

**Office of Clinical Standards and Quality/Survey & Certification Group**

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**Ref: S&C: 12-09-CLIA**

**DATE:** December 2, 2011

**TO:** State Survey Agency Directors

**FROM:** Director  
Survey and Certification Group

**SUBJECT:** Certificate and Regulatory Multiple Site Exceptions under the Clinical Laboratory Improvement Amendments of 1988 (CLIA)

**Memorandum Summary**

- **CLIA Certificate Regulatory Exception Guidance for Laboratories with Multiple Site Exceptions:** Additional clarification and guidance is given for certifying laboratories under the various regulatory multiple sites exceptions.
- **Scenarios for Each Type of Exception:** There are scenarios with guidance for all areas of the three regulatory exceptions for each type of certificate.
- **Reminder of State laws and Regional Office Oversight:** State laws must be considered and when certificates that meet a multi-site exception cross State/Regional lines, the corresponding regional offices must coordinate oversight.

**Background**

For each certificate type under the CLIA regulations (42 CFR sections 493.35(b), 493.43(b) and 493.55(b)) there are exceptions that allow a laboratory, in specific circumstances, to apply for a single certificate for multiple testing sites. The Centers for Medicare & Medicaid Services (CMS) is clarifying these requirements by offering examples for each type of exception due to questions and instances where the exceptions are applied to laboratories incorrectly.

**Types of CLIA Certificates and Regulatory Citations**

Caution should be used when determining if an entity can be issued one certificate for multiple sites. Each exception stands alone and must not be mixed with another exception. Each type of certificate has the same regulatory exceptions and certificates are listed below.

493.35 – Application for a Certificate of Waiver

493.43 – Application for Registration Certificate, Certificate for Provider Performed Microscopy (PPM) procedures and Certificate of Compliance

493.55 – Application for Registration Certificate and Certificate of Accreditation

The *CLIA Regulatory Multiple Site Exceptions: Clarifications and Scenarios* attachment provides clarifications and scenarios that will help with CLIA certification of laboratories using these certificate exceptions.

These scenarios and clarifications may not encompass every possible circumstance that the surveyor may encounter, but should provide enough guidance to allow the surveyor to make additional determinations for exception eligibility using their professional judgment.

If you have any questions about this memo, please contact Minnie Christian at 410-786-3339 or [Minnie.christian@cms.hhs.gov](mailto:Minnie.christian@cms.hhs.gov).

**Effective Date:** Immediately. This information should be communicated with all survey and certification staff, their managers, and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/

Thomas E. Hamilton

Attachment

cc: Survey and Certification Regional Office Management

## CLIA Regulatory Multiple Site Exceptions: Clarifications and Scenarios

### **EXCEPTION 1 -- Temporary Testing Sites and Mobile Units --493.35 (b)(1); 493.43(b)(1); 493.55(b)(1)**

The CLIA regulations for temporary testing sites are as follows:

*(b)(1) – Exception. Laboratories that are not at a fixed location, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address.*

#### **Mobile Units:**

- A mobile laboratory is defined as a movable, self contained operational laboratory with its own personnel, equipment and records. In order to be considered a mobile unit, equipment must be installed and located permanently within the mobile unit.
- If a vehicle is used to transport laboratory equipment from the primary site/home base to another site where testing is performed, the transporting vehicle is **not** a mobile unit. (See SOM, Chapter 6, section 6034)

#### **Temporary Testing Sites:**

- The regulation has no restrictions on the number of visits to a particular site or the type of testing performed.
- There are no terms such as scheduling in the regulation; therefore, we cannot apply rules that are more stringent than the CLIA regulation.

**For example:** ABC lab performs testing at a local pharmacy every Friday. All of the records are maintained at ABC labs. The local pharmacy is a temporary testing site. (See SOM, Chapter 6, section 6036.3. There is a pending revision that will state “The laboratory may move from testing site to testing site.”)

- Records, files, etc. for temporary testing sites are kept at the primary site or home base. The personnel, equipment, supplies, and reagents, etc. are not at the testing site permanently. For example, a healthcare entity provides screening tests at various local malls on different days at different times. The equipment, staff and supplies are transported to the testing site on the day of testing prior to patient arrival; i.e., there is no permanent testing site at the malls.

#### **Primary Site or Home Base:**

- The type of facility for the primary site or home base is not specified in the regulations.
- The primary site or home base is the location where the staff is based and records, equipment, supplies, etc. are maintained. For example, the main office for an ambulance service.

## Scenarios for Exception 1

### **Scenario 1: Temporary Testing Site Across State Lines**

Weaver lab, located in DE requests a certificate of waiver to perform health fair glucose testing in MD, PA and VA. Can they be issued one certificate to include temporary testing sites in the other three States?

#### **Consider:**

State and local laws that govern testing from an entity outside of a state

If there are no problems with state and local laws, issue a Certificate of Waiver (CW) to Weaver Laboratory with the Delaware site as the designated primary site or home base with temporary testing health fair sites in MD, PA and VA. The applicable RO/SA should coordinate if any or all of these sites are selected as part of the CW project educational visit sample. There is nothing in the CLIA regulations to prevent certification of entities across state lines.

