Assembly Bill No. 761

CHAPTER 714

An act to amend Sections 1206.5, 1209, and 3041 of the Business and Professions Code, relating to optometrists.

[Approved by Governor September 28, 2012. Filed with Secretary of State September 28, 2012.]

LEGISLATIVE COUNSEL'S DIGEST

AB 761, 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, and requires certification by the board for a licensed optometrist to use therapeutic pharmaceutical agents. Existing law authorizes a licensed optometrist certified to use therapeutic pharmaceutical agents to diagnose and treat specified conditions.

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, and would provide that a laboratory director may include a licensed optometrist serving as the director of a laboratory which only performs specified clinical laboratory testing, for purposes of waived examinations. The bill would authorize a licensed optometrist certified to use therapeutic pharmaceutical agents to additionally perform specified clinical laboratory tests or examinations classified as waived that are necessary for the diagnosis of conditions and diseases of the eye or adnexa, which the bill would define to mean ocular adnexa.

This bill would also incorporate changes to Section 1206.5 of the Business and Professions Code proposed by SB 1481 that would become operative only if SB 1481 and this bill are chaptered and become effective on or before January 1, 2013, and this bill is chaptered last.

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

SECTION 1. Section 1206.5 of the Business and Professions Code is amended to read:
1206.5. (a) Notwithstanding subdivision (b) of Section 1206 and except as otherwise provided in Section 1241, no person shall perform a clinical laboratory test or examination classified as waived under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:

1. A licensed physician and surgeon holding a M.D. or D.O. degree.
2. A licensed podiatrist, a licensed dentist, or a licensed naturopathic doctor, if the results of the tests can be lawfully utilized within his or her practice.
3. A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory.
4. A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code.
5. A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or 3535.
6. A person licensed under Chapter 6 (commencing with Section 2700).
7. A person licensed under Chapter 6.5 (commencing with Section 2840).
8. A perfusionist if authorized by and performed in compliance with Section 2590.
9. A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).
10. A medical assistant, as defined in Section 2069, if the waived test is performed pursuant to a specific authorization meeting the requirements of Section 2069.
11. A pharmacist, as defined in Section 4036, if ordering drug therapy-related laboratory tests in compliance with clause (ii) of subdivision (a) of Section 1241 of Part 3 of Division 101 of the Health and Safety Code.
12. A naturopathic doctor, if authorized by a supervising physician and surgeon in accordance with Section 3502 or 3535.
13. A person licensed under Chapter 7 (commencing with Section 3000).
14. Other health care personnel providing direct patient care.
15. Any other person performing nondiagnostic testing pursuant to Section 1244.

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

1. A licensed physician and surgeon holding a M.D. or D.O. degree.
2. A licensed podiatrist, a licensed dentist, or a licensed naturopathic doctor, if the results of the tests can be lawfully utilized within his or her practice.
3. A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory.
4. A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code.
5. A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or 3535.
6. A person licensed under Chapter 6 (commencing with Section 2700).
7. A person licensed under Chapter 6.5 (commencing with Section 2840).
8. A perfusionist if authorized by and performed in compliance with Section 2590.
9. A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).
10. A medical assistant, as defined in Section 2069, if the waived test is performed pursuant to a specific authorization meeting the requirements of Section 2069.
11. A pharmacist, as defined in Section 4036, if ordering drug therapy-related laboratory tests in compliance with clause (ii) of subdivision (a) of Section 1241 of Part 3 of Division 101 of the Health and Safety Code.
12. A naturopathic doctor, if authorized by a supervising physician and surgeon in accordance with Section 3502 or 3535.
13. A person licensed under Chapter 7 (commencing with Section 3000).
14. Other health care personnel providing direct patient care.
15. Any other person performing nondiagnostic testing pursuant to Section 1244.
director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:

