

# Frequently Asked Questions – CLIA & General Testing Questions for Ambulance Services

## CLIA Certificate of Waiver Testing Questions

### 1. What type of tests require a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver for ambulance services?

CLIA requires all facilities that perform even one applicable test, including waived tests, on “materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings” to obtain the appropriate certificate from CLIA.

Any ambulance service that will be performing only CLIA-waived testing, including waived tests, such as certain glucose tests, must obtain CLIA Certificate of Waiver as required by Centers for Medicare & Medicaid Services (CMS) Clinical Laboratory Improvement Amendments (CLIA) regulations found [here](#).

Ambulance services should adhere to manufacturer recommendations regarding intended use. Many devices are intended for single patient use only and are not indicated for pre-hospital, multi-patient use. Additional information can be found at [https://www.ecfr.gov/current/title-42/section-493.15#p-493.15\(e\)](https://www.ecfr.gov/current/title-42/section-493.15#p-493.15(e))

### 2. What are non-waived tests and what sort of Certificate is required?

Ambulance services that perform non-waived testing, which may include moderately complex testing such as certain lactic acid tests or certain Basic Metabolic Panel (BMP) test systems, are required to hold a CLIA Certificate of Compliance or Certificate of Accreditation and obtain state laboratory licensure

**State law requires that facilities performing non-CLIA waived tests to obtain state clinical laboratory licensure.** More information about CLIA complexity may be found here: <https://www.cdc.gov/clia/test-complexities.html>. **Please note that categorization depends on testing according to manufacturers' instructions, including Indications for Use.**

### 3. What is the cost of a Certificate of Waiver?

A Certificate of Waiver currently costs \$248 for a two-year certificate. Do not include payment with the application. When the application has been entered in the CMS

system, CMS will bill the service directly; payment instructions will be listed on the fee coupon. Also, CMS bills renewals approximately six months in advance of the expiration date and payment instructions are provided with the renewal notice. Here is a link to the [CLIA Certificate Fee Schedule](#)

Facilities may search the CMS website to confirm that a CLIA certificate is active: [CLIA Laboratory Search](#). Please note that applications processed very recently may not appear.

**4. What address do I use on the application since my ambulance moves around from emergency to emergency?**

You should complete the “home base” address in the CMS-116 form on page 1. However, on page 2, you should check the “YES” Box under Section V Multiple Sites. Under the three multiple site exceptions, you should select number 1, for mobile units. Record the Vehicle Identification Number (VIN) for each ambulance vehicle in this section, as directed. This will cover testing in the ambulance as it moves from different locations away from the “home base”.

**5. What if my information changes? (e.g. if the laboratory director changes, or there is a facility relocation)**

The notification requirements for Certificates of Waiver are located at 42 CFR 493.39. The laboratory must notify the Certification Bureau of changes in name, location, and director within 30 days of the change. A written notice of these changes is required; verbal notification is not sufficient. Please include your CLIA number, name of facility, name of laboratory director or owner, a description of the change(s) required on your CLIA certificate, and signature of the laboratory director or designee. Include your contact information in case we have further questions. Alternatively, a CMS-116 CLIA application may be submitted.

**6. Do I still need to apply for a CLIA certificate if my ambulance is run by the hospital and I use the hospital’s CLIA number?**

If you currently perform testing under the hospital's multiple site CLIA certificate you do not need to apply for a separate certificate.

The Vehicle Identification Number (VIN) still needs to be added to the hospital CLIA certificate information in order for the ambulance to be compliant with federal CLIA regulations.

## **7. What are those regulations that apply to Certificates of Waiver?**

The regulations for a Certificate of Waiver can be found at 42 CFR 493.35-493.39 in Subpart B.

## **8. I have a fixed wing/rotor wing ambulance service; does this apply to me or just to ground units?**

If you perform any laboratory tests, such as blood glucose testing with a glucose meter or blood gases, you need to have a CLIA certificate for your base location. The aircraft identification needs to be provided as a mobile testing site on the second page of the CMS-116 form Section V Multiple Sites.

## **9. Is there guidance for completing a CMS-116 CLIA Application?**

### **Guidance for filling out CLIA Application**

For your convenience, we are sharing some information that may help you fill out your CLIA application if your facility does not already have a CLIA Certificate of Waiver. Please be sure to complete all applicable parts of the CMS-116 CLIA application, including the following:

- Name of Ambulance Service
- Address of Home Base
- Point of Contact email
- Federal Tax ID
- Telephone number
- In Section I, please select "Initial Application"
- For the section requesting the Name/Credentials of the Director please input the individual who will have responsibility for oversight of the testing and ensuring compliance with CLIA requirements.
- In Section II, please select "Certificate of Waiver" if you will be performing only CLIA-waived tests.
- In Section III, please select the item most descriptive of your facility type, e.g. 01-Ambulance.
- In Section IV, please list the times during which laboratory testing will be performed.
- Check the "YES" Box under Section V Multiple Sites if mobile testing will be performed. Under the three multiple site exceptions, you should select number 1, for mobile units. Record the Vehicle Identification Number (VIN) for each ambulance vehicle in this section, as directed.

- In Section VI, please enter specific testing information as in the example provided. Incomplete information may result in processing delays if applications need to be resubmitted. Brands and manufacturer information are required.
- Skip Sections VII and VIII if only CLIA-waived tests will be performed.
- Complete Sections IX and X, ensuring that Type of Control and ownership information has been provided and that the Laboratory Director has signed/dated the application. Please completely fill out the other sections, as applicable, including the laboratory director signature section.