

AMENDED IN ASSEMBLY MAY 29, 1996

AMENDED IN ASSEMBLY MAY 13, 1996

CALIFORNIA LEGISLATURE—1995-96 REGULAR SESSION

ASSEMBLY BILL

No. 3109

Introduced by Assembly Member Margett

February 23, 1996

An act to amend Section 1209 of the Business and Professions Code, relating to clinical laboratories.

LEGISLATIVE COUNSEL'S DIGEST

AB 3109, as amended, Margett. Clinical laboratories.

Existing law provides for the licensure and regulation of clinical laboratories and various clinical laboratory health care professionals by the State Department of Health Services. Existing law defines "laboratory director" for purposes of these provisions.

This bill would expressly add ~~any licensed health care practitioner, as defined, who directs~~, *for the purposes of a laboratory that performs only tests classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA; 42 U.S.C. 263a; P.L. 100-578), a duly licensed registered nurse or pharmacist who substantially meets the laboratory director qualifications under CLIA for the type and complexity of tests being offered by the laboratory*, to the definition of a laboratory director.

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



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

1 SECTION 1. Section 1209 of the Business and
2 Professions Code is amended to read:
3 1209. (a) As used in this chapter, “laboratory
4 director” means any person who is a duly licensed
5 physician and surgeon, or is licensed to direct a clinical
6 laboratory under this chapter, *or, for purposes of a*
7 *laboratory that performs only tests classified as waived*
8 *under CLIA, is a duly licensed registered nurse or*
9 *pharmacist, and who substantially meets the laboratory*
10 *director qualifications under CLIA for the type and*
11 *complexity of tests being offered by the laboratory, or a*
12 ~~licensed health care practitioner, as defined in~~
13 ~~subdivision (f) of Section 900 who directs a laboratory~~
14 ~~that performs only tests classified as waived under CLIA.~~
15 *The laboratory laboratory. The laboratory* director, if
16 qualified under CLIA, may perform the duties of the
17 technical consultant, technical supervisor, clinical
18 consultant, general supervisor, and testing personnel, or
19 delegate these responsibilities to persons qualified under
20 CLIA. If the laboratory director reapportions
21 performance of those responsibilities or duties, he or she
22 shall remain responsible for ensuring that all those duties
23 and responsibilities are properly performed.
24 (b) The laboratory director is responsible for the
25 overall operation and administration of the clinical
26 laboratory, including administering the technical and
27 scientific operation of a clinical laboratory, the selection
28 and supervision of procedures, the reporting of results,
29 and active participation in its operations to the extent
30 necessary to assure compliance with this act and CLIA.
31 He or she shall be responsible for the proper performance
32 of all laboratory work of all subordinates and shall employ
33 a sufficient number of laboratory personnel with the
34 appropriate education and either experience or training
35 to provide appropriate consultation, properly supervise
36 and accurately perform tests, and report test results in
37 accordance with the personnel qualifications, duties, and
38 responsibilities described in CLIA and this chapter.



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

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

16 (1) Ensure that all personnel, prior to testing
17 biological specimens, have the appropriate education and
18 experience, receive the appropriate training for the type
19 and complexity of the services offered, and have
20 demonstrated that they can perform all testing
21 operations reliably to provide and report accurate results.
22 In determining the adequacy of qualifications, the
23 laboratory director shall comply with any regulations
24 adopted by the department that specify the minimum
25 qualifications for, and the type of procedures that may be
26 performed by, personnel in addition to any CLIA
27 requirements relative to the education or training of
28 personnel. The laboratory director shall not determine
29 that the qualifications of a person described in paragraph
30 (11) of subdivision (b) of Section 1206.5 are adequate
31 unless that person meets the minimum clinical laboratory
32 education, training, and experience requirements set
33 forth in regulations which shall be adopted by the
34 department.

35 (2) Ensure that policies and procedures are
36 established for monitoring individuals who conduct
37 preanalytical, analytical, and postanalytical phases of
38 testing to assure that they are competent and maintain
39 their competency to process biological specimens,
40 perform test procedures, and report test results promptly



1 and proficiently, and, whenever necessary, identify needs
2 for remedial training or continuing education to improve
3 skills.

4 (3) Specify in writing the responsibilities and duties of
5 each individual engaged in the performance of the
6 preanalytic, analytic, and postanalytic phases of clinical
7 laboratory tests or examinations, including which clinical
8 laboratory tests or examinations the individual is
9 authorized to perform, whether supervision is required
10 for the individual to perform specimen processing, test
11 performance, or results reporting, and whether
12 consultant, supervisor, or director review is required
13 prior to the individual reporting patient test results.

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

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

23 (A) Direct observations of routine patient test
24 performance, including patient preparation, if
25 applicable, and specimen handling, processing, and
26 testing.

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

29 (C) Review of intermediate test results or worksheets,
30 quality control records, proficiency testing results, and
31 preventive maintenance records.

32 (D) Direct observation of performance of instrument
33 maintenance and function checks.

34 (E) Assessment of test performance through testing
35 previously analyzed specimens, internal blind testing
36 samples, or external proficiency testing samples.

37 (F) Assessment of problem solving skills.

38 (2) Evaluation and documentation of staff
39 competency and performance shall occur at least
40 semiannually during the first year an individual tests



1 biological specimens. Thereafter, evaluations shall be
2 performed at least annually unless test methodology or
3 instrumentation changes, in which case, prior to
4 reporting patient test results, the individual's
5 performance shall be reevaluated to include the use of
6 the new test methodology or instrumentation.

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

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

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

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

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