1. A licensed physician and surgeon holding a M.D. or D.O. degree.
2. A licensed podiatrist or a licensed dentist if the results of the tests can be lawfully utilized within his or her practice.
3. A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory.
4. A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code.
5. A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or 3535.
6. A person licensed under Chapter 6 (commencing with Section 2700).
7. A perfusionist if authorized by and performed in compliance with Section 2590.
8. A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).
9. A person performing nuclear medicine technology if authorized by and performed in compliance with Article 6 (commencing with Section 107150) of Chapter 4 of Part 1 of Division 104 of the Health and Safety Code.
10. Any person if performing blood gas analysis in compliance with Section 1245.
11. (A) A person certified or licensed as an “Emergency Medical Technician II” or paramedic pursuant to Division 2.5 (commencing with Section 1797) of the Health and Safety Code while providing prehospital medical care, a person licensed as a psychiatric technician under Chapter 10 (commencing with Section 4500) of Division 2, as a vocational nurse pursuant to Chapter 6.5 (commencing with Section 2840), or as a midwife licensed pursuant to Article 24 (commencing with Section 2505) of Chapter 5, or certified by the department pursuant to Division 5 (commencing with Section 70001) of Title 22 of the California Code of Regulations as a nurse assistant or a home health aide, who provides direct patient care, if the person is performing the test as an adjunct to the provision of direct patient care by the person, is utilizing a point-of-care laboratory testing device at a site for which a laboratory license or registration has been issued, meets the minimum clinical laboratory education, training, and experience requirements set forth in regulations adopted by the department, and has demonstrated to the satisfaction of the laboratory director that he or she is competent in the operation of the point-of-care laboratory testing device for each analyte to be reported.
   (B) Prior to being authorized by the laboratory director to perform laboratory tests or examinations, testing personnel identified in subparagraph (A) shall participate in a preceptor program until they are able to perform the clinical laboratory tests or examinations authorized in this section with
results that are deemed accurate and skills that are deemed competent by
the preceptor. For the purposes of this section, a “preceptor program” means
an organized system that meets regulatory requirements in which a preceptor
provides and documents personal observation and critical evaluation,
including review of accuracy, reliability, and validity, of laboratory testing
performed.

(12) Any other person within a physician office laboratory if the test is
performed under the supervision of the patient’s physician and surgeon or
podiatrist who shall be accessible to the laboratory to provide onsite,
telephone, or electronic consultation as needed, and shall: (A) ensure that
the person is performing test methods as required for accurate and reliable
tests; and (B) have personal knowledge of the results of the clinical
laboratory testing or examination performed by that person before the test
results are reported from the laboratory.

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

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

(1) A licensed physician and surgeon holding a M.D. or D.O. degree.
(2) A licensed podiatrist or a licensed dentist if the results of the tests
can be lawfully utilized within his or her practice.
(3) A person licensed under this chapter to engage in clinical laboratory
practice or to direct a clinical laboratory if the test or examination is within
a specialty or subspecialty authorized by the person’s licensure.
(4) A person authorized to perform tests pursuant to a certificate issued
under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3
of Division 101 of the Health and Safety Code if the test or examination is
within a specialty or subspecialty authorized by the person’s certification.
(5) A licensed physician assistant if authorized by a supervising physician
and surgeon in accordance with Section 3502 or 3535.
(6) A perfusionist if authorized by and performed in compliance with
Section 2590.
(7) A respiratory care practitioner if authorized by and performed in
compliance with Chapter 8.3 (commencing with Section 3700).
(8) A person performing nuclear medicine technology if authorized by
and performed in compliance with Article 6 (commencing with Section
107150) of Chapter 4 of Part 1 of Division 104 of the Health and Safety
Code.
(9) Any person if performing blood gas analysis in compliance with
Section 1245.
(10) Any other person within a physician office laboratory if the test is
performed under the onsite supervision of the patient’s physician and surgeon
or podiatrist who shall: (A) ensure that the person is performing test methods
as required for accurate and reliable tests; and (B) have personal knowledge
of the results of clinical laboratory testing or examination performed by that
person before the test results are reported from the laboratory.

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

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

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

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

SEC. 1.5. Section 1206.5 of the Business and Professions Code is
amended to read:

1206.5. (a) Notwithstanding subdivision (b) of Section 1206 and except
as otherwise provided in Sections 1206.6 and 1241, no person shall perform
a clinical laboratory test or examination classified as waived under CLIA
unless the clinical laboratory test or examination is performed under the
overall operation and administration of the laboratory director, as described
in Section 1209, including, but not limited to, documentation by the
laboratory director of the adequacy of the qualifications and competency
of the personnel, and the test is performed by any of the following persons:

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

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

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

(4) A person authorized to perform tests pursuant to a certificate issued
under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3

