

## **Information for Ambulance Services about Certificates of Waiver**

### **What is the cost of a Certificate of Waiver?**

A Certificate of Waiver costs \$150 for a two-year certificate.

### **How do I apply for a Certificate of Waiver in the state of Montana?**

To apply for a Certificate of Waiver, complete a CMS-116 form, which may be downloaded from [www.cms.gov/CLIA](http://www.cms.gov/CLIA) or at <http://dphhs.mt.gov/qad/Certification/CLIA>.

Once this form is completed and signed by the appointed laboratory director, you may submit it to the State of Montana Department of Health and Human Services-Certification Bureau via FAX (406-444-3456), email ([mtssad@mt.gov](mailto:mtssad@mt.gov)), or mail (Certification Bureau-2<sup>nd</sup> Floor, 2401 Colonial Drive, PO Box 202953, Helena, MT 59620-2953).

### **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 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 all testing in the ambulance as it moves from different locations away from the “home base”.

### **What if my information changes? (Ex. if the laboratory director quits, or you move to a new location)**

The notification requirements for Certificates of Waiver are located at 42 CFR 493.39. The laboratory must notify the Certification Bureau (via fax, email, or mail listed above) 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, and the changes required on your CLIA certificate. Include your contact information in case we have further questions.

### **My ambulance is run by the hospital and I use the hospital’s CLIA number, do I still need to do this?**

If you currently use a hospital CLIA number, you still need to notify us of that fact. You do not need to apply for a separate certificate. Currently, no ambulances are listed under hospital CLIA certificates in the State of Montana. 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.

### **How do I know if all my tests are classified as waived by the FDA?**

Look in the manufacturer instructions for the CLIA classification (waived, moderate, or high complexity). If it is not listed there, check one of two FDA websites to determine the complexity of your test:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm>

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/analyteswaived.cfm>

Links to these websites can also be found at: <http://dphhs.mt.gov/qad/Certification/CLIA>.

### **Who qualifies to be the laboratory director for a Certificate of Waiver?**

Any person can qualify as laboratory director for a Certificate of Waiver in the state of Montana. This

person is responsible for ensuring that the regulations that apply to Certificates of Waiver are followed (42 CFR 493.35-493.39 in Subpart B).

**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. For a copy, you may download it from the <http://dphhs.mt.gov/qad/Certification/CLIA> website or from [www.cms.gov/CLIA](http://www.cms.gov/CLIA).

**Do I need to do anything differently than I do now?**

For a helpful resource on best laboratory practices for a Certificate of Waiver, please refer to the “Ready, Set, Test” workbook on the <http://dphhs.mt.gov/qad/Certification/CLIA> website.

**I am a non-transport EMS service (ex. Fire departments, ski patrol, border patrol, quick response unit, sheriff office, search and rescue department), does this apply to me?**

If you perform any laboratory tests, such as blood glucose with a glucometer, you need to have a CLIA certificate. If you do not perform any waived tests, then you do not need a certificate.

**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 glucometer 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.

**I am a county-owned fast response unit, does this apply to me?**

If you perform any laboratory tests, such as blood glucose with a glucometer, you need to have a CLIA certificate for your location. If you do not perform any waived testing, then you do not need a certificate. See the next question for combining county owned operations into one certificate to save money.

**I am a county-owned service with another county-owned service based at the same location. Do we need 2 separate certificates (ex. County EMS and a County Fire Department)?**

You may apply for 1 certificate if you have the *same tax ID and are a non-profit county owned provider*. On the second page of the CMS-116 application, check the “YES” box for the Multiple Sites section of the application. Under the three possible multiple site exceptions, select the #2 option of the “not-for-profit or Federal, State or local government laboratory engaged in limited (<15 tests total) public health testing.” List the information for the second provider in the boxes at the bottom of page 2 so that both sites are compliant with federal CLIA regulations.

**I don't charge Medicare for this test, do I still need this?**

Yes, if you perform any laboratory tests, such as blood glucose with a glucometer, regardless of how you bill for the services, you need to have a CLIA certificate for your location. If you do not perform any tests, then you do not need a certificate. Billing does not determine the need for a CLIA certificate. If you perform any laboratory services, you need to have a CLIA certificate.

**What happens if I don't do this?**

Purposely **failing to comply** with this requirement may result in a termination of the Medicare/Medicaid provider agreement for the ambulance service. CMS makes the termination/fine determination based on the information provided by this office of entities performing laboratory testing without a CLIA certificate.

**Why do I need one of these certificates now? I have never had one in the past, what changed?**

It has come to the attention of the Certification Bureau that ambulance services were not given the information concerning CLIA requirements. At this time, the misinformation has been corrected by this memo and all ambulance services need to apply for a CLIA certificate or notify this department of operating under an existing certificate if they perform any laboratory testing, even if it is merely finger-stick glucose checks.

**Do other states have to do this or this just in Montana?**

All states must comply with CMS CLIA requirements.

**What is all this I hear about glucometers and not using them on critically ill? Is this about that?**

You may have heard about the FDA addressing the use of glucometers in healthcare. This is a separate issue. This memo is correcting the lack of CLIA certificates for emergency medical providers using laboratory tests such as glucometers and blood gas analyzers without a CLIA certificate, which is in violation of the 42 CFR 493 federal regulations.

**Who can I call to answer my questions?**

For any further questions, please contact the Montana CLIA Program, Joyce Shepard at 406-444-2099. You may also email questions to [mtssad@mt.gov](mailto:mtssad@mt.gov). The Certification Bureau website also has information at <http://dphhs.mt.gov/qad/Certification/CLIA>.