NOTICE OF PROPOSED RULEMAKING
Title 17, California Code of Regulations

Clinical Laboratory Personnel Standards (DPH-20-007)
Notice Published December 1, 2023

Notice is hereby given that the California Department of Public Health (Department) is proposing the regulation described below. This notice of proposed rulemaking commences a rulemaking to make the regulations permanent after considering all comments, objections, and recommendations regarding the regulation.

PUBLIC PROCEEDINGS

The Department is conducting a 45-day written public proceeding 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 the Informative Digest/Policy Statement Overview section of this notice.

To request copies of the regulatory proposal in an alternate format, please write or call: Veronica Rollin, Office of Regulations, 1415 L Street Suite 500, Sacramento, CA 95814, at (279) 217-0836, email to veronica.rollin@cdph.ca.gov or use the California Relay Service by dialing 711.

PUBLIC HEARING

A public hearing has not been scheduled for this rulemaking. However, the Department will conduct a public hearing if a written request for a public hearing is received from any interested person, or his or her authorized representative, no later than 15 days prior to the close of the written comment period, pursuant to Government Code Section 11346.8.

Assistive Services:
For individuals with disabilities, the Department will provide assistive services such as conversion of written materials into Braille, large print, audiocassette, and computer disk. To request these assistive services, please call (916) 558-1710 or (California Relay at 711 or 1-800-735-2929), email regulations@cdph.ca.gov or write to the Office of Regulations at the address noted above.

WRITTEN COMMENT PERIOD

Written comments pertaining to this proposal, regardless of the method of transmittal, must be received by Office of Regulations by January 20, 2024, which is hereby designated as the close of the written comment period. Comments received after this date will not be considered timely.

Written comments must be submitted as follows:

1. By email to: regulations@cdph.ca.gov. It is requested that email transmission of comments, particularly those with attachments, contain the regulation package identifier "DPH-20-007" in the subject line~~;~~ to facilitate timely identification and review of the comment;

2. By fax transmission to: (916) 636-6220;

3. By postal service or hand delivered to: California Department of Public Health, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814.

All comments, including email or fax transmissions, should include the regulation package identifier, DPH-20-007 "Clinical Laboratory Personnel Standards," along with your name and your mailing address or email 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.

AUTHORITY AND REFERENCE

The Department proposes to amend the regulation sections identified under the authority provided in sections 1208, 1222.5, 1224, 1263, and 1264 of the Business and Professions Code (BPC); 100275 and 131200 of the Health and Safety Code (HSC); and 14105 of the Welfare and Institutions Code (WIC). This proposal implements, interprets, or makes specific, sections: 23.7, 1202.5, 1203, 1204, 1205, 1206, 1206.5, 1207, 1208, 1209, 1209.1, 1210, 1212, 1213, 1220, 1222, 1222.5, 1223, 1224, 1225, 1227, 1241, 1242, 1242.5, 1242.6, 1243, 1244, 1246, 1246.5, 1260, 1260.1, 1260.3, 1261, 1261.5, 1262, 1263, 1264, 1265, 1267, 1269, 1269.3, 1270, 1275, 1280, 1281, 1282, 1282.2, 1285, 1286, 1289, 1300, 1301, 1301.1, 1310, and 1320 of the BPC; sections 100275 and 120580 of the HSC; section 14123 of the WIC.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Summary of Proposal

The California Department of Public Health (Department) intends to adopt, amend, and repeal sections of the license and certification standards for clinical laboratory personnel regulated by the Department as specified in the Clinical Laboratory Regulations in the California Code of Regulations (CCR), title 17, sections 1029-1035.3. These changes specify requirements for education, training, experience, and examinations leading to

licensure and certification and specify scope of work. The purpose of these regulations is to:

- Facilitate licensure and certification of qualified laboratory personnel for employment in California.
- Standardize licensing and certification regulations for associate-level and baccalaureate-level license categories.
- Set updated requirements for academic coursework and degrees, practical training and experience, and examinations for licensure of clinical laboratory trainees, medical laboratory technicians, and clinical laboratory scientists.
- Repeal redundant or outdated standards, replace them with more relevant standards, and create new definitions as necessary.
- Modernize existing regulations to reflect changes in technology and the needs of current industry practice.
- Clarify and adopt terms used in the industry, terms mandated through statutory language, and terms defined under federal law.
- Create new requirements for education and training of qualified persons seeking licensure or certification that reflect changes in technology and education.

This proposal consists of portions of Article 1, sections 1029 (Definitions), Article 1.5, sections 1030 through 1032.5 (Licensure of Clinical Laboratory Personnel), Article 1.8, section 1034 (Examinations for Licensure and Certification and Certifying Organizations), and Article 2, sections 1035.1 through 1035.3 (Training Programs).

Background

The Department (through its Laboratory Field Services branch) is charged with ensuring the qualifications of personnel working in clinical laboratories by administering a licensure and certification program. California has one of the most extensive personnel licensure and certification programs in the nation. The Department monitors education, training, and experience of applicants, administers examinations, and oversees continuing education compliance to ensure that only qualified persons perform clinical laboratory testing. The Department also has authority to deny, suspend, and revoke licenses and certificates for failure to comply with California licensure and certification standards for quality assurance.

