

AMENDED IN SENATE AUGUST 16, 2005

AMENDED IN SENATE JUNE 20, 2005

AMENDED IN ASSEMBLY APRIL 26, 2005

CALIFORNIA LEGISLATURE—2005—06 REGULAR SESSION

ASSEMBLY BILL

No. 1161

Introduced by Assembly Member Niello

February 22, 2005

An act to amend Sections 1206, 1209, 1209.1, 1212, 1263, 1269, and 2069 of the Business and Professions Code, and to amend Section 117995 of the Health and Safety Code, relating to clinical laboratories, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

AB 1161, as amended, Niello. ~~Unlicensed personnel: regulation.~~
Health regulation.

Existing law provides for the regulation and licensure of clinical laboratories and clinical laboratory personnel by the State Department of Health Services. Under existing law, unlicensed personnel are authorized to perform designated duties in a clinical laboratory under specified levels of supervision. Existing law makes a violation of these provisions a crime.

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. The bill would make the laboratory director responsible for assuring that results are not reported until they have been critically reviewed and verified by authorized personnel or by autoverification, as defined. The bill would also require an applicant for licensure as a histocompatibility

laboratory director to successfully complete a written exam administered by the American Board of Histocompatibility and Immunogenetics and an oral exam administered by the department *and would specify requirements for licensure as a medical laboratory technician and trainee.*

Because the bill would revise requirements pertaining to clinical laboratories and their personnel, a violation of which is 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.

The bill would declare that it is to take effect immediately as an urgency statute.

Vote: $\frac{2}{3}$. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

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

1 *SECTION 1. The Legislature hereby finds and declares that*
2 *existing law relating to the authorized duties of laboratory*
3 *personnel, particularly unlicensed laboratory personnel, in*
4 *clinical laboratories is confusing, unclear, ambiguous, and has*
5 *been outdated by modern technology. In recognition of these*
6 *findings, it is the intent of the Legislature and this act to clarify*
7 *the existing law with respect to the designated duties that*
8 *laboratory personnel are authorized to perform and to update the*
9 *law to account for the changes made by modern technology.*

10 SECTION 1.

11 SEC. 2. Section 1206 of the Business and Professions Code is
12 amended to read:

13 1206. (a) The following definitions apply for purposes of this
14 chapter:

15 (1) ~~“Autoverification” means the review and verification of~~
16 ~~clinical laboratory test or examination results with the use of a~~
17 ~~the use of a computer algorithm when the in conjunction with~~
18 ~~automated clinical laboratory instrumentation to review and~~
19 ~~verify for accuracy and reliability, the results of a clinical~~

1 *laboratory test or examination. The laboratory director or a*
2 *authorized designee, who is authorized to engage in clinical*
3 *laboratory practice pursuant to this chapter has established and*
4 *validated, shall establish, validate, and document explicit criteria*
5 *by which the clinical laboratory test or examination results are*
6 *verified, and a autoverified. The laboratory director or*
7 *authorized designee shall annually revalidate the explicit criteria*
8 *by which the clinical laboratory test or examination results are*
9 *autoverified. The laboratory director shall approve and annually*
10 *reapprove the computer algorithm. A person authorized to*
11 *perform the applicable type and complexity of testing pursuant to*
12 *Section 1206.5 is shall be physically present onsite and in the*
13 *clinical laboratory and shall be responsible for those tests when*
14 *the results are released. Once established, the explicit criteria by*
15 *which the clinical laboratory test or examination results are*
16 *verified shall be revalidated at least annually. the accuracy and*
17 *reliability of the results of the clinical laboratory test or*
18 *examination when they are released.*

19 (2) “Biological specimen” means any material that is derived
20 from the human body.

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

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

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

38 (6) “Clinical laboratory science” means any of the sciences or
39 scientific disciplines used to perform a clinical laboratory test or
40 examination.

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

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

13 (9) “General supervision” means that a physician and surgeon
14 or a person licensed under this chapter other than a trainee, is
15 responsible for the conduct of unlicensed laboratory personnel
16 *and shall be available by telephone or other electronic means,*
17 but is not required to be present *onsite* during the performance of
18 activities by those personnel.