### **Scenario 2: Clarification of a Mobile Unit**

XYZ lab, located in MD, transports equipment to various Walmart sites in VA and PA to perform CBC's and cholesterol panels. The equipment is removed from the vehicle and taken inside the site to perform the testing. What exception to the regulation applies and why? What type of certificate is issued?

#### **Consider:**

- Actual site where testing is performed—is it a permanent test site?
- State and local laws that govern testing from an entity outside of a state

The testing performed is moderate complexity and is performed in a Walmart store. If there are no problems with state and local laws, a Certificate of Compliance is issued to XYZ laboratory with the MD site being the designated primary site or home base with temporary testing sites in VA and PA.

### **Scenario 3: Home Health Agency (HHA) Temporary Testing Sites**

An HHA employs 25 nurses that will perform waived testing in patients' homes in MD and DC. The agency has requested one certificate for all sites in which testing is performed. Explain the process and why.

The HHA can be issued a multi-site single Certificate of Waiver. The designated home base is where the agency is located. The patients' homes are temporary testing sites.

**NOTE:** If the nurse only ASSISTS the patients and provides the patients self testing result to the doctor, a certificate is not required.

**EXCEPTION 2 -- Limited Public Health Testing--493.35 (b)(2); 493.43(b)(2); 493.55(b)(2)**

The CLIA regulations for limited public health testing are as follows:

*(b)(2) – Exception. Not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests per certificate) public health testing may file a single application.*

- The facility must either be Not-for-profit, or a Federal, State or local government facility.
- Limited public health testing is not defined in the regulation.
- Not-for-profit is a legal designation.
- The testing is limited to 15 tests (a combination of moderate and waived).
- The various sites under this certificate may only perform tests within the 15 tests listed on the certificate application.
- An entity performing any high complexity testing cannot use this exception for a multi-site certificate.
- A Certificate of Waiver laboratory is eligible if it only performs 15 or less waived tests.
- The multi-sites cannot perform tests that are outside of those listed for the certificate issued to the primary site.
- The name of the tests must be shown on the CLIA application for this exception. (Although certificates are currently issued by specialty/subspecialty, the tests must be verified and shown on the CMS-116 CLIA application form.)

**Scenarios for Exception 2**

**Scenario 1: Clarification of Limited Public Health Testing**

Aurora Consolidated Laboratories owns 38 physician office laboratories (POLs) located in various areas. The not for profit POLs are performing public health testing, a combination of no more than 15 moderate and waived tests. They are requesting to consolidate these laboratories under one CLIA number using the 493.43(b)(2) exception.

**Consider:**

State and local laws

If there are no restrictions in the State and local laws, Aurora Consolidated Laboratories can be issued one certificate to include all of the 38 locations. There must be a legal not-for-profit document for each of the laboratories. The laboratory should be made aware that if one of the locations has a problem, there is the possibility of the loss of the certificate for all sites.

**NOTE:** There is nothing in the CLIA regulations to prevent this type of certification.

**Scenario 2: Clarification of Limited Public Health Testing**

A local Health Department performs gram stains for GC, urine pregnancy and hemoglobin testing as part of the WIC program in 15 different locations throughout the city. What type of certificate can be issued and why?

**Consider:**

Number and Complexity of tests on the test menu

The Health Department can be issued a single Certificate of Compliance to cover the 15 different locations providing the test menu does not exceed more than a combination of 15 moderate and waived tests.

**NOTE:** The testing performed in each of the various locations must match the tests on the certificate test menu. (Although the certificates show specialty/subspecialty, for this exception, the list of tests must be verified and shown on the cms-116 application form.)

**EXCEPTION 3 -- Hospital Exception --493.35 (b)(3); 493.43(b)(3); 493.55(b)(3)**

**The CLIA regulations for hospitals are as follows:**

*(b)(3) – Exception. Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application or multiple applications for the laboratory sites within the same physical location or street address.*

- This exception is only for hospitals. This includes large universities with large teaching hospitals. Other types of entities are not eligible.
- The buildings may be contiguous on the same campus or same physical location or street address.
- All of the multi-site labs must be under the same director.

**Scenarios for Exception 3**

**Scenario 1: Hospital Discretion for Multiple Site Certificates**

ABC hospital has 15 satellite labs in addition to the main lab. Waived, moderate and high complexity testing is performed in the various laboratories. How many and what type of certificate is required?

The hospital has the discretion to determine the number of certificates to be issued.

ABC hospital can be issued:

A single certificate to cover all of the hospital satellite laboratories, providing that all of the satellite labs are located at contiguous buildings on the same campus or within the same physical location or street address as the hospital and are under common direction;

OR

A separate certificate for each of the satellite laboratories based on the type of testing performed.

**Scenario 2: Lab Owned by Hospital Requesting Multiple Site Certificates**

Tucker Laboratory, owned by Jackson Memorial Hospital, is requesting a multiple site certificate for three other laboratories at separate locations.

Ownership is not considered under CLIA. The fact that the laboratory is owned by a hospital does not make it a hospital laboratory. In most of these cases, a multiple site certificate CANNOT be issued. Additional information should be requested and each requirement under (b)(3) must carefully be considered.