

AMENDED IN SENATE JULY 14, 1999

AMENDED IN SENATE JUNE 23, 1999

AMENDED IN ASSEMBLY MAY 28, 1999

AMENDED IN ASSEMBLY MAY 17, 1999

CALIFORNIA LEGISLATURE—1999–2000 REGULAR SESSION

ASSEMBLY BILL

No. 1557

**Introduced by Assembly Member Migden
(Principal coauthor: Assembly Member Bock)
(Coauthors: Assembly Members Aroner and Shelley)**

February 26, 1999

An act to amend Sections 1242, 1242.5, 1246, and 1269 of the Business and Professions Code, and to amend Section 120580 of the Health and Safety Code, relating to clinical laboratories.

LEGISLATIVE COUNSEL'S DIGEST

AB 1557, as amended, Migden. Clinical laboratories: unlicensed personnel.

Existing law regulates clinical laboratories. These provisions require, among other things, that individuals be licensed to perform various laboratory tests. However, certain provisions specifically authorize an unlicensed person employed by a licensed clinical laboratory to perform venipuncture or skin puncture for the purpose of withdrawing blood for test purposes, upon specific authorization from a licensed physician and surgeon, if that unlicensed person meets specified requirements. Existing law also authorizes the State

Department of Health Services to authorize by regulation unlicensed laboratory personnel to perform skin tests for specific diseases, venipuncture, arterial puncture, or skin puncture for the purposes of withdrawing blood or for test purposes, as specified.

Existing law authorizes an unlicensed person employed by a public health department as a venereal disease case investigator to perform venipuncture or skin puncture for the purpose of withdrawing blood for test purposes, as specified.

This bill would require the department to adopt regulations by January 1, 2001, for becoming a “certified phlebotomy technician,” would require unlicensed persons employed by a clinical laboratory or by a public health department who perform venipuncture or skin puncture to obtain certification pursuant to these regulations to perform the above-specified acts on and after the effective date of those regulations, and would authorize the department to charge fees not to exceed \$25 for application and renewal of these certificates. The bill would not require unlicensed persons employed by a clinical laboratory who are performing these duties on the effective date of these regulations to be certified pursuant to these regulations until 3 years after the effective date of those regulations. The bill would also provide that the department may adopt regulations to issue a separate certificate to unlicensed persons employed by a clinical laboratory who only perform skin puncture tests.

The bill would also make related changes.

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

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

1 SECTION 1. Section 1242 of the Business and
2 Professions Code is amended to read:
3 1242. Any person duly licensed under the provisions
4 of this chapter to perform tests called for in a clinical
5 laboratory may perform skin tests for specific diseases,
6 arterial puncture, venipuncture, or skin puncture for
7 purposes of withdrawing blood or for clinical laboratory
8 test purposes as defined by regulations established by the



1 department and upon specific authorization from any
2 person in accordance with the authority granted under
3 any provisions of law relating to the healing arts.

4 SEC. 2. Section 1242.5 of the Business and Professions
5 Code is amended to read:

6 1242.5. Notwithstanding paragraphs (2) and (3) of
7 subdivision (b) of Section 1241, *the* department may by
8 regulation authorize laboratory personnel certified
9 pursuant to Section 1246 to perform venipuncture,
10 arterial puncture, or skin puncture for the purposes of
11 withdrawing blood or for clinical laboratory test
12 purposes, as defined by regulations established by the
13 department.

14 SEC. 3. Section 1246 of the Business and Professions
15 Code is amended to read:

16 1246. (a) Except as provided in subdivision (b), and
17 in Section 23158 of the Vehicle Code, an unlicensed
18 person employed by a licensed clinical laboratory may
19 perform venipuncture or skin puncture for the purpose
20 of withdrawing blood or for clinical laboratory test
21 purposes upon specific authorization from a licensed
22 physician and surgeon provided that he or she meets both
23 of the following requirements:

24 (1) He or she works under the supervision of a person
25 licensed under this chapter or of a licensed physician or
26 surgeon or of a licensed registered nurse. A person
27 licensed under this chapter, a licensed physician or
28 surgeon, or a registered nurse shall be physically available
29 to be summoned to the scene of the venipuncture within
30 five minutes during the performance of those
31 procedures.

32 (2) He or she has been trained by a licensed physician
33 and surgeon or by a clinical laboratory bioanalyst in the
34 proper procedure to be employed when withdrawing
35 blood in accordance with training requirements
36 established by the State Department of Health Services
37 and has a statement signed by the instructing physician
38 and surgeon or by the instructing clinical laboratory
39 bioanalyst that such training has been successfully
40 completed.