19 (10) “Supervision and control” means ~~the activities of~~
20 ~~unlicensed laboratory personnel are supervised by a physician~~
21 *supervision of unlicensed personnel, as defined in subdivision (a)*
22 *of Section 1212, by a physician and surgeon or by a person*
23 *licensed under this chapter, other than a trainee, who is available*
24 *onsite during the entire time that unlicensed laboratory personnel*
25 *are engaged in the analytical activities specified in Section 1269.*
26 ~~The ratio of unlicensed laboratory personnel to a supervisor at~~
27 ~~the testing site shall not exceed four to one.~~ *than a trainee, to*
28 *perform the applicable type and complexity of the clinical*
29 *laboratory test or examination. The supervisor shall be both*
30 *physically present onsite in the clinical laboratory and in the*
31 *immediate vicinity of the unlicensed personnel. The supervisor*
32 *shall demonstrate competency in his or her area of responsibility*
33 *and provide critical evaluation of the unlicensed laboratory*
34 *personnel during the period of time that the unlicensed*
35 *laboratory personnel are engaged in activities specified in*
36 *subdivision (c) of Section 1269.*

37 (11) “Location” means either a street and city address, or a site
38 or place within a street and city address, where any of the clinical
39 laboratory sciences or scientific disciplines are practiced or

1 applied, or where any clinical laboratory tests or examinations
2 are performed.

3 (12) “Physician office laboratory” means a clinical laboratory
4 that is licensed or registered under Section 1265, and that is
5 either of the following:

6 (A) A clinical laboratory that is owned and operated by a
7 partnership or professional corporation that performs clinical
8 laboratory tests or examinations only for patients of five or fewer
9 physicians and surgeons or podiatrists who are shareholders,
10 partners, or employees of the partnership or professional
11 corporation that owns and operates the clinical laboratory.

12 (B) A clinical laboratory that is owned and operated by an
13 individual licensed physician and surgeon or a podiatrist, and that
14 performs clinical laboratory tests or examinations only for
15 patients of the physician and surgeon or podiatrist who owns and
16 operates the clinical laboratory.

17 (13) “Public health laboratory” means a laboratory that is
18 operated by a city or county in conformity with Article 5
19 (commencing with Section 101150) of Chapter 2 of Part 3 of
20 Division 101 of the Health and Safety Code and the regulations
21 adopted thereunder.

22 (14) “Specialty” means histocompatibility, microbiology,
23 diagnostic immunology, chemistry, hematology,
24 immunohematology, pathology, genetics, or other specialty
25 specified by regulation adopted by the department.

26 (15) “Subspecialty” for purposes of microbiology, means
27 bacteriology, mycobacteriology, mycology, parasitology,
28 virology, molecular biology, and serology for diagnosis of
29 infectious diseases, or other subspecialty specified by regulation
30 adopted by the department; for purposes of diagnostic
31 immunology, means syphilis serology, general immunology, or
32 other subspecialty specified by regulation adopted by the
33 department; for purposes of chemistry, means routine chemistry,
34 clinical microscopy, endocrinology, toxicology, or other
35 subspecialty specified by regulation adopted by the department;
36 for purposes of immunohematology, means ABO/Rh Type and
37 Group, antibody detection for transfusion, antibody detection *for*
38 nontransfusion, antibody identification, compatibility, or other
39 subspecialty specified by regulation adopted by the department;
40 for pathology, means tissue pathology, oral pathology, diagnostic

1 cytology, or other subspecialty specified by regulation adopted
2 by the department; for purposes of genetics, means molecular
3 biology related to the diagnosis of human genetic abnormalities,
4 cytogenetics, or other subspecialty specified by regulation
5 adopted by the department.

6 (16) “Direct and responsible supervision” means both of the
7 following:

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

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

17 (17) “Licensed laboratory” means a clinical laboratory
18 licensed pursuant to paragraph (1) of subdivision (a) of Section
19 1265.

20 (18) “Registered laboratory” means a clinical laboratory
21 registered pursuant to paragraph (2) of subdivision (a) of Section
22 1265.

23 (19) “Point-of-care laboratory testing device” means a
24 portable laboratory testing instrument to which the following
25 applies:

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

28 (B) It is used in accordance with the patient test management
29 system, the quality control program, and the comprehensive
30 quality assurance program established and maintained by the
31 laboratory pursuant to paragraph (2) of subdivision (d) of Section
32 1220.

