Assembly Bill No. 940

Passed the Assembly September 2, 2015

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Chief Clerk of the Assembly

Passed the Senate August 31, 2015

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Secretary of the Senate

This bill was received by the Governor this _____ day of _____, 2015, at _____ o'clock ___M.

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Private Secretary of the Governor

CHAPTER _____

An act to amend Sections 1203, 1209, 1260, 1264, and 1300 of the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 940, Ridley-Thomas. Clinical laboratories.

Existing law provides for the licensure, registration, and regulation of clinical laboratories and various clinical laboratory personnel by the State Department of Public Health. Existing law prohibits the performance of a clinical laboratory test or examination classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) unless the test or examination is performed under the overall operation and administration of a laboratory director. Existing law defines "laboratory director," for purposes of a clinical laboratory test or examination classified as waived, as any person who, among others, is licensed to direct a clinical laboratory and who substantially meets the laboratory director qualifications under CLIA.

This bill would delete the requirement that a laboratory director substantially meet the laboratory director qualifications under CLIA. The bill would instead limit the CLIA qualification requirements to a person serving as the CLIA laboratory director, as defined, in a laboratory that performs tests classified as moderate or high complexity.

Existing law authorizes a person licensed as a clinical laboratory bioanalyst or bioanalyst and qualified under CLIA, and other persons licensed in specified clinical specialties, to perform clinical laboratory tests or examinations classified as of high complexity under CLIA and the duties and responsibilities of a laboratory director, technical consultant, clinical consultant, technical supervisor, and general supervisor, within the area of the licensee's specialty.

This bill would specify that this authorization extends to a person who is not the CLIA laboratory director under specified circumstances.

Existing law requires an applicant for a clinical laboratory bioanalyst's license to meet specified requirements for education

and experience, including that the applicant have a minimum of 4 years' experience as a licensed clinical laboratory scientist performing clinical laboratory work embracing the various fields of clinical laboratory activity in a clinical laboratory approved by the State Department of Public Health.

This bill would revise the application requirements to provide that an applicant's minimum of 4 years' experience be in a clinical laboratory certified under CLIA.

Existing law authorizes the State Department of Public Health to issue specified licenses, including limited clinical laboratory scientist licenses and clinical licenses in specified fields, and establishes application and annual renewal fees for those licenses. Existing law deposits those fees in the Clinical Laboratory Improvement Fund for use, upon appropriation by the Legislature, for regulatory purposes relating to clinical laboratories, blood banks, or clinical laboratory personnel, as provided.

This bill would rename the license for clinical molecular biologist as the license for clinical genetic molecular biologist. The bill would apply existing license renewal fees to persons renewing a clinical cytogeneticist's license or clinical genetic molecular biologist's license.

The people of the State of California do enact as follows:

SECTION 1. Section 1203 of the Business and Professions Code is amended to read:

1203. As used in this chapter, "clinical laboratory bioanalyst" or "bioanalyst" means a person licensed under Section 1260 to engage in clinical laboratory practice and direction of a clinical laboratory.

(a) A person licensed as a clinical laboratory bioanalyst or bioanalyst and qualified under CLIA, who is not the CLIA laboratory director, may perform clinical laboratory tests or examinations classified as of high complexity under CLIA and the duties and responsibilities of a laboratory director in the specialties of histocompatibility, microbiology, diagnostic immunology, chemistry, hematology, immunohematology, genetics, or other specialty or subspecialty specified in regulations adopted by the department.

(b) A person licensed as a clinical laboratory bioanalyst or bioanalyst and qualified under CLIA may perform the duties and responsibilities of a CLIA laboratory director, technical consultant, clinical consultant, technical supervisor, and general supervisor, as specified under CLIA, in the specialties of histocompatibility, microbiology, diagnostic immunology, chemistry, hematology, immunohematology, genetics, or other specialty or subspecialty specified in regulations adopted by the department.

