AMENDED IN ASSEMBLY APRIL 21, 2009

AMENDED IN ASSEMBLY APRIL 14, 2009

CALIFORNIA LEGISLATURE—2009–10 REGULAR SESSION

ASSEMBLY BILL No. 549

Introduced by Assembly Member Furutani

February 25, 2009

An act to amend Sections 1207, 1261.5, and 1264 of, and to add Sections 1261.7, 1261.8, 1261.9, 1261.10, 1264.1, 1264.2, 1264.3, 1264.4, and 1264.5 to, 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 authorizes the department to issue limited clinical laboratory scientist's licenses in chemistry, microbiology, toxicology, histocompatibility, immunohematology, genetic molecular biology, cytogenetics, or other areas of laboratory specialty or subspecialty when determined necessary by the department, as specified. Existing law requires an applicant to meet various requirements in order to qualify for admission to the examination for a special clinical laboratory scientist's license.

This bill would revise these requirements by requiring an applicant to either (1) have graduated from an educational institution maintaining standards equivalent to specified accredited institutions and have one

year of full-time postgraduate specified training or experience or (2) have a doctoral degree from an accredited institution and provide evidence of completion of 2 years of postdoctoral training in a training program accredited by an approved accrediting body for the specialty, as specified. The bill would also authorize the department to issue a limited clinical laboratory scientist's license in biochemical genetics.

The bill would also, commencing January 1, 2010, require the department to issue a limited clinical laboratory scientist's license in cytogenetics, genetic molecular biology, biochemical genetics, and chemistry, to any person possessing a doctoral degree from an accredited institution who provides evidence of completing 2 years of ~~post-doctoral~~ *postdoctoral* training in a specified training program.

Existing law also requires the department to 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 a specified form who is also the holder of a master of science or doctoral degree in the specialty for which the applicant is seeking a license and who has met other requirements. Existing law requires the graduate education to have included 30 semester hours of coursework in the applicant's specialty.

This bill would specify that applicants possessing a doctoral degree from an accredited institution shall have the equivalent of 2 years of postdoctoral training in a training program accredited by a relevant accrediting body for the specialty and would also require each applicant to provide evidence of satisfactory performance on a specified written examination.

The bill would also, commencing January 1, 2010, require the department to issue a provisional license as a clinical cytogeneticist, clinical genetic molecular biologist, or a clinical biochemical geneticist to any person possessing a doctoral degree from an accredited institution who provides evidence of completing 2 years of postdoctoral training in a specified training program and would also require each applicant to provide evidence of satisfactory performance on a specified written examination.

Under existing law, a histocompatibility lab director, as defined, in order to be eligible for licensure, as a histocompatibility lab director, is required to provide evidence of satisfactory performance on a specified written and oral examination.

The bill would also, commencing January 1, 2010, require the department to issue a provisional license as a histocompatibility

laboratory director to any person possessing a doctoral degree from an accredited institution who provides evidence of completing 2 years of postdoctoral training in a specified training program and would also require each applicant to provide evidence of satisfactory performance on a specified written examination.

The bill would authorize the department to adopt emergency regulations with respect to some of these provisions.

The bill would make other related 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 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 shall have 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 genetics or other specialty or subspecialty specified by regulation adopted by the department.

SEC. 2. Section 1261.5 of the Business and Professions Code is amended to read:

1261.5. (a) The department may issue limited clinical laboratory scientist's licenses in chemistry, microbiology, toxicology, histocompatibility, immunohematology, biochemical genetics, genetic molecular biology, cytogenetics, or other areas

of laboratory specialty or subspecialty when determined to be necessary by the department in order for licensure categories to keep abreast of changes in laboratory or scientific technology. Whenever the department determines that a new limited clinical laboratory scientist license category is necessary, it shall adopt regulations identifying the category and the areas of specialization included within the category.

(b) To qualify for admission to the examination for a special clinical laboratory scientist's license, an applicant shall have met the requirements of either paragraph (1) or (2).

(1) (A) Have 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 with a baccalaureate or higher degree with a major appropriate to the field for which a license is being sought.

(B) Have one year of full-time postgraduate training or experience in the various areas of analysis in the field for which a license is being sought in a laboratory that has a license issued under this chapter or which the department determines is equivalent thereto.