33 (C) It meets the following criteria:

34 (i) Performs clinical laboratory tests or examinations classified
35 as waived or of moderate complexity under CLIA.

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

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

1 (iv) Performs clinical laboratory tests or examinations without
2 the necessity for testing personnel to perform calibration or
3 maintenance, except resetting pursuant to the manufacturer's
4 instructions or basic cleaning.

5 (20) "Analyte" means the substance or constituent being
6 measured including, but not limited to, glucose, sodium, or
7 theophylline, or any substance or property whose presence or
8 absence, concentration, activity, intensity, or other characteristics
9 are to be determined.

10 (21) "Analytical phase" means that part of a clinical laboratory
11 test or examination that commences when the ~~biological~~
12 ~~specimen is measured to start testing or is measured to assess~~
13 ~~volume, or when the gynecological or pathological slide is~~
14 ~~microscopically reviewed. The analytical phase of a biological~~
15 ~~specimen is analyzed, measured, or examined in order to~~
16 ~~produce a clinical laboratory test or examination result. The~~
17 ~~analytical phase of a clinical laboratory test or examination shall~~
18 ~~end when a test or examination result is generated, reviewed, and~~
19 ~~verified for accuracy, reliability, and validity by a person~~
20 ~~authorized to release tests clinical laboratory test or examination~~
21 ~~results or by autoverification pursuant to paragraph (1).~~

22 (b) Nothing in this chapter shall restrict, limit, or prevent any
23 person licensed to provide health care services under the laws of
24 this state, including, but not limited to, licensed physicians and
25 surgeons, and registered nurses, from practicing the profession or
26 occupation for which he or she is licensed.

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

36 ~~SEC. 2.~~

37 *SEC. 3.* Section 1209 of the Business and Professions Code is
38 amended to read:

39 1209. (a) As used in this chapter, "laboratory director"
40 means a person who is a duly licensed physician and surgeon, or

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

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

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

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

1 (d) As part of the overall operation and administration, the
2 laboratory director of a licensed laboratory shall do all of the
3 following:

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

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

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

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

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

1 (A) Direct observations of routine patient test performance,
2 including patient preparation, if applicable, and specimen
3 handling, processing, and testing.

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

5 (C) Review of intermediate test results or worksheets, quality
6 control records, proficiency testing results, and preventive
7 maintenance records.

8 (D) Direct observation of performance of instrument
9 maintenance and function checks.

10 (E) Assessment of test performance through testing previously
11 analyzed specimens, internal blind testing samples, or external
12 proficiency testing samples.

13 (F) Assessment of problem solving skills.

14 (2) Evaluation and documentation of staff competency and
15 performance shall occur at least semiannually during the first
16 year ~~on~~ *an* individual tests biological specimens. Thereafter,
17 evaluations shall be performed at least annually unless test
18 methodology or instrumentation changes, in which case, prior to
19 reporting patient test results, the individual's performance shall
20 be reevaluated to include the use of the new test methodology or
21 instrumentation.

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

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

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

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

1 (g) As part of the overall operation and administration, the
2 laboratory director of a clinical laboratory shall assure that
3 laboratory test or examination results are not reported by the
4 laboratory until the results have been critically reviewed and
5 verified for accuracy, reliability, and validity by a person
6 authorized to perform these tests pursuant to Section 1206.5 or
7 by autoverification pursuant to paragraph (1) of subdivision (a)
8 of Section 1206.

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

12 ~~SEC. 3.~~

13 *SEC. 4.* Section 1209.1 of the Business and Professions Code
14 is amended to read:

15 1209.1. (a) As used in this chapter “histocompatibility
16 laboratory director” means a person who has completed,
17 subsequent to graduation, four years of experience in
18 immunology, two of which have been in histocompatibility
19 testing, and who meets one of the following requirements:

20 (1) Is a licensed physician and surgeon.

21 (2) Is a bioanalyst.

22 (3) Has earned a doctoral degree in a biological science.

23 (b) In order to be eligible for licensure as a histocompatibility
24 laboratory director, an applicant shall provide evidence of
25 satisfactory performance on a written examination in
26 histocompatibility administered by the American Board of
27 Histocompatibility and Immunogenetics, and have demonstrated
28 satisfactory performance on an oral examination administered by
29 the department regarding this chapter and Part 493 (commencing
30 with Section 493.1) of Subchapter G of Chapter IV of Title 42 of
31 the Code of Federal Regulations.