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

(6) A person licensed under Chapter 6 (commencing with Section 2700).
(7) A person licensed under Chapter 6.5 (commencing with Section 2840).
(8) A perfusionist if authorized by and performed in compliance with Section 2590.
(9) A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).
(10) A medical assistant, as defined in Section 2069, if the waived test is performed pursuant to a specific authorization meeting the requirements of Section 2069.
(11) A pharmacist, as defined in Section 4036, if ordering drug therapy-related laboratory tests in compliance with paragraph (2) of subdivision (a) of Section 4052.1 or paragraph (2) of subdivision (a) of Section 4052.2, or if performing skin puncture in the course of performing routine patient assessment procedures in compliance with Section 4052.1.
(12) A naturopathic assistant, as defined in Sections 3613 and 3640.2, if the waived test is performed pursuant to a specific authorization meeting the requirements of Sections 3613 and 3640.2.
(13) A licensed optometrist as authorized under Chapter 7 (commencing with Section 3000).
(14) Other health care personnel providing direct patient care.
(15) Any other person performing nondiagnostic testing pursuant to Section 1244.
(b) Notwithstanding subdivision (b) of Section 1206, no person shall perform clinical laboratory tests or examinations classified as of moderate complexity under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:
(1) A licensed physician and surgeon holding a M.D. or D.O. degree.
(2) A licensed podiatrist or a licensed dentist if the results of the tests can be lawfully utilized within his or her practice.
(3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory.
(4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code.
(5) A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or 3535.
(6) A person licensed under Chapter 6 (commencing with Section 2700).
(7) A perfusionist if authorized by and performed in compliance with Section 2590.
(8) A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).
(9) A person performing nuclear medicine technology if authorized by and performed in compliance with Article 6 (commencing with Section
(10) Any person if performing blood gas analysis in compliance with Section 1245.

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

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

(12) Any other person within a physician office laboratory if the test is performed under the supervision of the patient’s physician and surgeon or podiatrist who shall be accessible to the laboratory to provide onsite, telephone, or electronic consultation as needed, and shall: (A) ensure that the person is performing test methods as required for accurate and reliable tests; and (B) have personal knowledge of the results of the clinical laboratory testing or examination performed by that person before the test results are reported from the laboratory.

(13) A pharmacist, if ordering drug therapy-related laboratory tests in compliance with paragraph (2) of subdivision (a) of Section 4052.1 or paragraph (2) of subdivision (a) of Section 4052.2.

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

1. A licensed physician and surgeon holding a M.D. or D.O. degree.
2. A licensed podiatrist or a licensed dentist if the results of the tests can be lawfully utilized within his or her practice.
3. A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory if the test or examination is within a specialty or subspecialty authorized by the person’s licensure.
4. A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code if the test or examination is within a specialty or subspecialty authorized by the person’s certification.
5. A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or 3535.
6. A perfusionist if authorized by and performed in compliance with Section 2590.
7. A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).
8. A person performing nuclear medicine technology if authorized by and performed in compliance with Article 6 (commencing with Section 107150) of Chapter 4 of Part 1 of Division 104 of the Health and Safety Code.
9. Any person if performing blood gas analysis in compliance with Section 1245.
10. Any other person within a physician office laboratory if the test is performed under the onsite supervision of the patient’s physician and surgeon or podiatrist who shall: (A) ensure that the person is performing test methods as required for accurate and reliable tests; and (B) have personal knowledge of the results of clinical laboratory testing or examination performed by that person before the test results are reported from the laboratory.

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

1. A licensed physician and surgeon using the microscope during the patient’s visit on a specimen obtained from his or her own patient or from a patient of a group medical practice of which the physician is a member or employee.
2. A nurse midwife holding a certificate as specified by Section 2746.5, a licensed nurse practitioner as specified in Section 2835.5, or a licensed physician assistant acting under the supervision of a physician pursuant to Section 3502 using the microscope during the patient’s visit on a specimen obtained from his or her own patient or from the patient of a clinic, group medical practice, or other health care provider of which the certified nurse midwife, licensed nurse practitioner, or licensed physician assistant is an employee.
(3) A licensed dentist using the microscope during the patient’s visit on a specimen obtained from his or her own patient or from a patient of a group dental practice of which the dentist is a member or an employee.

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

1209. (a) As used in this chapter, “laboratory director” means any person who is a duly licensed physician and surgeon, or, only for purposes of a clinical laboratory test or examination classified as waived, is a duly licensed naturopathic doctor, or a duly licensed optometrist serving as the director of a laboratory which only performs clinical laboratory tests authorized in paragraph (10) of subdivision (e) of Section 3041 that are classified as waived, or is licensed to direct a clinical laboratory under this chapter and who substantially meets the laboratory director qualifications under CLIA for the type and complexity of tests being offered by the laboratory. The laboratory director, if qualified under CLIA, may perform the duties of the technical consultant, technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to persons qualified under CLIA. If the laboratory director reapportions performance of those responsibilities or duties, he or she shall remain responsible for ensuring that all those duties and responsibilities are properly performed.

