

## INFORMATIVE DIGEST

### Information Digest/Policy Statement Overview

#### **Problem Statement:**

The clinical laboratory personnel licensing and certification standards are outdated and require revision to reflect changes in technology, industry standards, and education and training, as well as changes to statutory law. Existing regulations are outdated because they do not address advances in laboratory science and technology and consequent changes in processes, procedures, tests, techniques, and standards currently used in the industry. The regulated community has also requested regulations clarifying what the state expects and requires of them.

- Existing regulations regarding training school standards lack some of the newest and most necessary training required. In some cases, they mandate classes and coursework that are outdated and inapplicable to today's clinical laboratory industry.
- Existing regulations lack clarity about training programs, licensing and certification standards, and work scope for many positions.
- There is a need for some new license categories, for example, medical laboratory technician (MLT) trainees, and for new training, education, and license standards for these and other categories.
- For a licensed MLT to obtain a clinical laboratory scientist (CLS) license, existing regulations require the MLT to repeat classes they have already completed to obtain the MLT license. This is repetitive and redundant; it imposes an unnecessary burden on MLTs seeking promotion. The proposed regulations will create a new training process that will credit MLTs with coursework and training they have already completed. In 2019, California law was amended to require the Department to establish such an "MLT to CLS" pathway program. (BPC § 1261(b), SB 334, Chapter 144, Statutes of 2019)

Because the proposed regulations are extensive, the department will present them in a series of packages. This will allow for public review and comments and departmental review and response within the time constraints of the rulemaking process. Some of the changes referenced in this digest will appear in future packages. The fiscal and economic impact has been calculated based on changes that appear in the second package, DPH 20-007.

#### **Objectives (Goals):**

The goal of the proposed regulations is to ensure consistency and clarity in CDPH regulations.

- To ensure California laboratories satisfy federal Clinical Laboratory Improvement Amendments (CLIA) standards.

- To ensure consistency and quality in clinical laboratories throughout the state.
- To regulate new technological advances in the industry.
- To update the lists of accrediting associations and other organizations currently approved by the department for licensure purposes. Some of the organizations listed in current regulations no longer exist, and new ones have been approved. This is necessary to sustain opportunities for education, training, and examination towards gaining a license.
- To allow the Department to accept training and experience obtained in laboratories located outside the United States that meet Department standards, in order to expand the workforce of qualified laboratorians.
- To clarify the law and answer questions frequently received by CDPH.
- To create a system of definitions in alphabetical order for ease of reference for the reader.
- To create some new licensing categories and specify requirements for licensure and work scope and for the training programs that will prepare people for licensure. (Some of these changes will be made in future regulations packages.)
- To implement recommendations and requests from the program's Clinical Laboratory Technology Advisory Committee (CLTAC) and stakeholders.

**Benefits:**

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

The proposed regulations will protect the health and safety of the public by ensuring high quality training schools produce qualified clinical laboratory personnel. They will increase worker safety through ensuring proper education, training, and experience of those working in laboratories. They will promote fairness of the licensing and certification process through objective and consistent standards for applying and qualifying for licensure. They will protect the integrity and quality of test results produced by clinical laboratories. They will incorporate new scientific technologies and academic practices into the California regulatory scheme, thus promoting the use of new technologies. They will facilitate the licensure of qualified applicants who obtained education, training, and experience outside the United States, thus expanding the workforce available to staff California laboratories.

Renumbering and updating definitions and making non-substantive changes in existing regulations will benefit the industry and California residents by providing clarification and ease of reference. Clearer regulations will increase adherence to the regulations, and may also reduce calls to the Department from individuals requesting clarification of the regulations, which will increase efficient use of departmental time.

## **Determination of Inconsistency and Incompatibility with Existing State Regulations**

The department evaluated this proposal and determined that it, if adopted, will not be inconsistent or incompatible with existing state regulations. This evaluation included a review of the department's existing general regulations and those regulations specific to personnel in clinical laboratory science. An internet search of other state agency regulations was also performed. It was determined that no other state regulations address the same subject matter.