All clinical laboratory personnel must be qualified to perform clinical laboratory tests or examinations, pursuant to chapter 3 of the BPC. The validity of a person's qualifications is demonstrated by meeting licensing and certification standards specified in departmental regulations. These standards include requirements for education, training, experience, and examination that must be met to qualify for licensure or certification. Maintenance of current and valid licensure and certification requires completion of continuing education and payment of a renewal fee. Testing personnel must be licensed or otherwise authorized to do testing. The work scope of a licensed or certified person is limited to that defined by the person's license or certificate category. Failure to comply with personnel licensing and certification standards may result in sanctions such as revocation or suspension of licensure or certification.

The Department is responsible for administering initial issuance and renewal of licenses or certificates for 32 categories. The Department currently administers over 62,000 active clinical laboratory personnel licenses and certificates in California. Out of the estimated 62,000 total, 35 percent are licensed, and the remaining 65 percent are certified. The Department also has oversight of about 202 training programs and schools as well as accrediting agencies that provide continuing education offered to clinical laboratory personnel.

In August 2009, the Department held a stakeholder meeting in Richmond, California. At this meeting, LFS discussed 14 specific clinical laboratory personnel regulation issues related to existing law and potential changes. In 2010, the Department submitted a proposal to adopt, amend, or repeal sections of the license and certification standards for clinical laboratory personnel. That regulatory proposal (DPH-08-001) was withdrawn due to the high volume of public inquiries and comments received during the 45-day comment period, and the inability of the Department to respond to the volume of comments within the time constraints of the rulemaking process.

Due to the high volume of comments received in the past regarding proposal DPH-08-001, the proposed Clinical Laboratory Personnel regulations will be submitted in separate regulatory proposals to allow time for public review, submission of comments, and departmental response within the time constraints of the rulemaking process. This package is a subpart of the package pertaining to Clinical Laboratory Personnel. The following is the list:

Proposed regulatory package DPH-11-012 was codified and effective January 1, 2021. It pertained to portions of Article 1, Definitions and Article 5.3, Blood Electrolyte Analysis by Respiratory Care Practitioners.

Proposed regulatory package DPH-16-019, Clinical Laboratory Personnel Standards: Phlebotomists.

Proposed regulatory package DPH-16-020 Clinical Laboratory Personnel Standards: Applications/Renewal & Clean-up.

Proposed regulatory package DPH-18-017, Clinical Laboratory Personnel Standards: Unlicensed Personnel.

Proposed regulatory package DPH-19-009, Clinical Laboratory Personnel Standards: Clinical Laboratory Geneticists and Clinical Reproductive Biologists.

Proposed regulatory package DPH-20-005, Clinical Laboratory Personnel Standards: Bioanalysts and Master’s & Doctoral Degree Specialists.

Proposed regulatory package DPH-20-006, Clinical Laboratory Personnel Standards: Clinical Laboratory Scientists and CLS Training Programs.

Proposed regulatory package DPH-20-007, Clinical Laboratory Personnel Standards: Trainees, MLT, and CLS Who Meet Requirements for MLT Licensure.

Future packages, DPH-20-005, DPH-20-006, DPH 18-017, DPH 16-019, DPH 16-020, and DPH-19-009, which will be submitted at a later date, consist of (1) portions of Article 1, Definitions (mostly regarding licensed laboratory personnel) (2) portions of Article 1.5, Licensure of Clinical Laboratory Personnel (mainly licensure requirements and work scope of licensed laboratory personnel), (3) proposed Article 1.6, Unlicensed Laboratory Personnel, (4) portions of Article 2, Training Program Requirements, (5) Article 2.3, Clinical Laboratory Supervisors, (6) Article 2.5, Continuing Education, (7) Article 3, License, and (8) Article 7, Cytotechnology.

Problem Statement

Existing licensing and certification standards are outdated and require revision to reflect advances in laboratory science and technology and consequent changes in industry procedures, tests, techniques, and standards, and requirements for education and training. In addition, the standards need updating to account for changes to statutory law. The regulated community has also requested regulations to clarify the requirements of California laboratory law.

Objectives (Goals) of the Regulation

The goal of the proposed regulations is to ensure consistency and clarity in the Department regulations, specifically:

- To ensure California laboratories satisfy federal Clinical Laboratory Improvement Amendments (CLIA) standards.
- To ensure consistency and quality in clinical laboratories throughout the state.
- To address the regulatory challenges posed by new technological advances in the industry.
- To update the list of organizations whose training and examinations are accepted by the Department for licensure and certification purposes.
- To clarify the law and answer questions frequently received by the Department.
- To create a system of definitions in alphabetical order for ease of reference.
- To implement recommendations and proposals from the program's Clinical Laboratory Technology Advisory Committee (CLTAC) and stakeholders.

Anticipated Benefits

Implementation of these standards will enhance the efficiency of the licensing and certification program and help ensure compliance with related federal regulations.

