

ASSEMBLY BILL

No. 761

Introduced by Assembly Member Roger Hernández

February 17, 2011

An act to amend Sections 1206.5 and 1209 of the Business and Professions Code, relating to optometrists.

LEGISLATIVE COUNSEL'S DIGEST

AB 761, as introduced, Roger Hernández. Optometrists.

Existing law provides for the regulation and licensure of clinical laboratories and 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 unless the test or examination is performed under the overall operation and administration of a laboratory director, as defined, and is performed by specified persons, including certain health care personnel. Existing law provides for the licensure and regulation of optometrists by the State Board of Optometry.

This bill would expand the category of persons who may perform clinical laboratory tests or examinations that are classified as waived to include licensed optometrists if the results of the tests can be lawfully utilized within their practice, and would provide that a laboratory director may include a licensed optometrist, as specified for purposes of waived examinations.

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 1206.5 of the Business and Professions
2 Code is amended to read:

3 1206.5. (a) Notwithstanding subdivision (b) of Section 1206
4 and except as otherwise provided in Section 1241, no person shall
5 perform a clinical laboratory test or examination classified as
6 waived under CLIA unless the clinical laboratory test or
7 examination is performed under the overall operation and
8 administration of the laboratory director, as described in Section
9 1209, including, but not limited to, documentation by the laboratory
10 director of the adequacy of the qualifications and competency of
11 the personnel, and the test is performed by any of the following
12 persons:

13 (1) A licensed physician and surgeon holding a M.D. or D.O.
14 degree.

15 (2) A licensed podiatrist, a licensed dentist, *a licensed*
16 *optometrist*, or a licensed naturopathic doctor, if the results of the
17 tests can be lawfully utilized within his or her practice.

18 (3) A person licensed under this chapter to engage in clinical
19 laboratory practice or to direct a clinical laboratory.

20 (4) A person authorized to perform tests pursuant to a certificate
21 issued under Article 5 (commencing with Section 101150) of
22 Chapter 2 of Part 3 of Division 101 of the Health and Safety Code.

23 (5) A licensed physician assistant if authorized by a supervising
24 physician and surgeon in accordance with Section 3502 or 3535.

25 (6) A person licensed under Chapter 6 (commencing with
26 Section 2700).

27 (7) A person licensed under Chapter 6.5 (commencing with
28 Section 2840).

29 (8) A perfusionist if authorized by and performed in compliance
30 with Section 2590.

31 (9) A respiratory care practitioner if authorized by and
32 performed in compliance with Chapter 8.3 (commencing with
33 Section 3700).

34 (10) A medical assistant, as defined in Section 2069, if the
35 waived test is performed pursuant to a specific authorization
36 meeting the requirements of Section 2069.

37 (11) A pharmacist, as defined in Section 4036, if ordering drug
38 therapy-related laboratory tests in compliance with clause (ii) of

1 subparagraph (A) of paragraph (5) of, or subparagraph (B) of
2 paragraph (4) of, subdivision (a) of Section 4052, or if performing
3 skin puncture in the course of performing routine patient
4 assessment procedures in compliance with Section 4052.1.

5 (12) A naturopathic assistant, as defined in Sections 3613 and
6 3640.2, if the waived test is performed pursuant to a specific
7 authorization meeting the requirements of Sections 3613 and
8 3640.2.

9 (13) Other health care personnel providing direct patient care.

10 (14) Any other person performing nondiagnostic testing pursuant
11 to Section 1244.

12 (b) Notwithstanding subdivision (b) of Section 1206, no person
13 shall perform clinical laboratory tests or examinations classified
14 as of moderate complexity under CLIA unless the clinical
15 laboratory test or examination is performed under the overall
16 operation and administration of the laboratory director, as described
17 in Section 1209, including, but not limited to, documentation by
18 the laboratory director of the adequacy of the qualifications and
19 competency of the personnel, and the test is performed by any of
20 the following persons:

21 (1) A licensed physician and surgeon holding a M.D. or D.O.
22 degree.

