

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

July 26, 2022

FROM

GEORGINA YOSHIOKA, Interim Director, Department of Behavioral Health

SUBJECT

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

RECOMMENDATION(S)

1. Authorize the submission of 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 Owner's Attestation and Director's Attestation as required for new applications or renewal of existing applications for the Clinical and Public Health Laboratory License to the California Department of Public Health.
2. Authorize the Chief Executive Officer to act as the Authorized Representative and 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 Owner'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.
3. Authorize 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.
4. Authorize the Assistant Executive Officer of Department Operations, Deputy Executive Officer of Human Services, or Director of the Department of Behavioral Health to submit 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 Owner's Attestation and 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
5. Direct the Assistant Executive Officer of Department Operations, Deputy Executive Officer of Human Services, or Director of the Department of Behavioral Health to transmit all executed documents relating to the above Recommendations to the Clerk of the Board of Supervisors within 30 days of execution.

(Presenter: Georgina Yoshioka, Interim Director, 388-0801)

COUNTY AND CHIEF EXECUTIVE OFFICER GOALS & OBJECTIVES

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). Any applicable fees will be funded through 2011 Realignment funds. Adequate appropriation and revenue have been included in the Department of Behavioral Health's (DBH) 2022-23 budget and will be included in future recommended budgets.

BACKGROUND INFORMATION

Approval of this item will allow DBH to submit a Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, an Owner's Attestation, and Director's Attestation, which are needed for each clinic, to the California Department of Public Health (CDPH) for any new or renewal applications for the Clinical and Public Health Laboratory License (License).

DBH Substance Use Disorder and Recovery Services (SUDRS) provides Substance Use Disorder (SUD) treatment services to residents of San Bernardino County. An important therapeutic intervention for these services is the use of drug testing to determine a client's engagement 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.

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 drugs and alcohol detection. The Food and Drug Administration determines which tests meet these criteria when it reviews manufacturer's 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 the SUD treatment.

DBH currently has four SUDRS clinics authorized to administer drug tests and anticipates obtaining authorization for an additional four SUDRS clinics for this purpose. This would provide DBH a total of eight SUDRS clinics authorized to administer drug tests. In addition, DBH is evaluating obtaining authorization to provide these drug tests at several County operated general mental health clinics.

Of the four current SUDRS clinics authorized for drug testing, one clinic's License expired July 15, 2022, and another expires July 26, 2022. The clients require testing two times per month. All clients in these two clinics were tested at least once in July, and will be retested, if necessary, when the clinics are in compliance.

The renewals for the clinics' Licenses were delayed as it was necessary for the DBH Office of Compliance to research and determine if the waiver authorizations and CDPH licensing would still be necessary with the implementation of the California Advancing and Innovating Medi-Cal (CalAIM), as other California Department of Health Care Services licensing requirements will no

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longer be necessary. It was determined that the waiver authorization and CDPH licenses are still necessary.

Upon the Board of Supervisors' (Board) approval of this item and execution by the authorized signatories, DBH will submit the required documents to CDPH by the established July 26, 2022 deadline, as well as submitting the required documents to reinstate the License for the clinic that expired July 15, 2022.

California requires a 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 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 purpose of providing information for the diagnosis, prevention or treatment of a disease, impairment, or assessment of health.

For public behavioral health systems/entities, the Board will need to grant authority to an Authorized Representative to sign the Owner's Attestation. Recommendation No. 2 will authorize the Chief Executive Officer to sign the Owner's Attestation on behalf of DBH, which is required as part of the CLIA Application for Certification. The Owner's Attestation is confirming the information included in the CLIA Application for Certification is accurate. The Directors Attestation is confirming that the information provided is accurate and the Addiction Medicine Physician, as the Laboratory Medical Director of DBH, will be held responsible as the laboratory director. The laboratory director, as defined by Title 42, part 493.2, must be a physician, a midlevel practitioner authorized by the State, or a dentist.

Approval of this item will allow DBH to execute and submit the forms listed in the Recommendations 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.

PROCUREMENT

N/A

REVIEW BY OTHERS

This item has been reviewed by Behavioral Health Contracts (Natalie Kessee, Contracts Manager, 388-0869) on July 18, 2022; County Counsel (Dawn Martin, Deputy County Counsel, 387-5455) on July 20, 2022; Finance (Christopher Lange, Administrative Analyst, 386-8393) on July 18, 2022; and County Finance and Administration (Cheryl Adams, Deputy Executive Officer, 388-0238) on July 18, 2022.

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Record of Action of the Board of Supervisors
San Bernardino County

APPROVED (CONSENT CALENDAR)

Moved: Joe Baca, Jr. Seconded: Janice Rutherford

Ayes: Col. Paul Cook (Ret.), Janice Rutherford, Dawn Rowe, Curt Hagman, Joe Baca, Jr.

Lynna Monell, CLERK OF THE BOARD

BY



DATED: July 26, 2022



cc: File - Behavioral Health/General

JLL 07/27/2022