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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: Testing Standards for Laboratories Performing HIV Screening, DPH-07-010

PUBLIC PROCEEDINGS: Notice is hereby given that the California Department of Public Health (Department) 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 intention of Health and Safety (H&S) Code Section 120885 (Chapter 23, Statutes of 1985) was to ensure that safe blood and blood components were available for transfusion, and that testing would be provided for the probable causative agent of acquired immune deficiency syndrome (AIDS) as a function separate from blood donation. The uncodified Section 5 of the statute stated that no laboratory should provide human immunodeficiency virus (HIV) antibody testing without approval by the Department, formerly the California Department of Health Services. Under authority of H&S Code Sections 1603.1(f) and 100275 and Business and Professions (B&P) Code Section 1224, the Department set standards for approval of laboratories testing for HIV antibodies. These standards continue to this day.

The current standards for HIV screening tests differ substantially from existing comparable federal regulations regarding proficiency testing. Federal regulations at 42 Code of Federal Regulations (CFR) 493.803 state that, "Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS." There is no requirement in federal regulations that laboratories performing waived testing successfully participate in a proficiency testing program. Although implied in current regulations at Title 17 California Code of Regulations (CCR) Section 1230, amendments are proposed to clarify that waived HIV screening tests are not subject to proficiency testing requirements.

Because of changing technology and standards imposed since enactment of these regulations, the Department is proposing to repeal the existing Section 1230 and adopt a new Section 1230 which will include some of the requirements from the existing Section 1230.

Specifically, the changes to Section 1230 would:

1. Repeal the requirement that all laboratories, blood banks, public health laboratories, and serology laboratories be licensed or registered by the Department because this is redundant and unnecessary.
2. Repeal the requirement that all HIV screening facilities participate in proficiency testing as this is redundant and unnecessary.
3. Repeal the requirement that all laboratories be approved by the Department before testing for HIV antibodies.
4. Repeal the requirement for use of a federal Food and Drug Administration (FDA) approved HIV screening kit. A paragraph in the new Section 1230 is based on this requirement.
5. Repeal the requirement for confirmation of screened positive HIV results. A paragraph in the new Section 1230 is based on this requirement.
6. Repeal the requirement that all indeterminate HIV results be re-tested. A paragraph in the new Section 1230 is based on this requirement.
7. Repeal the requirement that all HIV-testing laboratories maintain confidential records as this is redundant and unnecessary.
8. Repeal the requirement that all laboratories performing HIV antibody screening submit monthly reports to the Department on number of tests performed and results.
9. Repeal the requirement that approval for laboratories performing HIV screening be denied or terminated for failure to comply with these standards to specify that sanctions shall be imposed for failure to comply. A subsection in the new Section 1230 is based on this requirement.
10. Adopt quality assurance procedures for laboratories performing waived HIV tests.

AUTHORITY: Sections 1603.1(f), 100275, 131050, and 131200 of the Health and Safety Code and Section 1224 of the Business and Professions Code.

REFERENCE: Sections 1220, and 1265, Business and Professions Code, and Sections 1603.1, 101160, 120895, 131050, 131051, 131052, 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 October 22, 2008, 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. The telephone numbers for accessing this service are: 1-800-735-2929, if you have a TDD; or 1-800-735-2922, if you do not have a TDD. Written comments may be submitted as follows:

1. By mail or hand-delivered to the Office of Regulations and Hearings, California Department of Public Health, MS 0507, 1501 Capitol Avenue, P.O. Box 997377, Sacramento, CA 95899-7377. 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 (it is requested that email transmissions of comments, particularly those with attachments, contain the regulation package identifier "DPH-07-010" 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 Karen Nickel of Laboratory Field Services at (510) 620-3790.

All other inquiries concerning the action described in this notice may be directed to Maureen Miyamura of the Office of Regulations and Hearings at (916) 440-7841, or to the designated backup contact person, Barbara Gallaway, at (916) 440-7689.

CONTACTS: In any inquiries or written comments, please identify the action by using the Department regulation package identifier, DPH-07-010.

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 [Proposed Regulations](#) or www.cdph.ca.gov and clicking on these links, in the following order: Decisions Pending and Opportunity for Public Participation (bottom of page), Regulations, Proposed and Emergency Regulations.

In order to request a copy of this public notice, the regulation text, and the initial statement of reasons be mailed to you, please call (916) 440-7695 (or California Relay at 711/1-800-735-2929), or email 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: None.
- B. Fiscal Effect on State Government: None.
- C. Fiscal Effect on Federal Funding of State Programs: None.
- 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: The agency is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.
- E. Other Nondiscretionary Cost or Savings Imposed on Local Agencies: None.

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.

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

DPH -07-010

Date: 7/30/08



Mark Horton, M.D., M.S.P.H.
Director