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Director

State of California—Health and Human Services Agency  
California Department of Public Health



ARNOLD SCHWARZENEGGER  
Governor

**ACTION:** Notice of Proposed Rulemaking  
Title 17, California Code of Regulations

**SUBJECT:** Clinical Laboratory Personnel Standards, DPH-08-001.

**PUBLIC PROCEEDINGS:** Notice is hereby given that the California Department of Public Health will conduct written public proceedings during which time any interested person or such person's duly authorized representative may present statements, arguments or contentions (all of which are hereinafter referred to as comments) relevant to the action described in this notice.

### **INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW**

The standards for licensure of clinical laboratory personnel are set in California Code of Regulations (CCR) Title 17, Public Health Division 1, State Department of Health Services, Chapter 2, Laboratories, Subchapter 1, Service Laboratories, Group 2, Clinical Laboratory Regulations, Article 1.5, Licensure of Clinical Laboratories. Standards were first enacted in 1939 with the licensure of clinical laboratory technologists ("medical technologists", now clinical laboratory scientists) and bioanalysts. Training standards were enacted in the 1950s. New license categories for clinical chemists and clinical microbiologists were added in the 1970s, and over the years the public has asked for new license categories as technology changed.

Many of the current licensing standards are outdated and difficult to administer. They serve as barriers to licensure of qualified persons, especially to those coming from outside California. Because of this, CDPH is proposing to amend the following sections of Title 17 of the CCR.

Specifically, the changes to 17CCR shall do the following

- Section 1029, shall add definitions of "an approved NAACLS-accredited training program", "clinical biochemical genetics", "clinical embryology", "critical review", "degrees or majors in biological science, chemical science or physical science", "official school transcript", "tests or examinations in molecular biology", "tests or examinations in molecular pathology" and amend the current definitions of "clinical genetic molecular biology" and of "accredited college or university";
- Sections 1030 - 1030.7, shall amend and clarify licensure requirements for masters or doctorate-degree license candidates;
- Sections 1031 to 1031.5, shall clarify licensure requirements of baccalaureate-or higher-degree scientist candidates;

- Sections 1031.6 and 1031.7, shall amend requirements for license applications and renewals;
- Sections 1031.7 – 1031.9 shall be renumbered without other change to Sections 1031.8 – 1031.10;
- Section 1031.11 shall specify conditions for approval of training performed at a clinical laboratory that is not CLIA-certified;
- Section 1031.12 shall clarify how LFS administers examinations on laboratory law for candidates for licensure;
- Section 1032, shall clarify licensure requirements of baccalaureate-degree clinical laboratory scientists;
- Section 1033, shall clarify training licensure requirements for medical laboratory technicians (MLT), clinical laboratory scientists (CLS), clinical laboratory specialists, postgraduate fellows, and an articulation route for MLTs training for CLS licensure;
- Section 1034, shall amend certification standards for phlebotomists;
- Section 1035, shall specify requirements for CLS and clinical laboratory specialist training programs;
- Section 1035.1, shall amend requirements for phlebotomy training programs;
- Section 1035.2, shall specify requirements for postgraduate fellow training programs;
- Section 1035.3, shall amend requirements for MLT training programs;
- Section 1035.5, shall specify requirements for training MLTs articulating to CLS licensure;
- Section 1036, shall amend the qualification requirements for a clinical consultant;
- Section 1036.1, shall amend the qualification requirements for a general supervisor;
- Section 1038.1, shall clarify time interval for completion, and number of hours required, of continuing education requirements to maintain licensure;
- Section 1038.6, shall clarify what needs to be done to reinstate an inactive license;
- Section 1039.2, shall clarify how training or experience gained outside California can be used to meet licensing requirements in California;
- Sections 1060 to 1062, shall be repealed, the standards amended and moved to Section 1031.4.
- The California Department of Health Services was legislatively reorganized as of July 1, 2007 (SB 162, Chapter 241, Statutes of 2006) into two separate departments, the new Department of Health Care Services and the new Department of Public Health. Health and Safety Code Section 131050 transferred the duties, powers, and responsibilities of the Laboratory Field Services program to the Department of Public Health, and Health and Safety Code Section 131200 vests the Department of Public Health with rulemaking authority for the execution of its duties.

AUTHORITY: Sections 1639 and 131200, Health and Safety Code and Sections 1208 and 1224, Business and Professions Code.

REFERENCE: Sections 119, 1202.5, 1203, 1205, 1206, 1206.5, 1207, 1208, 1209, 1209.1, 1210, 1212, 1213, 1222.5, 1225, 1242, 1242.5, 1246, 1260, 1261, 1261.5, 1262, 1263, 1264, 1265, 1269, 1270, 1271, 1280, 1282, 1285, 1286, 1288, 1288.5, 1289, 1300 and 1310, Business and Professions Code, and Sections 1639 and 131050, Health and Safety Code.

COMMENTS: Any written comments pertaining to these regulations, regardless of the method of transmittal, must be received by the Office of Regulations and Hearings by 5 p.m. on September 27, 2010, which is hereby designated as the close of the written comment period. Comments received after this date will not be considered timely. Persons wishing to use the California Relay Service may do so at no cost by dialing 711.

Written comments may be submitted as follows:

1. By mail to the Office of Regulations and Hearings, California Department of Public Health, MS 0507, P.O. Box 997377, Sacramento, CA 95899-7377 or hand-delivered to 1616 Capitol Avenue, Sacramento, CA 95814. It is requested but not required that written comments sent by mail or hand-delivered be submitted in triplicate; or,
2. By fax transmission: (916) 440-5747; or
3. By email to [regulations@cdph.ca.gov](mailto:regulations@cdph.ca.gov). It is requested that email transmission of comments, particularly those with attachments, contain the regulation package identifier "DPH -08-001" in the subject line to facilitate timely identification and review of the comment.

