ASSEMBLY BILL No. 185

Introduced by Assembly Member Dymally

January 24, 2007

An act to amend Sections 1202, 1205, 1206, 1206.5, 1209, 1209.5, 1212, 1222.5, 1243, 1263, and 2069 of, and to repeal and add Section 1269 of, the Business and Professions Code, and to amend Section 117995 of the Health and Safety Code, relating to clinical laboratories.

LEGISLATIVE COUNSEL'S DIGEST

AB 185, as introduced, Dymally. Clinical laboratories: personnel.

Existing law provides for the regulation and licensure of clinical laboratories and clinical laboratory personnel by the State Department of Health Services until June 30, 2007, and thereafter by the State Department of Public Health. Existing law makes a violation of these provisions a crime.

Existing law requires the department to license as trainees, as defined, those individuals desiring to train for either a clinical laboratory scientist's license or a limited clinical laboratory scientist's license, providing those individuals meet specified academic requirements.

This bill would instead specify that those individuals desiring to train for a clinical laboratory scientist's license, a limited clinical laboratory scientist's license, a cytotechnologist license, or a medical laboratory technician's license shall be considered authorized to engage in clinical laboratory practice as trainees providing they meet specified academic requirements. The bill would also redefine the term "trainee" for this purpose.

Existing law requires a laboratory director or a licensed authorized designee appointed by the laboratory director to establish, validate, and

document explicit criteria by which clinical laboratory test or examination results are autoverified, as defined.

This bill would instead require the laboratory director to assure that laboratory test or examination results are not reported by the clinical laboratory until the results have been either critically reviewed and verified, as specified, by a person authorized to perform those tests or examinations or critically reviewed and verified by autoverification, as specified.

Under existing law, unlicensed personnel are authorized to perform designated duties in a clinical laboratory under specified levels of supervision.

This bill would revise the duties that unlicensed personnel are authorized to perform in a clinical laboratory and the type of supervision required for their performance.

This bill would define and redefine various terms and would also make numerous technical, nonsubstantive, and conforming changes.

Because the bill would revise requirements pertaining to clinical laboratories and their personnel, a violation of which would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

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

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

SECTION 1. Section 1202 of the Business and Professions Code is amended to read:

1202. As used in this chapter, "department" means the State Department of ~~Health Services~~ *Public Health*.

SEC. 2. Section 1205 of the Business and Professions Code is amended to read:

1205. As used in this chapter, "trainee" means any person licensed under this chapter *on and before December 31, 2007, or, on and after January 1, 2008, any person authorized, as specified in subdivision (b) of Section 1263* for the purpose of receiving comprehensive practical experience and instruction in clinical

laboratory procedures in one of the sciences or in general clinical laboratory science under the direct and responsible supervision of a person authorized to direct a laboratory under the provisions of this chapter, clinical laboratory scientist, clinical chemist scientist, clinical microbiologist scientist, clinical toxicologist scientist, clinical immunohematologist scientist, clinical genetic molecular biologist scientist, clinical cytogeneticist scientist, clinical histocompatibility scientist, or other equivalent licensee in the science or specialty or subspecialty for which he or she is licensed in a clinical laboratory certified for this purpose by the department under this chapter.

SEC. 3. 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) "Biological specimen" means any material that is derived from the human body.

(2) "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.

(3) "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.

(4) "Calibration or calibrate or standardization" means the process of testing and adjusting an instrument or test system to establish a correlation between the measurement response and the concentration or amount of the substance that is being measured by the test procedure.

(5) "Calibration verification" means the assaying of materials of known concentration in the same manner as patient samples to substantiate the instrument or test system's calibration throughout the reportable range for patient test results.

~~(4)~~

(6) "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.

~~(5)~~

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

~~(6)~~

(8) "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.

~~(7)~~

(9) "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.

~~(8)~~

(10) "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.~~ *supervision of unlicensed laboratory personnel, as defined in subdivision (a) of Section 1212, by a physician and surgeon or by a person licensed under this chapter, other than a trainee, while the unlicensed laboratory personnel are performing limited analytical activities pursuant to subdivision (c) of Section 1269. The supervisor shall be both physically present onsite in the clinical laboratory and in the immediate vicinity of the unlicensed laboratory personnel but shall not be required to provide continuous observation. The supervisor shall meet the following requirements:*

(A) Demonstrate competency in the area of activity in which the unlicensed laboratory personnel are engaged.

