CLIA Certificate of Waiver

Instructions for an Initial Application or Updating your Existing Waiver for COVID-19 Testing

Are you interested in offering COVID-19 Testing and do not have a CLIA Certificate of Waiver? Follow the steps on page 1. Do you have a CLIA Certificate of Waiver but do not have a COVID-19 Point-of-Care Test listed on your existing Waiver? See Page 2.

Filling out an Initial CLIA Certificate of Waiver with an Emphasis on COVID-19 Testing

1. Click **HERE** to download an excel file (as of 7/23/20) to determine if your State requires additional information or a different process. [The most updated excel file by NCPA can be found by clicking **HERE** and click "Download Spreadsheet" beside "State Guidance on Pharmacist Authority to Administer COVID-19 Tests."]

   - 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
   - Access the CLIA Waiver (CMS-116 Form) application by clicking **HERE**.
     There are 2 Options to Learn How to Fill Out a CLIA Certificate of Waiver (CMS-116 Form)
     1. View the NCPA produced video by clicking **HERE** for a step-by-step process (length: 13 minutes; updated 7/23/2020).
     2. View the How-To table below and complete the sections in the CMS-116 Form.

3. Mail, Email or Fax the completed CLIA application to your state agency. Click **HERE** to view the state agency's information.

   - **Note:** Payment information is not sent at the time of applying. You will receive an invoice. ***The fee for a CLIA Certificate of Waiver is $180 and is valid for 2 years.***

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
- ☐ Click **HERE** to view the updated list of COVID-19 Tests. Within the CMS-116 Form, enter the information from the following 2 Columns:

- Manufacturer and Diagnostic (Letter of Authorization)
- ☐ Quidel COVID-19 Test Example, enter: "Quidel Corporation Sofia SARS Antigen FIA Test"
- ☐ Estimate the number of tests you will be performing annually (consider all tests listed)
- ☐ Consider adding other CLIA-waived tests, not just COVID-19 Tests

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

UPDATING Your Existing CLIA Certificate of Waiver with an Emphasis on COVID-19 Testing

If you already have a CLIA Certificate of Waiver (CMS-116 Form) and need to make updates such as adding a new test, you will need to update your state agency.

There are 2 Options to Learn How to Fill Out a CLIA Certificate of Waiver (CMS-116 Form)
1. View the NCPA produced video by clicking **HERE** for a step-by-step process (length: 5 minutes; updated 7/23/2020).
2. View the How-To table below.

HOW TO UPDATE YOUR
CLIA CERTIFICATE OF WAIVER (CMS-116) APPLICATION

1. **Update your CLIA Certificate of Waiver –** 2 options.
   - Access the CLIA Waiver (CMS-116 Form) application by clicking **HERE**
     - Complete the information as you had previously *(Overview is listed on page 1)*.
   - Open your previously edited PDF if you have it saved on your computer.

2. **In Section I** *(General Information)* **of the CMS-116 Form,** complete the following:
   - **Select "Other Changes"** and fill in the blank space with the reason for the change: "Add new test"
   - **Effective Date:** Enter the date that you are completing this updated CLIA Certificate of Waiver
   - **CLIA Identification Number:** This can be found on your Certificate on hand.

3. **Scroll to Section VI on page 3 of the CMS-116 Form.** Enter the test that you are adding.
   - Click **HERE** to view the updated list of COVID-19 Tests. Within the CMS-116 Form, enter the information from the following 2 Columns: Manufacturer and Diagnostic (Letter of Authorization)
   - Quidel COVID-19 Test Example, enter: "Quidel Corporation Sofia SARS Antigen FIA Test"

4. **Sign and Date the CMS-116 Form**

5. **Submit the form to your state agency via email or mail** depending on their preferred method.
   - Click **HERE** to view the state agency's information.
   - Double check with the state agency before submitting a change application in case they have more specific or different instructions than described above.

   *Some states may just require a simple email, be sure to check with your state.

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**.