32 (c) A person licensed under Section 1260.1 as a
33 histocompatibility laboratory director and qualified under CLIA
34 may perform clinical laboratory tests or examinations classified
35 as of high complexity under CLIA and the duties and
36 responsibilities of a laboratory director, technical consultant,
37 clinical consultant, technical supervisor, and general supervisor,
38 as specified under CLIA, in the specialty of histocompatibility,
39 immunology, or other specialty or subspecialty specified by
40 regulation adopted by the department. A person licensed as a

1 “histocompatibility laboratory director” may perform any clinical
 2 laboratory test or examination classified as waived or of
 3 moderate complexity under CLIA.

4 ~~SEC. 4.~~

5 *SEC. 5.* Section 1212 of the Business and Professions Code is
 6 amended to read:

7 1212. (a) As used in this chapter, “unlicensed laboratory
 8 personnel” means a laboratory assistant who meets the
 9 requirements of subdivision (a) of Section 1269 and who is
 10 authorized to assist in the performance of clinical laboratory tests
 11 or examinations as specified in subdivisions (c) and (d) of
 12 Section 1269 or unlicensed personnel who may perform
 13 preanalytical activities and postanalytical activities as specified
 14 in subdivision (b) of Section 1269.

15 (b) A person who is authorized under California law or
 16 regulation to perform a clinical laboratory test or examination, or
 17 to engage in clinical laboratory practice, shall not come within
 18 the definition of “unlicensed laboratory personnel” when
 19 performing the clinical laboratory test or examination or
 20 engaging in the clinical laboratory practice authorized.

21 *SEC. 6.* Section 1263 of the Business and Professions Code is
 22 amended to read:

23 1263. (a) The department shall license as trainees those
 24 individuals desiring to train for ~~either~~ a clinical laboratory
 25 scientist’s license ~~or~~, a limited clinical laboratory scientist’s
 26 license, ~~providing or a medical laboratory technician’s license if~~
 27 those individuals meet the academic requirements.

28 (b) ~~No clinical laboratory scientist trainee license or limited~~
 29 ~~clinical laboratory scientist trainee license shall be issued unless~~
 30 ~~the applicant has completed at least 90 semester hours or~~
 31 ~~equivalent quarter hours of university or college work, or the~~
 32 ~~essential equivalent as determined by the department which, that~~
 33 ~~must have included at least 23 semester hours or equivalent~~
 34 ~~quarter hours of courses in the sciences as determined by~~
 35 ~~regulations of the department. Applicants~~ *No medical laboratory*
 36 *technician trainee license shall be issued unless the applicant has*
 37 *completed at least 60 semester hours or 90 quarter hours at an*
 38 *accredited college or university, or the essential equivalent as*
 39 *determined by the department, that includes at least 36 semester*

1 *hours or equivalent quarter hours of courses in physical or*
2 *biological sciences.*

3 (c) Applicants who have completed military training schools
4 may be granted academic credit toward licensure by the
5 department on the basis of recommendations made by the
6 American Council on Education.

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

10 ~~SEC. 5.~~

11 *SEC. 7.* Section 1269 of the Business and Professions Code is
12 amended to read:

13 1269. (a) Unlicensed laboratory personnel, as defined in
14 Section 1212, shall meet all of the following requirements:

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

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

19 (3) Possess documentation of training signed by the laboratory
20 director, technical supervisor, or technical consultant, that is
21 appropriate to the duties and responsibilities of the laboratory
22 assistant to ensure that the individual has all of the following
23 skills and abilities:

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

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

30 ~~(C)~~

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

33 ~~(D)~~

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

36 ~~(E)~~

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

40 ~~(F)~~

- 1 (E) An awareness of the factors that influence test results.
- 2 (4) Provide documentation of his or her competency to
3 perform all job duties and responsibilities prior to assignment to
4 those duties and responsibilities, after six months of performing
5 those duties and responsibilities, and annually thereafter.
- 6 (5) Assist in the analytical phase of a clinical laboratory test or
7 examination or perform limited analytical activities pursuant to
8 subdivision (c) under supervision and control.
- 9 (6) Assist in the preanalytical phase or the postanalytical phase
10 of a clinical laboratory test or examination pursuant to
11 subdivision (b) under general supervision.
- 12 (b) Unlicensed laboratory personnel may perform the
13 following preanalytical and postanalytical activities under
14 general supervision:
- 15 (1) Biological specimen preparation, labeling, handling,
16 preservation or fixation, processing, transportation, and storage.
- 17 ~~(2) Assist in preventive maintenance and troubleshooting of~~
18 ~~instruments, including checking and cleaning equipment,~~
19 ~~replacing components, reading thermometers, and using~~
20 ~~electronic timers. Check and clean equipment.~~
- 21 (3) Preparation and storage of reagents and culture media.
- 22 ~~(4) Preparation of automated equipment, including electronic~~
23 (4) *Electronic* identification of biological specimens by
24 barcoding or other means, batching, loading and unloading
25 specimens, loading reagents, loading controls, loading standards
26 or calibrators, and priming equipment with reagents.
- 27 (5) In the specialty of hematology, stain slides for microscopic
28 review.
- 29 (6) In the specialty of microbiology, make primary
30 inoculations of test material onto appropriate culture media, stain
31 slides for microscopic review, and make subcultures from liquid
32 media, including blood cultures.
- 33 ~~(7) In the specialty of clinical cytogenetics, assist in slide~~
34 ~~preparation and staining, karyotype preparation, and maintenance~~
35 ~~of backup cultures.~~
- 36 ~~(8) In the specialty of genetic molecular biology, assist in~~
37 ~~hybridization and wash procedures.~~
- 38 ~~(9)~~
- 39 (7) In the subspecialty of cytology, accession specimens,
40 process specimens by staining, cover slipping, and labeling of

1 gynecologic and nongynecologic slides, ~~load and unload and~~
2 ~~loading and unloading~~ specimens on automated equipment or
3 sample processors, ~~perform equipment maintenance, and~~
4 ~~document temperatures for quality control.~~

5 ~~(10) (A) In the specialty of pathology, a pathologist's assistant~~
6 ~~certified by the American Association of Pathologists'~~
7 ~~Assistants, or an individual who otherwise qualifies under the~~
8 ~~CLIA, may perform the following activities under the~~
9 ~~supervision and control of a pathologist:~~

10 ~~(i) Prepare human surgical specimens for gross description and~~
11 ~~dissection, including description of gross features and selection~~
12 ~~of tissues for histological examination.~~

13 ~~(ii) Prepare and perform human postmortem examinations,~~
14 ~~including selection of tissues and fluids for further examination.~~

15 ~~(iii) Gather other information necessary for an autopsy report.~~

16 ~~(iv) Prepare a body for release.~~

17 ~~(B) A histotechnician, certified as a histologic technician or~~
18 ~~histotechnologist by the Board of Registry of the American~~
19 ~~Society for Clinical Pathology or other national accrediting~~
20 ~~agency approved by the department, may process tissues by~~
21 ~~trimming, embedding in paraffin, or slicing. On and after January~~
22 ~~1, 2010, an unlicensed person who is not certified as a histologic~~
23 ~~technician or histotechnologist by the American Society for~~
24 ~~Clinical Pathology or other national accrediting agency approved~~
25 ~~by the department may only do the following: accession~~
26 ~~specimens, stain, cover slip and label slides, and perform~~
27 ~~equipment maintenance.~~

28 ~~(8) A histologic technician or histotechnologist who meets the~~
29 ~~requirements specified under subdivision (a), may accession~~
30 ~~specimens; perform maintenance of equipment; stain, cover slip,~~
31 ~~and label slides; and process tissues by trimming, embedding in~~
32 ~~paraffin, or slicing. On or after January 1, 2011, the department~~
33 ~~may adopt regulations establishing qualification requirements to~~
34 ~~perform the duties described in this paragraph.~~

35 ~~(c) Unlicensed Unless otherwise specified, unlicensed~~
36 ~~laboratory personnel may perform the following limited~~
37 ~~analytical activities under supervision and control:~~

38 ~~(1) Monitor Operate, including monitoring electronic and~~
39 ~~mechanical performance of, fully automated, software-directed~~
40 ~~test system analyzers, alerting the supervisor of problems in the~~

1 ~~performance of standards, calibrators, controls, or specimens. any~~
2 *problems.* System adjustments shall be performed by a physician
3 and surgeon or a person licensed under this chapter.