(B) Perform a critical evaluation of performance as necessary to ensure the unlicensed laboratory personnel remain competent during the period of time the unlicensed laboratory personnel are engaged in activities specified in subdivision (c) of Section 1269.

(C) Supervise no more than four unlicensed laboratory personnel at a time.

(11) "Supervision and control" means that a physician and surgeon or a person licensed under this chapter, other than a trainee, is responsible for the conduct of unlicensed laboratory personnel and shall be available by telephone or other electronic means, but is not required to be present onsite during the performance of activities by those personnel.

~~(9)~~

(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.

~~(10)~~

(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.

~~(11)~~

(14) "Public health laboratory" means a laboratory that is operated by a city or county in conformity with ~~Chapter 7 (commencing with Section 1000) of Part 2 of Division 1~~ *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.

~~(12)~~

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

~~(13)~~

(16) "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.

~~(14)~~

(17) "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.

~~(15)~~

(18) "Licensed laboratory" means a clinical laboratory licensed pursuant to paragraph (1) of subdivision (a) of Section 1265.

~~(16)~~

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

~~(17)~~

(20) "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 CLIA.

(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.

~~(18)~~

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

(22) "Preanalytical phase" means that part of a clinical laboratory test or examination that occurs before the analytical phase begins and that is not otherwise included as part of the analytical phase.

(23) "Analytical phase" means that part of a clinical laboratory test or examination that commences when the biological specimen is analyzed, measured, or examined in order to produce a clinical laboratory test or examination result. The analytical phase of a clinical laboratory test or examination shall end when a test or examination result is generated, reviewed, and verified for

accuracy, reliability, and validity by a person authorized to release clinical laboratory test or examination results or by autoverification. The analytical phase shall include:

(A) Assessing the integrity and the adequacy or sufficiency of the specimen to be analyzed.

(B) Test method calibration and calibration verification.

(C) Assessing the results of controls.

(24) "Postanalytical phase" means that part of a clinical laboratory test or examination that occurs after the analytical phase ends.

(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. 4. 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~~ *Sections* 1241 *and 1263*, 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 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 ~~Section~~ 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 subparagraph (A) of paragraph (5) of, or subparagraph (B) of paragraph (4) of, subdivision (a) of Section 4052, or if performing skin puncture in the course of performing routine patient assessment procedures in compliance with Section 4052.1.

(12) Other health care personnel providing direct patient care.

(13) Any other person performing nondiagnostic testing pursuant to Section 1244.

(b) Notwithstanding subdivision (b) of Section 1206 *and except as otherwise provided in Section 1263*, 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 ~~Section~~ 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 *and except as otherwise provided in Section 1263*, 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 ~~Section~~ 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. 5. Section 1209 of the Business and Professions Code is amended to read:

1209. (a) As used in this chapter, "laboratory director" means ~~any~~ *a* person who is a duly licensed physician and surgeon, 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 assure compliance with this ~~act~~ *chapter* 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~~ *If* 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 assure 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~~ *preanalytical, analytical, and postanalytical* 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.

SEC. 6. Section 1209.5 of the Business and Professions Code is amended to read:

1209.5. (a) *As part of the overall operation and administration of a clinical laboratory, the laboratory director shall assure that laboratory test or examination results are not reported by the clinical laboratory until the results have been either critically reviewed and verified for accuracy, reliability, and validity by a person authorized to perform those tests or examinations pursuant to Section 1206.5 or critically reviewed and verified for accuracy, reliability, and validity by autoverification as specified in subdivision (b).*

(b) (1) "Autoverification" means the use of a computer algorithm in conjunction with automated clinical laboratory instrumentation to review and verify the results of a clinical laboratory test or examination for accuracy and reliability.

~~(b)~~

(2) The laboratory director or authorized designee shall establish, validate, and document explicit criteria by which the clinical laboratory test or examination results are autoverified.

