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EDMUND G. BROWN JR.  
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IMPORTANT NOTICE REGARDING CRITERIA FOR APPROVAL  
OF PRIVATE NON-PROFIT ACCREDITING ORGANIZATIONS  
TO INSPECT LABORATORIES FOR PURPOSES OF STATE LICENSURE

This notice informs California licensed or registered clinical laboratories that Section 1223 of the California Business and Professions Code (BPC) requires the California Department of Public Health to approve private non-profit accrediting organizations to inspect laboratories that operate in California or laboratories outside California that process specimens originating in California for the purpose of deeming them in compliance with California clinical laboratory law. The statute provides for an inspection process that includes state-based inspection components and determines compliance with federal and state requirements for clinical laboratories. (Please refer to [BPC §1223](#).)

Laboratory Field Services (LFS) in the California Department of Public Health (CDPH) has approved three accrediting organizations to deem laboratories to meet the requirements of California law for licensure or registration and anticipates that other organizations will be approved in the future. California laboratories now have the option to choose licensure or registration by the department or certification of deemed status by a private non-profit accrediting organization approved by the department.

California deemed status certification comprises two components. The first component sets requirements a private non-profit accrediting organization must meet to be approved by the department to inspect laboratories, issue certificates of deemed status, and provide continued oversight to ensure compliance with California law. This component also outlines the inspection and oversight responsibilities of approved organizations. Information about the requirements for approval and the process for submitting an application are posted on the department's website at <https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/All-Clinical-Laboratories-Letters.aspx>

The second component sets requirements a laboratory must meet if it chooses certification of deemed status by an approved private non-profit accrediting organization.

Additional information about requirements for accrediting organizations and laboratories will be communicated to the regulated community by means of an All Clinical Laboratories Letter (ACLL) posted on the department's website and mailed to laboratories licensed or registered by the department.

An ACLL is a letter from LFS to clinical laboratories that are licensed or registered by the department. ACLLs are posted on the LFS website at <https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/All-Clinical-Laboratories-Letters.aspx>. Public comment on an ACLL will be received and considered by the department for 30 days after posting online. The ACLL becomes final 45 days after posting, after which time it has the force of regulations.

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