NOTICE OF PROPOSED RULEMAKING
Title 17. Public Health
DPH-11-012 Clinical Laboratory Personnel Standards: Definitions
Notice Published: February 7, 2020

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 (916) 558-1710, email to veronica.rollin@CDPH.ca.gov or use the California Relay Service by dialing 711.

WRITTEN COMMENT PERIOD

Written comments pertaining to this proposal, regardless of the method of transmittal, must be received by Office of Regulations by March 23, 2020, which is hereby designated as the close of the written comment period. Comments received after this date will not be considered timely.

Written comments may 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-11-012 Clinical Laboratory Personnel Standards: Definitions" 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 submitted comments should include the regulation package identifier **"DPH-11-012 Clinical Laboratory Personnel Standards: Definitions"** with the comment author's name and email or mailing address.

PUBLIC HEARING

A public hearing has not been scheduled for this rulemaking. However, the Department will conduct a hearing if a written request for a public hearing is received from any interested person, or his or her duly 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 the conversion of written materials into Braille, large print, audiocassette, and computer disk. For public hearings, assistive services can include sign-language interpretation, real-time captioning, note taking, reading or writing assistance. 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. Note: The range of assistive services available may be limited if requests are made less than 10 business days prior to a public hearing.

AUTHORITY AND REFERENCE

The Department is proposing to adopt, repeal, and amend portions of the regulations in the CCR, title 17, sections 1029 through 1067.15, Clinical Laboratory Regulations, under the authority provided in sections 1208, 1222, 1222.5, 1224, 1262, 1263, 1264, and 1320 of the Business and Professions Code (BPC), section 131200 of the Health and Safety Code (HSC), and section 14105 of the Welfare and Institutions Code (WIC).

General authority:

- Under HSC section 131200, the Department has authority to adopt and enforce regulations for the execution of its duties.
- Under BPC section 1224, the Department has authority to adopt, amend, or repeal any regulations necessary for the administration or enforcement of Chapter 3, Clinical Laboratory Technology.

Specific Authority:

- Under BPC section 1208, the Department has authority to create new categories of laboratory personnel licenses and to modify education, training, examination, and licensing standards for existing license categories.
- Under BPC section 1262, the Department has authority to approve the evaluation of national or state accrediting boards for licensure.
- Under article 4, Licensing, sections 1262, 1263, and 1264 of the BPC, the Department has authority to issue licenses for clinical laboratory bioanalysts (Bus. & Prof. Code, § 1260), clinical laboratory scientists (Bus. & Prof. Code, §

1261), and clinical laboratory scientists limited to a specialty (Bus. & Prof. Code, § 1261.5), clinical laboratory scientist trainees and clinical laboratory scientist trainees limited to a specialty (Bus. & Prof. Code, § 1263), clinical chemists, clinical microbiologists, clinical toxicologists, clinical genetic molecular biologists, clinical cytogeneticists, and oral and maxillofacial pathologists (Bus. & Prof. Code, § 1264).

- Under BPC section 1222, the Department has authority to approve schools that are accredited by the National Accrediting Agency for Clinical Laboratory Sciences. Under BPC section 1246, the Department has authority to approve national accrediting agencies for phlebotomy (Bus. & Prof. Code, § 1246(b)(4)).

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 as specified in the Clinical Laboratory Regulations in the California Code of Regulations (CCR), title 17, sections 1029 through 1067.15. These changes specify requirements for education, training, experience, and examinations leading to licensure and certification.

Advancements in technology and the need for new avenues for training create new requirements for education and training of qualified persons seeking licensure or certification.

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 high-school graduate, associate-level, baccalaureate-level, masters-level, and doctorate-level license categories.
- Set requirements for academic coursework and degrees, practical training and experience, and examinations for each licensure and certification category.
- Repeal redundant or outdated standards and replace them with more relevant standards, and create new definitions as necessary.
- Modernize existing regulations to match the most updated technology and current demand of the industry.
- Clarify and adopt terms used in the industry, terms mandated through statutory language, and terms defined under federal law.

