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## ACLL 16-02 – Accrediting Organization Requirements

### ALL CLINICAL LABORATORIES LETTER REGARDING REQUIREMENTS FOR APPROVAL OF ACCREDITING ORGANIZATIONS TO INSPECT LABORATORIES FOR PURPOSES OF STATE LICENSURE

This All Clinical Laboratories Letter (ACLL) informs private, nonprofit accrediting organizations (AO) of the requirements and responsibilities they must meet to be approved by the California Department of Public Health (CDPH) to inspect clinical laboratories operating in California and laboratories outside California that process specimens originating in California. Approval will authorize AOs to deem laboratories to meet the requirements of California clinical laboratory law for licensure or registration.

Public comment on this ACLL will be received and considered by the Department for 30 days after posting online. The revised ACLL will become final 45 days after initial posting, after which time it has the force of regulations. Please address your comments to Laboratory Field Services (LFS) at [LFSAccOrg@cdph.ca.gov](mailto:LFSAccOrg@cdph.ca.gov) and refer to ACLL 16-02 in the subject line.

Section 1223 of the California Business and Professions Code (BPC) requires the Department to approve AOs to inspect laboratories for the purpose of deeming them to meet the requirements of California licensure or registration law. The statute provides for a process for the Department to approve AOs, issue certificates of deemed status to laboratories, and provide continued oversight to ensure compliance with California law. Please refer to [BPC §1223](#) for the complete text and see the notice regarding criteria for approval of AOs on the LFS website at <http://www.cdph.ca.gov/programs/lfs/Pages/default.aspx>.

#### A. Requirements for approval to deem laboratories to meet requirements for California licensure or registration.

1. Approval of deeming authority is granted subject to the requirements stipulated in BPC §1223, as well as any pertinent laws, including past and future ACLLs that may be posted on the LFS website in the future. The Department retains the authority to update its oversight of accrediting organizations (AO).



2. To be approved by the Department, an AO must be approved by the Centers for Medicare & Medicaid Services (CMS) pursuant to BPC §1223 (c)(1)(A) and do the following:
  - a. Notify the Department in writing of any change in the AO's status as an approved AO for CMS within 30 days of the change.
    - i. The Department will automatically suspend or revoke the deeming authority of an AO when its deeming authority is removed by CMS.
    - ii. An AO whose deeming authority has been suspended shall notify its accredited laboratories within 60 days that the Department has withdrawn approval of the AO.
    - iii. An AO dissatisfied with the imposition of an automatic suspension shall seek judicial review by filing a petition for writ of mandate in accordance with the provisions of the Code of Civil Procedure.
  - b. Provide information to the Department about its accreditation or approval requirements pursuant to BPC §1223 (c)(1)(A).
  - c. Provide to the Department proof of its non-profit status documented by a 501(c)(3) statement from the Internal Revenue Service.
  - d. Notify the Department in writing within 30 days of any change in its nonprofit status.
  - e. Maintain accreditation standards that are equal to, or more stringent than, California requirements for licensure or registration pursuant to BPC §1223 (c)(1)(A).
    - i. If the Department determines that an AO's survey standards are not substantially equivalent to state requirements the Department may revoke or suspend the AO's approval.
    - ii. The AO shall notify the Department in writing at least 30 days prior to making any changes to its accreditation requirements, standards, or policies to obtain Department approval for the changes.

**B. Responsibilities of inspection and oversight of laboratories for compliance with California law**

An AO approved for deeming laboratories in compliance with California law must:

1. Allow the Department to:
  - a. Retain jurisdiction to conduct complaint investigations and require submission of proficiency testing results to the Department to ensure any clinical laboratory's compliance with California standards, pursuant to BPC §1223 (f).
  - b. Conduct random on-site validation inspections and take disciplinary action against a clinical laboratory if indicated, pursuant to BPC §1223 (f).
  - c. Investigate complaints against the AO.
2. Provide to the Department:

- a. An explanation of the AO's terminology for deficiencies and sanctions that indicates the equivalent terminology used by the Department. When citing laboratories for deficiencies, the AO shall follow the Code of Federal Regulations Title 42, Part 493.2, as follows:
    - i. Standard level deficiencies, cited when standards are not met, are less serious, and must be corrected within one year.
    - ii. Condition-level deficiencies are cited when failure to meet one or more standards results in a serious situation that requires correction if the laboratory is to continue testing. Condition-level deficiencies must be corrected within 60 calendar days of the survey date. The survey date is the date of completion of the entire survey process. If condition-level deficiencies are not corrected within 60 days, sanctions become effective on the 90th day.
    - iii. Condition-level immediate jeopardy deficiencies result in a serious situation requiring immediate corrective action to prevent harm to a patient. Jeopardy must be removed and the laboratory must come into condition level compliance. If immediate jeopardy deficiencies are not corrected immediately, sanctions become effective on the 23rd day.
  - b. A list of inspection schedules each quarter for the purpose of conducting on-site validation inspections.
3. Conduct inspections of deemed laboratories for initial applications, routine renewals, revisits, and complaints in a manner that will ensure compliance with existing state laws and federal standards.
  4. Conduct on-site inspections of deemed laboratories on the following schedule, unless permission to extend the time period for a specific survey is received in writing from the Department:
    - a. Initial surveys shall be conducted within 60 days of the receipt of a complete application, and closed within 60 days after completion of the survey.
    - b. Routine renewal inspections shall be conducted within 60 days of the expiration date of the laboratory's certificate of deemed status, and closed within 60 days after completion of the survey.
    - c. Revisits to ensure compliance shall be conducted within 30 days of the issuance of a plan of correction, and closed within 45 days after completion of the survey.
    - d. Complaint investigations of condition-level deficiencies shall be conducted within 30 days of the receipt of the complaint, and closed within 60 days after completion of the survey.

- e. Complaint investigations of condition-level immediate jeopardy deficiencies shall be conducted within 5 days of the receipt of the complaint, and closed within 23 days after completion of the survey.
5. Notify the Department of the following in writing as specified:
  - a. Any deficiency that poses immediate jeopardy to public health, safety, or welfare, within 5 days after completion of a survey.
  - b. Any condition-level deficiency, within 30 days of the completion of a survey.
  - c. Any action by the organization to limit, withdraw, or revoke the accreditation of a clinical laboratory, within 5 days of the initiation of the action.
  - d. Any findings discovered during an investigation or routine inspection that show a laboratory is reporting and or billing for tests that were not performed by the laboratory, within 15 days of discovery.
  - e. Any findings discovered during an investigation or routine inspection that show a physician (MD or DO) has referred patients to a clinical laboratory in which he or she has a membership, proprietary interest, co-ownership in any form, or any profit-sharing arrangement not disclosed in writing to the patient, within 15 days of discovery.
  - f. Any violations of BPC §650 discovered during an investigation or routine inspection, within 15 days of discovery.
  - g. Voluntary withdrawal by a laboratory from accreditation by the organization, within 30 days of the action.
  - h. The investigation of any complaint and the results, including each plan of correction imposed, within 30 days of completion of the complaint investigation. The Department retains the right to conduct follow-up investigations of any complaints.
6. Report to the Department
  - a. The status of any accredited laboratory, at the request of the Department.
  - b. A quarterly report on a date specified by the Department that includes
    - i. The number of surveys conducted during the quarter.
    - ii. For each laboratory surveyed:
      1. Name.
      2. Address.
      3. State certificate of deemed status number, state license number, and CLIA number.
      4. Any condition-level deficiencies.
      5. Any condition-level deficiencies that pose immediate jeopardy.
      6. Date of survey.

- c. A summary annual report that includes for each California laboratory accredited by the organization:
  - i. Name.
  - ii. Address.
  - iii. State certificate of deemed status number, state license number, and CLIA number.
  - iv. Accreditation expiration date.
  - v. Specialties or subspecialties of accreditation.
- d. Other reports as defined and requested by the Department.