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

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

(c) As part of the overall operation and administration, the laboratory director of a registered laboratory shall document the adequacy of the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory test procedures and examinations. In determining the adequacy of qualifications, the laboratory director shall comply with any regulations adopted by the department that specify the minimum qualifications for personnel, in addition to any CLIA requirements relative to the education or training of personnel.
(d) As part of the overall operation and administration, the laboratory director of a licensed laboratory shall do all of the following:

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

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

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

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

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

   A. Direct observations of routine patient test performance, including patient preparation, if applicable, and specimen handling, processing, and testing.

   B. Monitoring the recording and reporting of test results.

   C. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

   D. Direct observation of performance of instrument maintenance and function checks.

   E. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples.

   F. Assessment of problem solving skills.
(2) Evaluation and documentation of staff competency and performance shall occur at least semiannually during the first year an individual tests biological specimens. Thereafter, evaluations shall be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual’s performance shall be reevaluated to include the use of the new test methodology or instrumentation.

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

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

(2) If there are two or more clinical laboratories of an acute care hospital, those additional clinical laboratories that are limited to the performance of blood gas analysis, blood electrolyte analysis, or both, may be directed by a physician and surgeon qualified as a laboratory director under subdivision (a), irrespective of whether a pathologist is available.

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

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

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

SEC. 3. Section 3041 of the Business and Professions Code is amended to read:

3041. (a) The practice of optometry includes the prevention and diagnosis of disorders and dysfunctions of the visual system, and the treatment and management of certain disorders and dysfunctions of the visual system, as well as the provision of rehabilitative optometric services, and is the doing of any or all of the following:

(1) The examination of the human eye or eyes, or its or their appendages, and the analysis of the human vision system, either subjectively or objectively.

(2) The determination of the powers or range of human vision and the accommodative and refractive states of the human eye or eyes, including the scope of its or their functions and general condition.

(3) The prescribing or directing the use of, or using, any optical device in connection with ocular exercises, visual training, vision training, or orthoptics.

(4) The prescribing of contact and spectacle lenses for, or the fitting or adaptation of contact and spectacle lenses to, the human eye, including
lenses that may be classified as drugs or devices by any law of the United States or of this state.

(5) The use of topical pharmaceutical agents for the purpose of the examination of the human eye or eyes for any disease or pathological condition.

(b) (1) An optometrist who is certified to use therapeutic pharmaceutical agents, pursuant to Section 3041.3, may also diagnose and treat the human eye or eyes, or any of its or their appendages, for all of the following conditions:

(A) Through medical treatment, infections of the anterior segment and adnexa, excluding the lacrimal gland, the lacrimal drainage system, and the sclera in patients under 12 years of age.

(B) Ocular allergies of the anterior segment and adnexa.

(C) Ocular inflammation, nonsurgical in cause except when comanaged with the treating physician and surgeon, limited to inflammation resulting from traumatic iritis, peripheral corneal inflammatory keratitis, episcleritis, and unilateral nonrecurrent nongranulomatous idiopathic iritis in patients over 18 years of age. Unilateral nongranulomatous idiopathic iritis recurring within one year of the initial occurrence shall be referred to an ophthalmologist. An optometrist shall consult with an ophthalmologist or appropriate physician and surgeon if a patient has a recurrent case of episcleritis within one year of the initial occurrence. An optometrist shall consult with an ophthalmologist or appropriate physician and surgeon if a patient has a recurrent case of peripheral corneal inflammatory keratitis within one year of the initial occurrence.

(D) Traumatic or recurrent conjunctival or corneal abrasions and erosions.

(E) Corneal surface disease and dry eyes.

(F) Ocular pain, nonsurgical in cause except when comanaged with the treating physician and surgeon, associated with conditions optometrists are authorized to treat.

(G) Pursuant to subdivision (f), glaucoma in patients over 18 years of age, as described in subdivision (j).

(2) For purposes of this section, “treat” means the use of therapeutic pharmaceutical agents, as described in subdivision (c), and the procedures described in subdivision (e).

(c) In diagnosing and treating the conditions listed in subdivision (b), an optometrist certified to use therapeutic pharmaceutical agents pursuant to Section 3041.3 may use all of the following therapeutic pharmaceutical agents:

(1) Pharmaceutical agents as described in paragraph (5) of subdivision (a), as well as topical miotics.

