

**REPORT/RECOMMENDATION TO THE BOARD OF SUPERVISORS  
OF SAN BERNARDINO COUNTY  
AND RECORD OF ACTION**

September 23, 2025

**FROM**

**GEORGINA YOSHIOKA, Director, Department of Behavioral Health**

**SUBJECT**

Clinical Laboratory Improvement Amendments Application for Certification and Attestations for Clinic Licensing

**RECOMMENDATION(S)**

1. Rescind Recommendation Nos. 3 and 5 of Item No. 18 from the July 26, 2022, Board agenda effective as of September 23, 2025.
2. Authorize the Behavioral Health Medical Director or Behavioral Health Physician IV, to be designated as a Laboratory Medical Director for each of the specified laboratory sites of the Department of Behavioral Health, to execute the Department of Health and Human Services Centers for Medicare and Medicaid Services' Clinical Laboratory Improvement Amendments Application for Certification, and the California Department of Public Health's Director's Attestation for the Clinical and Public Health Laboratory License to the California Department of Public Health, on behalf of the County, subject to review by County Counsel.  
(Presenter: Georgina Yoshioka, Director, 252-5142)

**COUNTY AND CHIEF EXECUTIVE OFFICER GOALS & OBJECTIVES**

**Promote the Countywide Vision.**

**Provide for the Safety, Health and Social Service Needs of County Residents.**

**Pursue County Goals and Objectives by Working with Other Agencies and Stakeholders.**

**FINANCIAL IMPACT**

This item does not impact Discretionary General Funding (Net County Cost). The Clinical Laboratory Improvement Amendments (CLIA) Application for Certification and Attestations for Clinic Licensing renewal applications require a \$113 processing fee for each clinic site, which will be funded by 2011 Realignment funds. Adequate appropriation and revenue have been included in the Department of Behavioral Health's (DBH) 2025-26 budget and will be included in future recommended budgets.

**BACKGROUND INFORMATION**

DBH is responsible for providing mental health and substance use disorder (SUD) services to county residents experiencing severe mental illness and/or SUD. DBH Substance Use Disorder and Recovery Services (SUDRS) provides SUD treatment services to the county residents. An important therapeutic intervention for these services is the use of drug testing to determine a client's engagement with and adherence to treatment goals. Title 42 Code of Federal Regulations (CFR) Part 493 sets forth conditions that all laboratories shall meet to be certified to perform testing under the CLIA of 1988. This regulation provides guidance on licensing and certification requirements for waived tests.

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Waived tests, as defined by CLIA, are categorized as “simple laboratory examinations and procedures that have an insignificant risk of an erroneous result”, such as urinalysis and saliva strips for drug and alcohol detection. The Food and Drug Administration determines which tests meet these criteria when it reviews manufacturers’ applications for test system waiver. Further waived testing can be performed to determine other related health factors of a client or the client’s suitability for specific treatment interventions, such as Medication Assisted Treatment, which is the use of prescription medications, in combination with counseling and behavioral therapies, to provide a whole-person approach to SUD treatment.

California requires a Clinical and Public Health Laboratory License (License) and a CLIA Application for Certification when clinics perform waived tests as a part of SUD treatment. The License application is completed online through the California Department of Public Health (CDPH) portal with information provided from the CLIA Application for Certification, the Owner’s Attestation, and the Director’s Attestation documents. The License is renewed annually and the CLIA Application for Certification is renewed every two years. The CLIA Application for Certification is required for every facility that performs drug tests for the provision of information for the diagnosis, prevention or treatment of a disease; impairment; or assessment of health.

DBH currently has seven DBH clinics (five SUDRS and two mental health) authorized to administer CLIA waived laboratory testing and anticipates obtaining authorization for two additional mental health clinics for this purpose.

A Directors Attestation must be submitted to the California Department of Public Health for each laboratory to confirm that the laboratory meets all applicable CLIA and state requirements as stipulated in both federal and California laws (Code of Federal Regulations, Title 42, Section 493.1407, 493.1445; California Business and Professions Code, Section 1209). The Directors Attestation also confirms the Behavioral Health Medical Director or Behavioral Health Physician IV as the Laboratory Medical Directors of DBH, will be held responsible as the laboratory directors. Laboratory directors, as defined by Title 42, part 493.2, must be a physician, a mid-level practitioner authorized by the State, or a dentist.

Recommendation No. 3 of Item 18 on the July 26, 2022 Board agenda authorized the Addiction Medicine Physician, as the Laboratory Medical Director of the Department of Behavioral Health, in the capacity of laboratory director, to execute the Department of Health and Human Services Centers for Medicare and Medicaid Services’ Clinical Laboratory Improvement Amendments Application for Certification, and the California Department of Public Health’s Director’s Attestation for the Clinical and Public Health Laboratory License to the California Department of Public Health, on behalf of the County, subject to review by County Counsel. Recommendation No. 3 of Item 18 on the July 26, 2022, Board agenda is being rescinded to allow additional Laboratory Medical Directors to have the same delegated authority. Additionally, Recommendation No. 5 of Item 18 on July 26, 2022 Board agenda authorized the transmission of all executed documents to the Clerk of the Board of Supervisors within 30 days of execution; it has been determined that DBH will be responsible for maintaining the executed documents.

Approval of this item will clarify which DBH medical staff are authorized as Laboratory Medical Directors to execute and submit the forms listed in the Recommendation No. 2 in order to complete any new Licenses or Licenses requiring renewal in order for the clinics to perform waived tests as a part of SUD treatment. Not renewing the License needed for CLIA waivers would place DBH out of compliance with the DCHS drug testing requirements and would directly impact patient care.

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**PROCUREMENT**

Not applicable.

**REVIEW BY OTHERS**

This item has been reviewed by Behavioral Health (Diana Barajas, Administrative Supervisor I, 388-0862) on August 14, 2025; County Counsel (Charles Phan, Supervising Deputy County Counsel, 387-5455) on August 26, 2025; and County Finance and Administration (Paul Garcia, Administrative Analyst, 386-8392) on September 9, 2025.

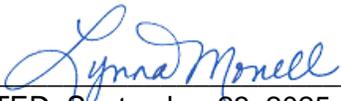
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Record of Action of the Board of Supervisors  
San Bernardino County

**APPROVED (CONSENT CALENDAR)**

Moved: Joe Baca, Jr. Seconded: Curt Hagman  
Ayes: Col. Paul Cook (Ret.), Jesse Armendarez, Dawn Rowe, Curt Hagman, Joe Baca, Jr.

Lynna Monell, CLERK OF THE BOARD

BY  \_\_\_\_\_  
DATED: September 23, 2025



cc: File - Behavioral Health  
CCM 09/30/2025