(2) Have a doctoral degree from an accredited institution and provide evidence of completion of two years of postdoctoral training in a training program accredited by an approved accrediting body for the specialty. Each applicant shall also provide evidence of satisfactory performance on a written examination approved by the department relevant to each limited clinical laboratory scientist's license. The following accrediting bodies shall be ~~deemed approved~~ *considered appropriate* for the purposes of this paragraph:

(A) The American Board of Medical Microbiology.

(B) The American Board of Clinical Chemistry.

(C) The American Board of Medical Genetics.

(D) The Canadian Council of Medical Genetics.

(E) The American Academy of Clinical Toxicology.

(F) Any board approved by the United States Department of Health and Human Services pursuant to paragraph (3) of subsection (b) of Section 493.1443 of Title 42 of the Code of Federal Regulations.

(c) Written documentation from the accredited training program indicating an applicant's completion of the program shall constitute sufficient evidence for the purposes of subdivision (b).

(d) Whenever a limited clinical laboratory scientist's license is established for a specific area of specialization, the department may issue the license 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.

(e) The department shall adopt regulations to implement this section.

SEC. 3. Section 1261.7 is added to the Business and Professions Code, to read:

1261.7. (a) Commencing January 1, 2010, the department shall issue a limited clinical laboratory scientist's license in cytogenetics to any person possessing a doctoral degree from an accredited institution who provides evidence of completing two years of postdoctoral cytogeneticist training in a training program accredited by a relevant accrediting body for the specialty. Written documentation from the accredited training program indicating an applicant's completion of the program shall constitute sufficient evidence for this purpose. Each applicant shall also provide evidence of satisfactory performance on a written examination administered by the National Credentialing Agency for Laboratory Personnel in the specialty of cytogenetic scientist. Written documentation from the National Credentialing Agency for Laboratory Personnel indicating an applicant's satisfactory performance on the written examination shall constitute sufficient evidence for this purpose.

(b) Nothing in this section shall alter the licensure requirements for a limited clinical laboratory scientist pursuant to Section 1261.5.

SEC. 4. Section 1261.8 is added to the Business and Professions Code, to read:

1261.8. (a) Commencing January 1, 2010, the department shall issue a limited clinical laboratory scientist's license in genetic molecular biology to any person possessing a doctoral degree from an accredited institution who provides evidence of completing two years of postdoctoral molecular biologist training in a training program accredited by a relevant accrediting body for the specialty. Written documentation from the accredited training program indicating an applicant's completion of the program shall constitute

sufficient evidence for this purpose. Each applicant shall also provide evidence of satisfactory performance on a written examination administered by the National Credentialing Agency for Laboratory Personnel in the specialty of genetic molecular biologist scientist. Written documentation from the National Credentialing Agency for Laboratory Personnel indicating an applicant's satisfactory performance on the written examination shall constitute sufficient evidence for this purpose.

(b) Nothing in this section shall alter the licensure requirements for a limited clinical laboratory scientist pursuant to Section 1261.5.

SEC. 5. Section 1261.9 is added to the Business and Professions Code, to read:

1261.9. (a) Commencing January 1, 2010, the department shall issue a limited clinical laboratory scientist's license in biochemical genetics to any person possessing a doctoral degree from an accredited institution who provides evidence of completing two years of postdoctoral training in a biochemical genetics training program accredited by a relevant accrediting body for the specialty. Written documentation from the accredited training program indicating an applicant's completion of the program shall constitute sufficient evidence for this purpose. Each applicant shall also provide evidence of satisfactory performance on a written examination administered by the National Credentialing Agency for Laboratory Personnel in the specialty of biochemical geneticist scientist. Written documentation from the National Credentialing Agency for Laboratory Personnel indicating an applicant's satisfactory performance on the written examination shall constitute sufficient evidence for this purpose.

(b) Nothing in this section shall alter the licensure requirements for a limited clinical laboratory scientist pursuant to Section 1261.5.