(c) A person licensed as a clinical laboratory bioanalyst or bioanalyst may perform any clinical laboratory test or examination classified as waived or of moderate complexity under CLIA.

SEC. 2. Section 1209 of the Business and Professions Code is amended to read:

1209. (a) As used in this chapter, "laboratory director" means any person who is any of the following:

(1) A duly licensed physician and surgeon.

(2) Only for purposes of a clinical laboratory test or examination classified as waived, is any of the following:

(A) A duly licensed clinical laboratory scientist.

(B) A duly licensed limited clinical laboratory scientist.

(C) A duly licensed naturopathic doctor.

(D) A duly licensed optometrist serving as the director of a laboratory that only performs clinical laboratory tests authorized in paragraph (10) of subdivision (e) of Section 3041.

(3) Licensed to direct a clinical laboratory under this chapter.

(b) (1) A person defined in paragraph (1) or (3) of subdivision (a) who is identified as the CLIA laboratory director of a laboratory that performs clinical laboratory tests classified as moderate or high complexity shall also meet the laboratory director qualifications under CLIA for the type and complexity of tests being offered by the laboratory.

(2) As used in this subdivision, "CLIA laboratory director" means the person identified as the laboratory director on the CLIA certificate issued to the laboratory by the federal Centers for Medicare and Medicaid Services (CMS).

(c) The laboratory director, if qualified under CLIA, may perform the duties of the technical consultant, technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to persons qualified under CLIA. If the laboratory director reapportions performance of those

responsibilities or duties, he or she shall remain responsible for ensuring that all those duties and responsibilities are properly performed.

(d) (1) The laboratory director is responsible for the overall operation and administration of the clinical laboratory, including administering the technical and scientific operation of a clinical laboratory, the selection and supervision of procedures, the reporting of results, and active participation in its operations to the extent necessary to ensure compliance with this act and CLIA. He or she shall be responsible for the proper performance of all laboratory work of all subordinates and shall employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests, and report test results in accordance with the personnel qualifications, duties, and responsibilities described in CLIA and this chapter.

(2) Where a point-of-care laboratory testing device is utilized and provides results for more than one analyte, the testing personnel may perform and report the results of all tests ordered for each analyte for which he or she has been found by the laboratory director to be competent to perform and report.

(e) As part of the overall operation and administration, the laboratory director of a registered laboratory shall document the adequacy of the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory test procedures and examinations. In determining the adequacy of qualifications, the laboratory director shall comply with any regulations adopted by the department that specify the minimum qualifications for personnel, in addition to any CLIA requirements relative to the education or training of personnel.

(f) As part of the overall operation and administration, the laboratory director of a licensed laboratory shall do all of the following:

(1) Ensure that all personnel, prior to testing biological specimens, have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. In determining the adequacy of qualifications, the laboratory director

shall comply with any regulations adopted by the department that specify the minimum qualifications for, and the type of procedures that may be performed by, personnel in addition to any CLIA requirements relative to the education or training of personnel. Any regulations adopted pursuant to this section that specify the type of procedure that may be performed by testing personnel shall be based on the skills, knowledge, and tasks required to perform the type of procedure in question.

(2) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to ensure that they are competent and maintain their competency to process biological specimens, perform test procedures, and report test results promptly and proficiently, and, whenever necessary, identify needs for remedial training or continuing education to improve skills.

(3) Specify in writing the responsibilities and duties of each individual engaged in the performance of the preanalytic, analytic, and postanalytic phases of clinical laboratory tests or examinations, including which clinical laboratory tests or examinations the individual is authorized to perform, whether supervision is required for the individual to perform specimen processing, test performance, or results reporting, and whether consultant, supervisor, or director review is required prior to the individual reporting patient test results.

(g) The competency and performance of staff of a licensed laboratory shall be evaluated and documented by the laboratory director, or by a person who qualifies as a technical consultant or a technical supervisor under CLIA depending on the type and complexity of tests being offered by the laboratory.

