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: QSO-18-20-CLIA

DATE: **July 20, 2018**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Clarification of the Operation of Multiple Laboratories at the Same Location and the Discontinued Use of the Term "Shared Laboratory"

Memorandum Summary

The Centers for Medicare & Medicaid Services (CMS) is clarifying the operation of multiple laboratories at the same location and the discontinued use of the term "*shared laboratory*" related to the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Certification.

- Multiple laboratories with separate CLIA numbers may operate at one location as long as it can be demonstrated that each laboratory is operating as a separate and distinct entity. They are not to be referred to as "*shared laboratories*".

- **This memorandum supersedes all prior guidance regarding the registration of shared laboratories for CLIA**.

Background

During the early implementation of the CLIA program in 1993, many laboratories sought to register multiple CLIA numbers at a single location (i.e. a separate CLIA number for each physician financially affiliated with the entity operating at the location). The term *"shared laboratory***"** was used solely for the purpose of identifying and properly registering such laboratories in the CLIA program. The term "shared laboratory" is not found in the CLIA regulations, and as discussed below, laboratories are generally required to file a separate application for each laboratory location. Therefore multiple laboratories at the same location or in the same suite should not be referred to as a *"shared laboratory"*. The Division of Clinical Laboratory Improvement and Quality continues to receive inquiries as to whether multiple CLIA numbers at the same location are allowed under CLIA. This memo seeks to clarify guidance on the operation of multiple laboratories at the same location.

Policy Clarification

The CLIA regulations [42 CFR §493.35(a), §493.43(a) and §493.55(a)] generally require all laboratories performing waived and non-waived testing to file a separate application for each laboratory location. Multiple laboratories may operate at the same physical location (e.g., same

building or suite, as applicable) with separate CLIA numbers, as long as each laboratory can demonstrate that it is operating as a separate and distinct entity. Each CLIA certificate represents a laboratory, and each laboratory is responsible for complying with the applicable CLIA requirements. This letter reinforces existing guidance on multiple laboratories at the same location.

In addition, multiple laboratories that operate at the same physical location and use the same testing personnel and equipment must meet the following conditions:

- All records (e.g., quality control, procedure manuals, personnel competency) must be kept separate and distinct for each laboratory and must clearly show that each laboratory is operating independently.
- The hours of operation must be specified for each laboratory.
- The hours of operation for each laboratory must be separate and distinct. The times of testing cannot overlap and cannot be simultaneous.

Entities that have questions concerning Medicare or Medicaid billing (including, but not limited to, the sharing of expenses) should be informed that these are not CLIA quality and safety issues. Laboratories should refer their questions or concerns to the appropriate Medicare or Medicaid contacts to ensure they meet all appropriate billing requirements.

This memorandum supersedes all prior guidance regarding the registration of shared laboratories for CLIA, including the use of the term "shared laboratory".

Contact: If you have any questions regarding this memorandum, please direct them to LabExcellence@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/
David R. Wright

cc: Survey and Certification Regional Office Management
CLIA RO Consultants