This proposal consists of Article 1, sections 1029 through 1029.197 (Definitions) and Article 5.3, sections 1054.1 and 1054.2 (Blood Electrolyte Analysis by Respiratory Care Practitioners). Future proposals will pertain to portions of Article 1 (Definitions), Article

1.5 (Licensure and Certification of Clinical Laboratory Personnel), Article 1.6 (Unlicensed Laboratory Personnel), Article 1.7 (Application and Renewal, Continuing Education), and Article 2 (Training Schools and 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 in an effort to ensure that persons performing or assisting with clinical laboratory testing are well qualified. 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 who perform or assist with clinical laboratory tests or examinations must be qualified 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% are licensed and the remaining 65% 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 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. As a result of that experience, the Department will submit proposed Clinical Laboratory Personnel regulations in eight separate regulatory proposals. This is the first of the eight proposals. This will allow adequate time for public review, submission of comments, and departmental response required by the rulemaking process.

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, 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 that 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 of those working in laboratories.
- Promoting fairness of the licensing and certification process through more objective, consistent, and equitable standards for applying and qualifying for licensure and certification.
- Protecting the integrity and quality of test results produced by clinical laboratories.
- Implementing proper and safe use of new technologies.

Renumbering of all definitions and making non-substantive changes in existing regulations will benefit the industry and California residents by providing clarification and

ease of reference, and clearer regulations will increase adherence to the regulations. This change may also reduce calls to the Department from individuals requesting clarification of the regulations, which will increase efficient use of departmental time.

EVALUATION AS TO WHETHER THE PROPOSED REGULATION ARE INCONSISTENT OR INCOMPATIBLE WITH EXISTING STATE AND FEDERAL 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.

FORMS INCORPORATED BY REFERENCE

Not applicable.

MANDATED BY FEDERAL LAW OR REGULATIONS

Not applicable.

OTHER STATUTORY REQUIREMENTS

Not applicable.

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

A) Cost to any local agencies or school districts that must be reimbursed pursuant to Section 17561 of Government Code:

None.

B) The cost or savings to any state agency:

None.

C) Impact on any cost or savings in federal funding of the program:

None.

D) Other nondiscretionary costs or savings imposed on local agencies:

None.

HOUSING COSTS

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

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

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

STATEMENT OF THE RESULTS OF THE ECONOMIC IMPACT ASSESSMENT

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, and repeals of outdated and unused regulations for clarification and ease of reference.

Creation or elimination of jobs within California: There would likely be no significant creation or elimination of jobs within the state. There may be a slight possible increase in the creation of jobs in California.

An applicant for licensure who submits a transcript from an educational institution located outside the U. S. and not accredited by a Department-approved accreditation association must submit an evaluation of the transcript by a Department-approved transcript evaluation service. This ensures that the education obtained in a non-U.S. educational institution is equivalent to an education obtained from an accredited college or university in the US, and that the applicant meets the Department's educational requirements.

The existing regulatory law requires foreign transcript evaluations provided by an organization that no longer performs that service. The proposed regulations will allow the Department to accept transcripts evaluated by other transcript evaluation services. Since the proposed regulations will allow applicants to use other transcript evaluation services, applicants who obtained education at non-U.S. colleges and universities will have a choice of approved evaluation services to show, via their transcript evaluation, that they satisfy the Department's educational requirement. More applicants who obtained education in a foreign country may apply for licensure. California laboratories have been unable to fill vacant positions because of the shortage of qualified personnel. The proposed regulations may enable them to fill the vacant positions or create new positions if a larger number of qualified individuals apply for and receive California licensure, expanding the number of employees in their businesses in California. Since applicants with non-U.S. education are a small percentage of license applicants, this

expansion of the number of acceptable evaluation services will not likely have a significant effect.

Creation or elimination of new businesses within California: There would likely be no significant creation or elimination of businesses within the state.

The clarification of the types of clinical laboratory techniques and procedures (in the proposed section 1029 definition of "Clinical Laboratory Practice") is not likely to eliminate existing laboratories or create new laboratories. Instead, it will likely enable existing clinical laboratories to standardize their business practices. Clinical laboratories are not regionalized in the United States; therefore, the effect, if any, will affect the state as a whole.