SEC. 6. Section 1261.10 is added to the Business and Professions Code, to read:

1261.10. (a) Commencing January 1, 2010, the department shall issue a limited clinical chemist scientist license to any person possessing a doctoral degree from an accredited institution who provides evidence of completing two years of postdoctoral training in clinical chemistry in a training program accredited by a relevant accrediting body for the specialty. Written documentation from the accredited training program indicating an applicant's completion of the program shall constitute sufficient evidence for

this purpose. Each applicant shall also provide evidence of satisfactory performance on a written examination administered by the American Society for Clinical Pathology, the National Registry in Certified Chemistry, the American Board of Clinical Chemistry, or other certification agency approved by the department. Written documentation from the certification agency indicating an applicant's satisfactory performance on the written examination shall constitute sufficient evidence for this purpose.

(b) Nothing in this section shall alter the licensure requirements for a limited clinical laboratory scientist pursuant to Section 1261.5.

SEC. 7. 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) The graduate education shall have included 30 semester hours of coursework in the applicant's specialty.

(1) 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) Applicants possessing a doctoral degree from an accredited institution shall have the equivalent of two years of postdoctoral training in a training program accredited by a relevant accrediting body for the specialty. Written documentation from the accredited training program indicating an applicant's completion of the program shall constitute sufficient evidence for this purpose. Each applicant shall also provide evidence of satisfactory performance on a written examination in the applicant's specialty administered by an appropriate accrediting body. Written documentation from the ~~National Credentialing Agency for Laboratory Personnel~~ *accrediting body* indicating an applicant's satisfactory performance on the written examination shall constitute sufficient evidence for this purpose.

(B) For purposes of this subdivision, the following accrediting bodies shall be ~~deemed~~ *considered* appropriate accrediting bodies. ~~Postdoctoral training programs approved by these accrediting bodies shall be deemed approved by the department.~~

(i) The American Board of Medical Microbiology.

(ii) The American Board of Clinical Chemistry.

(iii) The American Board of Bioanalysis.

(iv) The American Board of Medical Laboratory Immunology.

(v) The American Board of Forensic Toxicology.

(vi) The American Board of Medical Genetics.

(vii) The Canadian Council of Medical Genetics.

(viii) The American Academy of Clinical Toxicology.

(ix) The American Board of Pathology.

(x) The American Board of Histocompatibility and Immunogenetics.

(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. 8. Section 1264.1 is added to the Business and Professions Code, to read:

1264.1. (a) Commencing January 1, 2010, the department shall issue a provisional license as a clinical cytogeneticist to any person possessing a doctoral degree from an accredited institution who also provides evidence of completing two years of postdoctoral training in cytogenetics in a training program accredited by a relevant accrediting body for that specialty. Written documentation from the accredited training program indicating an applicant completed the program shall constitute sufficient evidence for this purpose. Each applicant shall also provide evidence of satisfactory performance on a written examination administered by the American Board of Medical Genetics or the Canadian Council of Medical Genetics in the specialty of cytogenetics. Written documentation from either of these bodies indicating an applicant's satisfactory performance on the written examination shall constitute sufficient evidence for this purpose.

(b) Each person licensed pursuant to this section shall work under the supervision of a laboratory director. If the licensee is qualified under CLIA, he or she may perform clinical laboratory tests or examinations classified as of high complexity under CLIA, and shall have the duties and responsibilities of a technical supervisor and general supervisor, as specified under CLIA, limited to the specialty of cytogenetics.

(c) Any person licensed pursuant to this section shall be eligible for licensure as a laboratory director within the meaning of Section 1209, upon the completion of two years of experience supervising or performing clinical laboratory tests or examinations in clinical

cytogenetics in a clinical laboratory that possesses a certificate issued under CLIA for performing high-complexity testing, provided his or her license is not then suspended or revoked.

SEC. 9. Section 1264.2 is added to the Business and Professions Code, to read:

1264.2. (a) Commencing January 1, 2010, the department shall issue a provisional license as a clinical genetic molecular biologist to any person possessing a doctoral degree from an accredited institution who also provides evidence of completing two years of postdoctoral training in molecular biology in a training program accredited by a relevant accrediting body for that specialty. Written documentation from the accredited training program indicating an applicant completed the program shall constitute sufficient evidence for this purpose. Each applicant shall also provide evidence of satisfactory performance on a written examination administered by the American Board of Medical Genetics or the Canadian Council of Medical Genetics in the specialty of molecular biology. Written documentation from either of these bodies indicating an applicant's satisfactory performance on the written examination shall constitute sufficient evidence for this purpose.