All comments, including email or fax transmissions, should include the author's name and U.S. Postal Service mailing address in order for the Department to provide copies of any notices for proposed changes to the regulation text on which additional comments may be solicited.

INQUIRIES: Inquiries regarding the substance of the proposed regulations described in this notice may be directed to Bea O'Keefe, Laboratory Field Services, at (510) 867-9484.

All other inquiries concerning the action described in this notice may be directed to Rosalie Dvorak-Remis, Office of Regulations and Hearings, at (916) 327-4310, or to the designated backup contact person, Marylyn Willis, at (916) 440-7807.

**CONTACTS: In any inquiries or written comments, please identify the action by using the Department regulation package identifier, DPH-08-001.**

AVAILABILITY OF STATEMENT OF REASONS AND TEXT OF REGULATIONS: The Department has prepared and has available for public review an initial statement of

reasons for the proposed regulations, all the information upon which the proposed regulations are based, and the text of the proposed regulations. The Office of Regulations and Hearings, at the address noted above, will be the location of public records, including reports, documentation, and other material related to the proposed regulations (rulemaking file). In addition, a copy of the final statement of reasons (when prepared) will be available upon request from the Office of Regulations and Hearings.

Materials regarding the action described in this notice (including this public notice, the regulation text, and the initial statement of reasons) that are available via the Internet may be accessed at [www.cdph.ca.gov](http://www.cdph.ca.gov) by clicking on these links, in the following order: Decisions Pending and Opportunity for Public Participation, Proposed Regulations.

In order to request that a copy of this public notice, the regulation text, and the initial statement of reasons or alternate formats for these documents be mailed to you, please call (916) 327-4310 (or the California Relay Service at 711), send an email to [regulations@cdph.ca.gov](mailto:regulations@cdph.ca.gov), or write to the Office of Regulations and Hearings at the address noted above. Upon specific request, these documents will be made available in Braille, large print, and audiocassette or computer disk.

**AVAILABILITY OF CHANGED OR MODIFIED TEXT:** The full text of any regulation which is changed or modified from the express terms of the proposed action will be made available by the Department's Office of Regulations and Hearings at least 15 days prior to the date on which the Department adopts, amends, or repeals the resulting regulation.

#### FISCAL IMPACT ESTIMATE:

- A. Fiscal Effect on Local Government: There is no impact on local health agencies for this program operation.
- B. Fiscal Effect on State Government:  
Direct Cost to the State

The Personnel Licensing Section of CDPH Laboratory Field Services is supported by license fees established by statute, so there is no direct cost to the State General Fund for increased costs of program operation.

There will be no impact on the Medi-Cal program.

CDPH proposes to add four new categories of licenses: clinical biochemical geneticist, clinical immunologist, clinical embryologist, and clinical embryologist scientist. CDPH estimates that about 160 persons shall be licensed in these categories after five years. This shall generate new revenue from application and renewal fees of \$54,240 over five years. This additional workload shall not require any additional staff and shall be handled with current authorized positions.

- C. Fiscal Effect on Federal Funding of State Programs: There will be no impact on federal funds or on matching federal funds for these licensure activities.
- D. All cost impacts, known to the Department at the time the notice of proposed action was submitted to the Office of Administrative Law, that a representative private person or business would necessarily incur in reasonable compliance with the proposed action:

There shall be a small impact on private individuals paying license application fees and examination fees to certifying organizations. This shall be offset by their employability in California once licensed. This action will not affect salaries or personnel, and will not affect fees charged to the public for tests.

- E. Other Nondiscretionary Cost or Savings Imposed on Local Agencies: There is no impact on local health agencies for this program operation.

**DETERMINATIONS:** The Department has determined that the regulations would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by Part 7 (commencing with Section 17500) of Division 4 of the Government Code.

The Department has made an initial determination that the regulations would not have a significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

The Department has determined that the regulations would not significantly affect the following:

- (1) The creation or elimination of jobs within the State of California.
- (2) The creation of new businesses or the elimination of existing businesses within the State of California.
- (3) The expansion of businesses currently doing business within the State of California.

The Department has determined that the regulations would affect small business.

The Department has determined that the regulations will have no impact on housing costs.

**ADDITIONAL STATEMENTS AND COMMENTS:** In accordance with Government Code Section 11346.5(a)(13), the Department must determine that no reasonable alternative considered by the Department or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed action.

No hearing has been scheduled; however any interested person or his or her duly authorized representative may request in writing, no later than 15 days prior to the close of the written comment period, a public hearing pursuant to Government Code Section 11346.8. For individuals with disabilities, should a public hearing be scheduled, the Department will provide assistive services such as sign-language interpretation, real-time captioning, note takers, reading or writing assistance, and conversion of written public hearing materials into Braille, large print, audiocassette, or computer disk. Note: The range of assistive services available may be limited if requests are received less than ten business days prior to a public hearing.

To request such services or copies of materials in an alternate format, please write to Rosalie Dvorak-Remis, Office of Regulations and Hearings, MS 0507, P.O. Box 997377, Sacramento, CA 95899-7377, or call (916) 327-4310, or use the California Relay Service by dialing 711.

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

DPH-08-001



Date:

*Aug. 6, 2010*

Mark B Horton, MD, MSPH  
Director