

Financing an HIV/STI Self-Testing Program at Health Departments, Community-Based Organizations, and Health Facilities

Overview of HIV/STI Self-Testing

HIV/STI self-testing is individuals using HIV/STI tests in their home or a private location.¹ There are two types of HIV self-testing (HIVST): rapid or mail-in.¹ Currently, the OraQuick® In-Home HIV Test is the only FDA-approved rapid HIV self-test.² It is an HIV 1/2 antibody test. Mail-in HIV and STI self-testing uses a lab collection kit that is mailed to the client, who after completing the self-collection, mails the kit back to a laboratory to be analyzed.¹

Possible Funding Options for Self-Tests and Other Necessary Items

Funding Options	Rapid HIV Self-Test	Mail-In HIV/STI Self-Test	Other Programmatic Items*	Considerations
340B Savings	✓	✓	✓	It is important that the purchase of these items ensures compliance with the 340B program.
Grant Funding	✓	✓	✓	It is important to verify that these items are covered by the grant.
Insurance	✗	✓	✗	To be billed through the client's insurance, the mail-in HIV/STI self-tests need to be in-network and ordered by a healthcare provider.

*Items such as staffing, marketing, incentives, and office visit, labs, medication costs for uninsured clients

340B Savings

The 340B Drug Pricing Program requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at discounted prices to 340B program-enrolled or -covered health care organizations. Eligible organizations are qualifying hospitals, federal grantees from United States (US) Health Resources & Services Administration (HRSA), the US Centers for Disease Control and Prevention (CDC), the US Department of Health and Human Services' (HHS) Office of Population Affairs, and the Indian Health Service (IHS).³ Examples of organizations eligible for the 340B program are Federally Qualified Health Centers (FQHCs), Title X Family Planning Clinics, and Sexually Transmitted Disease Clinics.³ Enrolled or covered entities care for many uninsured and low-income patients.⁴

"Revenue" or savings can be generated between the 340B price and the full price of the drug when 340B enrolled or covered entities, directly or through a pharmacy, *dispense and bill* for the

drug at retail price.⁴ Savings between the 340B cost and the retail cost can be used to buy self-tests and other self-testing programmatic items.⁵ It is important that the items purchased for the self-testing program using 340B revenue are in accordance with program compliance and consistent with the revenue's designated non-profit status. It is also important to keep the 340B expenditures accounted for separate from public awards, grants, or cooperative agreement funds in case of an audit.⁵

Grant and Cooperative Agreement Funding

Grant and cooperative agreement funds may be used to purchase self-tests and self-testing programmatic items. These include state and local government grants. It is always important to verify that the items your agency is purchasing are covered by the public funds used to pay for them. To determine if your funding award allows self-testing items, refer to the terms and conditions of the award. Other options are to reach out to your CDC or HRSA Project Officer, your state health department office contact, or any other grant contact.

Insurance

Clients' insurance cannot be used for rapid HIV self-tests or other programmatic items. Currently, there is no Current Procedural Terminology (CPT) code for the OraQuick In-Home HIV Test.⁶ If your agency wants to bill client insurance for the mail-in HIV/STI self-test, the test needs to be in-network (which varies by states) and ordered by a healthcare provider.⁷

References

1. Centers for Disease Control and Prevention. HIV Self-Testing (Home Testing). <https://www.cdc.gov/hiv/basics/hiv-testing/hiv-self-tests.html>. Published 2020. Updated October 23, 2020.
2. US Food and Drug Administration. Facts about in-home HIV testing. <https://www.fda.gov/consumers/consumer-updates/facts-about-home-hiv-testing>. Updated June 25, 2020.
3. US Health Resources and Services Administration. 340B Eligibility. Last Updated May 2018. <https://www.hrsa.gov/opa/eligibility-and-registration/index.html>.
4. American Hospital Association. Fact Sheet: The 340B Drug Pricing Program. Published March 2021. <https://www.aha.org/fact-sheets/2020-01-28-fact-sheet-340b-drug-pricing-program>
5. US Health Resources and Services Administration. 340B Frequently Asked Questions: FAQ ID 1339. <https://www.340bpvp.com/hrsa-faqs>.
6. OraSure Technologies Inc. OraQuick. <http://www.oraquick.com/>. Published 2016.
7. NASTAD. "Self-Testing": A strategy to improve access to HIV, Viral Hepatitis, and STI testing. <https://www.nastad.org/resource/self-testing-strategy-improve-access-hiv-viral-hepatitis-and-sti-testing>. Published 2021. Last Updated April 15, 2021.