



Accreditation News Special Supplement

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California State Registration for Waived Testing

The Joint Commission accreditation surveys for Clinical Laboratories is including a review of relevant licenses and certificates for operations. While this includes the traditional State of California license and the CLIA certificates, issued by the Centers for Medicare and Medi-caid Services (CMS) surveyors are also looking to ensure that laboratories operated by the hospital as “remote” sites, including those that are doing point-of-care testing, have appropriate registration or licensure.

The California Business and Professions Code Section §1265(a)(2) requires a registration of the laboratory with the State of California. Section §1265(d)(4) defines the requirements pertaining to the specific location of the laboratory.

§1265(a)(2) A clinical laboratory performing clinical laboratory tests or examinations subject to a certificate of waiver or a certificate of provider-performed microscopy under CLIA, shall register with the Department. The Department shall issue a clinical laboratory registration to any person who has applied for the registration on forms provided by the Department and is found to be in compliance with this chapter, the regulations pertaining thereto, and the CLIA requirements for either a certificate of waiver or a certificate of provider-performed microscopy.

§1265(d) A separate license or registration shall be obtained for each laboratory location, with the following exceptions:

- (1) Laboratories that are not at a fixed location, that is, laboratories that move from one testing site to another, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations, may apply for and obtain one license or registration for the designated primary site or home base, using the address of that primary site.
- (2) Not-for-profit, or federal, state, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests, as defined under CLIA, per license) public health testing may apply for and obtain a single license or registration.
- (3) Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction, may file a single application or multiple applications for a license or registration of laboratory locations within the same campus or street address.
- (4) Locations within a single street and city address that are under common ownership may apply for and obtain a single license or registration or multiple licenses or registrations, at the discretion of the owner or owners.

Please review all of your laboratory sites to ensure that they possess proper licensure and/or registration. Failure to obtain and maintain a license or registration can result in a Preliminary Denial of Accreditation from the Joint Commission, under PDA06, which states “The organization does not possess a license, certificate, and/or permit, as, or when, required by applicable law and regulation, to provide the health care services for which the organization is seeking accreditation.”

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