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CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL

No. 940

Introduced by Assembly Members Ridley-Thomas and Waldron

February 26, 2015

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, as amended, 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 ~~the clinical~~ *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.*

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

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

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

3 1203. As used in this chapter, “clinical laboratory bioanalyst”
4 or “bioanalyst” means a person licensed under Section 1260 to
5 engage in clinical laboratory practice and direction of a clinical
6 laboratory.

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

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

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

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

29 1209. (a) As used in this chapter, “laboratory director” means
30 any person who is any of the following:

- 31 (1) A duly licensed physician and surgeon.
32 (2) Only for purposes of a clinical laboratory test or examination
33 classified as waived, is any of the following:
34 (A) A duly licensed clinical laboratory scientist.
35 (B) A duly licensed limited clinical laboratory scientist.
36 (C) A duly licensed naturopathic doctor.

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

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

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

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

15 (c) The laboratory director, if qualified under CLIA, may
16 perform the duties of the technical consultant, technical supervisor,
17 clinical consultant, general supervisor, and testing personnel, or
18 delegate these responsibilities to persons qualified under CLIA.
19 If the laboratory director reapportions performance of those
20 responsibilities or duties, he or she shall remain responsible for
21 ensuring that all those duties and responsibilities are properly
22 performed.

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

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

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

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

14 (1) Ensure that all personnel, prior to testing biological
15 specimens, have the appropriate education and experience, receive
16 the appropriate training for the type and complexity of the services
17 offered, and have demonstrated that they can perform all testing
18 operations reliably to provide and report accurate results. In
19 determining the adequacy of qualifications, the laboratory director
20 shall comply with any regulations adopted by the department that
21 specify the minimum qualifications for, and the type of procedures
22 that may be performed by, personnel in addition to any CLIA
23 requirements relative to the education or training of personnel.
24 Any regulations adopted pursuant to this section that specify the
25 type of procedure that may be performed by testing personnel shall
26 be based on the skills, knowledge, and tasks required to perform
27 the type of procedure in question.

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

35 (3) Specify in writing the responsibilities and duties of each
36 individual engaged in the performance of the preanalytic, analytic,
37 and postanalytic phases of clinical laboratory tests or examinations,
38 including which clinical laboratory tests or examinations the
39 individual is authorized to perform, whether supervision is required
40 for the individual to perform specimen processing, test

1 performance, or results reporting, and whether consultant,
2 supervisor, or director review is required prior to the individual
3 reporting patient test results.

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

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

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

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

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

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

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

23 (F) Assessment of problem solving skills.

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

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

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

39 (2) If there are two or more clinical laboratories of an acute care
40 hospital, those additional clinical laboratories that are limited to

1 the performance of blood gas analysis, blood electrolyte analysis,
2 or both, may be directed by a physician and surgeon qualified as
3 a laboratory director under subdivision (a), irrespective of whether
4 a pathologist is available.

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

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

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

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

17 1260. The department shall issue a clinical laboratory
18 bioanalyst's license to each person who is a lawful holder of a
19 degree of master of arts, master of science, or an equivalent or
20 higher degree as determined by the department with a major in
21 chemical, physical, biological, or clinical laboratory sciences. This
22 education shall have been obtained in one or more established and
23 reputable institutions maintaining standards equivalent, as
24 determined by the department, to those institutions accredited by
25 the Western Association of Schools and Colleges or an essentially
26 equivalent accrediting agency, as determined by the department.
27 The applicant also shall have a minimum of four years' experience
28 as a clinical laboratory scientist performing clinical laboratory
29 work embracing the various fields of clinical laboratory activity
30 in a clinical laboratory certified under CLIA. The quality and
31 variety of this experience shall be satisfactory to the department
32 and shall have been obtained within the six-year period
33 immediately antecedent to admission to the examination. The
34 applicant shall successfully pass a written examination and an oral
35 examination conducted by the department or a committee
36 designated by the department to conduct the examinations,
37 indicating that the applicant is properly qualified. The department
38 may issue a license without conducting a written examination to
39 an applicant who has passed a written examination of a national
40 accrediting board having requirements that are, in the determination

1 of the department, equal to or greater than those required by this
2 chapter and regulations adopted by the department. The department
3 shall establish by regulation the required courses to be included
4 in the college or university training.