23 (2) A licensed podiatrist or a licensed dentist if the results of
24 the tests can be lawfully utilized within his or her practice.

25 (3) A person licensed under this chapter to engage in clinical
26 laboratory practice or to direct a clinical laboratory.

27 (4) A person authorized to perform tests pursuant to a certificate
28 issued under Article 5 (commencing with Section 101150) of
29 Chapter 2 of Part 3 of Division 101 of the Health and Safety Code.

30 (5) A licensed physician assistant if authorized by a supervising
31 physician and surgeon in accordance with Section 3502 or 3535.

32 (6) A person licensed under Chapter 6 (commencing with
33 Section 2700).

34 (7) A perfusionist if authorized by and performed in compliance
35 with Section 2590.

36 (8) A respiratory care practitioner if authorized by and
37 performed in compliance with Chapter 8.3 (commencing with
38 Section 3700).

39 (9) A person performing nuclear medicine technology if
40 authorized by and performed in compliance with Article 6

1 (commencing with Section 107150) of Chapter 4 of Part 1 of
2 Division 104 of the Health and Safety Code.

3 (10) Any person if performing blood gas analysis in compliance
4 with Section 1245.

5 (11) (A) A person certified or licensed as an “Emergency
6 Medical Technician II” or paramedic pursuant to Division 2.5
7 (commencing with Section 1797) of the Health and Safety Code
8 while providing prehospital medical care, a person licensed as a
9 psychiatric technician under Chapter 10 (commencing with Section
10 4500) of Division 2, as a vocational nurse pursuant to Chapter 6.5
11 (commencing with Section 2840), or as a midwife licensed pursuant
12 to Article 24 (commencing with Section 2505) of Chapter 5, or
13 certified by the department pursuant to Division 5 (commencing
14 with Section 70001) of Title 22 of the California Code of
15 Regulations as a nurse assistant or a home health aide, who
16 provides direct patient care, if the person is performing the test as
17 an adjunct to the provision of direct patient care by the person, is
18 utilizing a point-of-care laboratory testing device at a site for which
19 a laboratory license or registration has been issued, meets the
20 minimum clinical laboratory education, training, and experience
21 requirements set forth in regulations adopted by the department,
22 and has demonstrated to the satisfaction of the laboratory director
23 that he or she is competent in the operation of the point-of-care
24 laboratory testing device for each analyte to be reported.

25 (B) Prior to being authorized by the laboratory director to
26 perform laboratory tests or examinations, testing personnel
27 identified in subparagraph (A) shall participate in a preceptor
28 program until they are able to perform the clinical laboratory tests
29 or examinations authorized in this section with results that are
30 deemed accurate and skills that are deemed competent by the
31 preceptor. For the purposes of this section, a “preceptor program”
32 means an organized system that meets regulatory requirements in
33 which a preceptor provides and documents personal observation
34 and critical evaluation, including review of accuracy, reliability,
35 and validity, of laboratory testing performed.

36 (12) Any other person within a physician office laboratory if
37 the test is performed under the supervision of the patient’s
38 physician and surgeon or podiatrist who shall be accessible to the
39 laboratory to provide onsite, telephone, or electronic consultation
40 as needed, and shall: (A) ensure that the person is performing test

1 methods as required for accurate and reliable tests; and (B) have
2 personal knowledge of the results of the clinical laboratory testing
3 or examination performed by that person before the test results are
4 reported from the laboratory.

5 (13) A pharmacist, if ordering drug therapy-related laboratory
6 tests in compliance with clause (ii) of subparagraph (A) of
7 paragraph (5) of, or subparagraph (B) of paragraph (4) of,
8 subdivision (a) of Section 4052.