(2) Topical lubricants.

(3) Antiinflammatories. In using topical steroid medication for the treatment of ocular allergies, an optometrist shall consult with an ophthalmologist if the patient’s condition worsens 21 days after diagnosis.

(4) Topical and oral anti-inflammatories. In using steroid medication for:
(A) Unilateral nonrecurrent nongranulomatous idiopathic iritis or episcleritis, an optometrist shall consult with an ophthalmologist or appropriate physician and surgeon if the patient’s condition worsens 72 hours after the diagnosis, or if the patient’s condition has not resolved three weeks after diagnosis. If the patient is still receiving medication for these conditions six weeks after diagnosis, the optometrist shall refer the patient to an ophthalmologist or appropriate physician and surgeon.

(B) Peripheral corneal inflammatory keratitis, excluding Moorens and Terriens diseases, an optometrist shall consult with an ophthalmologist or appropriate physician and surgeon if the patient’s condition worsens 72 hours after diagnosis.

(C) Traumatic iritis, an optometrist shall consult with an ophthalmologist or appropriate physician and surgeon if the patient’s condition worsens 72 hours after diagnosis and shall refer the patient to an ophthalmologist or appropriate physician and surgeon if the patient’s condition has not resolved one week after diagnosis.

(5) Topical antibiotic agents.
(6) Topical hyperosmotics.
(7) Topical and oral antiglaucoma agents pursuant to the certification process defined in subdivision (f).

(A) The optometrist shall refer the patient to an ophthalmologist if requested by the patient or if angle closure glaucoma develops.

(B) If the glaucoma patient also has diabetes, the optometrist shall consult with the physician treating the patient’s diabetes in developing the glaucoma treatment plan and shall inform the physician in writing of any changes in the patient’s glaucoma medication.

(8) Nonprescription medications used for the rational treatment of an ocular disorder.

(9) Oral antihistamines.
(10) Prescription oral nonsteroidal anti-inflammatory agents.
(11) Oral antibiotics for medical treatment of ocular disease.

(A) If the patient has been diagnosed with a central corneal ulcer and the central corneal ulcer has not improved 48 hours after diagnosis, the optometrist shall refer the patient to an ophthalmologist.

(B) If the patient has been diagnosed with preseptal cellulitis or dacryocystitis and the condition has not improved 48 hours after diagnosis, the optometrist shall refer the patient to an ophthalmologist.

(12) Topical and oral antiviral medication for the medical treatment of the following: herpes simplex viral keratitis, herpes simplex viral conjunctivitis, and periocular herpes simplex viral dermatitis; and varicella zoster viral keratitis, varicella zoster viral conjunctivitis, and periocular varicella zoster viral dermatitis.

(A) If the patient has been diagnosed with herpes simplex keratitis or varicella zoster viral keratitis and the patient’s condition has not improved seven days after diagnosis, the optometrist shall refer the patient to an ophthalmologist. If a patient’s condition has not resolved three weeks after diagnosis, the optometrist shall refer the patient to an ophthalmologist.
(B) If the patient has been diagnosed with herpes simplex viral conjunctivitis, herpes simplex viral dermatitis, varicella zoster viral conjunctivitis, or varicella zoster viral dermatitis, and if the patient’s condition worsens seven days after diagnosis, the optometrist shall consult with an ophthalmologist. If the patient’s condition has not resolved three weeks after diagnosis, the optometrist shall refer the patient to an ophthalmologist.

(13) Oral analgesics that are not controlled substances.

(14) Codeine with compounds and hydrocodone with compounds as listed in the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code) and the United States Uniform Controlled Substances Act (21 U.S.C. Sec. 801 et seq.). The use of these agents shall be limited to three days, with a referral to an ophthalmologist if the pain persists.

(d) In any case where this chapter requires that an optometrist consult with an ophthalmologist, the optometrist shall maintain a written record in the patient’s file of the information provided to the ophthalmologist, the ophthalmologist’s response, and any other relevant information. Upon the consulting ophthalmologist’s request and with the patient’s consent, the optometrist shall furnish a copy of the record to the ophthalmologist.