(1) The procedures for evaluating the competency of the staff shall include, but are not limited to, all of the following:

(A) Direct observations of routine patient test performance, including patient preparation, if applicable, and specimen handling, processing, and testing.

(B) Monitoring the recording and reporting of test results.

(C) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

(D) Direct observation of performance of instrument maintenance and function checks.

(E) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples.

(F) Assessment of problem solving skills.

(2) Evaluation and documentation of staff competency and performance shall occur at least semiannually during the first year an individual tests biological specimens. Thereafter, evaluations shall be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance shall be reevaluated to include the use of the new test methodology or instrumentation.

(h) The laboratory director of each clinical laboratory of an acute care hospital shall be a physician and surgeon who is a qualified pathologist, except as follows:

(1) If a qualified pathologist is not available, a physician and surgeon or a clinical laboratory bioanalyst qualified as a laboratory director under subdivision (a) may direct the laboratory. However, a qualified pathologist shall be available for consultation at suitable intervals to ensure high-quality service.

(2) If there are two or more clinical laboratories of an acute care hospital, those additional clinical laboratories that are limited to the performance of blood gas analysis, blood electrolyte analysis, or both, may be directed by a physician and surgeon qualified as a laboratory director under subdivision (a), irrespective of whether a pathologist is available.

As used in this subdivision, a qualified pathologist is a physician and surgeon certified or eligible for certification in clinical or anatomical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology.

(i) Subdivision (h) does not apply to any director of a clinical laboratory of an acute care hospital acting in that capacity on or before January 1, 1988.

(j) A laboratory director may serve as the director of up to the maximum number of laboratories stipulated by CLIA, as defined under Section 1202.5.

SEC. 3. Section 1260 of the Business and Professions Code is amended to read:

1260. The department shall issue a clinical laboratory bioanalyst's license to each person who is a lawful holder of a degree of master of arts, master of science, or an equivalent or

higher degree as determined by the department with a major in chemical, physical, biological, or clinical laboratory sciences. This education shall have been obtained in one or more established 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 applicant also shall have a minimum of four years' experience as a clinical laboratory scientist performing clinical laboratory work embracing the various fields of clinical laboratory activity in a clinical laboratory certified under CLIA. The quality and variety of this experience shall be satisfactory to the department and shall have been obtained within the six-year period immediately antecedent to admission to the examination. The applicant shall successfully pass a written examination and an oral examination conducted by the department or a committee designated by the department to conduct the examinations, indicating that the applicant is properly qualified. The department may issue a license without conducting a written examination to an applicant who has passed a written examination of a national accrediting board having requirements that are, in the determination of the department, equal to or greater than those required by this chapter and regulations adopted by the department. The department shall establish by regulation the required courses to be included in the college or university training.

SEC. 4. Section 1264 of the Business and Professions Code is amended to read:

1264. The department shall issue a clinical chemist, clinical microbiologist, clinical toxicologist, clinical genetic molecular biologist, or clinical cytogeneticist license to each person who has applied for the license on forms provided by the department, who is a lawful holder of a master of science or doctoral degree in the specialty for which the applicant is seeking a license and who has met such additional reasonable qualifications of training, education, and experience as the department may establish by regulations. The department shall issue an oral and maxillofacial pathologist license to every applicant for licensure who has applied for the license on forms provided by the department, who is a registered Diplomate of the American Board of Oral and Maxillofacial Pathology, and who meets any additional and reasonable

qualifications of training, education, and experience as the department may establish by regulation.

