AMENDED IN ASSEMBLY JANUARY 25, 2010

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CALIFORNIA LEGISLATURE—2009–10 REGULAR SESSION

ASSEMBLY BILL No. 549

Introduced by Assembly Member Furutani

February 25, 2009

An act to amend Sections 1206, 1207, ~~and 1264~~ *1264, and 1300* of the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 549, as amended, Furutani. Licensure: clinical laboratory personnel.

Existing law provides for the regulation and licensure of clinical laboratories and clinical laboratory personnel by the State Department of Public Health. Existing law requires the department to issue a clinical chemist, clinical microbiologist, clinical toxicologist, clinical molecular biologist, or clinical cytogeneticist license to each person who has applied for the license on a specified form, who also holds a master of science or doctoral degree in the specialty for which the applicant is seeking a license, and who has met other requirements, *including the payment of specified application and license fees*. Existing law requires the department to determine by examination, except as specified, whether an applicant is qualified. Existing law requires the graduate

education to have included 30 semester hours of coursework in the applicants's specialty.

This bill would require the department to issue a clinical biochemical geneticist license to a person meeting these requirements in the subspecialty of biochemical genetics. For these specialities and subspecialties, it would specify that *a formal letter or* written documentation from an accredited training program indicating that an applicant completed the program, and ~~written documentation~~ from a clinical laboratory confirming the applicant's employment experience, shall constitute sufficient evidence. The bill would also require an applicant to provide evidence of satisfactory performance on a written examination in the applicant's specialty *or subspecialty* administered by an appropriate accrediting body recognized by the department. The bill would also make conforming changes.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

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

SECTION 1. Section 1206 of the Business and Professions Code is amended to read:

1206. (a) For the purposes of this chapter the following definitions are applicable:

(1) "Biological specimen" means any material that is derived from the human body.

(2) "Blood electrolyte analysis" means the measurement of electrolytes in a blood specimen by means of ion selective electrodes on instruments specifically designed and manufactured for blood gas and acid-base analysis.

(3) "Blood gas analysis" means a clinical laboratory test or examination that deals with the uptake, transport, and metabolism of oxygen and carbon dioxide in the human body.

(4) "Clinical laboratory test or examination" means the detection, identification, measurement, evaluation, correlation, monitoring, and reporting of any particular analyte, entity, or substance within a biological specimen for the purpose of obtaining scientific data which may be used as an aid to ascertain the presence, progress, and source of a disease or physiological condition in a human being, or used as an aid in the prevention, prognosis, monitoring, or treatment of a physiological or

pathological condition in a human being, or for the performance of nondiagnostic tests for assessing the health of an individual.

(5) "Clinical laboratory science" means any of the sciences or scientific disciplines used to perform a clinical laboratory test or examination.

(6) "Clinical laboratory practice" means 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.

(7) "Clinical laboratory" means any place used, or any establishment or institution organized or operated, for the performance of clinical laboratory tests or examinations or the practical application of the clinical laboratory sciences. That application may include any means that applies the clinical laboratory sciences.

(8) "Direct and constant supervision" means personal observation and critical evaluation of the activity of unlicensed laboratory personnel by a physician and surgeon, or by a person licensed under this chapter other than a trainee, during the entire time that the unlicensed laboratory personnel are engaged in the duties specified in Section 1269.

(9) "Location" means either a street and city address, or a site or place within a street and city address, where any of the clinical laboratory sciences or scientific disciplines are practiced or applied, or where any clinical laboratory tests or examinations are performed.

(10) "Physician office laboratory" means a clinical laboratory that is licensed or registered under Section 1265, and that is either: (A) a clinical laboratory that is owned and operated by a partnership or professional corporation that performs clinical laboratory tests or examinations only for patients of five or fewer physicians and surgeons or podiatrists who are shareholders, partners, or employees of the partnership or professional corporation that owns and operates the clinical laboratory; or (B) a clinical laboratory that is owned and operated by an individual licensed physician and surgeon or a podiatrist, and that performs clinical laboratory tests or examinations only for patients of the physician and surgeon or podiatrist who owns and operates the clinical laboratory.