Clarification regarding the acceptance of transcript evaluations is not likely to have a significant impact on the creation or elimination of business in California. AACRAO, the one organization specified under current regulations to review transcripts from a foreign educational institution, no longer reviews transcripts. The proposed regulations will allow applicants to submit a transcript evaluation from two specified organizations or another organization approved by the Department. Since there is no significant difference in the cost of services charged by these proposed transcript evaluation services versus the costs previously charged by AACRAO, there is no significant change in cost to individuals.

Clarification regarding the accreditation of U.S. educational institutions is also not likely to have a significant impact on the creation or elimination of businesses in California. Colleges and universities that provide education and training to clinical laboratory personnel will not be significantly impacted by changing the list of accreditation associations that accredit these educational institutions. (See the proposed section 1029 definition of "Accredited College or University".) For over a decade the Department has been using authorized statutory discretion to accept education obtained at colleges or universities accredited not only by the Western Association of Schools and Colleges, which is the accreditation association listed in the existing regulations, but those with "equivalent standards." These other associations include the associations listed by name in the proposed regulations.

Few, if any, colleges and universities will need to apply for new accreditation from an association listed in the proposed regulations and the Department will continue to accept education obtained at accredited educational institutions as usual. The proposed change to the list of acceptable accrediting associations is unlikely to increase or decrease the number of accredited educational institutions considered acceptable by the Department, and is thus not likely to affect the instructors or the graduates of those institutions.

Impact on California Businesses to compete with businesses in other states: There is no foreseeable negative impact on the ability of California businesses to compete with businesses in other states. The potential positive impact is not significant.

The regulations may create a slight increase in the number of out-of-state laboratory personnel who apply and receive a license because (1) the proposed definition of official school transcript will now include optional electronic transcript submission in place of the paper submission currently required, (2) applicants will be able to have their transcripts evaluated by one of the newly approved transcript evaluation services, and (3) specifying the national accreditation associations acceptable by the Department creates clarity and reassurance to training programs and licensure applicants as to which educational institutions offer credentials that will qualify them. These changes may slightly increase the pool of qualified job candidates. This increase may provide a slight increase in the number of jobs created and/or increase the ability of California businesses to hire qualified clinical laboratory personnel. This will likely reduce the current industry shortage of licensed clinical personnel in California. However, there will be no significant economic or fiscal impact on businesses in California.

***Expansion of businesses currently doing business within the state*:** There is not likely to be significant expansion of businesses currently doing business within the state. The proposed regulations are unlikely to affect educational institutions accredited by associations previously considered acceptable by the Department based on statutory departmental authority. (See the discussion under “Creation or elimination of new businesses within California.”)

The existing regulatory law allows for transcript evaluation services by a single organization, which no longer performs that service. The proposed regulations now allow applicants who obtained education at non-U.S. educational institutions to use other evaluation services when applying for Department licensure and certification. Expanding the number of transcript evaluation services available to applicants with transcripts from non-U.S. institutions increases the potential number of clinical laboratory license applicants, which may address the shortage of qualified clinical laboratory staff and allow for a small expansion of clinical laboratory businesses in the state. More staff may allow clinical laboratories to be more efficient, perform more tests or examinations, and possibly expand the number of laboratories in California. If there is an increase, it is likely not a substantial one. (See the discussion under “Impact on California Businesses to compete with businesses in other states.")

Benefits of the regulation to the health and welfare of California residents, worker safety, and the state’s environment: There are several broad and specific benefits to the proposed regulations. Implementation of these standards will enhance the efficiency of the licensing and certification process.

The proposed regulations enable the Department to accept transcripts submitted through secure electronic systems. There are benefits to enabling the use of a secure electronic system for submitting official transcripts (by adopting the definition of “Official School Transcript” as listed in section 1029). It will improve efficiency, reduce environmental impact, reduce cost to applicants and the Department, and decrease fraud. For example, using electronic means to request and submit transcripts is easier than using a paper form, and submitting electronic documents through a computer

system is quicker than mailing them. Further, electronic submissions received directly from educational institutions are harder to intercept and forge. The use of electronic systems reduces the amount of paper printed by the educational institutions and the amount of copying by the Department. The increase in speed and efficiency through use of electronic systems will likely increase productivity and decrease time and expenditures by educational institutions and by the Department.