9 (c) Notwithstanding subdivision (b) of Section 1206, no person
10 shall perform clinical laboratory tests or examinations classified
11 as of high complexity under CLIA unless the clinical laboratory
12 test or examination is performed under the overall operation and
13 administration of the laboratory director, as described in Section
14 1209, including, but not limited to, documentation by the laboratory
15 director of the adequacy of the qualifications and competency of
16 the personnel, and the test is performed by any of the following
17 persons:

18 (1) A licensed physician and surgeon holding a M.D. or D.O.
19 degree.

20 (2) A licensed podiatrist or a licensed dentist if the results of
21 the tests can be lawfully utilized within his or her practice.

22 (3) A person licensed under this chapter to engage in clinical
23 laboratory practice or to direct a clinical laboratory if the test or
24 examination is within a specialty or subspecialty authorized by
25 the person's licensure.

26 (4) A person authorized to perform tests pursuant to a certificate
27 issued under Article 5 (commencing with Section 101150) of
28 Chapter 2 of Part 3 of Division 101 of the Health and Safety Code
29 if the test or examination is within a specialty or subspecialty
30 authorized by the person's certification.

31 (5) A licensed physician assistant if authorized by a supervising
32 physician and surgeon in accordance with Section 3502 or 3535.

33 (6) A perfusionist if authorized by and performed in compliance
34 with Section 2590.

35 (7) A respiratory care practitioner if authorized by and
36 performed in compliance with Chapter 8.3 (commencing with
37 Section 3700).

38 (8) A person performing nuclear medicine technology if
39 authorized by and performed in compliance with Article 6

1 (commencing with Section 107150) of Chapter 4 of Part 1 of
2 Division 104 of the Health and Safety Code.

3 (9) Any person if performing blood gas analysis in compliance
4 with Section 1245.

5 (10) Any other person within a physician office laboratory if
6 the test is performed under the onsite supervision of the patient’s
7 physician and surgeon or podiatrist who shall: (A) ensure that the
8 person is performing test methods as required for accurate and
9 reliable tests; and (B) have personal knowledge of the results of
10 clinical laboratory testing or examination performed by that person
11 before the test results are reported from the laboratory.

12 (d) Clinical laboratory examinations classified as
13 provider-performed microscopy under CLIA may be personally
14 performed using a brightfield or phase/contrast microscope by one
15 of the following practitioners:

16 (1) A licensed physician and surgeon using the microscope
17 during the patient’s visit on a specimen obtained from his or her
18 own patient or from a patient of a group medical practice of which
19 the physician is a member or employee.

20 (2) A nurse midwife holding a certificate as specified by Section
21 2746.5, a licensed nurse practitioner as specified in Section 2835.5,
22 or a licensed physician assistant acting under the supervision of a
23 physician pursuant to Section 3502 using the microscope during
24 the patient’s visit on a specimen obtained from his or her own
25 patient or from the patient of a clinic, group medical practice, or
26 other health care provider of which the certified nurse midwife,
27 licensed nurse practitioner, or licensed physician assistant is an
28 employee.

29 (3) A licensed dentist using the microscope during the patient’s
30 visit on a specimen obtained from his or her own patient or from
31 a patient of a group dental practice of which the dentist is a member
32 or an employee.

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

35 1209. (a) As used in this chapter, “laboratory director” means
36 any person who is a duly licensed physician and surgeon, or, only
37 for purposes of a clinical laboratory test or examination classified
38 as waived, is a duly licensed naturopathic doctor, *or a duly licensed*
39 *optometrist*, or is licensed to direct a clinical laboratory under this
40 chapter and who substantially meets the laboratory director

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

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

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

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

38 (d) As part of the overall operation and administration, the
39 laboratory director of a licensed laboratory shall do all of the
40 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 (e) 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 (f) The laboratory director of each clinical laboratory of an acute
- 19 care hospital shall be a physician and surgeon who is a qualified
- 20 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 (g) Subdivision (f) 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 (h) 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.

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