

AMENDED IN ASSEMBLY AUGUST 2, 2010

AMENDED IN ASSEMBLY JUNE 15, 2010

AMENDED IN SENATE APRIL 15, 2010

AMENDED IN SENATE APRIL 5, 2010

SENATE BILL

No. 1246

Introduced by Senator Negrete McLeod

February 19, 2010

An act to amend Sections 1206.5, 1209, and 3613 of, and to add Sections 3640.2 and 3640.3 to, the Business and Professions Code, relating to naturopathic medicine.

LEGISLATIVE COUNSEL'S DIGEST

SB 1246, as amended, Negrete McLeod. Naturopathic medicine.

Existing law provides for the regulation and licensure of clinical laboratories and clinical laboratory personnel by the State Department of Health Care Services. 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, the Naturopathic Doctors Act, provides for the regulation and licensure of naturopathic doctors by the Naturopathic Medicine Committee.

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

purposes of waived examinations. The bill would define a naturopathic assistant for purposes of the Naturopathic Doctors Act, would authorize those assistants to perform certain medical procedures under the supervision of a naturopathic doctor, and would also authorize those assistants to perform specified naturopathic technical support services, and additional technical support services under regulations and standards established by the Naturopathic Medicine Committee. The bill would prohibit a naturopathic assistant from being employed for inpatient care in a licensed general acute care hospital.

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, or a licensed
16 naturopathic doctor, if the results of the tests can be lawfully
17 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).

1 (7) A person licensed under Chapter 6.5 (commencing with
2 Section 2840).

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

5 (9) A respiratory care practitioner if authorized by and
6 performed in compliance with Chapter 8.3 (commencing with
7 Section 3700).

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

11 (11) A pharmacist, as defined in Section 4036, if ordering drug
12 therapy-related laboratory tests in compliance with clause (ii) of
13 subparagraph (A) of paragraph (5) of, or subparagraph (B) of
14 paragraph (4) of, subdivision (a) of Section 4052, or if performing
15 skin puncture in the course of performing routine patient
16 assessment procedures in compliance with Section 4052.1.

17 (12) A naturopathic assistant, as defined in Sections 3613 and
18 3640.2, if the waived test is performed pursuant to a specific
19 authorization meeting the requirements of Sections 3613 and
20 3640.2.

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

22 (14) Any other person performing nondiagnostic testing pursuant
23 to Section 1244.

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

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

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

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

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

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

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

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

10 (8) A respiratory care practitioner if authorized by and
11 performed in compliance with Chapter 8.3 (commencing with
12 Section 3700).

13 (9) A person performing nuclear medicine technology if
14 authorized by and performed in compliance with Article 6
15 (commencing with Section 107150) of Chapter 4 of Part 1 of
16 Division 104 of the Health and Safety Code.

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

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

39 (B) Prior to being authorized by the laboratory director to
40 perform laboratory tests or examinations, testing personnel

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

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

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

23 (c) Notwithstanding subdivision (b) of Section 1206, no person
24 shall perform clinical laboratory tests or examinations classified
25 as of high complexity under CLIA unless the clinical laboratory
26 test or examination is performed under the overall operation and
27 administration of the laboratory director, as described in Section
28 1209, including, but not limited to, documentation by the laboratory
29 director of the adequacy of the qualifications and competency of
30 the personnel, and the test is performed by any of the following
31 persons:

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

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

36 (3) A person licensed under this chapter to engage in clinical
37 laboratory practice or to direct a clinical laboratory if the test or
38 examination is within a specialty or subspecialty authorized by
39 the person’s licensure.

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

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

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

10 (7) A respiratory care practitioner if authorized by and
11 performed in compliance with Chapter 8.3 (commencing with
12 Section 3700).

13 (8) A person performing nuclear medicine technology if
14 authorized by and performed in compliance with Article 6
15 (commencing with Section 107150) of Chapter 4 of Part 1 of
16 Division 104 of the Health and Safety Code.

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

19 (10) Any other person within a physician office laboratory if
20 the test is performed under the onsite supervision of the patient's
21 physician and surgeon or podiatrist who shall: (A) ensure that the
22 person is performing test methods as required for accurate and
23 reliable tests; and (B) have personal knowledge of the results of
24 clinical laboratory testing or examination performed by that person
25 before the test results are reported from the laboratory.

