

Submission for Approval by the Department of a Private, Nonprofit Organization

California Business and Professions Code Section 1223 states that it is the public policy of the state to ensure that California's laboratory standards, including its laboratory personnel standards, are sustained in order to provide accurate, reliable, and necessary test results. The provisions of the section permit laboratories, accredited by a private nonprofit organization that has been approved by the department, to be deemed by the department to meet state licensure or registration requirements and to be issued a certificate of that deemed status by the department.

Private, nonprofit organizations that accredit laboratories and wish to be approved by the department should submit an application which includes the following information:

Contact Information:

- 1) The complete name and address of the private, nonprofit accrediting organization.
- 2) The name(s) of contact person(s) and email(s), fax(s) and telephone number(s).

Accrediting Organization Information:

- 1) Documentation of approval by the federal Center for Medicare and Medicaid Services as an accreditation body under CLIA.
- 2) Detailed comparison of the individual accreditation or approval requirements, with the comparable California condition-level requirements, including standards.
- 3) Detailed description of the inspection process including the following:
 - a) Frequency of inspections.
 - b) Copies of inspection forms.
 - c) Instructions and guidelines
 - d) A description of the review and decision making process of inspections.
 - e) A statement concerning whether inspections are announced or unannounced.
 - f) A description of the steps taken to monitor the correction of deficiencies.
 - g) A description of the process for monitoring proficiency testing performance, including action to be taken in response to unsuccessful participation.
 - h) A description of the process for notifying the department of any deficiency that poses an immediate jeopardy to the laboratory's patients or a hazard to the general public
- 4) A list of all of its current California licensed or registered laboratories with California Identification number, CLIA number and the expiration date of their accreditation, state licensure, or registration, as applicable.

- 5) Mechanism by which the nonprofit organization will ensure that the laboratory agrees to permit the private, nonprofit organization to provide any records or other information to the department, its agents, or contractors, as the department may require.
- 6) Mechanism by which the nonprofit organization will ensure that the laboratory agrees to authorize its proficiency testing organization to furnish to the department and the private, nonprofit organization the results of the laboratory's participation in an approved proficiency testing program, as defined in 42 C.F.R. 493.2, for the purpose of monitoring the laboratory's proficiency testing, along with explanatory information needed to interpret the proficiency testing results, upon request of the department.
- 7) Mechanism by which the nonprofit organization will ensure that the laboratory agrees to authorize the private, nonprofit organization to release to the department a notification of every violation of condition level requirements, including the actions taken by the organization as a result of the violation, within 30 days of the initiation of the action.
- 8) Mechanism by which the nonprofit organization will ensure that the laboratory agrees to authorize the private, nonprofit organization to give notice to the department of any withdrawal of the laboratory's accreditation.

Private, nonprofit organizations that are approved by the department as having accreditation standards that are equal to, or more stringent than, state requirements for licensure and registration are required to conduct inspections of clinical laboratories in a manner that will determine compliance with federal standards and California laws.

If the private, nonprofit organization has withdrawn or revoked its accreditation of a laboratory, the laboratory shall retain its certificate of deemed status for 45 days after the laboratory receives notice of the withdrawal or revocation of the accreditation, or the effective date of any action taken by the department, whichever is earlier.

The department retains the authority to conduct complaint investigations, sample validation inspections, or require submission of proficiency testing results to the department to ensure compliance of any clinical laboratory with state standards.

Governing Statutes and regulations:

- Business and Professions Code Chapter 3, Sections 1200-1320 (laboratory facilities).
- Title 17 California Code of Regulations, Section 1029 to 1075 (personnel).
- Health and Safety Code Sections 1600 – 1626 (biologics, blood banks).
- Health and Safety Code Section 1635 to 1647 (tissue banks).

- Clinical Laboratory Improvement Amendment of 1988 (CLIA), Public Law 100-578, Section 353 of the Public Health Services Act (42 U.S.C. 263(a); 42 Code of Federal Regulations, Part 493.
- Business and Professions Code Chapter 3, Sections 1220 & 1327.

Send Applications to:

California Department of Public Health

Laboratory Field Services

Attn: Beatrice O'Keefe, Chief

850 Marina Bay Parkway, Bldg P, 1st fl.

Richmond, CA 95804-6403