### **Mandated by Federal Law or Regulations**

This regulatory proposal does not duplicate or conflict with any existing federal law or regulations.

### **Business Reporting Requirements**

There is no significant statewide adverse economic impact, thus no reporting requirements for businesses.

### **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.

### **Fiscal Impact Estimates**

#### **A. Cost of Savings to any State Agency:**

There are no significant cost savings to any state agency.

#### **B. Cost to any Local Agency or School District:**

There are no costs to any local agency or school district.

#### **C. Other Nondiscretionary Cost or Savings Imposed on Local Agencies:**

There are no nondiscretionary costs or savings imposed on local agencies.

#### **D. Cost or Savings in Federal Funding to the State:**

There are no fiscal effects on federal funding of state programs.

### **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.

Two sections of the proposed regulations will have a significant economic impact on individuals. The first change will establish a pathway allowing an MLT to apply experience and training from a Department-approved MLT training program towards the

completion of a CLS training program, allowing these individuals to move from employment as an MLT to higher-paid employment as a CLS in an expedited program.

The second change would affect some applicants for all levels of clinical laboratory professional licensure. It would broaden the current regulations to accept training and experience obtained at laboratories located outside the United States while ensuring that the licensure applicant received training and experience equivalent to training and experience obtained in a clinical laboratory certified by CLIA. This will make it possible for the Department to license qualified applicants with training or experience from other countries and expand opportunities for the qualified personnel to work as clinical laboratory professionals in the United States.

There are no estimated total costs to individuals. The effect on individuals will be a net gain in wages when they move from employment as an MLT to higher-paid employment as a CLS, or gain employment as licensed laboratorians in California laboratories.

The proposed new regulations have no associated costs for businesses and are not expected to result in the expansion of laboratory businesses in California or the creation of new businesses, but may expand the workforce, alleviating a current workforce shortage and allowing California clinical laboratories to fill positions that are currently vacant.

### **Housing Costs**

The department has determined that the amendments will have no impact on housing costs. The regulations affect standards only for clinical laboratory personnel in licensed or registered clinical laboratories, accredited colleges and universities, approved training schools and programs, military specialist programs, and U.S. government laboratories.

### **Effects on Small Businesses**

There are no estimated initial or ongoing costs for small businesses. The department has determined that the proposed amendments will have no adverse impact on small businesses. Most clinical laboratories are not small businesses. Most training schools or programs are part of or administered by a company, director, and/or administrator.

### **Significant Statewide Adverse Economic Impact Directly Affecting Business, Including Ability to Compete**

The Department has made the initial determination that the proposed 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. Most of the proposed changes to the regulations are clarifications and updates to definitions, licensure requirements, and training program requirements and repeals of outdated regulations.

### **Results of the Economic Impact Assessment**

The Department has made an initial determination that the proposed regulations would not significantly affect the creation or elimination of jobs, the creation of new businesses or the elimination of existing businesses, or the expansion of businesses currently doing business within California. By enabling MLTs to move up the laboratory career ladder to full CLS licensure, and enabling the Department to license qualified applicants trained outside the U.S., the proposed regulations will expand employment opportunities for laboratory professionals. This in turn will expand the laboratory workforce, and help alleviate a current shortage of qualified laboratorians and allow California clinical laboratories to fill vacant laboratory positions or create new positions.

### **Alternatives Considered**

The Department has made the initial determination that no reasonable alternative considered by the Department or otherwise 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 proposed regulations modernize regulations to match the most updated technology and current demand of the industry, implement one change mandated by statutory change, and clarify, update, and implement other statutes. Significant deviation from the proposals in this package might reduce clarity and consistency and would not satisfy legal necessity. There is no reasonable alternative to non-substantial changes such as correcting language, punctuation, and numbering errors.