(11) “Public health laboratory” means a laboratory that is operated by a city or county in conformity with Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code and the regulations adopted thereunder.

(12) “Specialty” means histocompatibility, microbiology, diagnostic immunology, chemistry, hematology, immunohematology, pathology, genetics, or other specialty specified by regulation adopted by the department.

(13) “Subspecialty” for purposes of microbiology, means bacteriology, mycobacteriology, mycology, parasitology, virology, molecular biology, and serology for diagnosis of infectious diseases, or other subspecialty specified by regulation adopted by the department; for purposes of diagnostic immunology, means syphilis serology, general immunology, or other subspecialty specified by regulation adopted by the department; for purposes of chemistry, means routine chemistry, clinical microscopy, endocrinology, toxicology, or other subspecialty specified by regulation adopted by the department; for purposes of immunohematology, means ABO/Rh Type and Group, antibody detection for transfusion, antibody detection nontransfusion, antibody identification, compatibility, or other subspecialty specified by regulation adopted by the department; for pathology, means tissue pathology, oral pathology, diagnostic cytology, or other subspecialty specified by regulation adopted by the department; for purposes of genetics, means molecular biology related to the diagnosis of human genetic abnormalities, biochemical genetics, cytogenetics, or other subspecialty specified by regulation adopted by the department.

(14) “Direct and responsible supervision” means both of the following:

(A) Personal observation and critical evaluation of the activity of a trainee by a physician and surgeon, or by a person licensed under this chapter other than a trainee, during the entire time that the trainee is performing clinical laboratory tests or examinations.

(B) Personal review by the physician and surgeon or the licensed person of all results of clinical laboratory testing or examination performed by the trainee for accuracy, reliability, and validity before the results are reported from the laboratory.

(15) “Licensed laboratory” means a clinical laboratory licensed pursuant to paragraph (1) of subdivision (a) of Section 1265.

(16) “Registered laboratory” means a clinical laboratory registered pursuant to paragraph (2) of subdivision (a) of Section 1265.

(17) “Point-of-care laboratory testing device” means a portable laboratory testing instrument to which the following applies:

(A) It is used within the proximity of the patient for whom the test or examination is being conducted.

(B) It is used in accordance with the patient test management system, the quality control program, and the comprehensive quality assurance program established and maintained by the laboratory pursuant to paragraph (2) of subdivision (d) of Section 1220.

(C) It meets the following criteria:

(i) Performs clinical laboratory tests or examinations classified as waived or of moderate complexity under CLIA.

(ii) Performs clinical laboratory tests or examinations on biological specimens that require no preparation after collection.

(iii) Provides clinical laboratory tests or examination results without calculation or discretionary intervention by the testing personnel.

(iv) Performs clinical laboratory tests or examinations without the necessity for testing personnel to perform calibration or maintenance, except resetting pursuant to the manufacturer’s instructions or basic cleaning.

(18) “Analyte” means the substance or constituent being measured including, but not limited to, glucose, sodium, or theophyline, or any substance or property whose presence or absence, concentration, activity, intensity, or other characteristics are to be determined.

(b) Nothing in this chapter shall restrict, limit, or prevent any person licensed to provide health care services under the laws of this state, including, but not limited to, licensed physicians and surgeons and registered nurses, from practicing the profession or occupation for which he or she is licensed.

(c) Nothing in this chapter shall authorize any person to perform or order health care services, or utilize the results of the clinical laboratory test or examination, unless the person is otherwise authorized to provide that care or utilize the results. The inclusion of a person in Section 1206.5 for purposes of performing a clinical

laboratory test or examination shall not be interpreted to authorize a person, who is not otherwise authorized, to perform venipuncture, arterial puncture, or skin puncture.