(a) The graduate education shall have included 30 semester hours of coursework in the applicant's specialty. Applicants possessing only a master of science degree shall have the equivalent of one year of full-time, directed study or training in procedures and principles involved in the development, modification or evaluation of laboratory methods, including training in complex methods applicable to diagnostic laboratory work. Each applicant must have had one year of training in his or her specialty in a clinical laboratory acceptable to the department and three years of experience in his or her specialty in a clinical laboratory, two years of which must have been at a supervisory level. The education shall have been obtained in one or more established and reputable institutions maintaining standards equivalent, as determined by the department, to those institutions accredited by an agency acceptable to the department. The department shall determine by examination that the applicant is properly qualified. Examinations, training, or experience requirements for specialty licenses shall cover only the specialty concerned.

(b) The department may issue licenses without examination to applicants who have passed examinations of other states or national accrediting boards whose requirements are equal to or greater than those required by this chapter and regulations established by the department. The evaluation of other state requirements or requirements of national accrediting boards shall be carried out by the department with the assistance of representatives from the licensed groups. This section shall not apply to persons who have passed an examination by another state or national accrediting board prior to the establishment of requirements that are equal to or exceed those of this chapter or regulations of the department.

(c) The department may issue licenses without examination to applicants who had met standards of education and training, defined by regulations, prior to the date of the adoption of implementing regulations.

(d) The department shall adopt regulations to conform to this section.

SEC. 5. Section 1300 of the Business and Professions Code is amended to read:

1300. The amount of application, registration, and license fees under this chapter shall be as follows:

(a) The application fee for a histocompatibility laboratory director's, clinical laboratory bioanalyst's, clinical chemist's, clinical microbiologist's, clinical laboratory toxicologist's, clinical cytogeneticist's, or clinical genetic molecular biologist's license is sixty-three dollars ($63) commencing on July 1, 1983.

(b) The annual renewal fee for a histocompatibility laboratory director's, clinical laboratory bioanalyst's, clinical chemist's, clinical microbiologist's, clinical laboratory toxicologist's, clinical cytogeneticist's, or clinical genetic molecular biologist's license is sixty-three dollars ($63) commencing on July 1, 1983.

(c) The application fee for a clinical laboratory scientist's or limited clinical laboratory scientist's license is thirty-eight dollars ($38) commencing on July 1, 1983.

(d) The application and annual renewal fee for a cytotechnologist's license is fifty dollars ($50) commencing on January 1, 1991.

(e) The annual renewal fee for a clinical laboratory scientist's or limited clinical laboratory scientist's license is twenty-five dollars ($25) commencing on July 1, 1983.

(f) A clinical laboratory applying for a license to perform tests or examinations classified as of moderate or of high complexity under CLIA and a clinical laboratory applying for certification under subdivision (c) of Section 1223 shall pay an application fee for that license or certification based on the number of tests it performs or expects to perform in a year, as follows:

(1) Less than 2,001 tests: two hundred seventy dollars ($270).

(2) Between 2,001 and 10,000, inclusive, tests: eight hundred twenty dollars ($820).

(3) Between 10,001 and 25,000, inclusive, tests: one thousand three hundred fifteen dollars ($1,315).

(4) Between 25,001 and 50,000, inclusive, tests: one thousand five hundred eighty dollars ($1,580).

(5) Between 50,001 and 75,000, inclusive, tests: one thousand nine hundred sixty dollars ($1,960).

(6) Between 75,001 and 100,000, inclusive, tests: two thousand three hundred forty dollars ($2,340).

(7) Between 100,001 and 500,000, inclusive, tests: two thousand seven hundred forty dollars ($2,740).

(8) Between 500,001 and 1,000,000, inclusive, tests: four thousand nine hundred ten dollars ($4,910).

(9) More than 1,000,000 tests: five thousand two hundred sixty dollars ($5,260) plus three hundred fifty dollars ($350) for every 500,000 tests over 1,000,000, up to a maximum of 15,000,000 tests.

(g) A clinical laboratory performing tests or examinations classified as of moderate or of high complexity under CLIA and a clinical laboratory with a certificate issued under subdivision (c) of Section 1223 shall pay an annual renewal fee based on the number of tests it performed in the preceding calendar year, as follows:

(1) Less than 2,001 tests: one hundred seventy dollars ($170).