Expanding the number of transcript evaluation services available to applicants educated at foreign educational institutions increases the potential number of clinical laboratory license applicants with degrees from foreign educational institutions, which may address the shortage of staff and allow for a small expansion of clinical laboratory businesses in the state.

These regulations are proposed to protect the health and safety of California residents by ensuring high quality training schools and programs that produce qualified clinical laboratory personnel. Other benefits of these proposed regulations include:

- Increasing the efficiency and accuracy of laboratory test results.
- Increasing worker safety by ensuring proper education, training, and experience of clinical laboratory personnel.
- Promoting fairness of the licensing and certification process by establishing more objective and equitable standards for applying and qualifying for licensure and certification.
- Protecting the integrity and quality of test results produced by clinical laboratories.
- Implementing proper and safe use of new technologies.

COST IMPACTS ON REPRESENTATIVE PERSON OR BUSINESS

The cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action would result from the following:

The total *initial* costs for individuals who obtained their education outside the U.S. and must submit a transcript evaluation are about $12. There are no total *annual* ongoing costs for individuals because an applicant does not need to resubmit a transcript after the initial submission. Only a low percentage of applicants will incur the additional costs. Most applicants obtain their education in U.S. educational institutions and are not required to submit a transcript evaluation. Only applicants who submit transcripts from foreign educational institutions will incur the additional cost of submitting a transcript evaluation; therefore, no new cost will be incurred by most applicants. The costs for transcript evaluations by the services specified in the proposed regulations are not significantly different from the cost charged by the service specified in current regulations. Therefore, this new requirement is likely to cause no significant economic or fiscal impact.

BUSINESS REPORTING REQUIREMENT

The proposed regulatory amendments do not change current business reporting requirements.

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. Repealing outdated sections on blood electrolyte analysis by respiratory care practitioners will have no impact because those regulations are currently not being implemented; authorization for respiratory care practitioners to perform those tests is addressed in another section of the law.

SPECIFIC TECHNOLOGIES OR EQUIPMENT

This regulation does not mandate the use of specific technologies or equipment.

ALTERNATIVES CONSIDERED

In accordance with Government Code section 11346.5, subdivision (a)(13), the Department must determine that no reasonable alternative it considered or that has otherwise been identified and brought to the attention of the agency 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 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 invites interested persons to present statements or arguments with respect to alternatives to the proposed regulations at the scheduled hearing or during the written comment period.

The CCR, title 17, section 1029, will define “Official School Transcript” and lay out the requirements and prescriptive standards of what the Department will consider an acceptable transcript and acceptable delivery method of a transcript. For example, a transcript must contain certain variables of information and must be physically sealed or electronically submitted by the registrar’s office of the college or university. The Department reviews various forms of transcripts from many sources around the world. Using a performance standard to evaluate whether a transcript seems official or fraudulent is more subjective, more burdensome, less reliable, and has been problematic for the Department in the past. Ensuring a more objective and fair method of accepting a transcript will mandate using prescriptive rather than performance standards.

The CCR, title 17, section 1029, will explicitly name the “accreditation associations” acceptable by the Department, which is a prescriptive standard. The Department will only accept degrees issued by educational institutions accredited by the accreditation associations listed in the definition, rather than accepting degrees from institutions accredited by any and all accreditation associations. The Department has vetted the named associations. It would be an unreasonable burden for the Department to research and vet any and all accreditation associations. It would also increase the

possibility of subjectivity on the part of Department personnel in assessing and vetting any and all accreditation associations as opposed to using a standard list. Finally, using the performance non-standard list would increase the cost, increase the time, and decrease the efficiency of the application process.

TECHNICAL, THEORETICAL, 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 at (510) 620-3793. All other inquiries concerning the action described in this notice may be directed to, Veronica Rollin, Office of Regulations, at (916) 558-1710, or to the designated backup contact, Linda Cortez, Office of Regulations, at (916) 558-1710.

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, at the address previously noted, will be the location of public records, including reports, documentation, and other material related to the 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) 558-1710 (or the California Relay Service at 711), or 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.

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 www.cdph.ca.gov and by clicking on the following: Programs, Office of Regulations, and the Proposed Regulations link.