(b) Each person licensed pursuant to this section shall work under the supervision of a laboratory director. If the licensee is qualified under CLIA, he or she may perform clinical laboratory tests or examinations classified as of high complexity under CLIA, and shall have the duties and responsibilities of a technical supervisor and general supervisor, as specified under CLIA, limited to the specialty of genetic molecular biology.

(c) Any person licensed pursuant to this section shall be eligible for licensure as a laboratory director within the meaning of Section 1209, upon the completion of two years of experience supervising or performing clinical laboratory tests or examinations in genetic molecular biology in a clinical laboratory that possesses a certificate issued under CLIA for performing high-complexity testing, provided his or her license is not then suspended or revoked.

SEC. 10. Section 1264.3 is added to the Business and Professions Code, to read:

1264.3. (a) Commencing January 1, 2010, the department shall issue a provisional license as a clinical biochemical geneticist to any person possessing a doctoral degree from an accredited

institution who also provides evidence of completing two years of postdoctoral training in biochemical genetics in a training program accredited by a relevant accrediting body for the specialty. Written documentation from the accredited training program indicating an applicant completed the program shall constitute sufficient evidence for this purpose. Each applicant shall also provide evidence of satisfactory performance on a written examination administered by the American Board of Medical Genetics or the Canadian Council of Medical Genetics in the specialty of biochemical genetics. Written documentation from either of these bodies indicating an applicant's satisfactory performance on the written examination shall constitute sufficient evidence for this purpose.

(b) Each person licensed pursuant to this section shall work under the supervision of a laboratory director. If the licensee is qualified under CLIA, he or she may perform clinical laboratory tests or examinations classified as of high complexity under CLIA, and shall have the duties and responsibilities of a technical supervisor and general supervisor, as specified under CLIA, limited to the specialty of biochemical genetics.

(c) Any person licensed pursuant to this section shall be eligible for licensure as a laboratory director within the meaning of Section 1209, upon the completion of two years of experience supervising or performing clinical laboratory tests or examinations in clinical biochemical genetics in a clinical laboratory that possesses a certificate issued under CLIA for performing high-complexity testing, provided his or her license is not then suspended or revoked.

SEC. 11. Section 1264.4 is added to the Business and Professions Code, to read:

1264.4. (a) Commencing January 1, 2010, the department shall issue a provisional license as a histocompatibility laboratory director to any person possessing a doctoral degree from an accredited institution who also provides evidence of completing two years of postdoctoral training in histocompatibility and immunology in a training program accredited by a relevant accrediting body for the specialty. Written documentation from the accredited training program indicating an applicant completed the program shall constitute sufficient evidence for this purpose. Each applicant shall also provide evidence of satisfactory

performance on a written examination administered by the American Board of Histocompatibility and Immunogenetics in the specialty of histocompatibility. Written documentation from that board indicating an applicant's satisfactory performance on the written examination shall constitute sufficient evidence for this purpose.

(b) Each person licensed pursuant to this section shall work under the supervision of a laboratory director. If the licensee is qualified under CLIA, he or she may perform clinical laboratory tests or examinations classified as of high complexity under CLIA, and shall have the duties and responsibilities of a technical supervisor and general supervisor, as specified under CLIA, limited to the specialty of histocompatibility and immunology.

(c) Any person licensed pursuant to this section shall be eligible for licensure as a histocompatibility laboratory director pursuant to Section 1209.1, upon the completion of two years of experience supervising or performing clinical laboratory tests or examinations in histocompatibility and immunology in a clinical laboratory that possesses a certificate issued under CLIA for performing high-complexity testing, provided his or her license is not then suspended or revoked.

SEC. 12. Section 1264.5 is added to the Business and Professions Code, to read:

1264.5. The department may adopt emergency regulations in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) to implement Sections 1264, 1264.1, 1264.2, 1264.3, and 1264.4 if the department deems necessary to implement these sections. The adoption of the regulations shall be considered by the Office of Administrative Law to be necessary for the immediate preservation of the public peace, health and safety, or general welfare. The emergency regulations shall be submitted to the Office of Administrative Law for filing with the Secretary of State and publication in the California Code of Regulations, and shall be replaced with final, permanent regulations within 120 days following the date of their adoption.

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