

AMENDED IN SENATE JULY 14, 2015

AMENDED IN SENATE JULY 1, 2015

AMENDED IN ASSEMBLY APRIL 23, 2015

AMENDED IN ASSEMBLY MARCH 23, 2015

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, ~~1204~~, ~~1205~~, ~~1206~~, ~~1207~~, 1209, ~~1210~~, ~~1260~~, ~~1261.5~~, ~~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 defines a "clinical laboratory scientist" as any person, other than a licensed clinical laboratory bioanalyst or trainee, who is licensed, as specified, to engage in a clinical laboratory practice under the overall operation and administration of a laboratory director.~~

~~The bill would add "reproductive biology" to the list of specialties that a clinical laboratory scientist may perform. The bill would make conforming changes.~~

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 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 authorize the department to issue limited clinical laboratory scientist licenses and clinical licenses in reproductive biology and biochemical genetics, as provided, and would apply existing application and license renewal fees to persons applying for additional~~

~~clinical licenses: renewing a clinical cytogeneticist’s or clinical 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 1204 of the Business and Professions Code is~~
28 ~~amended to read:~~

29 ~~1204. As used in this chapter, “clinical laboratory scientist”~~
30 ~~means any person, other than a licensed clinical laboratory~~
31 ~~bioanalyst or trainee, who is licensed under Sections 1261 and~~
32 ~~1262 to engage in clinical laboratory practice under the overall~~
33 ~~operation and administration of a laboratory director, unless serving~~

1 as a director of a waived laboratory as provided in Section 1209.
2 A person licensed as a clinical laboratory scientist and qualified
3 under CLIA may perform clinical laboratory tests or examinations
4 classified as of high complexity under CLIA and the duties and
5 responsibilities of a waived laboratory director, as specified under
6 CLIA, technical consultant, clinical consultant, technical
7 supervisor, and general supervisor, as specified under CLIA, in
8 the specialties of histocompatibility, microbiology, diagnostic
9 immunology, chemistry, hematology, immunohematology,
10 genetics, reproductive biology, or other specialty or subspecialty
11 specified by regulation adopted by the department. A person
12 licensed as a “clinical laboratory scientist” may perform any
13 clinical laboratory test or examination classified as waived or of
14 moderate complexity under CLIA.

15 SEC. 3. Section 1205 of the Business and Professions Code is
16 amended to read:

17 1205. As used in this chapter, “trainee” means any person
18 licensed under this chapter for the purpose of receiving
19 comprehensive practical experience and instruction in clinical
20 laboratory procedures in one of the sciences or in general clinical
21 laboratory science. The training provided to a trainee shall be
22 provided under the direct and responsible supervision of any of
23 the following individuals: a person authorized to direct a laboratory
24 under the provisions of this chapter, a clinical laboratory scientist,
25 clinical chemist scientist, clinical microbiologist scientist, clinical
26 toxicologist scientist, clinical immunohematologist scientist,
27 clinical genetic molecular biologist scientist, clinical cytogeneticist
28 scientist, clinical biochemical geneticist scientist, clinical
29 reproductive biologist scientist, clinical histocompatibility scientist,
30 or other equivalent licensee in the science or specialty or
31 subspecialty for which he or she is licensed in a clinical laboratory
32 certified for this purpose by the department under this chapter.

33 SEC. 4. Section 1206 of the Business and Professions Code is
34 amended to read:

35 1206. (a) For the purposes of this chapter the following
36 definitions are applicable:

37 (1) “Analyte” means the substance or constituent being
38 measured, including, but not limited to, glucose, sodium, or
39 theophylline, or any substance or property whose presence or

1 absence, concentration, activity, intensity, or other characteristics
2 are to be determined.

