

How to Apply for a CLIA Certificate of Waiver

Obtaining a Certificate of Waiver is a straightforward process. The four-page application is available at the [CMS Website](#) and takes about 10 minutes to complete if you have all the needed information. Here is section-by-section guidance on completing the application:

1. **General Information** – Check “Initial Application” and provide your street address, name of director (owner), and federal tax ID number. *If you are not the PIC at the applying pharmacy, you should enter the PIC’s name because he/she would be responsible for the testing conducted under the waiver. Be sure to complete the “MAILING/BILLING ADDRESS” section if your pharmacy’s mailing address differs from your physical location.*
2. **Type of Certificate Requested** – Check the first box, “Certificate of Waiver.”
3. **Type of Laboratory** – Check Box #20, “Pharmacy”
4. **Hours of Laboratory Testing** – Indicate the times you plan to do testing. *If you are not yet sure what these hours will be, just list the hours your pharmacy is open (you don’t have to do testing during all hours you list).*
5. **Multiple Sites** – Select “No.” *Note: Even if you have multiple locations, APRx and NCPA recommend that you check “No” and submit a separate application for each pharmacy location.*
6. **Waived Testing** – List all the tests for which you are requesting approval and estimate the number of tests you will be performing annually. *Note 1: The list of approved tests varies by state, and you should contact your state health department for the list applicable to your state. Enter them all – you don’t have to actually do testing for all of them if you choose not to. We strongly encourage you at a minimum to enter COVID-19, Blood Glucose, Hemoglobin A1C, Rapid Strep, Rapid Pneumococcal, and Influenza. Note 2: state requirements vary on how to list COVID-19 in this section – be sure you get the correct verbiage from your state health department.*
7. **PPM Testing** – Skip this section.
8. **Non-Waived Testing** – Skip this section.
9. **Type of Control** – Under “FOR PROFIT,” Check “04 Proprietary”
10. **Director Affiliation With Other Laboratories** – If you own other pharmacies that have a CLIA waiver, enter the CLIA numbers, names and addresses for those here as well as the name you entered in Section 1. *Note: CLIA regulations allow a director to direct up to five CLIA-waived pharmacies.*
11. **Consent and Signature** – carefully read the consent information at the bottom of page 4 before signing and dating the application.



Send the completed application to your state CLIA agency (View [CLIA contacts for all states](#)).

The fee for a Certificate of waiver is \$150. **DO NOT SEND PAYENT WITH YOUR APPLICATION.** After your application is processed and approved, you will receive an invoice from CMS for the \$150 fee. After paying the \$150, you will receive your actual certificate, which is valid for two years.

For more information or help with the application, call CMS Toll-Free at 877-267-2323 or view the CMS document [How to Obtain a CLIA Certificate of Waiver](#).