

What is Point-of-Care Testing?

- Point-of-Care Testing (POCT) involves performing a diagnostic test outside of a laboratory that produces a rapid and reliable result, aiding in identifying or managing chronic disease and acute infections.
- These tests are waived under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and pharmacists can charge patients directly or possibly bill third party payers.
- Point-of-care testing provides an excellent opportunity for community pharmacists to enhance revenue by expanding patient care services while improving patient and population health. POCT allows for the screening and treatment (depending on states' regulation) to be completed during a single encounter, thereby improving access to care, counseling, and patient outcomes.

STEP 1: Apply for a CLIA Certificate of Waiver

- A certificate of waiver is required by CMS to perform tests categorized as waived.
- The CLIA application form, CMS-116, should be completed and mailed to your state agency.
- The CLIA Application for Certification includes identification of waived testing to be performed. All tests categorized as waived are regulated under CLIA Certificate of Waiver. The certificate renews every two years; it is encouraged to update your application for additional services you wish to provide.

HOW TO FILL OUT A CLIA CERTIFICATE OF WAIVER (CMS-116) APPLICATION cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf	
Section I. General Information <ul style="list-style-type: none"> • Check initial application and leave the CLIA identification number blank • Complete this section providing your pharmacy's specific information • Name of Director – can be anyone in the pharmacy but recommended to be the pharmacist overseeing the testing in the pharmacy 	Section VI. Waived Testing <ul style="list-style-type: none"> • List the tests you will be performing. Verify with your state which tests you can perform • Estimate the total number of tests you will be performing annually (consider all tests listed)
Section II. Type of Certificate Requested <ul style="list-style-type: none"> • Only check the first box: "Certificate of Waiver" 	Section VII. PPM Testing and VIII. Non-waived Testing: Skip these sections if you are only conducting waived tests
Section III. Type of Laboratory <ul style="list-style-type: none"> • Check box 20: Pharmacy 	Section IX. Type of Control <ul style="list-style-type: none"> • Check the box that best describes your pharmacy (most community pharmacies are Box 4: Proprietary, but select the one that is most appropriate)
Section IV. Hours of Laboratory Testing <ul style="list-style-type: none"> • Indicate the times your pharmacy will provide testing 	Section X. Director Affiliation with other Laboratories <ul style="list-style-type: none"> • If this is the first time filling out this application, you will probably leave blank • If the Director listed in Section I has been registered to other sites, list them here.
Section V. Multiple Sites <ul style="list-style-type: none"> • Check "no" if you are only applying for one pharmacy (it is recommended to fill out a separate CLIA application for each location if multiple locations are owned.) 	Consent and Signature <ul style="list-style-type: none"> • Carefully read the consent information at the bottom of page 4 before signing and dating

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