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ACLL 16-02 – ACCREDITING ORGANIZATION REQUIREMENTS

ALL CLINICAL LABORATORIES LETTER REGARDING
REQUIREMENTS FOR APPROVAL OF LABORATORIES TO OPT FOR
A CERTIFICATE OF DEEMED STATUS ISSUED BY
AN ACCREDITING ORGANIZATION

NOTICE OF FINAL ACTION

Subject: This is the Final Action on the Notice of Proposed Changes posted as ACLL 16-02 on July 6, 2016, at:
<http://www.cdph.ca.gov/programs/lfs/Documents/AOs%20-%20ACLL%2016-02.pdf>.

Date of Adoption: The Final Action was effective August 20, 2016.

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.

You may contact Laboratory Field Services (LFS) about this ACLL at LFSaccorg@cdph.ca.gov. Please refer to ACLL 16-02 in the subject line. Accrediting organizations may also submit questions or request information from LFS at LFSaccorg@cdph.ca.gov. Please include “Accrediting Organization Inquiry” in the subject line.

Section 1223 of the California Business and Professions Code (BPC) requires the Department to approve accrediting organizations to inspect laboratories for the purpose

of deeming them in compliance with California clinical laboratory law. Laboratories licensed by the Department have the option to choose licensure or registration by the Department or certification of deemed status by an accrediting organization approved by the Department. All laboratories seeking California licensure must apply to LFS.

Private, nonprofit accrediting organizations approved to inspect clinical laboratories operating in California and laboratories outside California that process specimens originating in California must meet the requirements listed below.

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~~ withdraws its approval and recognition of the AO under CLIA.
 - ii. An AO whose deeming authority has been suspended or revoked 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 or revocation 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.

1. An AO approved for deeming laboratories in compliance with California law must:
2. Allow the Department to:
 - a. Retain jurisdiction to conduct complaint investigations at the discretion of the Department 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.
3. 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 ensure the laboratories meet standards equivalent to follow the Code of Federal Regulations (CFR) Title 42, Part 493.2, as follows:
 - i. Deficiencies equivalent to CFR Sstandard level deficiencies, cited when standards are not met, are less serious, and must be corrected within one year.
 - ii. Deficiencies equivalent to CFR Gcondition-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 date of survey date completion. The date of survey date completion 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. Deficiencies equivalent to CFR Ccondition-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.
4. 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.
5. 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. If a revisits is required to ensure compliance, it 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 deficiencies equivalent to CFR 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 deficiencies equivalent to CFR condition-level immediate jeopardy deficiencies shall be conducted within 5 business days of the receipt of the complaint, and closed within 23 days after completion of the survey.
6. 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, including the name, state certificate of deemed status number, and CLIA number of the laboratory, date of survey, and the condition(s) cited.
 - b. Any deficiency equivalent to CFR condition-level deficiency, within 30 days of the completion of a survey, including the name, state certificate of deemed status number, and CLIA number of the laboratory, date of survey, and the condition(s) cited.
 - c. Any action by the organization to limit, withdraw, or revoke the accreditation of a clinical laboratory, within ~~5~~ 10 days of the initiation of the action, including the name, state certificate of deemed status number, and CLIA number of the laboratory.
 - 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, including the name, state certificate of deemed status number, and CLIA number of the laboratory.
 - 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.
7. 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:
 - a. Name.
 - b. Address.
 - c. State certificate of deemed status number, ~~state license number,~~ and CLIA number.
 - d. Date of survey.
 - e. Any deficiencies equivalent to CFR condition-level deficiencies.
 - f. Any ~~condition-level~~ deficiencies that pose immediate jeopardy.
 - 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 or renewal date.
 - v. Specialties or subspecialties of accreditation.
 - d. Other reports as defined and requested by the Department.

The provisions of this ACLL do not modify or otherwise affect existing law and do not modify the Department's authority to enforce its laws.