3 (2) ~~“Biological specimen” means any material that is derived
4 from the human body.~~

5 (3) ~~“Blood electrolyte analysis” means the measurement of
6 electrolytes in a blood specimen by means of ion selective
7 electrodes on instruments specifically designed and manufactured
8 for blood gas and acid-base analysis.~~

9 (4) ~~“Blood gas analysis” means a clinical laboratory test or
10 examination that deals with the uptake, transport, and metabolism
11 of oxygen and carbon dioxide in the human body.~~

12 (5) ~~“Clinical laboratory test or examination” means the
13 detection, identification, measurement, evaluation, correlation,
14 monitoring, and reporting of any particular analyte, entity, or
15 substance within a biological specimen for the purpose of obtaining
16 scientific data which may be used as an aid to ascertain the
17 presence, progress, and source of a disease or physiological
18 condition in a human being, or used as an aid in the prevention,
19 prognosis, monitoring, or treatment of a physiological or
20 pathological condition in a human being, or for the performance
21 of nondiagnostic tests for assessing the health of an individual.~~

22 (6) ~~“Clinical laboratory science” means any of the sciences or
23 scientific disciplines used to perform a clinical laboratory test or
24 examination.~~

25 (7) ~~“Clinical laboratory practice” means the application of
26 clinical laboratory sciences or the use of any means that applies
27 the clinical laboratory sciences within or outside of a licensed or
28 registered clinical laboratory. Clinical laboratory practice includes
29 consultation, advisory, and other activities inherent to the
30 profession.~~

31 (8) ~~“Clinical laboratory” means any place used, or any
32 establishment or institution organized or operated, for the
33 performance of clinical laboratory tests or examinations or the
34 practical application of the clinical laboratory sciences. That
35 application may include any means that applies the clinical
36 laboratory sciences.~~

37 (9) ~~“Direct and constant supervision” means personal
38 observation and critical evaluation of the activity of unlicensed
39 laboratory personnel by a physician and surgeon, or by a person
40 licensed under this chapter other than a trainee, during the entire~~

1 time that the unlicensed laboratory personnel are engaged in the
2 duties specified in Section 1269.

3 (10) ~~“Direct and responsible supervision” means both of the~~
4 ~~following:~~

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

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

13 (11) ~~“Licensed laboratory” means a clinical laboratory licensed~~
14 ~~pursuant to paragraph (1) of subdivision (a) of Section 1265.~~

15 (12) ~~“Location” means either a street and city address, or a site~~
16 ~~or place within a street and city address, where any of the clinical~~
17 ~~laboratory sciences or scientific disciplines are practiced or applied,~~
18 ~~or where any clinical laboratory tests or examinations are~~
19 ~~performed.~~

20 (13) ~~“Physician office laboratory” means a clinical laboratory~~
21 ~~that is licensed or registered under Section 1265, and that is either:~~

22 (A) ~~a clinical laboratory that is owned and operated by a partnership~~
23 ~~or professional corporation that performs clinical laboratory tests~~
24 ~~or examinations only for patients of five or fewer physicians and~~
25 ~~surgeons or podiatrists who are shareholders, partners, or~~
26 ~~employees of the partnership or professional corporation that owns~~
27 ~~and operates the clinical laboratory; or (B) a clinical laboratory~~
28 ~~that is owned and operated by an individual licensed physician~~
29 ~~and surgeon or a podiatrist, and that performs clinical laboratory~~
30 ~~tests or examinations only for patients of the physician and surgeon~~
31 ~~or podiatrist who owns and operates the clinical laboratory.~~