Other benefits of the proposed regulations include:

- Protecting the health and safety of the public by helping ensure high quality training schools produce qualified clinical laboratory personnel.
- Increasing worker safety through ensuring proper education, training, and experience for personnel employed in laboratories.
- Promoting fairness of the licensing and certification process through objective, consistent, and equitable standards for applying and qualifying for licensure.

- Protecting the integrity and quality of test results produced by clinical laboratories.
- Implementing proper and safe use of new technologies.

Non-substantive changes in existing regulations will benefit the industry and California residents by providing clarification and ease of reference; clearer regulations will likely increase adherence to those regulations. Further, this should increase departmental efficiency, as fewer individuals will need to ask for clarification on regulations.

Evaluation as to Whether the Proposed Regulations Are Inconsistent or Incompatible with Existing State and Federal Regulations

The Department evaluated whether the regulations are inconsistent or incompatible with existing state regulations. This evaluation included a review of the Department's existing state regulations and those regulations specific to Laboratory Field Services regulations. An internet search of other state agency regulations was also performed, and it was determined that no other state agency regulation addressed the same subject matter, and that this proposal is not inconsistent or incompatible with other state regulations. Therefore, the Department has determined that the regulations is not inconsistent or incompatible with existing state regulations.

FORMS INCORPORATED BY REFERENCE

None.

MANDATED BY FEDERAL LAW OR REGULATIONS

The proposed regulations are not mandated by federal law or regulations.

LOCAL MANDATE

The Department has determined that the proposed regulations would not impose a mandate on local agencies or school districts, and not impose any costs for which reimbursement is required by part 7 (commencing with section 17500) of division 4 of the Government Code.

DISCLOSURES REGARDING THE PROPOSED ACTION

FISCAL IMPACT ESTIMATES

Cost to any local agencies or school districts that must be reimbursed pursuant to Section 17561 of Government Code:
None

The cost or savings to any state agency
None

Other Nondiscretionary Cost or Savings Imposed on Local Agencies:

None

Cost or Savings in Federal Funding to the State:
None

HOUSING COSTS

The Department has determined that the proposed regulations would not have an impact on housing costs.

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING ABILITY TO COMPETE

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

STATEMENT OF THE RESULTS OF THE ECONOMIC IMPACT ASSESSMENT (EIA)

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

A. The creation or elimination of jobs within the state.

B. The creation of new businesses or the elimination of existing businesses within the state.

C. The expansion of businesses currently doing business within the state.

The regulations will benefit the health and welfare of California residents and improve worker safety.

COST IMPACTS ON REPRESENTATIVE PERSON OR BUSINESS

The Department is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

BUSINESS REPORTING REQUIREMENTS

None.

EFFECT ON SMALL BUSINESS

The Department has determined that the proposed regulations will have no adverse impact on small businesses. Defining terms used in the industry does not create new policies, procedures, or programs that do not already exist. Licensure requirements and scope of work standards adopted in this package do not have an impact on small

businesses and do not introduce substantial changes to existing requirements that would affect small businesses.

SPECIFIC TECHNOLOGIES OR EQUIPMENT

None.

ALTERNATIVES CONSIDERED

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, would be as effective and less burdensome to affected private persons than the proposed action or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

The Department itself has made an initial determination that there are no acceptable alternatives to the regulations to protect the public interest. However, the Department invites interested persons to present alternatives with respect to the proposed regulation either during the public comment period or at the public hearing (if scheduled).

TECHNICAL, THERETICAL, AND/OR EMPIRICAL STUDIES, REPORTS OR DOCUMENTS RELIED UPON

None.

CONTACT PERSON

Inquiries regarding the substance of the proposed regulations described in this notice may be directed to Mary Wogec of the Laboratory Field Services Branch.

All other inquiries concerning the action described in this notice may be directed to Veronica Rollin, Office of Regulations, at (279) 217-0836, or to the designated backup contact person, Christy Correa at (279) 217-0674.

In any inquiries or written comments, please identify the action by using the Department regulation package identifier, DPH-20-007.

AVAILABILITY STATEMENTS

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, 1415 L Street, Suite 500, Sacramento, CA 95814, will be the custodian of public records, including reports, documentation, and other material related to the proposed regulations (rulemaking file).

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 (279) 217-0836 (or the California Relay Service at 711), send an email to regulations@cdph.ca.gov, or write to the Office of Regulations at the address previously noted. Upon specific request, these documents will be made available in Braille, large print, audiocassette, or computer disk.

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 at least 15 days prior to the date on which the Department adopts, amends, or repeals the resulting regulation.

Final Statement of Reasons
A copy of the final statement of reasons (when prepared) will be available upon request from the Office of Regulations.

INTERNET ACCESS

Materials regarding the action described in this notice (including this public notice, the text of the proposed regulations, and the initial statement of reasons) that are available via the Internet may be accessed at the Department's website (www.cdph.ca.gov) by clicking on these links, in the following order: Decisions Pending & Opportunities for Public Participation, Proposed Regulations.