~~(c)~~

(3) The laboratory director or authorized designee shall annually revalidate the explicit criteria by which the clinical laboratory test or examination results are autoverified. The laboratory director shall approve and annually reapprove the computer algorithm.

~~(d)~~

(4) An authorized designee ~~shall~~ *may* be appointed by the laboratory director for the purposes of this ~~section~~ *subdivision*. The authorized designee shall be licensed to engage in clinical laboratory practice pursuant to this chapter and shall be qualified as a clinical consultant, technical supervisor, general supervisor, or technical consultant pursuant to regulations adopted by the department.

~~(e)~~

(5) A person licensed to perform the applicable type and complexity of testing pursuant to Section 1206.5 shall be physically present onsite in the clinical laboratory and shall have documented competency pursuant to Section 1209 in all tests being autoverified, and shall be responsible for the accuracy and reliability of the results of the clinical laboratory test or examination when the results are autoverified and reported.

SEC. 7. Section 1212 of the Business and Professions Code is amended to read:

1212. (a) As used in this chapter, "unlicensed laboratory personnel" means ~~a laboratory aide, histocompatibility technician, cardiopulmonary technician, or other person performing the activities authorized by Section 1269~~ *an individual who meets the criteria of subdivision (a) of Section 1269 or a person described in Section 1269.3*.

(b) ~~Any~~ *A* person who is authorized under California law or regulation to perform a clinical laboratory test or examination, or to engage in clinical laboratory practice, shall not come within the definition of "unlicensed laboratory personnel" when performing the clinical laboratory test or examination or engaging in the clinical laboratory practice authorized.

SEC. 8. Section 1222.5 of the Business and Professions Code is amended to read:

1222.5. The department may approve schools seeking to provide instruction in clinical laboratory ~~technic~~ *technique* which 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. The department shall establish by regulation the ratio of licensed clinical laboratory scientists to ~~licensed~~ *authorized* trainees on the staff of the laboratory approved as a school and the minimum requirements for training in any specialty or in the entire field of clinical laboratory science or practice. *A trainee authorized to engage in clinical laboratory practice pursuant to this chapter shall be considered as a licensed trainee in regulations adopted by the department.* Application for approval shall be made on forms provided by the department.

SEC. 9. Section 1243 of the Business and Professions Code is amended to read:

1243. ~~A~~ *An individual who is enrolled in an approved school, as specified in Sections 1222 and 1222.5, and the regulations promulgated thereunder, or a* student regularly matriculated in any college or university accredited by an accrediting agency acceptable to the department, or in any legally chartered school approved by the department for training purposes may perform arterial puncture, venipuncture, or skin puncture as a part of the necessary training program when done under the direct and responsible supervision of a person licensed to perform tests under the provisions of this chapter or a licensed physician and surgeon.

SEC. 10. Section 1263 of the Business and Professions Code is amended to read:

1263. ~~The~~ *(a) On and before December 31, 2007, the* department shall license as trainees those individuals desiring to train for either a clinical laboratory scientist's license or a limited clinical laboratory scientist's license, providing those individuals meet the academic requirements.

No trainee license shall be issued unless the applicant has completed at least 90 semester hours or equivalent quarter hours of university or college work or the essential equivalent as determined by the department which must have included at least 23 semester hours or equivalent quarter hours of courses in the sciences as determined by regulations of the department. ~~Applicants who have completed military training schools may be granted academic credit toward licensure by the department on the basis of recommendations made by the American Council on Education.~~

Applicants shall apply for the license on forms provided by the department and meet the requirements of this chapter and any standards as are established by regulations of the department.

(b) On and after January 1, 2008, those individuals desiring to train for a clinical laboratory scientist's license, a limited clinical laboratory scientist's license, a cytotechnologist license, or a medical laboratory technician license, who enroll in an approved school, as specified in Sections 1222 and 1222.5 and the regulations promulgated thereunder, shall be authorized to engage in clinical laboratory practice as trainees pursuant to subdivision (b) of Section 1205, providing those individuals meet the appropriate academic requirements as specified in paragraphs (1), (2), and (3).

