



# Clinical Laboratory Registration Policy

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**Policy** It is the policy of the Department of Behavioral Health (DBH) to ensure DBH clinics adhere to federal and state regulations while performing clinical laboratory testing.

**Purpose** To provide instruction for DBH clinics to obtain a Certificate of Waiver and State Clinical Laboratory Registration, and to conduct onsite waived clinical laboratory tests.

**Definition(s)** **Clinical Laboratory Improvement Amendments (CLIA):** The Clinical Laboratory Improvement Amendments of 1988 statute is an amendment to the Public Health Services Act in which Congress revised the federal program for certification and oversight of clinical laboratory testing.

**CLIA Certificate of Waiver (CLIA CoW):** A CLIA CoW is a type of CLIA certification that allows a facility, primarily laboratories, to legally examine a person through waived tests to assess health, diagnose, and determine treatment.

**DBH Laboratory Director:** Centers for Medicare and Medicaid Services (CMS) regulations require DBH clinical laboratories to operate under the supervision of a Laboratory Director. The DBH Director designates a DBH Physician to fulfil this role.

**Point of Care Testing (POCT):** POCT is medical diagnostic testing that allows staff and physicians to accurately achieve real-time lab-quality diagnostic results within minutes.

**State Clinical Laboratory Registration (SCLR):** Laboratories in California must be registered to conduct waived tests. The CLIA CoW is a prerequisite as this identifies what types of testing DBH is certified to perform.

**Waived Tests:** The United States' Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) require that a waived test employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible or pose no reasonable risk of harm to the patient if the test is performed incorrectly.

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## Clinical Laboratory Registration Policy, Continued

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### Application Process

The application process for the CLIA CoW and SCLR requires knowledge of specific departmental information and shall only be completed by assigned DBH staff. The application requires the signatures of the San Bernardino County Chief Executive Officer (County CEO) and a Laboratory Director designated for each DBH laboratory.

The application shall be completed online and may be accessed on the California Department of Public Health (CDPH) website's Laboratory Field Services page at:  
<https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/OnlineNewApplication.aspx>

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### Renewal Schedule

The CLIA CoW must be renewed biennially, and the California SCLR must be renewed annually. Refer to Clinical Laboratory Registration Policy (MDS2033-1) for specific instructions.

### Related Policy or Procedure

#### [DBH Standard Practice Manual:](#)

- Clinical Laboratory Registration Procedure (MDS2033-1)
  - Clinical Laboratory Onsite Testing Procedure (MDS2033-2)
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### Reference(s)

- CMS Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services (Appendix C) (Centers for Medicare and Medicaid Services State Operations Manual)
  - Standards and Certification: Laboratory Requirements (Code of Federal Regulations Title 42, Section 493)
  - Clinical Laboratory Improvement Amendments (U.S. Code Title 42, Section 263a)
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