(2) Between 2,001 and 10,000, inclusive, tests: seven hundred twenty dollars ($720).

(3) Between 10,001 and 25,000, inclusive, tests: one thousand one hundred fifteen dollars ($1,115).

(4) Between 25,001 and 50,000, inclusive, tests: one thousand three hundred eighty dollars ($1,380).

(5) Between 50,001 and 75,000, inclusive, tests: one thousand seven hundred sixty dollars ($1,760).

(6) Between 75,001 and 100,000, inclusive, tests: two thousand forty dollars ($2,040).

(7) Between 100,001 and 500,000, inclusive, tests: two thousand four hundred forty dollars ($2,440).

(8) Between 500,001 and 1,000,000, inclusive, tests: four thousand six hundred ten dollars ($4,610).

(9) More than 1,000,000 tests per year: four thousand nine hundred sixty dollars ($4,960) plus three hundred fifty dollars ($350) for every 500,000 tests over 1,000,000, up to a maximum of 15,000,000 tests.

(h) The application fee for a trainee's license is thirteen dollars ($13) commencing on July 1, 1983.

(i) The annual renewal fee for a trainee's license is eight dollars ($8) commencing on July 1, 1983.

(j) The application fee for a duplicate license is five dollars ($5) commencing on July 1, 1983.

(k) The personnel licensing delinquency fee is equal to the annual renewal fee.

(*l*) The director may establish a fee for examinations required under this chapter. The fee shall not exceed the total cost to the department in conducting the examination.

(m) A clinical laboratory subject to registration under paragraph (2) of subdivision (a) of Section 1265 and performing only those clinical laboratory tests or examinations considered waived under CLIA shall pay an annual fee of one hundred dollars ($100). A clinical laboratory subject to registration under paragraph (2) of subdivision (a) of Section 1265 and performing only provider-performed microscopy, as defined under CLIA, shall pay an annual fee of one hundred fifty dollars ($150). A clinical laboratory performing both waived and provider-performed microscopy shall pay an annual registration fee of one hundred fifty dollars ($150).

(n) The costs of the department in conducting a complaint investigation, imposing sanctions, or conducting a hearing under this chapter shall be paid by the clinical laboratory. The fee shall be no greater than the fee the laboratory would pay under CLIA for the same type of activities and shall not be payable if the clinical laboratory would not be required to pay those fees under CLIA.

(o) The state, a district, city, county, city and county, or other political subdivision, or any public officer or body shall be subject to the payment of fees established pursuant to this chapter or regulations adopted thereunder.

(p) In addition to the payment of registration or licensure fees, a clinical laboratory located outside the State of California shall reimburse the department for travel and per diem to perform any necessary onsite inspections at the clinical laboratory in order to ensure compliance with this chapter.

(q) The department shall establish an application fee and a renewal fee for a medical laboratory technician license, the total fees collected not to exceed the costs of the department for the implementation and operation of the program licensing and regulating medical laboratory technicians pursuant to Section 1260.3.

(r) The costs of the department to conduct any reinspections to ensure compliance of a laboratory applying for initial licensure shall be paid by the laboratory. This additional cost for each visit shall be equal to the initial application fee and shall be paid by the

laboratory prior to issuance of a license. The department shall not charge a reinspection fee if the reinspection is due to error or omission on the part of the department.

(s) A fee of twenty-five dollars ($25) shall be assessed for approval of each additional location authorized by paragraph (2) of subdivision (d) of Section 1265.

(t) On or before July 1, 2013, the department shall report to the Legislature during the annual legislative budget hearing process the extent to which the state oversight program meets or exceeds federal oversight standards and the extent to which the federal Department of Health and Human Services is accepting exemption applications and the potential cost to the state for an exemption.

Approved _____, 2015

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Governor