



COVID-19 Change Package #3

Applying for a CLIA Certificate of Waiver

On April 8, 2020, the U.S. Department of Health & Human Services issued guidance authorizing licensed pharmacists to order and administer COVID-19 tests, including serology tests, that the FDA has authorized.

NCPA is currently seeking clarification on this authorization. **In the meantime, community pharmacies who do not have a CLIA Certificate of Waiver (CLIA waiver) are encouraged to apply for one as a first step.**

Matt Osterhaus (Osterhaus Pharmacy Owner, CPESN USA and CPESN Iowa Luminary) has provided answers as to why a CLIA waiver is important for you to consider beyond COVID-19.

What can a CLIA waiver do for...

YOUR PRACTICE?

The ability to perform point of care testing in a community pharmacy has the potential to enhance your position as a health care provider in the eyes of your patients, employers, and the community.

YOUR PATIENTS?

Point of care testing opens opportunities for patient convenience (e.g., strep tests) and to monitor progress towards patient goals (HgA1C, lipids). Access to this information can be a motivator for patients to be active in improving their health.

EMPLOYERS?

On-site or in practice health screenings can help employers assess risk factors of their employees as part of a wellness program. Instant access to lab results can assist the pharmacist in designing wellness activities for the employee to choose from and/or a reinforcing measure to follow your referral advice.

YOUR COMMUNITY?

Conducting health screenings at community health fairs or in-practice screenings reinforces our role as health care providers and can bring new patients to your practice.

The majority of these services have historically been cash or contract based. Our changing status as providers (in particular states, but nationally next?) has the potential to change this dramatically in the future.

Pharmacies must have a CLIA Waiver in order to provide point-of-care testing (POCT). POCT is performing a test outside of a laboratory that produces a rapid and reliable result aiding in identifying or managing chronic diseases and acute infections (e.g. COVID-19). Examples of CLIA waived tests/POCT include A1c, blood glucose, influenza, and Strep A. To see the FDA's listing of tests that are CLIA waived, click [here](#).

Overview of Filling out a CLIA Certificate of Waiver

1. Determine which Point of Care Tests can be performed in your state and which ones you want to offer.
 - a. Completing this now will prepare you for COVID-19 testing.
 - b. All states are different, but for the majority of states, to file for a CLIA waiver is as simple as filling out the form and sending to your state agency. However, there are some states where Point of Care Tests are not allowed by statute to be performed by pharmacists or in a pharmacy and some may require additional information to be sent. Check with your State Pharmacy Association, Board of Pharmacy, and Department of Health to make sure you have all of the information needed to proceed.
2. Fill out a CLIA waiver application - **SIMPLE! After step 1, it takes 10 minutes or less to complete.**
 - a. Page 2 includes how to fill out a CLIA waiver application.
3. Mail the completed CLIA waiver application to your state agency. Click [here](#).

Access the **CLIA Waiver (CMS-116 Form)** application by clicking [here](#).

The fee for a CLIA waiver is \$180 and is valid for 2 years.

You can follow along while NCPA Staff quickly walk you through filling out the form by clicking [here](#).

HOW TO FILL OUT A CLIA CERTIFICATE OF WAIVER (CMS-116) APPLICATION

Section I. General Information

- 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 in the pharmacy overseeing the testing

Section II. Type of Certificate Requested

- Only check the first box: "Certificate of Waiver"

Section III. Type of Laboratory

- Check box 20: Pharmacy

Section IV. Hours of Laboratory Testing

- Indicate the times your pharmacy will provide testing

Section V. Multiple Sites

- Check no if you are only applying for one pharmacy (NCPA recommends filling out a separate CLIA application for each location if multiple locations are owned.)

Section VI. Waived Testing

- List the tests you will be performing. Verify with your state which tests you can perform

- Estimate the number of tests you will be performing annually (consider all tests listed)
- For COVID-19 testing, you either need to be specific for the currently available tests with an EUA that has a "W" under authorized setting* OR do not list COVID-19 tests for now. You can always update the tests at a later date.

Section VII. PPM Testing and VII. Non-waived testing: Skip this section

Section IX. Type of Control

- Check the box that best describes your pharmacy (most community pharmacies are Box 4: Proprietary, but select the one that's most appropriate)

Section X. Director Affiliation with other Laboratories

- If this is the first time filling out this application, you will probably leave blank
- If other pharmacies that you own are CLIA waived, list those in this section

Consent and Signature

- Carefully read the consent information at the bottom of page 4 before signing and dating

*Tests with a EUA and a "W": Click [here](#)

Additional Information to Consider:

1. Click [here](#) to review **NCPA Resources for Point of Care Testing**. These assist you in developing a business plan, payment methods, and follow-up care.
 - a. Note: Most liability insurance policies will cover appropriate legal practice in terms of dispensing medications, delivering immunizations, and performing point-of-care testing with follow-up-care.
2. **CDC Self-Assessment Checklist for good testing practices**: Click [here](#) to read through the CDC self-assessment checklist to understand what is involved with good testing practices or to utilize after you start to administer CLIA waived tests.
3. Follow the manufacturer's instructions in the package insert for each waived test you are performing
 - a. The package insert provides instructions for specimen collection and handling, control procedures, test and reagent preparation, and instructions for test performance, interpretation, and reporting.

Resources:

[CDC: CLIA Law & Regulation](#)

[CMS Brochure on Obtaining CLIA Certificate of Waiver](#)

[CDC: How to Obtain a Clinical Laboratory Improvement Amendments \(CLIA\) Certificate of Waiver](#)

For additional information or assistance in filling out the CLIA waiver application, please call CMS Toll-Free: 877-267-2323 or visit the [CLIA website](#).