Initial Statement of Reasons

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.

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- Repeal redundant or outdated standards and replace them with more relevant standards, and create new definitions as necessary.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.

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.

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).

POLICY STATEMENT OVERVIEW

***Problem statement*:** Existing licensing and certification standards are outdated and require revision to reflect advances in laboratory science and technology and consequent changes in industry procedures, tests, techniques, standards, and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)*:** 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.

***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.

AUTHORITY AND REFERENCES

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)).

This proposal implements, interprets, and 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, 1269.5, 1270, 1275, 1280, 1281, 1282, 1285, 1286, 1288, 1288.5, 1289, 1300, 1301, 1301.1, 1310, 1320, 1322, 1323, 1324, 1325, and 1326of the BPC; sections 1002, 100275, 120580, 120775, 131050, 131051, and 131052 of the HSC; section 14123 of the WIC; sections 11503 and 11504 of the Government Code, 42 United States Code, section 1395w-2 (Section 1846 of the federal Social Security Act); 42 United States Code, Section 1396a(a)(9), and 42 United States Code, section 263a.

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 perform 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.

Stakeholder Input

The Department has involved and considered advice from its advisory committee, the Clinical Laboratory Technology Advisory Committee (CLTAC). CLTAC is a multi-

disciplinary committee mandated by statute at BPC section 1228 to "assist, advise, and make recommendations for the establishment of rules and regulations necessary to insure proper administration and enforcement of the provisions of this chapter and to assist and advise the Department in matters concerning examinations for licensees of this chapter." It is composed of 21 voting members and one non-voting member, who represent the various interest groups related to clinical laboratories.

CLTAC holds four public meetings per year, and posts the agendas and minutes from those meetings on the Department LFS website. (*Clinical Laboratory Technology Advisory Committee (CLTAC)*, Laboratory Field Services, California Department of Public Health, https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/AdvisoryCommittee-CLTAC.aspx [as of December 19, 2017].) The Department also posts agendas and minutes of meetings of the CLTAC Regulations Subcommittee. Interested members of the public are welcome to attend the meetings.

The Department requested that CLTAC convene a subcommittee to consult and advise the Department about this regulatory proposal. The subcommittee has served as the conduit between the industry, interested stakeholders, and the Department in order to provide feedback to the Department on its regulation proposals.

CONSIDERATION OF REASONABLE ALTERNATIVES TO THE REGULATIONS AND THE DEPARTMENT'S REASONS FOR REJECTING THOSE ALTERNATIVES

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 this 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 consist of terms used in the industry, terms mandated through statutory language, and terms defined under federal law. Significant deviation from the proposed language might reduce clarity and consistency, and not satisfy legal necessity.

DETAILED DISCUSSION OF PROPOSED CHANGES

The Department proposes definitions for Clinical Laboratory Regulations, specified in the CCR, title 17, sections 1029 through 1029.197 be merged into section 1029 and listed in alphabetical order for clarity and ease of reference. The following sections are amended: Article 1, sections 1029 through 1029.196 (Definitions) and Article 5.3, sections 1054.1 and 1054.2 (Blood Electrolyte Analysis by Respiratory Care Practitioners).

The following definitions listed in Article 1 with no asterisks are being renumbered only. The following definitions listed in Article 1 with an asterisk may contain non-substantive punctuation, grammar, format, or synonymous word changes.

Article 1. Definitions

The following sections are renumbered to section 1029 for clarity and ease of reference.