(e) An optometrist who is certified to use therapeutic pharmaceutical agents pursuant to Section 3041.3 may also perform all of the following:

(1) Corneal scraping with cultures.
(2) Debridement of corneal epithelia.
(3) Mechanical epilation.
(4) Venipuncture for testing patients suspected of having diabetes.
(5) Suture removal, with prior consultation with the treating physician and surgeon.
(6) Treatment or removal of sebaceous cysts by expression.
(7) Administration of oral fluorescein to patients suspected as having diabetic retinopathy.
(8) Use of an auto-injector to counter anaphylaxis.
(9) Ordering of smears, cultures, sensitivities, complete blood count, mycobacterial culture, acid fast stain, urinalysis, tear fluid analysis, and X-rays necessary for the diagnosis of conditions or diseases of the eye or adnexa. An optometrist may order other types of images subject to prior consultation with an ophthalmologist or appropriate physician and surgeon.
(10) A clinical laboratory test or examination classified as waived under CLIA and designated as waived in paragraph (9) necessary for the diagnosis of conditions and diseases of the eye or adnexa, or if otherwise specifically authorized by this chapter.
(11) Punctal occlusion by plugs, excluding laser, diathermy, cryotherapy, or other means constituting surgery as defined in this chapter.
(12) The prescription of therapeutic contact lenses, including lenses or devices that incorporate a medication or therapy the optometrist is certified to prescribe or provide.
(13) Removal of foreign bodies from the cornea, eyelid, and conjunctiva with any appropriate instrument other than a scalpel or needle. Corneal foreign bodies shall be nonperforating, be no deeper than the midstroma, and require no surgical repair upon removal.

(14) For patients over 12 years of age, lacrimal irrigation and dilation, excluding probing of the nasal lacrimal tract. The board shall certify any optometrist who graduated from an accredited school of optometry before May 1, 2000, to perform this procedure after submitting proof of satisfactory completion of 10 procedures under the supervision of an ophthalmologist as confirmed by the ophthalmologist. Any optometrist who graduated from an accredited school of optometry on or after May 1, 2000, shall be exempt from the certification requirement contained in this paragraph.

The board shall grant a certificate to an optometrist certified pursuant to Section 3041.3 for the treatment of glaucoma, as described in subdivision (j), in patients over 18 years of age after the optometrist meets the following applicable requirements:

(1) For licensees who graduated from an accredited school of optometry on or after May 1, 2008, submission of proof of graduation from that institution.

(2) For licensees who were certified to treat glaucoma under this section prior to January 1, 2009, submission of proof of completion of that certification program.

(3) For licensees who have substantially completed the certification requirements pursuant to this section in effect between January 1, 2001, and December 31, 2008, submission of proof of completion of those requirements on or before December 31, 2009. “Substantially completed” means both of the following:

(A) Satisfactory completion of a didactic course of not less than 24 hours in the diagnosis, pharmacological, and other treatment and management of glaucoma.

(B) Treatment of 50 glaucoma patients with a collaborating ophthalmologist for a period of two years for each patient that will conclude on or before December 31, 2009.

(4) For licensees who completed a didactic course of not less than 24 hours in the diagnosis, pharmacological, and other treatment and management of glaucoma, submission of proof of satisfactory completion of the case management requirements for certification established by the board pursuant to Section 3041.10.

(5) For licensees who graduated from an accredited school of optometry on or before May 1, 2008, and not described in paragraph (2), (3), or (4), submission of proof of satisfactory completion of the requirements for certification established by the board pursuant to Section 3041.10.

(g) Other than for prescription ophthalmic devices described in subdivision (b) of Section 2541, any dispensing of a therapeutic pharmaceutical agent by an optometrist shall be without charge.

(h) The practice of optometry does not include performing surgery. “Surgery” means any procedure in which human tissue is cut, altered, or
otherwise infiltrated by mechanical or laser means. “Surgery” does not include those procedures specified in subdivision (e). Nothing in this section shall limit an optometrist’s authority to utilize diagnostic laser and ultrasound technology within his or her scope of practice.

(i) An optometrist licensed under this chapter is subject to the provisions of Section 2290.5 for purposes of practicing telehealth.

(j) For purposes of this chapter, “glaucoma” means either of the following:
   (1) All primary open-angle glaucoma.
   (2) Exfoliation and pigmentary glaucoma.

(k) For purposes of this chapter, “adnexa” means ocular adnexa.

(l) In an emergency, an optometrist shall stabilize, if possible, and immediately refer any patient who has an acute attack of angle closure to an ophthalmologist.

SEC. 4. Section 1.5 of this bill incorporates amendments to Section 1206.5 of the Business and Professions Code proposed by both this bill and Senate Bill 1481. It shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2013, (2) each bill amends Section 1206.5 of the Business and Professions Code, and (3) this bill is enacted after Senate Bill 1481, in which case Section 1 of this bill shall not become operative.