(1) No individual desiring to train for a clinical laboratory scientist's license or a limited clinical laboratory scientist's license shall engage in clinical laboratory practice as a trainee, as specified in Section 1205, unless the individual's enrollment in an approved school is current, and the individual has completed at least 90 semester hours or equivalent quarter hours of university or college work, or the essential equivalent as determined by the department, that must have included at least 23 semester hours or equivalent quarter hours of courses in the sciences as determined by regulations of the department.

(2) No individual desiring to train for a medical laboratory technician license shall engage in clinical laboratory practice as a trainee, as specified in Section 1205, unless the individual's enrollment in an approved school is current, and the individual has completed at least 60 semester hours or 90 quarter hours at an accredited college or university, or the essential equivalent as determined by the department, that includes at least 36 semester hours or equivalent quarter hours of courses in physical or biological sciences.

(3) No individual desiring to train for a cytotechnologist license shall engage in clinical laboratory practice as a trainee, as specified in Section 1205, unless the individual's enrollment in an approved school is current.

(c) No individual shall engage in clinical laboratory practice pursuant to subdivision (b) for more than one training enrollment period without written authorization from the department.

(d) Individuals who have completed military training schools may be granted academic credit toward licensure by the department on the basis of recommendations made by the American Council on Education.

SEC. 11. Section 1269 of the Business and Professions Code is repealed.

~~1269. (a) Unlicensed laboratory personnel may perform any of the activities identified in subdivision (b), in a licensed clinical laboratory, under the direct and constant supervision of a physician and surgeon, or a person licensed under this chapter other than a trainee, upon meeting all of the following criteria:~~

~~(1) Have earned a high school diploma, or its equivalent, as determined by HCFA under CLIA.~~

~~(2) Have documentation of training appropriate to ensure that the individual has all of the following skills and abilities:~~

~~(A) The skills required for proper specimen collection, including patient preparation, labeling, handling, preservation or fixation, processing or preparation, and transportation and storage of specimens.~~

~~(B) The skills required for assisting a licensed physician and surgeon or personnel licensed under this chapter, other than trainees, in a licensed clinical laboratory.~~

~~(C) The skills required for performing preventive maintenance, and troubleshooting.~~

~~(D) A working knowledge of reagent stability and storage.~~

~~(E) The skills required for assisting in the performance of quality control procedures, and an understanding of the quality control policies of the laboratory.~~

~~(F) An awareness of the factors that influence test results.~~

~~(b) The activities that may be performed are:~~

~~(1) Biological specimen collection, including patient preparation, labeling, handling, preservation or fixation, processing or preparation, and transportation and storage of specimens.~~

~~(2) Assisting a licensed physician and surgeon or personnel licensed under this chapter, other than trainees, in a licensed clinical laboratory.~~

~~(3) Assisting in preventive maintenance, and troubleshooting.~~

~~(4) Preparation and storage of reagents and culture media.~~

~~(5) Assisting in the performance of quality control procedures.~~

~~(c) Notwithstanding subdivision (a), unlicensed laboratory personnel, other than a trainee, may, under the supervision and control of a physician and surgeon or person licensed under this chapter, perform specimen labeling, handling, preservation or fixation, processing or preparation, transportation, and storing if he or she meets the requirements of subparagraph (A) of paragraph (2) of, and paragraph (1) of, subdivision (a).~~

~~(d) Unlicensed laboratory personnel shall not do any of the following:~~

~~(1) Record test results, but he or she may transcribe results that have been previously recorded, either manually by a physician and surgeon or personnel licensed under this chapter, or automatically by a testing instrument.~~

~~(2) Perform any test or part thereof that involves the quantitative measurement of the specimen or test reagent, or any mathematical calculation relative to determining the results or the validity of a test procedure.~~

~~(3) Perform any phase of clinical laboratory tests or examinations in the specialty of immunohematology beyond initial collection and centrifugation.~~

~~(e) When any of the following manual methods are employed, the activities of unlicensed laboratory personnel shall be limited as follows:~~

~~(1) In the case of qualitative and semi-quantitative "spot, tablet, or stick" tests, the personnel may add the test reagent to the specimen or vice versa, but the results must be read by a physician and surgeon or person licensed under this chapter.~~

~~(2) In the case of microbiological tests the unlicensed laboratory personnel may make primary inoculations of test material onto appropriate culture media, stain slide preparations for microscopic examination, and subculture from liquid media.~~