(1) * Renumber section 1029.5 "Accreditation Body."
(2) * Renumber section 1029.9 "Accredited Institution."
(3) * Renumber section 1029.10 "Accusation."
(4) Renumber section 1029.15 "Alternative Sanction."
(5) Renumber section 1029.20 "Antibody."
(6) Renumber section 1029.25 "Antigen."
(7) * Renumber section 1029.30 "Approved Public Health Laboratory."
(8) Renumber section 1029.31 "Arterial Puncture."
(9) * Renumber section 1029.34 "Certifying Organization."
(10) Renumber section 1029.35 "Chapter 3."
(11) * Renumber section 1029.40 "Civil and Money Penalties."
(12) * Renumber section 1029.45 "CLIA Certificate."
(13) * Renumber section 1029.50 "CLIA Exempt Status."
(14) * Renumber section 1029.51 "Clinical Consultant."
(15) * Renumber section 1029.52 "Clinical Cytogenetics."
(16) Renumber section 1029.55 "Condition Level Deficiency."
(17) Renumber section 1029.60 "Condition Level Requirement."
(18) Renumber section 1029.65 "Deficiency.
(19) * Renumber section 1029.70 "Direct Patient Care."
(20) * Renumber section 1029.75 "Directed Plans of Correction."
(21) * Renumber section 1029.80 "Electrolytes."
(22) * Renumber section 1029.83 "General Supervisor."
(23) Renumber section 1029.85 "HHS."
(24) Renumber section 1029.86 "High Complexity Tests or Examinations."
(25) Renumber section 1029.90 "Human Immunodeficiency Virus."
(26) * Renumber section 1029.95 "Immediate Jeopardy."
(27) * Renumber section 1029.100 "Instrument."
(28) * Renumber section 1029.105 "Intermediate Sanction."
(29) * Renumber section 1029.108 "License."
(30) Renumber section 1029.110 "Licensed General Acute Care Hospital."
(31) Renumber section 1029.115 "Licensed Surgical Clinic."
(32) * Renumber section 1029.118 "Moderate Complexity Laboratory Technical Consultant."
(33) Renumber section 1029.119 "Moderate Complexity Tests or Examinations."
(34) * Renumber section 1029.120 "Notice of Defense."
(35) * Renumber section 1029.125 "Onsite monitoring."
(36) * Renumber section 1029.127 "Oral Pathology."
(37) Renumber section 1029.132 "Phlebotomist."
(38) * Renumber section 1029.133 "Phlebotomy."
(39) * Renumber section 1029.134 "Practical Experience."
(40) * Renumber section 1029.135 "Preceptor."

(41) Renumber section 1029.140 "Principal Sanction."
(42) * Renumber section 1029.145 "Provider of Service."
(43) * Renumber section 1020.150 "Respiratory Care Practitioner."
(44) * Renumber section 1029.153 "Satisfactory Performance."
(45) Renumber section 1029.154 "Skin Puncture."
(46) Renumber section 1029.155 "Specimen."
(47) Renumber section 1029.165 "State Registration."
(48) * Renumber section 1029.168 "Statement of Issues."
(49) * Renumber section 1029.171 "Technical Supervisor."
(50) * Renumber section 1029.173 "Temporary Suspension of a License, Registration or Approval."
(51) * Renumber section 1029.175 "Temporary Suspension of a Provider of Service Under the Medi-Cal Program."
(52) * Renumber section 1029.180 "Test Purposes."
(53) Renumber section 1029.185 "Testing Event."
(54) * Renumber section 1029.190 "Unprofessional Conduct."
(55) Renumber section 1029.195 "Venipuncture."
(56) Renumber section 1029.197 "Waived Tests."

REPEALS, ADOPTIONS, and AMENDMENTS

As previously addressed in "Detailed Discussion of Proposed Changes," the renumbered definitions will be compiled alphabetically and incorporated into section 1029 for clarity and ease of reference.

The Department proposes to adopt, repeal, or make substantive changes to the following definitions as well as to renumber them.

(57) Amend section 1029.7 "Accredited College or University" and renumber in section 1029.

This will clarify what constitutes an accredited college or university and update the list of accreditation associations accepted by the Department. The accreditation associations named in this definition accredit two-year colleges as well as undergraduate and graduate colleges and universities in the United States (U.S.).

The existing definition relies on accreditation of U.S. educational institutions by outdated associations (the United States of America Accrediting Commission for Senior Colleges and Universities, and the Accrediting Commission for Community and Junior Colleges). Under the proposed regulations, the Department will accept accreditations from the following associations: (1) Middle States Commission on Higher Education, (2) New England Association of Schools and Colleges, Commission on Institutions of Higher Education, (3) North Central Association of Colleges and Schools, The Higher Learning Commission, (4) Northwest Commission on Colleges and Universities, (5) Southern Association of Colleges and Schools, Commission on Colleges, (6) Western Association of Schools and Colleges (WASC), Accrediting Commission for Community and Junior Colleges, and (7) Western Association of Schools and Colleges, Senior

Colleges and University Commission. These associations are recognized by the U.S. Department of Education as the reliable authorities on educational quality, and the effectiveness of the higher education institutions and programs they accredit.

