

Change of Laboratory Owner AND Director

California Business and Professions Code (BPC) section 1265 (g) requires clinical laboratories to notify Laboratory Field Services within 30 days of any change in ownership, name, location, or laboratory director. **Pursuant to BPC 1265 (e), a clinical laboratory license will be automatically revoked 30 days after a major change of directorship or ownership.**

“A major change in ownership” means a change in ownership where 50 percent or more of the ownership interest is owned by persons other than the owners to whom the current clinical laboratory license is issued. See BPC 1211 (f).

“A major change in laboratory directorship” means a change in laboratory director or directors resulting in the situation where less than 50 percent of the laboratory directors to whom the current laboratory license is issued remain after the change. See BPC 1211 (j).

The laboratory must submit a completed application for a new clinical laboratory license within 30 days of a major change of ownership and/or directorship or cease engaging in clinical laboratory practice.

Clinical Laboratory License Fee and Required Documents:

- **License fee** payable to the State of California Department of Public Health. The fee is non-refundable and subject to change with each fiscal year. View the current fee schedule at <http://www.cdph.ca.gov/programs/lfs/Documents/A-License-FeeSchedules.pdf> .
- **State forms to complete:**
- **LAB 144** – Application for Clinical Laboratory License
- **LAB 144B** – Application for Additional Clinical Laboratory Testing Sites, ONLY if qualified for multiple site exception under California Business and Professions Code 1265 (d).
- **LAB 1513** - Disclosure of Ownership and Control Interest Statement, including home addresses of all owners and corporate officers
- **LAB 116** – Laboratory Personnel Report
- **LAB 144A** – Laboratory Testing Declaration, including name(s) of manufacturer(s) and/or equipment(s) and annual volumes
- **LAB 183** - Director’s Attestation (each director or co-director must file a separate attestation)
- **If applicable, LAB 165** – Application for Approval to Perform HIV Tests. Check the box for change of director

Federal forms to complete:

- **CMS 116** – Application for Certification (CLIA)
- **CMS 209** – Laboratory Personnel Report (CLIA)

Other requirements:

- **Official documents of ownership transaction:** Copy of Bill of Sale, Sales Agreement, Merger Agreement, Partnership Agreement or Articles of incorporation which includes all owners' name(s), list of Board of Directors and home addresses.
- **Resignation letter from the previous director** with effective date and original signature.
- **Original signatures** must be on all forms where signatures are required.

State **LAB** forms and **Fee Schedule** can be downloaded from

<http://www.cdph.ca.gov/pubsforms/forms/Pages/RegulatedLaboratories.aspx>
<http://cdphinternet/programs/lfs/Documents/A-License-FeeSchedules.pdf>.

Federal **CMS 116** and **CMS 209** forms can be downloaded from

<http://www.cms.hhs.gov/cmsforms/downloads/cms116.pdf> and
<http://www.cms.hhs.gov/cmsforms/downloads/cms209.pdf> .

Submit fee and all required documents to:

**CDPH - Laboratory Field Services Branch
Facility Licensing Section
850 Marina Bay Parkway Bldg P, 1st Floor
Richmond, CA 94804**

Note: No clinical laboratory license shall be issued by the department unless the clinical laboratory is found to be in compliance with applicable state laws and regulations.