1 (b) (1) On and after the effective date of the
2 regulations specified in paragraph (2), any unlicensed
3 person employed by a clinical laboratory performing the
4 duties described in this section shall possess a valid and
5 current certification as a “certified phlebotomy
6 technician” issued by the department. However, an
7 unlicensed person employed by a clinical laboratory to
8 perform these duties pursuant to subdivision (a) on that
9 date shall comply with this requirement within three
10 years after the effective date of those regulations.

11 (2) The department shall adopt regulations for
12 certification by January 1, 2001, as a “certified
13 phlebotomy technician” that shall include all of the
14 following:

15 (A) The applicant shall hold a valid, current
16 certification as a phlebotomist issued by a national
17 accreditation agency approved by the department, and
18 shall submit proof of that certification when applying for
19 certification pursuant to this section.

20 (B) The applicant shall complete education, training,
21 and experience requirements as specified by regulations
22 that shall include, but not be limited to, the following:

23 (i) At least 40 hours of didactic instruction.

24 (ii) At least 40 hours of practical instruction.

25 (iii) At least 50 successful venipunctures.

26 *However, an applicant who has been performing these*
27 *duties pursuant to subdivision (a) may be exempted from*
28 *the requirements specified in clauses (ii) and (iii) if he or*
29 *she has at least 1040 hours of work experience, as specified*
30 *in regulations adopted by the department.*

31 *It is the intent of the Legislature to permit persons*
32 *performing these duties pursuant to subdivision (a) to*
33 *use educational leave provided by their employers for*
34 *purposes of meeting the requirements of this section.*

35 (3) Each “certified phlebotomy technician” shall
36 complete at least three hours per year or six hours every
37 two years of continuing education or training. The
38 department shall consider a variety of programs in
39 determining the programs that meet the continuing
40 education or training requirement.



1 (4) He or she has been found to be competent in
2 phlebotomy by a licensed physician and surgeon or
3 person licensed pursuant to this chapter.

4 (5) He or she works under the supervision of a licensed
5 physician and surgeon, licensed registered nurse, or
6 person licensed under this chapter, ~~or that physician and~~
7 ~~surgeon's, registered nurse's, or person's designee.~~ *the*
8 *designee of a licensed physician and surgeon or the*
9 *designee of a person licensed under this chapter.*

10 (6) The department shall adopt regulations
11 establishing standards for approving training programs
12 designed to prepare applicants for certification pursuant
13 to this section. The standards shall ensure that these
14 programs meet the state's minimum education and
15 training requirements for comparable programs.

16 (7) The department shall adopt regulations
17 establishing standards for approving national
18 accreditation agencies to administer certification
19 examinations and tests pursuant to this section.

20 (8) The department shall charge fees for application
21 for and renewal of the certificate authorized by this
22 section of no more than twenty-five dollars (\$25).

23 (c) The department may adopt regulations providing
24 for the issuance of a certificate to an unlicensed person
25 employed by a clinical laboratory authorizing only the
26 performance of skin punctures for test purposes.

27 SEC. 4. Section 1269 of the Business and Professions
28 Code is amended to read:

29 1269. (a) Unlicensed laboratory personnel may
30 perform any of the activities identified in subdivision (b),
31 in a licensed clinical laboratory, under the direct and
32 constant supervision of a physician and surgeon, or a
33 person licensed under this chapter other than a trainee,
34 upon meeting all of the following criteria:

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

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



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

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

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

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

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

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

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

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

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

27 (3) Assisting in preventive maintenance, and
28 troubleshooting.

29 (4) Preparation and storage of reagents and culture
30 media.

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

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



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

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

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

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

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

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

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

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

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

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

39 (3) Quantitatively measuring any sample or reagents
40 unless done automatically by the instrument in the course



1 of its normal operation or by the use of previously
2 calibrated and approved automatic syringes or other
3 dispensers.

4 SEC. 5. Section 120580 of the Health and Safety Code
5 is amended to read:

6 120580. Notwithstanding any other provision of law,
7 a person employed by a public health department may
8 perform venipuncture or skin puncture for the purpose
9 of withdrawing blood for test purposes, upon specific
10 authorization from a licensed physician and surgeon,
11 even though he or she is not otherwise licensed to
12 withdraw blood; provided that the person meets all of the
13 following requirements:

14 (1) He or she works under the direction of a licensed
15 physician and surgeon.

16 (2) He or she has been trained by a licensed physician
17 and surgeon or by a licensed clinical laboratory scientist
18 or bioanalyst in the proper procedures to be employed
19 when withdrawing blood, in accordance with training
20 requirements established by the department, and has a
21 statement signed by the instructing physician and
22 surgeon that the training has been successfully
23 completed.

24 (b) Any person employed by a public health
25 department to perform venipuncture or skin puncture
26 shall hold a valid and current certification after the
27 effective date of the regulations adopted pursuant to
28 Section 1246 of the Business and Professions Code.

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