The new listing of accreditation associations in the proposed regulations clarifies current procedures. This is not a significant change from existing policy and procedure. BPC section 1261.5 states that to qualify for admission to the examination for a clinical laboratory scientist specialty or subspecialty license, an applicant must "[h]ave graduated from a college or university maintaining *standards equivalent*, *as determined by the department*, to those institutions accredited by the Western Association of Schools and Colleges or *an essentially equivalent accrediting agency, as determined by the department.*" (Emphasis added.) BPC section 1260 uses similar language for a clinical laboratory bioanalyst license: "[e]stablished and reputable institutions maintaining standards equivalent, *as determined by the department*, to those institutions accredited by the Western Association of Schools and Colleges *or an essentially equivalent accrediting agency, as determined by the department*." The Department has been exercising this discretionary authority and deeming associations other than WASC to be equivalent accreditation associations. As such, the Department has been accepting degrees from colleges or universities accredited by these equivalent accreditation associations and this proposed change will not have a significant legal, economic, or fiscal impact.

There is a lack of means for applicants who obtained education at colleges and universities outside the U.S. to have their transcripts reviewed and deemed equivalent for qualifying for licensure. American Association of Collegiate Registrars and Admissions Officers (AACRAO), the only organization designated in current regulations to review foreign transcripts, no longer reviews transcripts. This has created a general hardship hindering graduates of non-U.S. educational institutions from being considered for employment in California laboratories. This has limited the pool of qualified licensees and contributed to a laboratory personnel shortage in some license categories. This proposed regulation will provide three options for graduates of non-U.S. institutions to obtain a degree evaluation; they may submit an evaluation by (1) a current member of the National Association of Credential Evaluation Services; (2) an endorsed member of the Association of International Credential Evaluators, Inc.; or (3) another organization approved by the Department. The last option is necessary to avoid a sudden shortage in case an approved evaluator ceases to provide service, as happened with AACRAO.

(58) Adopt "CLIA" as a definition listed in section 1029.
The term CLIA is used throughout the Clinical Laboratory Regulations. For ease of reference, to avoid requiring the reader to search throughout the BPC for the definition, it is being added to the alphabetized list of definitions in section 1029 of these regulations.

(59) Adopt "Clinical Laboratory Practice" as a definition listed in section 1029.
The regulated community requests clarification and greater specificity as to what activities are allowed within the scope of "clinical laboratory practice." The statute gives the Department, in consultation with community experts, the discretion to define the scope and specifications of clinical laboratory practices. To achieve this, the proposed regulatory text is more specific and detailed than the statutory definition, more congruent with the latest technology, and more detailed in specifying which laboratory practices are allowed. Adopting this regulatory definition will allow the Department to clarify, standardize, and ensure quality standards of clinical laboratory activities. The statutory term "clinical laboratory practice" is defined in BPC section 1206 (a)(7) as: "The application of clinical laboratory sciences or the use of any means that applies the clinical laboratory sciences within or outside of a licensed or registered clinical laboratory. Clinical laboratory practice includes consultation, advisory, and other activities inherent to the profession." In the proposed regulatory text, clinical laboratory practice is defined as "activities that support clinical laboratory science, such as collecting and processing biological specimens, solving technical or instrument problems, providing general and technical supervision and consultation, reviewing quality control data, developing test methods, performing and reporting tests, and other activities defined in the work scope of the license category."

There are many examples of clinical laboratory practices affected by this proposal, which include but are not limited to:

- Collecting and processing biological specimens, such as drawing blood, performing a throat swab or adding preservative to a urine specimen.
- Providing supervision to a trainee or an unlicensed person. This supervision must be provided by a general supervisor.
- Providing technical consultation, including, but not limited to, preparing reagents, assessing reagent expiration dates, and monitoring temperature devices.
- Tracking quality control data for trends or drifts after tests have been reported.
- Developing new tests and troubleshooting existing methods.

For training schools or programs, the proposed regulation clarifies the didactic course content the training schools or programs must offer their students and trainees. For students, trainees, licensees, and certificate holders, the regulation will ensure they are versed in all areas of their license or certificate category work scopes. This will ensure consistency in the training and experience of licensees and certificate holders.

The work scopes of license and certificate categories addressed in related future regulation proposals will include performance of clinical laboratory practices appropriate to the license or certificate category. This definition is added to recognize the importance of these activities in maintaining quality standards in a clinical laboratory.

(60) Adopt "Direct and Constant Supervision" as a definition listed in section 1029.

For ease of reference, and to avoid requiring the reader to search through the BPC for the definition, the Department is incorporating the exact federal statutory definition as incorporated into section 1206 of the BPC.