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

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

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

40 (C) ~~It meets the following criteria:~~

- 1 (i) Performs clinical laboratory tests or examinations classified
2 as waived or of moderate complexity under the federal Clinical
3 Laboratory Improvement Amendments of 1988 (CLIA) (42 U.S.C.
4 Sec. 263a).
- 5 (ii) Performs clinical laboratory tests or examinations on
6 biological specimens that require no preparation after collection.
- 7 (iii) Provides clinical laboratory tests or examination results
8 without calculation or discretionary intervention by the testing
9 personnel.
- 10 (iv) Performs clinical laboratory tests or examinations without
11 the necessity for testing personnel to perform calibration or
12 maintenance, except resetting pursuant to the manufacturer's
13 instructions or basic cleaning.
- 14 (15) "Public health laboratory" means a laboratory that is
15 operated by a city or county in conformity with Article 5
16 (commencing with Section 101150) of Chapter 2 of Part 3 of
17 Division 101 of the Health and Safety Code and the regulations
18 adopted thereunder.
- 19 (16) "Registered laboratory" means a clinical laboratory
20 registered pursuant to paragraph (2) of subdivision (a) of Section
21 1265.
- 22 (17) "Specialty" means histocompatibility, microbiology,
23 diagnostic immunology, chemistry, hematology,
24 immunohematology, pathology, genetics, reproductive biology,
25 or other specialty specified by regulation adopted by the
26 department.
- 27 (18) "Subspecialty" for purposes of microbiology, means
28 bacteriology, mycobacteriology, mycology, parasitology, virology,
29 molecular biology, and serology for diagnosis of infectious
30 diseases, or other subspecialty specified by regulation adopted by
31 the department; for purposes of diagnostic immunology, means
32 syphilis serology, general immunology, or other subspecialty
33 specified by regulation adopted by the department; for purposes
34 of chemistry, means routine chemistry, clinical microscopy,
35 endocrinology, toxicology, or other subspecialty specified by
36 regulation adopted by the department; for purposes of
37 immunohematology, means ABO/Rh Type and Group, antibody
38 detection for transfusion, antibody detection nontransfusion,
39 antibody identification, compatibility, or other subspecialty
40 specified by regulation adopted by the department; for pathology,

1 means tissue pathology, oral pathology, diagnostic cytology, or
2 other subspecialty specified by regulation adopted by the
3 department; for purposes of genetics, means molecular biology
4 related to the diagnosis of human genetic abnormalities,
5 cytogenetics, biochemical genetics, or other subspecialty specified
6 by regulation adopted by the department.

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

12 (c) Nothing in this chapter shall authorize any person to perform
13 or order health care services, or utilize the results of the clinical
14 laboratory test or examination, unless the person is otherwise
15 authorized to provide that care or utilize the results. The inclusion
16 of a person in Section 1206.5 for purposes of performing a clinical
17 laboratory test or examination shall not be interpreted to authorize
18 a person, who is not otherwise authorized, to perform venipuncture,
19 arterial puncture, or skin puncture.

20 SEC. 5.— Section 1207 of the Business and Professions Code is
21 amended to read:

22 1207. (a) (1) (A) As used in this chapter, “clinical chemist,”
23 or “clinical microbiologist,” or “clinical toxicologist,” or “clinical
24 genetic molecular biologist,” or “clinical cytogeneticist,” or
25 “clinical reproductive biologist,” or “clinical biochemical
26 geneticist,” or “oral and maxillofacial pathologist” means any
27 person licensed by the department under Section 1264 to engage
28 in, or supervise others engaged in, clinical laboratory practice
29 limited to his or her area of specialization or to direct a clinical
30 laboratory, or portion thereof, limited to his or her area of
31 specialization.

32 (B) A person described in subparagraph (A) may perform the
33 duties and responsibilities of a laboratory director, who is not the
34 CLIA laboratory director, limited to his or her area of specialty or
35 subspecialty as described in subdivision (b), and shall only direct
36 a clinical laboratory providing service within those specialties or
37 subspecialties.

38 (C) If a person described in subparagraph (A) is qualified under
39 CLIA, he or she may perform clinical laboratory tests or
40 examinations classified as of high complexity under CLIA, and

1 the duties and responsibilities of a CLIA laboratory director,
2 technical consultant, clinical consultant, technical supervisor, and
3 general supervisor, as specified under CLIA, limited to his or her
4 area of specialty or subspecialty as described in subdivision (b),
5 and shall only direct a clinical laboratory providing service within
6 those specialties or subspecialties.

7 (2) A person licensed as a “clinical chemist,” or “clinical
8 microbiologist,” or “clinical toxicologist,” or “clinical genetic
9 molecular biologist,” or “clinical cytogeneticist,” or “clinical
10 reproductive biologist,” or “clinical biochemical geneticist,” or
11 “oral and maxillofacial pathologist” may perform any clinical
12 laboratory test or examination classified as waived or of moderate
13 complexity under CLIA.