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

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

34 (2) A nurse midwife holding a certificate as specified by Section
35 2746.5, a licensed nurse practitioner as specified in Section 2835.5,
36 or a licensed physician assistant acting under the supervision of a
37 physician pursuant to Section 3502 using the microscope during
38 the patient's visit on a specimen obtained from his or her own
39 patient or from the patient of a clinic, group medical practice, or
40 other health care provider of which the certified nurse midwife,

1 licensed nurse practitioner, or licensed physician assistant is an
2 employee.

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

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

9 1209. (a) As used in this chapter, "laboratory director" means
10 any person who is a duly licensed physician and surgeon, or, only
11 for purposes of a clinical laboratory test or examination classified
12 as waived, is a duly licensed naturopathic doctor, or is licensed to
13 direct a clinical laboratory under this chapter and who substantially
14 meets the laboratory director qualifications under CLIA for the
15 type and complexity of tests being offered by the laboratory. The
16 laboratory director, if qualified under CLIA, may perform the
17 duties of the technical consultant, technical supervisor, clinical
18 consultant, general supervisor, and testing personnel, or delegate
19 these responsibilities to persons qualified under CLIA. If the
20 laboratory director reapportions performance of those
21 responsibilities or duties, he or she shall remain responsible for
22 ensuring that all those duties and responsibilities are properly
23 performed.

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

37 (2) Where a point-of-care laboratory testing device is utilized
38 and provides results for more than one analyte, the testing
39 personnel may perform and report the results of all tests ordered

1 for each analyte for which he or she has been found by the
2 laboratory director to be competent to perform and report.

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

13 (d) As part of the overall operation and administration, the
14 laboratory director of a licensed laboratory shall do all of the
15 following:

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

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

37 (3) Specify in writing the responsibilities and duties of each
38 individual engaged in the performance of the preanalytic, analytic,
39 and postanalytic phases of clinical laboratory tests or examinations,
40 including which clinical laboratory tests or examinations the

1 individual is authorized to perform, whether supervision is required
2 for the individual to perform specimen processing, test
3 performance, or results reporting, and whether consultant,
4 supervisor, or director review is required prior to the individual
5 reporting patient test results.

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

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

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

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

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

20 (D) Direct observation of performance of instrument
21 maintenance and function checks.

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

25 (F) Assessment of problem solving skills.

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

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

36 (1) If a qualified pathologist is not available, a physician and
37 surgeon or a clinical laboratory bioanalyst qualified as a laboratory
38 director under subdivision (a) may direct the laboratory. However,
39 a qualified pathologist shall be available for consultation at suitable
40 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 3613 of the Business and Professions Code is amended to read:

3613. The following definitions apply for the purposes of this chapter:

(a) “Committee” means the Naturopathic Medicine Committee within the Osteopathic Medical Board of California. Any reference in any law or regulation to the Bureau of Naturopathic Medicine shall be deemed to refer to the Naturopathic Medicine Committee within the Osteopathic Medical Board of California.

(b) “Naturopathic childbirth attendance” means the specialty practice of natural childbirth by a naturopathic doctor that includes the management of normal pregnancy, normal labor and delivery, and the normal postpartum period, including normal newborn care.

(c) “Naturopathic medicine” means a distinct and comprehensive system of primary health care practiced by a naturopathic doctor for the diagnosis, treatment, and prevention of human health conditions, injuries, and disease.

(d) “Naturopathic doctor” means a person who holds an active license issued pursuant to this chapter.

(e) “Naturopathy” means a noninvasive system of health practice that employs natural health modalities, substances, and education to promote health.

(f) “Drug” means any substance defined as a drug by Section 11014 of the Health and Safety Code.

(g) “Naturopathic assistant” means a person who may be unlicensed, who performs basic administrative, clerical, and technical supportive services in compliance with this chapter for a licensed naturopathic doctor or naturopathic corporation and who is at least 18 years of age, and who has had at least the minimum amount of hours of appropriate training pursuant to standards established by the Medical Board of California for a medical assistant pursuant to Section 2069. The naturopathic assistant shall be issued a certificate by the training institution or instructor indicating satisfactory completion of the required training. A copy of the certificate shall be retained as a record by each employer or the naturopathic assistant.

(h) “Naturopathic technical supportive services” means simple routine medical tasks and procedures that may be safely performed by a naturopathic assistant who has limited training and who functions under the supervision of a licensed naturopathic doctor.