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

7 1264. The department shall issue a clinical chemist, clinical
8 microbiologist, clinical toxicologist, clinical *genetic* molecular
9 biologist, or clinical cytogeneticist license to each person who has
10 applied for the license on forms provided by the department, who
11 is a lawful holder of a master of science or doctoral degree in the
12 specialty for which the applicant is seeking a license and who has
13 met such additional reasonable qualifications of training, education,
14 and experience as the department may establish by regulations.
15 The department shall issue an oral and maxillofacial pathologist
16 license to every applicant for licensure who has applied for the
17 license on forms provided by the department, who is a registered
18 Diplomate of the American Board of Oral and Maxillofacial
19 Pathology, and who meets any additional and reasonable
20 qualifications of training, education, and experience as the
21 department may establish by regulation.

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

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

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

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

18 ~~SEC. 4.~~

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

21 1300. The amount of application, registration, and license fees
22 under this chapter shall be as follows:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 (9) More than 1,000,000 tests: five thousand two hundred sixty
26 dollars (\$5,260) plus three hundred fifty dollars (\$350) for every
27 500,000 tests over 1,000,000, up to a maximum of 15,000,000
28 tests.

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

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

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

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

- 1 (4) Between 25,001 and 50,000, inclusive, tests: one thousand
2 three hundred eighty dollars (\$1,380).
- 3 (5) Between 50,001 and 75,000, inclusive, tests: one thousand
4 seven hundred sixty dollars (\$1,760).
- 5 (6) Between 75,001 and 100,000, inclusive, tests: two thousand
6 forty dollars (\$2,040).
- 7 (7) Between 100,001 and 500,000, inclusive, tests: two thousand
8 four hundred forty dollars (\$2,440).
- 9 (8) Between 500,001 and 1,000,000, inclusive, tests: four
10 thousand six hundred ten dollars (\$4,610).
- 11 (9) More than 1,000,000 tests per year: four thousand nine
12 hundred sixty dollars (\$4,960) plus three hundred fifty dollars
13 (\$350) for every 500,000 tests over 1,000,000, up to a maximum
14 of 15,000,000 tests.
- 15 (h) The application fee for a trainee's license is thirteen dollars
16 (\$13) commencing on July 1, 1983.
- 17 (i) The annual renewal fee for a trainee's license is eight dollars
18 (\$8) commencing on July 1, 1983.
- 19 (j) The application fee for a duplicate license is five dollars (\$5)
20 commencing on July 1, 1983.
- 21 (k) The personnel licensing delinquency fee is equal to the
22 annual renewal fee.
- 23 (l) The director may establish a fee for examinations required
24 under this chapter. The fee shall not exceed the total cost to the
25 department in conducting the examination.
- 26 (m) A clinical laboratory subject to registration under paragraph
27 (2) of subdivision (a) of Section 1265 and performing only those
28 clinical laboratory tests or examinations considered waived under
29 CLIA shall pay an annual fee of one hundred dollars (\$100). A
30 clinical laboratory subject to registration under paragraph (2) of
31 subdivision (a) of Section 1265 and performing only
32 provider-performed microscopy, as defined under CLIA, shall pay
33 an annual fee of one hundred fifty dollars (\$150). A clinical
34 laboratory performing both waived and provider-performed
35 microscopy shall pay an annual registration fee of one hundred
36 fifty dollars (\$150).
- 37 (n) The costs of the department in conducting a complaint
38 investigation, imposing sanctions, or conducting a hearing under
39 this chapter shall be paid by the clinical laboratory. The fee shall
40 be no greater than the fee the laboratory would pay under CLIA

1 for the same type of activities and shall not be payable if the
2 clinical laboratory would not be required to pay those fees under
3 CLIA.

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

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

13 (q) The department shall establish an application fee and a
14 renewal fee for a medical laboratory technician license, the total
15 fees collected not to exceed the costs of the department for the
16 implementation and operation of the program licensing and
17 regulating medical laboratory technicians pursuant to Section
18 1260.3.

19 (r) The costs of the department to conduct any reinspections to
20 ensure compliance of a laboratory applying for initial licensure
21 shall be paid by the laboratory. This additional cost for each visit
22 shall be equal to the initial application fee and shall be paid by the
23 laboratory prior to issuance of a license. The department shall not
24 charge a reinspection fee if the reinspection is due to error or
25 omission on the part of the department.

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

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