SEC. 2. Section 1207 of the Business and Professions Code is amended to read:

1207. (a) As used in this chapter, "clinical chemist," or "clinical microbiologist," or "clinical toxicologist," or "clinical genetic molecular biologist," or "clinical biochemical geneticist," or "clinical cytogeneticist," or "oral and maxillofacial pathologist" means any person licensed by the department under Section 1264 to engage in, or supervise others engaged in, clinical laboratory practice limited to his or her area of specialization or to direct a clinical laboratory, or portion thereof, limited to his or her area of specialization. Such a licensed person who is qualified under CLIA may 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, as specified under CLIA, limited to his or her area of specialty or subspecialty as described in subdivision (b), and shall only direct a clinical laboratory providing service within those specialties or subspecialties. A person licensed as a "clinical chemist," or "clinical microbiologist," or "clinical toxicologist," or "clinical genetic molecular biologist," or "*clinical biochemical geneticist*," *or* "clinical cytogeneticist," or "oral and maxillofacial pathologist" may perform any clinical laboratory test or examination classified as waived or of moderate complexity under CLIA.

(b) The specialty or subspecialty for each of the limited license categories identified in subdivision (a), and the clinical laboratories that may be directed by persons licensed in each of those categories, are the following:

(1) For a person licensed under this chapter as a clinical chemist, the specialty of chemistry and the subspecialties of routine chemistry, endocrinology, clinical microscopy, toxicology, or other specialty or subspecialty specified by regulation adopted by the department.

(2) For a person licensed under this chapter as a clinical microbiologist, the specialty of microbiology and the subspecialties of bacteriology, mycobacteriology, mycology, parasitology, virology, molecular biology, and serology for diagnosis of

infectious diseases, or other specialty or subspecialty specified by regulation adopted by the department.

(3) For a person licensed under this chapter as a clinical toxicologist, the subspecialty of toxicology within the specialty of chemistry or other specialty or subspecialty specified by regulation adopted by the department.

(4) For a person licensed under this chapter as a clinical genetic molecular biologist, the subspecialty of molecular biology related to diagnosis of human genetic abnormalities within the specialty of genetics or other specialty or subspecialty specified by regulation adopted by the department.

(5) For a person licensed under this chapter as a clinical cytogeneticist, the subspecialty of cytogenetics within the specialty of genetics or other specialty or subspecialty specified by regulation adopted by the department.

(6) For a person licensed under this chapter as an oral and maxillofacial pathologist, the subspecialty of oral pathology within the specialty of pathology or other specialty or subspecialty specified by regulation adopted by the department.

(7) For a person licensed under this chapter as a clinical biochemical geneticist, the subspecialty of biochemical genetics within the specialty of genetics or other speciality or subspecialty specified by regulation adopted by the department.

SEC. 3. 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 molecular biologist, clinical biochemical geneticist, 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) (1) Unless otherwise required by regulation, 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.

(2) A formal letter or other written documentation from an accredited training program indicating an applicant's completion of the program, and from a clinical laboratory or laboratories confirming the applicant's employment experience as required by regulation, shall constitute sufficient evidence for the purpose of this subdivision. Each applicant shall also provide evidence of satisfactory performance on a written examination in the applicant's specialty or subspecialty administered by an appropriate accrediting body recognized by the department. In order to constitute sufficient evidence for this purpose, formal letters or other documentation required by this paragraph ~~must~~ *shall* be provided directly by the examining agency or appropriate accrediting body to the department.

(b) The department may issue licenses without the examination required by paragraph (1) of subdivision (a) to applicants who have passed examinations of other states or an appropriate accrediting body 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 appropriate accrediting bodies 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 appropriate accrediting body 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. 4. 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 biochemical geneticist's,* clinical cytogeneticist's, or clinical 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, ~~or~~ clinical laboratory toxicologist's, *or clinical biochemical geneticist'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.

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