(61) Adopt "Direct and Responsible Supervision" as a definition listed in section 1029.

For ease of reference, and to avoid requiring the reader to search through the BPC for the definition, the Department is incorporating the exact statutory definition found in section 1206 of the BPC.

(62) Adopt "Direct Supervision" as a definition listed in section 1029.

For ease of reference, and to avoid requiring the reader to search through the BPC for the definition, the Department is incorporating the exact statutory definition found in section 1269.3 of the BPC.

(63) Amend section 1029.81 "Evidence of Satisfactory Performance" and renumber to section 1029.

For consistency, this will amend the title of section 1029.81 to capitalize all words in the title similar to other definitions in Article 1.

This will also amend the definition to clarify and specify that the written certifying examination must be one approved by the Department for the specific license or certificate category, not just any written certifying examination.

(64) Amend section 1029.82 "Field Related to Genetics" and renumber to section 1029.

This definition is amended to revise the list of fields related to genetics to reflect advances in the field of genetics. The current definition defines "field related to genetics" as "a major in" several areas of academic study. The definition is amended to define "field related to genetics" more accurately by giving examples of academic fields and coursework acceptable to the department for licensure purposes. The revised list retains several of the fields in the current definition (molecular biology, reproductive biology, biochemistry, medical genetics, biochemical genetics, and clinical laboratory science).

The list is expanded to include new areas of genetic research, including biomedical engineering, biotechnology, molecular and cellular biology, and genomics, which is

added to clinical genetics, clinical cytogenetics, clinical molecular genetics, and human genetics to reflect the growing importance of that aspect of the study of genetics.

In addition, the new definition lists examples of coursework associated with the various fields of study acceptable to the department (biochemistry, bioinformatics, biology, cell biology, developmental biology, developmental genetics, evolutionary genetics, gene expression, gene mapping, genetic analysis, human genetics, inherited disease, inorganic chemistry, molecular genetics, organic chemistry, and population genetics). The inclusion of coursework broadens the Department's options for accepting an applicant whose field of study uses different terminology from that listed in the definition.

(65) Amend section 1029.95 "Immediate Jeopardy" and renumber to section 1029.

This definition is amended, in a non-substantive change, to make this definition consistent with the existing definition of "immediate jeopardy" in section 1280.3 (g) of the Health and Safety Code.

(66) Adopt "Official School Transcript" as a definition listed in section 1029.

Traditionally, the Department has required official transcripts to be sent directly to its office in an unopened sealed envelope from the office of the school, college, or university registrar. This is still the preferred method. However, an increasing number of educational institutions now provide secure electronic verification of a person's education. Implementing these regulations will improve efficiency, reduce environmental impact, reduce cost to applicants and the Department, and decrease fraud. For example, requesting and obtaining transcripts electronically is easier than using a paper form. Further, submitting electronic documents through a computer system is quicker than mailing them, and receiving electronic submissions directly from educational institutions are harder to intercept and forge. In addition, use of electronic systems reduces the amount of paper printed and therefore reduces the amount of copying by the Department. The increase in speed and efficiency through use of electronic systems should increase productivity and decrease time and expenditures by educational institutions and by the Department.

The proposed definition of "official school transcript" establishes new elements to reduce submission of fraudulent paper transcripts. Applicants have attempted to submit fraudulent transcripts and have asked for exemptions to the customary industry standards of official transcripts. Existing regulations require that a transcript for an applicant for licensure must come from a school registrar, show all courses, course credits, degrees conferred, and dates of conference, and must be in English. Transcripts that are not written in English and all transcripts from educational institutions outside the United States must also be evaluated by an evaluation service accepted by the Department. Existing regulations require an applicant for certification as a phlebotomist to submit a transcript containing dates of attendance, coursework completed, and date of graduation, or documentation of a passing score on the GED test. The proposed regulations specify that a transcript must also show grades (not just

course completion), dates of attendance, and academic major(s). The proposed regulations also require that the paper copy of a transcript bear an official school seal or signature, and be sealed in an envelope bearing a tamper-proof mark or seal attached by the school.

(67) Amend section 1029.130 "Oral and Maxillofacial Pathology Laboratory Director" and renumber to section 1029.

This amends the phrase "valid, unexpired license" to add the word "California" to specify that the definition refers to a license issued by the Department, for clarification of meaning.

(68) Amend section 1029.130 "Patient" and renumber to section 1029.