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

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

23 (2) For a person licensed under this chapter as a clinical
24 microbiologist, the specialty of microbiology and the subspecialties
25 of bacteriology, mycobacteriology, mycology, parasitology,
26 virology, molecular biology, and serology for diagnosis of
27 infectious diseases, or other specialty or subspecialty specified by
28 regulation adopted by the department.

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

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

38 (5) For a person licensed under this chapter as a clinical
39 cytogeneticist, the subspecialty of cytogenetics within the specialty

1 of genetics or other specialty or subspecialty specified by regulation
2 adopted by the department.

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

7 ~~(7) For a person licensed under this chapter as a clinical
8 reproductive biologist, the specialty of reproductive biology or
9 other specialty or subspecialty specified by regulation adopted by
10 the department.~~

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

15 ~~SEC. 6.~~

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

18 1209. (a) As used in this chapter, “laboratory director” means
19 any person who is any of the following:

20 (1) A duly licensed physician and surgeon.

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

23 (A) A duly licensed clinical laboratory scientist.

24 (B) A duly licensed limited clinical laboratory scientist.

25 (C) A duly licensed naturopathic doctor.

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

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

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

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

1 (c) The laboratory director, if qualified under CLIA, may
2 perform the duties of the technical consultant, technical supervisor,
3 clinical consultant, general supervisor, and testing personnel, or
4 delegate these responsibilities to persons qualified under CLIA.
5 If the laboratory director reapportions performance of those
6 responsibilities or duties, he or she shall remain responsible for
7 ensuring that all those duties and responsibilities are properly
8 performed.

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

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

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

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

1 (1) Ensure that all personnel, prior to testing biological
2 specimens, have the appropriate education and experience, receive
3 the appropriate training for the type and complexity of the services
4 offered, and have demonstrated that they can perform all testing
5 operations reliably to provide and report accurate results. In
6 determining the adequacy of qualifications, the laboratory director
7 shall comply with any regulations adopted by the department that
8 specify the minimum qualifications for, and the type of procedures
9 that may be performed by, personnel in addition to any CLIA
10 requirements relative to the education or training of personnel.
11 Any regulations adopted pursuant to this section that specify the
12 type of procedure that may be performed by testing personnel shall
13 be based on the skills, knowledge, and tasks required to perform
14 the type of procedure in question.

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

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

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

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

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

- 1 (B) Monitoring the recording and reporting of test results.
2 (C) Review of intermediate test results or worksheets, quality
3 control records, proficiency testing results, and preventive
4 maintenance records.
5 (D) Direct observation of performance of instrument
6 maintenance and function checks.
7 (E) Assessment of test performance through testing previously
8 analyzed specimens, internal blind testing samples, or external
9 proficiency testing samples.
10 (F) Assessment of problem solving skills.
11 (2) Evaluation and documentation of staff competency and
12 performance shall occur at least semiannually during the first year
13 an individual tests biological specimens. Thereafter, evaluations
14 shall be performed at least annually unless test methodology or
15 instrumentation changes, in which case, prior to reporting patient
16 test results, the individual's performance shall be reevaluated to
17 include the use of the new test methodology or instrumentation.
18 (h) The laboratory director of each clinical laboratory of an
19 acute care hospital shall be a physician and surgeon who is a
20 qualified pathologist, except as follows:
21 (1) If a qualified pathologist is not available, a physician and
22 surgeon or a clinical laboratory bioanalyst qualified as a laboratory
23 director under subdivision (a) may direct the laboratory. However,
24 a qualified pathologist shall be available for consultation at suitable
25 intervals to ensure high-quality service.
26 (2) If there are two or more clinical laboratories of an acute care
27 hospital, those additional clinical laboratories that are limited to
28 the performance of blood gas analysis, blood electrolyte analysis,
29 or both, may be directed by a physician and surgeon qualified as
30 a laboratory director under subdivision (a), irrespective of whether
31 a pathologist is available.
32 As used in this subdivision, a qualified pathologist is a physician
33 and surgeon certified or eligible for certification in clinical or
34 anatomical pathology by the American Board of Pathology or the
35 American Osteopathic Board of Pathology.
36 (i) Subdivision (h) does not apply to any director of a clinical
37 laboratory of an acute care hospital acting in that capacity on or
38 before January 1, 1988.

