

Requirements for pharmacists providing laboratory screening services to OHP members

CLIA (Clinical Laboratory Improvement Amendments) requirements

Pharmacies providing PrEP and PEP (HIV screening for pre- and post-exposure prophylaxis) services to Oregon Health Plan members must obtain a CLIA waiver. The waiver authorizes the pharmacy to perform laboratory services. Oregon Health Authority will only reimburse PrEP and PEP testing for pharmacies with a current CLIA waiver.

1. Familiarize yourself with the CLIA regulations:

The CLIA regulations establish quality standards for laboratory testing. Before applying for a CLIA waiver, it's important to understand the regulations and requirements. To learn more, [read the Ready Set Test Booklet from the Centers for Disease Control and Prevention](#).

2. Obtain an FDA-approved rapid HIV test.

To apply for a CLIA waiver for HIV screening, you'll need to use an FDA-approved rapid HIV test. These tests are designed for use in non-laboratory settings, such as pharmacies. Find approved tests on the FDA website at www.fda.gov.

3. Train staff on the testing procedure:

In your training, make sure staff members who will be administering the test understand:

- The testing procedure.
- How to interpret the results.
- The regulations surrounding the test.
- How to follow manufacturer package inserts for the test kit (storage, quality control, etc.)

4. Apply for a CLIA waiver and pay fees:

Once you have an FDA-approved test and trained staff, you can apply for a CLIA waiver through the Centers for Medicare & Medicaid Services (CMS). The application process involves completing an application form, paying a fee, and demonstrating that you meet the requirements for a waiver.

Certificate waivers cost \$180 every 2 years.

[Visit the Certificate of Waiver page](#) to learn more about applying for a CLIA waiver.

5. Maintain quality control measures:

After obtaining a CLIA waiver, it is important to maintain quality control measures to ensure accurate and reliable testing. This includes regularly monitoring test performance and adhering to manufacturer instructions for storage and handling of test kits.

Contact Provider Enrolment to add your CLIA waiver number to your provider record

Before submitting PrEP or PEP claims, contact OHP Provider Services at 800-336-6016. Give them your CLIA Waiver number. You cannot bill PrEP or PEP claims without this number on file.

Other resources

Use the [Fee-for-service professional billing for retail FAQ](#) for guidance on billing for medical services.

[Visit the Oregon State University catalog](#) for continued education for pharmacists providing clinical services and prescribing services to OHP members.