(i) “Specific authorization” means a specific written order prepared by the supervising naturopathic doctor authorizing the procedures to be performed on a patient, which shall be placed in the patient’s medical record, or a standing order prepared by the supervising naturopathic doctor authorizing the procedures to be performed. A notation of the standing order shall be placed on the patient’s medical record.

(j) “Supervision” means the supervision of procedures authorized under this section or Section 3640.2 by a naturopathic doctor, within his or her scope of practice, who is physically present in the treatment facility during the performance of those procedures.

SEC. 4. Section 3640.2 is added to the Business and Professions Code, to read:

3640.2. Notwithstanding any other provision of law, a naturopathic assistant may do all of the following:

(a) Administer medication only by intradermal, subcutaneous, or intramuscular injections and perform skin tests and additional technical support services upon the specific authorization and supervision of a licensed naturopathic doctor. A naturopathic assistant may also perform all these tasks and services in a clinic licensed pursuant to subdivision (a) of Section 1204 of the Health and Safety Code upon the specific authorization of a naturopathic doctor.

(b) Perform venipuncture or skin puncture for the purposes of withdrawing blood upon specific authorization and under the supervision of a licensed naturopathic doctor if prior thereto the naturopathic assistant has met the educational and training requirements for medical assistants as established in Section 2070. A copy of any related certificates shall be retained as a record by each employer of the assistant.

(c) Perform the following naturopathic technical support services:

(1) Administer medications orally, sublingually, topically, vaginally, or rectally, or by providing a single dose to a patient for immediate self-administration. Administer medication by inhalation if the medications are patient-specific and have been or will be repetitively administered to the patient. In every instance, prior to administration of medication by the naturopathic assistant, the naturopathic doctor shall verify the correct medication and dosage.

(2) Apply and remove bandages.

(3) Collect by noninvasive techniques and preserve specimens for testing, including urine, sputum, semen, and stool.

(4) Assist patients to and from a patient ~~exam room or exam~~ examination room or examination table.

(5) As authorized by the naturopathic doctor, provide patient information and instructions.

(6) Collect and record patient data, including height, weight, temperature, pulse, respiration rate, and blood pressure, and basic information about the presenting and previous conditions.

(7) Perform simple laboratory and screening tests customarily performed in a medical office.

(d) Perform additional naturopathic technical support services under the regulations and standards established by the committee. The committee shall, prior to the adoption of any regulations, request recommendations regarding these standards from appropriate public agencies, including, but not limited to, *the Osteopathic Medical Board of California*, the Medical Board of California, the Board of Registered Nursing, the Board of Vocational Nursing and Psychiatric Technicians of the State of California, the Laboratory Field Services division of the State Department of Public Health, and the Physical Therapy Examining Committee. The Naturopathic Medicine Committee shall also request recommendations regarding these standards from

1 associations of medical assistants, physicians, and others, as
2 appropriate, including, but not limited to, *the Osteopathic*
3 *Physicians and Surgeons of California*, the California Medical
4 Association, the California Society of Medical Assistants, and the
5 California Medical Assistants' Association. Nothing in this
6 subdivision shall be construed to supersede or modify that portion
7 of the Administrative Procedure Act that relates to the procedure
8 for the adoption of regulations set forth in Article 5 (commencing
9 with Section 11346) of Chapter 3.5 of Part 1 of Division 3 of Title
10 2 of the Government Code.

11 SEC. 5. Section 3640.3 is added to the Business and Professions
12 Code, to read:

13 3640.3. (a) Nothing in this chapter shall be construed as
14 authorizing the licensure of naturopathic assistants. Nothing in
15 this chapter shall be construed as authorizing the administration
16 of local anesthetic agents by a naturopathic assistant. Nothing in
17 this chapter shall be construed as authorizing the Naturopathic
18 Medicine Committee to adopt any regulations that violate the
19 prohibitions on diagnosis or treatment in Section 2052.

20 (b) Nothing in this chapter shall be construed as authorizing a
21 naturopathic assistant to perform any clinical laboratory test or
22 examination for which he or she is not authorized under Chapter
23 3 (commencing with Section 1200).

24 (c) Notwithstanding any other provision of law, a naturopathic
25 assistant may not be employed for inpatient care in a licensed
26 general acute care hospital as defined in subdivision (a) of Section
27 1250 of the Health and Safety Code.