AMENDED IN ASSEMBLY AUGUST 23, 2012

AMENDED IN ASSEMBLY AUGUST 6, 2012

AMENDED IN ASSEMBLY JUNE 19, 2012

AMENDED IN SENATE JANUARY 4, 2012

AMENDED IN SENATE MARCH 24, 2011

SENATE BILL No. 289

Introduced by Senator Hernandez

February 14, 2011

An act to amend Sections 1206, 1222.5, and 2069 of the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

SB 289, as amended, Hernandez. Clinical laboratory techniques: training and instruction.

Existing law provides for the licensure and regulation of clinical laboratories and various clinical laboratory health care professionals by the State Department of *Public* Health ~~Care Services~~. Existing law authorizes the department to approve schools seeking to provide instruction in clinical laboratory techniques, as specified.

This bill would authorize the department to approve specified institutions seeking to provide *clinical laboratory scientist programs for* instruction in clinical laboratory techniques, as specified, including, among others, a California licensed clinical laboratory and an accredited college or university in the United States. *The bill would also specify that, upon approval by the department, clinical laboratory scientist programs may use multiple clinical laboratories apportioned in any*

percentage to provide training in clinical laboratory techniques, if specified conditions are met.

The bill would also make technical, nonsubstantive changes to these provisions.

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

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

SECTION 1. Section 1206 of the Business and Professions Code is amended to read:

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

(1) "Analyte" means the substance or constituent being measured including, but not limited to, glucose, sodium, or theophyline, or any substance or property whose presence or absence, concentration, activity, intensity, or other characteristics are to be determined.

(2) "Biological specimen" means any material that is derived from the human body.

(3) "Blood electrolyte analysis" means the measurement of electrolytes in a blood specimen by means of ion selective electrodes on instruments specifically designed and manufactured for blood gas and acid-base analysis.

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

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

(6) "Clinical laboratory science" means any of the sciences or scientific disciplines used to perform a clinical laboratory test or examination.

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

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

~~(9) “Clinical training site” means any place, establishment, or institution used by a department-approved program for the training of clinical laboratory scientists or limited clinical laboratory scientists to conduct training or instruction of licensed trainees or phlebotomy students in clinical laboratory practice, techniques, theory, or other training required pursuant to this chapter.~~

~~(10)~~

(9) “Direct and constant supervision” means personal observation and critical evaluation of the activity of unlicensed laboratory personnel by a physician and surgeon, or by a person licensed under this chapter other than a trainee, during the entire time that the unlicensed laboratory personnel are engaged in the duties specified in Section 1269.

~~(11)~~

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

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

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

~~(12)~~

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

~~(13)~~

(12) "Location" means either a street and city address, or a site or place within a street and city address, where any of the clinical laboratory sciences or scientific disciplines are practiced or applied, or where any clinical laboratory tests or examinations are performed.

~~(14)~~

(13) "Physician office laboratory" means a clinical laboratory that is licensed or registered under Section 1265, and that is either: (A) a clinical laboratory that is owned and operated by a partnership or professional corporation that performs clinical laboratory tests or examinations only for patients of five or fewer physicians and surgeons or podiatrists who are shareholders, partners, or employees of the partnership or professional corporation that owns and operates the clinical laboratory; or (B) a clinical laboratory that is owned and operated by an individual licensed physician and surgeon or a podiatrist, and that performs clinical laboratory tests or examinations only for patients of the physician and surgeon or podiatrist who owns and operates the clinical laboratory.

~~(15)~~

(14) "Point-of-care laboratory testing device" means a portable laboratory testing instrument to which the following applies:

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

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

(C) It meets the following criteria:

(i) Performs clinical laboratory tests or examinations classified as waived or of moderate complexity under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) (42 U.S.C. Sec. 263a).

(ii) Performs clinical laboratory tests or examinations on biological specimens that require no preparation after collection.

(iii) Provides clinical laboratory tests or examination results without calculation or discretionary intervention by the testing personnel.

(iv) Performs clinical laboratory tests or examinations without the necessity for testing personnel to perform calibration or

maintenance, except resetting pursuant to the manufacturer's instructions or basic cleaning.

~~(16)~~

(15) "Public health laboratory" means a laboratory that is operated by a city or county in conformity with Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code and the regulations adopted thereunder.

~~(17)~~

(16) "Registered laboratory" means a clinical laboratory registered pursuant to paragraph (2) of subdivision (a) of Section 1265.

~~(18)~~

(17) "Specialty" means histocompatibility, microbiology, diagnostic immunology, chemistry, hematology, immunohematology, pathology, genetics, or other specialty specified by regulation adopted by the department.

~~(19)~~

(18) "Subspecialty" for purposes of microbiology, means bacteriology, mycobacteriology, mycology, parasitology, virology, molecular biology, and serology for diagnosis of infectious diseases, or other subspecialty specified by regulation adopted by the department; for purposes of diagnostic immunology, means syphilis serology, general immunology, or other subspecialty specified by regulation adopted by the department; for purposes of chemistry, means routine chemistry, clinical microscopy, endocrinology, toxicology, or other subspecialty specified by regulation adopted by the department; for purposes of immunohematology, means ABO/Rh Type and Group, antibody detection for transfusion, antibody detection nontransfusion, antibody identification, compatibility, or other subspecialty specified by regulation adopted by the department; for pathology, means tissue pathology, oral pathology, diagnostic cytology, or other subspecialty specified by regulation adopted by the department; for purposes of genetics, means molecular biology related to the diagnosis of human genetic abnormalities, cytogenetics, or other subspecialty specified by regulation adopted by the department.

