires a contractor that can establish and administer a customized solution for distributing donated medication to eligible recipients under the donation agreement.

The finite duration of the Gilead donation requires HHS to begin distributing the medication as quickly as possible in order to maximize access for those who need it. Maximizing that access is a public health imperative.

Gilead has experience serving a similar patient population. And Gilead is the only company that operates a similar distribution program for PrEP medication. Therefore, Gilead is uniquely positioned to quickly enroll eligible patients and distribute its PrEP medication according to the donation agreement in a compliant, accurate, and effective way.

Under the contract with Gilead, distribution shall begin within two months.

### **How will the program work?**

To qualify for the program, patients must:

- lack health insurance coverage for outpatient prescription drugs;
- have a valid "on-label" prescription; and
- have appropriate testing showing that the patient is HIV-negative.

Eligible patients can enroll in the program and receive donated medication through the mail or at a pharmacy.

### **What prevents patients in Gilead's existing MAP program from moving to the HHS program, thereby undermining the goal of expanded access?**

The contract with Gilead generally prohibits patients who are currently enrolled or have been enrolled in the last 12 months in the MAP program from enrolling in the HHS program.

### **How much will the drug cost patients enrolled in the program?**

Nothing.

### **How many patients will be served under the contract?**

4,250 patients under the six-month contract, and an additional 5,750 patients under an optional six-month extension. Truvada currently costs approximately \$1,800 for a thirty-day supply in the United States; therefore, a 6-month supply for 4,250 patient would cost over \$45 million. This contract awards Gilead approximately \$6 million to cover the costs of its vendors and subcontractors for administering the distribution of donated medication.

**Why would only 10,000 patients be served in the maximum twelve-month period? The donation covers up to 200,000 patients each year.**

The eligible patients represent the hardest-to-reach populations who are not covered with existing federal resources. The President's FY21 budget seeks an infusion of new funding to reach these patients and bring them into care utilizing a scaled approach.

**What is the length of the contract?**

Six months with a six-month option.

**Who will implement the distribution of PrEP after the expiration of the award to Gilead?**

HHS will announce a full and open competition for longer-term distribution of the donated product.

**When will the donated Product become available to eligible recipients?**

Fall/winter 2019.