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

4 ~~SEC. 7. Section 1210 of the Business and Professions Code is~~
5 ~~amended to read:~~

6 ~~1210. (a) As used in this chapter, “clinical chemist scientist,”~~
7 ~~“clinical microbiologist scientist,” “clinical toxicologist scientist,”~~
8 ~~“clinical immunohematologist scientist,” “clinical genetic~~
9 ~~molecular biologist scientist,” “clinical biochemical geneticist~~
10 ~~scientist,” “clinical reproductive biologist scientist,” “clinical~~
11 ~~cytogeneticist scientist,” and “clinical histocompatibility scientist”~~
12 ~~means any person, other than a person licensed to direct a clinical~~
13 ~~laboratory, or licensed as a clinical laboratory scientist or trainee,~~
14 ~~who is licensed under Sections 1261, 1261.5, and 1262 to engage~~
15 ~~in clinical laboratory practice. Such a licensed person who is~~
16 ~~qualified under CLIA may perform clinical laboratory tests~~
17 ~~classified as of high complexity under CLIA and the duties and~~
18 ~~responsibilities of a technical consultant, clinical consultant,~~
19 ~~technical supervisor, and general supervisor limited to the specialty~~
20 ~~or subspecialty as identified in subdivision (b) for which he or she~~
21 ~~is licensed by the department. A person licensed as a “clinical~~
22 ~~chemist scientist,” or “clinical microbiologist scientist,” or “clinical~~
23 ~~toxicologist scientist,” or “clinical immunohematologist scientist,”~~
24 ~~or “clinical genetic molecular biologist scientist,” or “clinical~~
25 ~~biochemical geneticist scientist,” or “clinical reproductive biologist~~
26 ~~scientist,” or “clinical cytogeneticist scientist,” or a “clinical~~
27 ~~histocompatibility scientist” may perform any clinical laboratory~~
28 ~~test or examination classified as waived or of moderate complexity~~
29 ~~under CLIA.~~

30 ~~(b) The specialties and subspecialties included in each of the~~
31 ~~license categories identified in subdivision (a), are the following:~~

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

37 ~~(2) For a person licensed under this chapter as a clinical~~
38 ~~microbiologist scientist, the specialty of microbiology and the~~
39 ~~subspecialties of bacteriology, mycobacteriology, mycology,~~
40 ~~parasitology, virology, or molecular biology and serology for~~

1 diagnosis of infectious diseases, or other specialty or subspecialty
2 specified by regulation adopted by the department.

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

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

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

16 ~~(6) For a person licensed under this chapter as a clinical
17 biochemical geneticist scientist, the subspecialty of biochemical
18 genetics within the specialty of genetics or other specialty or
19 subspecialty specified by regulation adopted by the department.~~

20 ~~(7) For a person licensed under this chapter as a clinical
21 reproductive biologist scientist, the specialty of reproductive
22 biology, or other specialty or subspecialty specified by regulation
23 adopted by the department.~~

24 ~~(8) For a person licensed under this chapter as a clinical
25 immunohematologist scientist, the specialty of immunohematology
26 or other specialty or subspecialty specified by regulation adopted
27 by the department.~~

28 ~~(9) For a person licensed under this chapter as a clinical
29 histocompatibility scientist, the specialty of histocompatibility or
30 other specialty or subspecialty specified by regulation adopted by
31 the department.~~

32 ~~(e) Clinical chemist scientists, clinical microbiologist scientists,
33 clinical toxicologist scientists, clinical immunohematologist
34 scientists, clinical genetic molecular biologist scientists, clinical
35 cytogeneticist scientists, and clinical histocompatibility scientists
36 shall engage in clinical laboratory practice authorized by their
37 licensure only under the overall operation and administration of a
38 laboratory director.~~