~~(f) When any of the following mechanical or electronic instruments are employed, unlicensed laboratory personnel shall not perform any of the following activities:~~

~~(1) Standardizing or calibrating the instrument or assessing its performance by monitoring results of appropriate standards and control.~~

~~(2) Reading or recording test results, except that the personnel may transcribe results that have been previously recorded automatically by a testing instrument.~~

~~(3) Quantitatively measuring any sample or reagents unless done automatically by the instrument in the course of its normal operation or by the use of previously calibrated and approved automatic syringes or other dispensers.~~

SEC. 12. Section 1269 is added to the Business and Professions Code, to read:

1269. (a) Unlicensed laboratory personnel shall meet all of the following requirements:

(1) Possess a high school diploma, or its equivalent, as specified in regulations implementing Section 1246.

(2) Have job duties and responsibilities designated in writing by the laboratory director.

(3) Possess documentation of training signed by the laboratory director, technical supervisor, or technical consultant, that is appropriate to the duties and responsibilities of unlicensed laboratory personnel to ensure that the individual has all of the following skills and abilities.

(A) The skills required for proper specimen preparation, labeling, handling, preservation, staining or fixation, processing, transportation, and storage.

(B) The skills required for assisting in performing preventive maintenance and troubleshooting of instruments.

(C) A working knowledge of reagent preparation, stability, and storage.

(D) The skills required for assisting in the performance of quality control procedures, and an understanding of the quality control policies of the laboratory.

(E) An awareness of the factors that influence test results.

(4) Provide documentation of his or her competency to perform all job duties and responsibilities before assignment to those duties and responsibilities, after six months of performing those duties and responsibilities, and annually thereafter.

(5) Assist in the preanalytical phase or the postanalytical phase of a clinical laboratory test or examination pursuant to subdivision (b).

(6) Assist in the analytical phase of a clinical laboratory test or examination or perform limited analytical activities pursuant to subdivision (c).

(b) Unlicensed laboratory personnel may perform the following preanalytical and postanalytical activities under supervision and control:

(1) Biological specimen preparation, labeling, handling, preservation or fixation, processing, transportation, and storage.

(2) Check and clean equipment.

(3) Preparation and storage of reagents and culture media.

(4) Electronic identification of biological specimens by barcoding or other means, batching, loading and unloading specimens, loading reagents, loading controls, loading standards or calibrators, and priming equipment with reagents.

(5) In the specialty of hematology, stain slides for microscopic review.

(6) In the specialty of microbiology, make primary inoculations of test material onto appropriate culture media, stain slides for microscopic review, and make subcultures from liquid media, including blood cultures.

(7) In the subspecialty of cytology, accession specimens, process specimens by staining, cover slipping, and labeling of gynecologic and nongynecologic slides, and loading and unloading specimens on automated equipment or sample processors.

(c) Unless otherwise specified, unlicensed laboratory personnel may perform the following limited analytical activities under direct and constant supervision:

(1) Operate fully automated, software-directed test system analyzers, including monitoring electronic and mechanical performance and alerting the supervisor of any problems. System adjustments shall be performed by a physician and surgeon or a person licensed under this chapter.

(2) Assist in preventive maintenance and troubleshooting of instruments, including replacing components, reading thermometers, and using electronic timers.

(3) Perform quantitative measurement of test reagents, patient specimens, controls, standards or calibrators by use of automatic syringes or single-volume pipetting dispensers previously calibrated and approved by a physician and surgeon or a person licensed under this chapter.

(4) Assist in performing quality control procedures, except the acceptance of quality control parameters shall be the responsibility of a physician and surgeon or a person licensed under this chapter.

(5) For qualitative and semiqualitative tests, add test reagent to the specimen or specimen to the reagent. The results shall be read by a physician and surgeon or a person licensed under this chapter.

(6) In the specialty of clinical cytogenetics, assist in slide preparation and staining.

(d) Unlicensed laboratory personnel shall not do any of the following:

(1) Record test results produced without the use of autoverification, except an unlicensed person may transcribe or transmit results that have been previously recorded, either manually by a physician and surgeon or a person licensed under this chapter, or automatically by a testing instrument, or provided by another laboratory, when test results were reviewed and released by a person authorized to do so by the testing laboratory.