(b) Nothing in this chapter shall restrict, limit, or prevent any person licensed to provide health care services under the laws of

this state, including, but not limited to, licensed physicians and surgeons and registered nurses, from practicing the profession or occupation for which he or she is licensed.

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

SEC. 2. Section 1222.5 of the Business and Professions Code is amended to read:

1222.5. (a) The department may approve any of the following seeking to provide *clinical laboratory scientist programs for* instruction in clinical laboratory ~~technic which~~ *technique that,* in the judgment of the department, will provide instruction adequate to prepare individuals to meet the requirements for licensure or performance of duties under this chapter and regulations of the department:

(1) A California licensed clinical laboratory.

(2) An accredited college or university in the United States of America.

(3) A United States military medical laboratory specialist program of at least 52 weeks duration.

(4) A laboratory owned and operated by the United States government.

(b) Upon approval by the department, clinical laboratory scientist programs approved by the department may use multiple clinical laboratories to provide training in clinical laboratory technique, provided the following conditions are met:

(1) The program may apportion the clinical training among multiple clinical laboratories in any percentage as long as the total training meets the requirements established by the department.

(2) Each clinical laboratory has been approved by the department as part of the program in accordance with regulations. The program shall notify the department in writing within 30 days of a change in clinical laboratories used by the program to provide training.

(3) The director of the approved program shall be responsible for notifying the department in advance of the start and end date of training for each trainee. The program shall coordinate with the department in meeting established requirements.

(4) The director of the approved program shall ensure that all of the department's requirements for training and affiliation are met.

(5) The program has submitted an application on forms provided by the department for approval.

~~(b)~~

(c) The department shall establish by regulation the ratio of licensed clinical laboratory scientists to licensed trainees on the staff of the clinical ~~training site~~ *laboratory* and the minimum requirements for training in any specialty or in the entire field of clinical laboratory science or practice. Application for approval shall be made on forms provided by the department.

SEC. 3. Section 2069 of the Business and Professions Code is amended to read:

2069. (a) (1) Notwithstanding any other provision of law, a medical assistant may administer medication only by intradermal, subcutaneous, or intramuscular injections and perform skin tests and additional technical supportive services upon the specific authorization and supervision of a licensed physician and surgeon or a licensed podiatrist. A medical 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 physician assistant, a nurse practitioner, or a nurse-midwife.

(2) The supervising physician and surgeon at a clinic described in paragraph (1) may, at his or her discretion, in consultation with the nurse practitioner, nurse-midwife, or physician assistant provide written instructions to be followed by a medical assistant in the performance of tasks or supportive services. These written instructions may provide that the supervisory function for the medical assistant for these tasks or supportive services may be delegated to the nurse practitioner, nurse-midwife, or physician assistant within the standardized procedures or protocol, and that tasks may be performed when the supervising physician and surgeon is not onsite, so long as the following apply:

(A) The nurse practitioner or nurse-midwife is functioning pursuant to standardized procedures, as defined by Section 2725, or protocol. The standardized procedures or protocol shall be developed and approved by the supervising physician and surgeon, the nurse practitioner or nurse-midwife, and the facility administrator or his or her designee.

(B) The physician assistant is functioning pursuant to regulated services defined in Section 3502 and is approved to do so by the supervising physician or surgeon.

(b) As used in this section and Sections 2070 and 2071, the following definitions shall apply:

(1) "Medical assistant" means a person who may be unlicensed, who performs basic administrative, clerical, and technical supportive services in compliance with this section and Section 2070 for a licensed physician and surgeon or a licensed podiatrist, or group thereof, for a medical or podiatry corporation, for a physician assistant, a nurse practitioner, or a nurse-midwife as provided in subdivision (a), or for a health care service plan, 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 Division of Licensing. The medical 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 of the medical assistant.

(2) "Specific authorization" means a specific written order prepared by the supervising physician and surgeon or the supervising podiatrist, or the physician assistant, the nurse practitioner, or the nurse-midwife as provided in subdivision (a), 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 physician and surgeon or the supervising podiatrist, or the physician assistant, the nurse practitioner, or the nurse-midwife as provided in subdivision (a), authorizing the procedures to be performed, the duration of which shall be consistent with accepted medical practice. A notation of the standing order shall be placed on the patient's medical record.

(3) "Supervision" means the supervision of procedures authorized by this section by the following practitioners, within the scope of their respective practices, who shall be physically

present in the treatment facility during the performance of those procedures:

(A) A licensed physician and surgeon.

(B) A licensed podiatrist.

(C) A physician assistant, nurse practitioner, or nurse-midwife as provided in subdivision (a).

(4) "Technical supportive services" means simple routine medical tasks and procedures that may be safely performed by a medical assistant who has limited training and who functions under the supervision of a licensed physician and surgeon or a licensed podiatrist, or a physician assistant, a nurse practitioner, or a nurse-midwife as provided in subdivision (a).

(c) Nothing in this section shall be construed as authorizing the licensure of medical assistants. Nothing in this section shall be construed as authorizing the administration of local anesthetic agents by a medical assistant. Nothing in this section shall be construed as authorizing the division to adopt any regulations that violate the prohibitions on diagnosis or treatment in Section 2052.

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

(e) Nothing in this section shall be construed as authorizing a medical assistant to perform any clinical laboratory test or examination for which he or she is not authorized by Chapter 3 (commencing with Section 1206.5). Nothing in this section shall be construed as authorizing a nurse practitioner, nurse-midwife, or physician assistant to be a laboratory director of a clinical laboratory, as those terms are defined in paragraph (8) of subdivision (a) of Section 1206 and subdivision (a) of Section 1209.

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