1 ~~SEC. 8.~~

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

4 1260. The department shall issue a clinical laboratory
5 bioanalyst’s license to each person who is a lawful holder of a
6 degree of master of arts, master of science, or an equivalent or
7 higher degree as determined by the department with a major in
8 chemical, physical, biological, or clinical laboratory sciences. This
9 education shall have been obtained in one or more established and
10 reputable institutions maintaining standards equivalent, as
11 determined by the department, to those institutions accredited by
12 the Western Association of Schools and Colleges or an essentially
13 equivalent accrediting agency, as determined by the department.
14 The applicant also shall have a minimum of four years’ experience
15 as a clinical laboratory scientist performing clinical laboratory
16 work embracing the various fields of clinical laboratory activity
17 in a clinical laboratory certified under CLIA. The quality and
18 variety of this experience shall be satisfactory to the department
19 and shall have been obtained within the six-year period
20 immediately antecedent to admission to the examination. The
21 applicant shall successfully pass a written examination and an oral
22 examination conducted by the department or a committee
23 designated by the department to conduct the examinations,
24 indicating that the applicant is properly qualified. The department
25 may issue a license without conducting a written examination to
26 an applicant who has passed a written examination of a national
27 accrediting board having requirements that are, in the determination
28 of the department, equal to or greater than those required by this
29 chapter and regulations adopted by the department. The department
30 shall establish by regulation the required courses to be included
31 in the college or university training.

32 ~~SEC. 9.~~ Section 1261.5 of the Business and Professions Code
33 is amended to read:

34 ~~1261.5.~~ The department may issue limited clinical laboratory
35 scientist’s licenses in chemistry, microbiology, toxicology,
36 histocompatibility, immunohematology, reproductive biology,
37 biochemical genetics, genetic molecular biology, cytogenetics, or
38 other areas of laboratory specialty or subspecialty when determined
39 to be necessary by the department in order for licensure categories
40 to keep abreast of changes in laboratory or scientific technology.

1 ~~Whenever the department determines that a new limited clinical~~
2 ~~laboratory scientist license category is necessary, it shall adopt~~
3 ~~regulations identifying the category and the areas of specialization~~
4 ~~included within the category.~~

5 ~~To qualify for admission to the examination for a special clinical~~
6 ~~laboratory scientist's license, an applicant shall have all the~~
7 ~~following:~~

8 ~~(a) Have graduated from a college or university maintaining~~
9 ~~standards equivalent, as determined by the department, to those~~
10 ~~institutions accredited by the Western Association of Schools and~~
11 ~~Colleges or an essentially equivalent accrediting agency with a~~
12 ~~baccalaureate or higher degree with a major appropriate to the~~
13 ~~field for which a license is being sought.~~

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

19 ~~(c) Whenever a limited clinical laboratory scientist's license is~~
20 ~~established for a specific area of specialization, the department~~
21 ~~may issue the license without examination to applicants who had~~
22 ~~met standards of education and training, defined by regulations,~~
23 ~~prior to the date of the adoption of implementing regulations.~~

24 ~~(d) The department shall adopt regulations to implement this~~
25 ~~section.~~

26 ~~SEC. 10. Section 1264 of the Business and Professions Code~~
27 ~~is amended to read:~~

28 ~~1264. The department shall issue a clinical chemist, clinical~~
29 ~~microbiologist, clinical toxicologist, clinical reproductive biologist,~~
30 ~~clinical biochemical geneticist, clinical molecular biologist, or~~
31 ~~clinical cytogeneticist license to each person who has applied for~~
32 ~~the license on forms provided by the department, who is a lawful~~
33 ~~holder of a master of science or doctoral degree in the specialty~~
34 ~~for which the applicant is seeking a license and who has met such~~
35 ~~additional reasonable qualifications of training, education, and~~
36 ~~experience as the department may establish by regulations. The~~
37 ~~department shall issue an oral and maxillofacial pathologist license~~
38 ~~to every applicant for licensure who has applied for the license on~~
39 ~~forms provided by the department, who is a registered Diplomate~~
40 ~~of the American Board of Oral and Maxillofacial Pathology, and~~

1 who meets any additional and reasonable qualifications of training,
2 education, and experience as the department may establish by
3 regulation.