(2) Perform any mathematical calculation relative to determining the results or the validity of a test procedure.

(3) Perform any phase of clinical laboratory tests or examinations in the specialty of immunohematology beyond initial collection and centrifugation.

(4) In the specialty of clinical cytogenetics, process specimens beyond initial centrifugation or perform staining procedures, except as specified in paragraph (6) of subdivision (c).

(5) In the specialty of genetic molecular biology, process specimens beyond initial centrifugation or perform hybridization or wash procedures.

(6) Standardize or calibrate an instrument or assess its performance by analyzing results of standards and controls, except that he or she may load standards, calibrators, or controls as authorized in subdivision (b) and monitor performance of fully automated, software-directed test system analyzers, alerting the supervisor of any problems, as authorized in subdivision (c).

(7) Quantitatively measure any sample or reagents unless done automatically by the instrument in the course of its normal operation or by the use of automatic syringes or other dispensers previously calibrated and approved by a licensed physician and surgeon or a person licensed under this chapter.

(8) Determine the integrity, adequacy or sufficiency of a biological specimen, except the unlicensed person shall alert the supervisor of any problems or concerns pursuant to the skills and abilities required by subdivision (a).

SEC. 13. 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)~~ *1200)*. 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 ~~(7)~~ *(9)* of subdivision (a) of Section 1206 and subdivision (a) of Section 1209.

SEC. 14. Section 117995 of the Health and Safety Code is amended to read:

117995. The registration and annual permit fee for large quantity generators shall be set in following amounts:

(a) (1) A general acute care hospital, as defined in subdivision (a) of Section 1250, that has one or more beds, but not more than 99 beds, shall pay six hundred dollars ($600), a facility with 100 or more beds, but not more than 199 beds, shall pay eight hundred sixty dollars ($860), a facility with 200 or more beds, but not more than 250 beds shall pay one thousand one hundred dollars ($1,100), and a facility with 251 or more beds shall pay one thousand four hundred dollars ($1,400).

(2) In addition to the fees specified in paragraph (1), a general acute care hospital which is providing onsite treatment of medical waste shall pay an annual medical waste treatment facility inspection and permit fee of three hundred dollars ($300), if the facility has one or more beds but not more than 99 beds, five hundred dollars ($500), if the facility has 100 or more beds but not more than 250 beds, and one thousand dollars ($1,000), if the facility has 251 or more beds.

(b) A specialty clinic, providing surgical, dialysis, or rehabilitation services, as defined in subdivision (b) of Section 1204, shall pay three hundred fifty dollars ($350).

(c) A skilled nursing facility, as defined in subdivision (c) of Section 1250, that has one or more beds, but not more than 99 beds

shall pay two hundred seventy-five dollars ($275), a facility with 100 or more beds, but not more than 199 beds shall pay three hundred fifty dollars ($350), and a facility with 200 or more beds shall pay four hundred dollars ($400).

(d) An acute psychiatric hospital, as defined in subdivision (b) of Section 1250, shall pay two hundred dollars ($200).

(e) An intermediate care facility, as defined in subdivision (d) of Section 1250, shall pay three hundred dollars ($300).

(f) A primary care clinic, as defined in Section 1200.1, shall pay three hundred fifty dollars ($350).

(g) A licensed clinical laboratory, as defined in paragraph ~~(3)~~ *(9)* of subdivision (a) of Section 1206 of the Business and Professions Code, shall pay two hundred dollars ($200).

(h) A health care service plan facility, as defined in subdivision (f) of Section 1345, shall pay three hundred fifty dollars ($350).

(i) A veterinary clinic or veterinary hospital shall pay two hundred dollars ($200).

(j) A large quantity generator medical office shall pay two hundred dollars ($200).

(k) In addition to the fees specified in subdivisions (b) to (j), inclusive, a large quantity generator of medical waste which is providing onsite treatment of medical waste shall pay an annual medical waste treatment facility inspection and permit fee of three hundred dollars ($300).

(*l*) The department may collect annual fees and issue permits on a biennial basis.

SEC. 15. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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