

# CMS-116 Tips

## TIPS FOR COMPLETING CMS FORM 116

To obtain the proper credential for your pharmacy to begin CLIA waived testing, begin by completing form CMS-116 as outlined below:

- As a retail pharmacy you will probably be applying to perform only those tests that are considered CLIA **waived**. Form CMS-116 contains instructions for completing the application.
- In general, retail pharmacies usually perform CLIA WAIVED tests only and typically **do NOT perform any of the tests on the NON WAIVED list that is included on the application.**
- Click on the link below to obtain an editable, printable form CMS-116.
- Fill out this PDF application by typing in information. For CLIA waived testing you only need to fill out sections 1-6 and sections 9 and 10. **You DO NOT need to fill out sections 7 and 8.** These are for NON WAIVED testing and are usually not performed in retail pharmacies. If you skip any of the required sections, your application will be rejected and returned.

### • SECTION 1

- If this is your first time applying for a CLIA waiver license indicate this by checking "Initial Application."
- If this is an initial application leave the CLIA identification number blank.
- Fill in your pharmacy specific information as requested. Name, address, etc. Please provide the physical address where the testing will take place under the "Facility Address" header. You have the option to include a separate mailing address for the receipt of your certificate and bill if needed.
- You must indicate the name of a "lab director" under the "Name of Director" header. This is usually a pharmacist that will oversee the adherence to proper testing procedures. You should provide the pharmacist's PharmD or BSPHarm as credentials. **Please note that unless you perform NON WAIVED testing, no special credentials are needed to be the lab director.**

### • SECTION 2

- For the type of testing requested select "Certificate of Waiver."

### • SECTION 3

- Select type of laboratory- box 20 "Pharmacy."

### • SECTION 4

- Indicate your laboratory hours. Note- these are usually your pharmacy hours of operation. If you limit the hours of testing, you may limit your chances for a successful program.

## • SECTION 5

- Typically, each retail pharmacy site must have its' own CLIA Waived Certificate. If you own multiple stores and will test in multiple stores you need to apply for a CLIA certificate for EACH location unless you are not for profit, using a mobile testing site or you are a hospital with several labs. Each location will need a separate form CMS-116 completed. In general most retail sites will check the NO box here and go to section 6.

## • SECTION 6

- Indicate the type of test(s) you will perform.
  - You should be specific when possible: "BD VERITOR Influenza type A and B and Group A Strep" "CHOLESTECH LDL, HDL, Total Cholesterol, Blood Glucose" are examples. List each test you plan to perform and the machine used.
  - COVID-19 testing requirements and options are rapidly changing so naming a specific brand of test may be difficult at this time. You may want to consider a broad listing such as "FDA authorized COVID-19 related testing" if you would like to perform these tests. Some departments may accept this verbiage and others may require you to amend your application when you have an exact test brand.
- Indicate total annual test volume.
  - When estimating the total annual test volume consider the number of tests you think you can perform in a day and extrapolate an annual volume from that estimate. As an example: the busiest outpatient clinics will do 60-90 flu tests in a season.

## • SECTION 7 & 8

- The only thing you need to do in this section is "Check if no PPM tests are performed." Skip the other sections unless you do NON WAIVED tests. (*Very unlikely.*)

## • SECTION 9

- Type of Control. This will **usually** be 'FOR PROFIT' and if so, you should check box 04 Proprietary.

## • SECTION 10

- If your selected lab director is affiliated with other CLIA labs, please indicate this here by providing the other CLIA lab name(s) and respective CLIA waiver number(s). This may be the case for multi-store owners if 1 pharmacist is overseeing multiple labs. Most of the time this will not be the case and this section can remain blank.

- Once you have completed CMS form 116, you should print it, sign it in ink, and scan it into your computer.

# FORM CMS-116

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