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

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

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

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

1 ~~SEC. 11.~~

2 *SEC. 4.* Section 1300 of the Business and Professions Code is
3 amended to read:

4 1300. The amount of application, registration, and license fees
5 under this chapter shall be as follows:

6 (a) The application fee for a histocompatibility laboratory
7 director's, clinical laboratory bioanalyst's, clinical chemist's,
8 clinical microbiologist's, clinical laboratory toxicologist's, ~~clinical~~
9 ~~reproductive biologist's, clinical biochemical geneticist's,~~ clinical
10 cytogeneticist's, or clinical molecular biologist's license is
11 sixty-three dollars (\$63) commencing on July 1, 1983.

12 (b) The annual renewal fee for a histocompatibility laboratory
13 director's, clinical laboratory bioanalyst's, clinical chemist's,
14 clinical microbiologist's, clinical laboratory toxicologist's, ~~clinical~~
15 ~~reproductive biologist's, clinical biochemical geneticist's,~~ clinical
16 cytogeneticist's, or clinical molecular biologist's license is
17 sixty-three dollars (\$63) commencing on July 1, 1983.

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

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

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

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

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

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

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

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

- 1 (5) Between 50,001 and 75,000, inclusive, tests: one thousand
2 nine hundred sixty dollars (\$1,960).
- 3 (6) Between 75,001 and 100,000, inclusive, tests: two thousand
4 three hundred forty dollars (\$2,340).
- 5 (7) Between 100,001 and 500,000, inclusive, tests: two thousand
6 seven hundred forty dollars (\$2,740).
- 7 (8) Between 500,001 and 1,000,000, inclusive, tests: four
8 thousand nine hundred ten dollars (\$4,910).
- 9 (9) More than 1,000,000 tests: five thousand two hundred sixty
10 dollars (\$5,260) plus three hundred fifty dollars (\$350) for every
11 500,000 tests over 1,000,000, up to a maximum of 15,000,000
12 tests.
- 13 (g) A clinical laboratory performing tests or examinations
14 classified as of moderate or of high complexity under CLIA and
15 a clinical laboratory with a certificate issued under subdivision (c)
16 of Section 1223 shall pay an annual renewal fee based on the
17 number of tests it performed in the preceding calendar year, as
18 follows:
- 19 (1) Less than 2,001 tests: one hundred seventy dollars (\$170).
- 20 (2) Between 2,001 and 10,000, inclusive, tests: seven hundred
21 twenty dollars (\$720).
- 22 (3) Between 10,001 and 25,000, inclusive, tests: one thousand
23 one hundred fifteen dollars (\$1,115).
- 24 (4) Between 25,001 and 50,000, inclusive, tests: one thousand
25 three hundred eighty dollars (\$1,380).
- 26 (5) Between 50,001 and 75,000, inclusive, tests: one thousand
27 seven hundred sixty dollars (\$1,760).
- 28 (6) Between 75,001 and 100,000, inclusive, tests: two thousand
29 forty dollars (\$2,040).
- 30 (7) Between 100,001 and 500,000, inclusive, tests: two thousand
31 four hundred forty dollars (\$2,440).
- 32 (8) Between 500,001 and 1,000,000, inclusive, tests: four
33 thousand six hundred ten dollars (\$4,610).
- 34 (9) More than 1,000,000 tests per year: four thousand nine
35 hundred sixty dollars (\$4,960) plus three hundred fifty dollars
36 (\$350) for every 500,000 tests over 1,000,000, up to a maximum
37 of 15,000,000 tests.
- 38 (h) The application fee for a trainee's license is thirteen dollars
39 (\$13) commencing on July 1, 1983.

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

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

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

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

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

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

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

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

37 (q) The department shall establish an application fee and a
38 renewal fee for a medical laboratory technician license, the total
39 fees collected not to exceed the costs of the department for the
40 implementation and operation of the program licensing and

1 regulating medical laboratory technicians pursuant to Section
2 1260.3.

3 (r) The costs of the department to conduct any reinspections to
4 ensure compliance of a laboratory applying for initial licensure
5 shall be paid by the laboratory. This additional cost for each visit
6 shall be equal to the initial application fee and shall be paid by the
7 laboratory prior to issuance of a license. The department shall not
8 charge a reinspection fee if the reinspection is due to error or
9 omission on the part of the department.

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

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