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

7 (3) Perform quantitative measurement of test reagents, patient
8 specimens, or calibrators by use of ~~previously calibrated and~~
9 ~~approved~~ automatic syringes or other pipetting dispensers
10 *previously calibrated and approved by a physician and surgeon*
11 *or a person licensed under this chapter.*

12 ~~(3)~~
13 (4) Assist in performing quality control procedures.
14 Acceptance of parameters shall be the responsibility of a
15 physician and surgeon or a person licensed under this chapter.

16 ~~(4)~~
17 (5) For qualitative and semiquantitative tests, add test reagent to
18 the specimen or specimen to the reagent. The results shall be read
19 by a physician and surgeon or a person licensed under this
20 chapter.

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

23 (7) *In the specialty of pathology, a pathologist's assistant*
24 *certified by the American Association of Pathologists' Assistants,*
25 *the Board of Registry of the American Society for Clinical*
26 *Pathology, or other national accrediting agency approved by the*
27 *department, may perform the following activities under the*
28 *general supervision of a pathologist:*

29 (A) *Prepare human surgical specimens for gross description*
30 *and dissection, including description of gross features and*
31 *selection of tissues for histological examination.*

32 (B) *Prepare and perform human postmortem examinations,*
33 *including selection of tissues and fluids for further examination.*

34 (C) *Gather other information necessary for an autopsy report.*

35 (D) *Prepare a body for release.*

36 (8) (A) *The following persons may prepare human surgical*
37 *specimens for gross description and dissection under the*
38 *supervision and control of a qualified pathologist, including*
39 *description of gross features and selection of tissues for*
40 *histological examination, if they meet the requirements specified*

1 *in subdivision (a) and the minimum education and training*
2 *requirements for high complexity testing personnel under CLIA:*

3 *(i) A pathologist's assistant who does not meet the*
4 *certification requirements of paragraph (7).*

5 *(ii) A histologic technician.*

6 *(iii) A histotechnologist.*

7 *(iv) A laboratory assistant, as defined in Section 1212.*

8 *(B) On or after January 1, 2011, the department may adopt*
9 *regulations establishing qualification requirements to perform*
10 *the duties described in this paragraph.*

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

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

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

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

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

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

31 ~~(4)~~

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

39 ~~(5)~~

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

7 ~~SEC. 6.~~

8 *SEC. 8.* Section 2069 of the Business and Professions Code is
 9 amended to read:

10 2069. (a) (1) Notwithstanding any other provision of law, a
 11 medical assistant may administer medication only by
 12 intradermal, subcutaneous, or intramuscular injections and
 13 perform skin tests and additional technical supportive services
 14 upon the specific authorization and supervision of a licensed
 15 physician and surgeon or a licensed podiatrist. A medical
 16 assistant may also perform all these tasks and services in a clinic
 17 licensed pursuant to subdivision (a) of Section 1204 of the Health
 18 and Safety Code upon the specific authorization of a physician
 19 assistant, a nurse practitioner, or a nurse-midwife.

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

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

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

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

3 (1) “Medical assistant” means a person who may be
4 unlicensed, who performs basic administrative, clerical, and
5 technical supportive services in compliance with this section and
6 Section 2070 for a licensed physician and surgeon or a licensed
7 podiatrist, or group thereof, for a medical or podiatry
8 corporation, for a physician assistant, a nurse practitioner, or a
9 nurse-midwife as provided in subdivision (a), or for a health care
10 service plan, who is at least 18 years of age, and who has had at
11 least the minimum amount of hours of appropriate training
12 pursuant to standards established by the Division of Licensing.
13 The medical assistant shall be issued a certificate by the training
14 institution or instructor indicating satisfactory completion of the
15 required training. A copy of the certificate shall be retained as a
16 record by each employer of the medical assistant.

17 (2) “Specific authorization” means a specific written order
18 prepared by the supervising physician and surgeon or the
19 supervising podiatrist, or the physician assistant, the nurse
20 practitioner, or the nurse-midwife as provided in subdivision (a),
21 authorizing the procedures to be performed on a patient, which
22 shall be placed in the patient’s medical record, or a standing
23 order prepared by the supervising physician and surgeon or the
24 supervising podiatrist, or the physician assistant, the nurse
25 practitioner, or the nurse-midwife as provided in subdivision (a),
26 authorizing the procedures to be performed, the duration of
27 which shall be consistent with accepted medical practice. A
28 notation of the standing order shall be placed ~~on~~ in the patient’s
29 medical record.