This non-substantive change amends the phrase "licensed clinic or a clinic that is exempt from licensure, or licensed home health agency, or who is a patient of a licensed physician . . . ." Specifically, the word "or" is added before "licensed home health agency" for clarification of meaning.

(69) Amend section 1029.160 "State License" and renumber to section 1029.

This will amend the definition to omit the word "license" from the existing phrase "'State license' or 'license'" to clarify the difference between a "state license" and a "license." "License" as defined in section 1029.108 (now being renumbered to section 1029) pertains to any license or registration of facilities and any license or certification of personnel in Clinical Laboratory Regulations (Cal. Code Regs., tit.17, §§ 1029 – 1067.15). In contrast to "license," "State license" as defined in section 1029.160 pertains only to facility licenses issued by the State as specified in BPC section 1265(a)(1).

(70) Amend section 1029.169 "Subspecialty of Histocompatibility" and renumber to section 1029.

This amends the definition to correct the citation of the Code of Federal Regulations (CFR). Histocompatibility is now addressed in section 493.1278 of title 42, CFR.

(71) Amend section 1029.196 "Waived Laboratory Supervisor" to read "Waived Laboratory Technical Supervisor, Also Called Waived Laboratory Technical Consultant" and renumber to section 1029.

Existing regulation section 1029.196 is titled "Waived Laboratory Supervisor:" however, the definition in the text refers to "waived laboratory technical consultant." These terms are used interchangeably in the professional community. This will amend the title of the section to include both terms, "waived laboratory technical supervisor" and "waived laboratory technical consultant," for ease of reference in section 1029. It will also include both terms in the definition for clarity.

(72) Repeal Article 5.3, Blood Electrolyte Analysis by Respiratory Care Practitioners.

Prior to 1995, the personnel performing blood electrolyte analysis were mainly clinical laboratory scientists or physician and surgeons. In 1995, the California legislature

passed state law equal to or more stringent than the federal CLIA regulations, which expressly permit respiratory care practitioners to perform blood electrolyte analysis. This part of the new law included section 1206.5 of the BPC; therefore, this article (and the included sections) are no longer necessary.

(73) Repeal Section 1054.1, Conditions for Performance.
The entire Article 5.3 is being repealed as described in the detailed discussion of (72). The repeal includes this section.

(74) Repeal Section 1054.2, Training.
The entire Article 5.3 is being repealed as described in the detailed discussion of (72). The repeal includes this section.

Cost Impacts on Representative Private Persons or Businesses (Significant Statewide Adverse Economic Impact Directly Affecting Private Persons, or Businesses, Including Ability to Compete)
The Department has determined that the proposed regulatory action would have no significant direct economic impact on California business enterprises or individuals, including the ability of California businesses to compete with businesses in other states.

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 a foreign educational institution 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.

Evaluation as to whether the proposed regulations are inconsistent or incompatible 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 Prescription of Specific Actions or Procedures Rather than Performance Standards as an Alternative

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.

The CCR, title 17, section 1029, will explicitly name the transcript evaluation services acceptable by the Department, which is a prescriptive standard. The Department will only accept transcript evaluations performed by transcript evaluations services listed in the definition, rather than accepting evaluations performed by any and all transcript evaluation services. The Department has vetted the named services. It would be an unreasonable burden for the Department to research and vet any and all transcript evaluation services. It would also increase the possibility of subjectivity on the part of Department personnel in assessing and vetting any and all transcript evaluation services 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.

STATEMENTS OF DETERMINATION

(a) ***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.

(b) ***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.

(c) ***Housing Costs Determination:*** 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.

ECONOMIC IMPACT ANALYSIS

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. The existing regulatory law allows for foreign transcript evaluation services 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, more applicants who obtained education at non-U.S. colleges and universities may show, via their transcript evaluation, that they satisfy the educational requirement. More applicants who obtained education in a foreign country may qualify to 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 more 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 in clinical laboratory jobs in general, and the recent lack of transcript evaluation went into effect in July 2016, this expansion of possible 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.

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”.) ACRAAO, 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 ACCRAO, there is no significant change in cost to individuals. In addition, 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 accreditation association listed in the existing regulations, but those with “equivalent standards.” These other associations include the associations explicitly listed 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 are granted a license because (1) the proposed definition of official school transcript will now include optional electronic application submission in place of the paper submission, (2) applicants will be able to have their transcripts evaluated by one of the newly accepted 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. This may slightly increase the pool of qualified job candidates. This 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 departmental online 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.