SENATE COMMITTEE ON APPROPRIATIONS
Senator Anna Caballero, Chair
2025 - 2026 Regular Session

AB 481 (Blanca Rubio) - Healing arts: clinical laboratories: personnel

Version: April 2, 2025
Urgency: No
Hearing Date: August 18, 2025
Policy Vote: B., P. & E.D. 7 - 0
Mandate: Yes
Consultant: Janelle Miyashiro

Bill Summary: AB 481 authorizes to assist in moderate and high complexity testing in a clinical laboratory if the person meets requirements under the Clinical Laboratory Improvement Act (CLIA), as specified.

Fiscal Impact: The California Department of Public Health (CDPH) reports annual costs ranging from $860,000 to $975,000 in Fiscal Year (FY) 2026-27, $710,000 to $975,000 in FY 2027-28 and 2028-29, and $619,000 to $975,000 ongoing (Clinical Laboratory Improvement Fund). Costs include an additional 3.0 to 6.0 staff dedicated to compliance oversight of unlicensed personnel, and for workload to promulgate regulations and modify the existing laboratory personnel database.

Background: The Centers for Medicare & Medicaid Services regulate laboratory testing on humans through CLIA. CLIA regulations establish quality standards for all testing to ensure test results are accurate, reliable and timely. These regulations apply to all U.S. facilities that test human specimens for assessment or to diagnose, prevent, or treat disease. The federal Food and Drug Administration (FDA) determines the complexity of laboratory tests using criteria within CLIA regulations which are categorized as either waived, moderate or high complexity tests. Waived clinical laboratory tests include certain tests listed in CLIA regulations, tests that have been cleared by the FDA for home use, classified as simple tests with a low risk of incorrect results such as urine pregnancy tests or blood glucose tests. Clinical laboratories that perform only waived tests must have a CLIA certificate and follow the manufacturer's instructions.

Moderate and high complexity testing is determined by CLIA categorization criteria using a scoreboard to determine the level of complexity. Criteria factors used include: scientific and technical knowledge required, minimal to specialized training required, characteristics of operational steps, testing materials used, test system troubleshooting and equipment maintenance, and use of interpretation and judgement. Clinical laboratories or facilities that perform these tests need to have an appropriate CLIA certificate, be inspected and meet CLIA quality standards. The training and licensing requirements of laboratory personnel differ for moderate and high complexity testing.

CLIA regulations allow the state to regulate licensed clinical laboratories and impose stricter regulations through the CDPH Laboratory Field Services (LFS) branch. The LFS is responsible for overseeing the licensing and registration of clinical laboratories including regulating laboratory personnel to ensure they have the required education, training, and experience. The LFS also administers regular inspections to monitor laboratory testing procedure compliance with state and federal regulations.

Proposed Law:

- Authorizes unlicensed laboratory personnel to assist in moderate and high complexity testing if they meet the CLIA requirements for moderate and high complexity testing.

- Defines “assist or assisting” to mean activities performed by trained and competent personnel who follow specific instruction from a licensed physician and surgeon or personnel licensed as defined, other than a trainee, under direct and constant supervision, and includes the following activities prior to, during, and after the laboratory testing process:
    - Load and unload barcoded specimens and barcoded quality control material onto automated instruments.
    - Load and replenish premeasured reagents and supplies onto automated instruments.
    - Load and unload samples and their byproducts into or onto shakers, incubators, refrigerators, freezers, thermal cyclers, and other automated equipment or instruments.
    - Unload and store reagents from an automated instrument.
    - Move assay from one piece of equipment to the next.
    - Clean and disinfect laboratory equipment.
    - Replacement of consumable laboratory equipment, supplies, and reagents.
    - Transfer samples, quality control material, or reagents by the use of previously calibrated and approved automatic syringes, fixed volume pipettes, or other dispensers.

- Requires unlicensed laboratory personnel to have documentation of the following training, in addition to existing required training: a working knowledge of the factors that influence test results; reading and understanding of the procedures receiving verbal instruction on how the task is performed by licensed personnel, and directly observing the task performed by licensed personnel.

- Requires unlicensed personnel, prior to performing any of the above mentioned skills, under direct and constant supervision, to demonstrate the skills and ability to satisfactorily perform the task.

- Requires the laboratory director to designate the supervisor and maintain overall responsibility for the supervision and performance of the unlicensed laboratory personnel.

- Defines “supervision and control” to mean direction, management, and awareness of the activity of unlicensed laboratory personnel by a physician and surgeon or by a person licensed, as defined, other than a trainee, who must be physically present in the laboratory and readily available for consultation during the entire time that the unlicensed laboratory personnel are engaged in the duties.

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