30 (3) “Supervision” means the supervision of procedures
31 authorized by this section by the following practitioners, within
32 the scope of their respective practices, who shall be physically
33 present in the treatment facility during the performance of those
34 procedures:

35 (A) A licensed physician and surgeon.

36 (B) A licensed podiatrist.

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

39 (4) “Technical supportive services” means simple routine
40 medical tasks and procedures that may be safely performed by a

1 medical assistant who has limited training and who functions
 2 under the supervision of a licensed physician and surgeon or a
 3 licensed podiatrist, or a physician assistant, a nurse practitioner,
 4 or a nurse-midwife as provided in subdivision (a).

5 (c) Nothing in this section shall be construed as authorizing
 6 the licensure of medical assistants. Nothing in this section shall
 7 be construed as authorizing the administration of local anesthetic
 8 agents by a medical assistant. Nothing in this section shall be
 9 construed as authorizing the division to adopt any regulations
 10 that violate the prohibitions on diagnosis or treatment in Section
 11 2052.

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

16 (e) Nothing in this section shall be construed as authorizing a
 17 medical assistant to perform any clinical laboratory test or
 18 examination for which he or she is not authorized by Chapter 3
 19 (commencing with Section 1200). Nothing in this section shall be
 20 construed as authorizing a nurse practitioner, nurse-midwife, or
 21 physician assistant to be a laboratory director of a clinical
 22 laboratory, as those terms are defined in paragraph (8) of
 23 subdivision (a) of Section 1206 and subdivision (a) of Section
 24 1209.

25 ~~SEC. 7.~~

26 *SEC. 9.* Section 117995 of the Health and Safety Code is
 27 amended to read:

28 117995. The registration and annual permit fee for large
 29 quantity generators shall be set in *the* following amounts:

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

38 (2) In addition to the fees specified in paragraph (1), a general
 39 acute care hospital which is providing onsite treatment of
 40 medical waste shall pay an annual medical waste treatment

1 facility inspection and permit fee of three hundred dollars (\$300),
2 if the facility has one or more beds but not more than 99 beds,
3 five hundred dollars (\$500), if the facility has 100 or more beds
4 but not more than 250 beds, and one thousand dollars (\$1,000), if
5 the facility has 251 or more beds.

6 (b) A specialty clinic, providing surgical, dialysis, or
7 rehabilitation services, as defined in subdivision (b) of Section
8 1204, shall pay three hundred fifty dollars (\$350).

9 (c) A skilled nursing facility, as defined in subdivision (c) of
10 Section 1250, that has one or more beds, but not more than 99
11 beds shall pay two hundred seventy-five dollars (\$275), a facility
12 with 100 or more beds, but not more than 199 beds shall pay
13 three hundred fifty dollars (\$350), and a facility with 200 or more
14 beds shall pay four hundred dollars (\$400).

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

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

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

21 (g) A licensed clinical laboratory, as defined in paragraph (8)
22 of subdivision (a) of Section 1206 of the Business and
23 Professions Code, shall pay two hundred dollars (\$200).

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

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

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

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

36 ~~SEC. 8.~~

37 *SEC. 10.* No reimbursement is required by this act pursuant to
38 Section 6 of Article XIII B of the California Constitution because
39 the only costs that may be incurred by a local agency or school
40 district will be incurred because this act creates a new crime or

1 infraction, eliminates a crime or infraction, or changes the
2 penalty for a crime or infraction, within the meaning of Section
3 17556 of the Government Code, or changes the definition of a
4 crime within the meaning of Section 6 of Article XIII B of the
5 California Constitution.

6 ~~SEC. 9.~~

7 *SEC. 11.* This act is an urgency statute necessary for the
8 immediate preservation of the public peace, health, or safety
9 within the meaning of Article IV of the Constitution and shall go
10 into immediate effect. The facts constituting the necessity are:

11 In order to promote public safety as soon as possible by
12 revising the provisions regulating unlicensed persons performing
13 analytical activities in clinical laboratories, it is necessary that
14 this act take effect immediately.

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