DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: S&C-09-23 EXPIRED

DATE: **December 04, 2025**

TO: State Survey Agency Directors

FROM: Director, Quality, Safety & Oversight Group (QSOG)

SUBJECT: **EXPIRED:** Clarification of Policies and Procedures for the Certification of Entities with One Certificate for Multiple Sites Under the Clinical Laboratory Improvement Amendments (CLIA)

Memo Information:
Memo expiration date: **2025-12-04**
Original release date: **2009-02-06**

Memorandum Summary

- This memorandum further defines and clarifies the Centers for Medicare & Medicaid Services (CMS) existing policies for the certification of laboratories performing limited public health testing.
- It also clarifies the policies and procedures for the certification of entities with multiple sites, specifically for home health agencies (HHAs) and hospices.

The purpose of this memorandum is to further clarify CLIA certification policies and procedures stated in Chapter 6 of the State Operations Manual (SOM) concerning certification of entities with multiple sites.

Regulatory Overview

For each of the certificate type requirements in the CLIA regulations (42 CFR sections 493.35(b), 493.43(b) and 493.55(b)) there are exceptions that allow one certificate for multiple sites. In most instances, the names of various entities, (e.g., HHAs), are not mentioned specifically in these exceptions.

SOM Policy Clarifications

The title for SOM Section 6008 - **Laboratory Location - Criteria for Meeting the Exceptions** - has been changed to reflect the regulatory exceptions as well as the separate policies for HHAs and hospices. The changes for section 6008 are as follows:

SOM Section 6008 - - Criteria for One Certificate for Multiple Sites

Location

Each location where laboratory tests are performed must file a **separate** application, unless it meets one of the following exceptions as **outlined** in 42 CFR 493.35(b), 493.43(b), or 493.55(b):

- Laboratories that are not at a fixed location, i.e., 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 CLIA certificate and address of the designated primary site or home base.

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

- 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 CLIA certificate(s) for the laboratory sites within the same physical location or street address.

Home Health Agencies (HHAs)

A parent HHA with multiple branches may apply for one CLIA certificate as long as these sites are under one HHA provider number, i.e., parent branch. Subunits by definition operate independently and have a unique provider number; therefore, each subunit must apply for a separate CLIA certificate.

NOTE: The parent or provider location **must** perform laboratory testing. Since branches cannot operate independently, the parent defines the services provided in the branches and is responsible for the day-to-day operation, supervision, and administration of laboratory testing, including the employment of qualified personnel.

For consistency, the Medicare designated terms parent and branches are used for this policy.

Hospices

The guidance as for HHAs applies to Hospices. The Medicare designated term for the hospice multiple sites is multiple locations instead of branches.

SOM Section 6036.2 Laboratories Performing Limited Public Health Testing

The changes to section 6036.2 are as follows:

Not-for-profit or Federal, State, or local government laboratories engaged in limited public health testing, (e.g., WIC clinics), may file a single application for multiple sites regardless of the physical location. The limited public health CLIA certificate includes a combination of no more than 15 tests, waived or of moderately complexity. The location designated as the primary site on the CLIA application/certificate must perform testing and hold the certificate. Each site may perform different test(s), but the total test menu for all sites must not exceed

the 15 moderate complexity or waived tests specified in the CLIA application/certificate. The primary site must also identify the type of testing performed at each site. If any of the multi-site laboratories are located in more than one State, the State agency (SA) contacts the Regional Office to determine which State conducts the inspection.

Proficiency Testing (PT) is required "per certificate," and the primary location must enroll in PT for any non-waived analyte listed in subpart I of the regulations. The PT samples may be rotated among the multiple sites under the single certificate; however, all five samples from each event must be tested at a single location.

In contrast to the allowance for limited testing sites, not-for-profit or Federal, State or local government laboratories that perform high complexity testing must file a separate application for certification of each laboratory performing high complexity testing regardless of their profit or government status.

At a minimum, the SA verifies that all laboratory sites are included in a laboratory's comprehensive Quality Assessment program that monitors the correlation of each site's results with the instruments, test systems, and methods covered by the PT program. Failure of a laboratory to monitor and evaluate the quality of testing at each location is a deficiency.

Contact:
For questions or concerns relating to this memorandum, please contact LabExcellence@cms.hhs.gov

Effective Date:
Immediately. Please communicate to all appropriate staff within 30 days.

/s/
David R. Wright
Director, Quality, Safety & Oversight Group

Resources to Improve Quality of Care:
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- *Recognize deficiencies*
- *Incorporate solutions into your facility's standards of care*

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