

**ASSEMBLY BILL**

**No. 586**

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**Introduced by Assembly Member Nation**

February 21, 2001

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An act to amend Section 1206.5 of the Business and Professions Code, relating to clinical laboratory technology.

LEGISLATIVE COUNSEL'S DIGEST

AB 586, as introduced, Nation. Clinical laboratory technology: pharmacists.

Existing law prohibits the performance of a clinical laboratory test or examination classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 unless it is performed under the overall operation and administration of the laboratory director, as specified, and is performed by a designated healing arts practitioner. Existing law includes among these practitioners a pharmacist, if ordering drug therapy-related laboratory tests in compliance with provisions of existing law regulating that practice.

This bill would correct an erroneous cross-reference within that provision.

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 1206.5 of the Business and Professions
- 2 Code is amended to read:
- 3 1206.5. (a) Notwithstanding subdivision (b) of Section
- 4 1206, no person shall perform a clinical laboratory test or

- 1 examination classified as waived under CLIA unless the clinical  
2 laboratory test or examination is performed under the overall  
3 operation and administration of the laboratory director, as  
4 described in Section 1209, including, but not limited to,  
5 documentation by the laboratory director of the adequacy of the  
6 qualifications and competency of the personnel, and the test is  
7 performed by any of the following persons:
- 8 (1) A licensed physician and surgeon holding a M.D. or D.O.  
9 degree.
  - 10 (2) A licensed podiatrist or a licensed dentist ~~when~~ *if* the results  
11 of the tests can be lawfully utilized within his or her practice.
  - 12 (3) A person licensed under this chapter to engage in clinical  
13 laboratory practice or to direct a clinical laboratory.
  - 14 (4) A person authorized to perform tests pursuant to a  
15 certificate issued under Article 5 (commencing with Section  
16 101150) of Chapter 2 of Part 3 of Division 101 of the Health and  
17 Safety Code.
  - 18 (5) A licensed physician assistant ~~when~~ *if* authorized by a  
19 supervising physician and surgeon in accordance with Section  
20 3502 or Section 3535.
  - 21 (6) A person licensed under Chapter 6 (commencing with  
22 Section 2700).
  - 23 (7) A person licensed under Chapter 6.5 (commencing with  
24 Section 2840).
  - 25 (8) A perfusionist ~~when~~ *if* authorized by and performed in  
26 compliance with Section 2590.
  - 27 (9) A respiratory care practitioner ~~when~~ *if* authorized by and  
28 performed in compliance with Chapter 8.3 (commencing with  
29 Section 3700).
  - 30 (10) A medical assistant, as defined in Section 2069, ~~when~~ *if*  
31 the waived test is performed pursuant to a specific authorization  
32 meeting the requirements of Section 2069.
  - 33 (11) A pharmacist, ~~when~~ *if* ordering drug therapy-related  
34 laboratory tests in compliance with clause (ii) of subparagraph (A)  
35 of paragraph (5) of ~~subdivision (a) of~~, or ~~paragraph (6) of~~  
36 *subparagraph (B) of paragraph (4) of* subdivision (a) of, Section  
37 4052.
  - 38 (12) Other health care personnel providing direct patient care.
  - 39 (b) Notwithstanding subdivision (b) of Section 1206, no person  
40 shall perform clinical laboratory tests or examinations classified



1 as of moderate complexity under CLIA unless the clinical  
2 laboratory test or examination is performed under the overall  
3 operation and administration of the laboratory director, as  
4 described in Section 1209, including, but not limited to,  
5 documentation by the laboratory director of the adequacy of the  
6 qualifications and competency of the personnel, and the test is  
7 performed by any of the following persons:

8 (1) A licensed physician and surgeon holding a M.D. or D.O.  
9 degree.

10 (2) A licensed podiatrist or a licensed dentist ~~when~~ *if* the results  
11 of the tests can be lawfully utilized within his or her practice.

12 (3) A person licensed under this chapter to engage in clinical  
13 laboratory practice or to direct a clinical laboratory.

14 (4) A person authorized to perform tests pursuant to a  
15 certificate issued under Article 5 (commencing with Section  
16 101150) of Chapter 2 of Part 3 of Division 101 of the Health and  
17 Safety Code.

18 (5) A licensed physician assistant ~~when~~ *if* authorized by a  
19 supervising physician and surgeon in accordance with Section  
20 3502 or Section 3535.

21 (6) A person licensed under Chapter 6 (commencing with  
22 Section 2700).

23 (7) A perfusionist ~~when~~ *if* authorized by and performed in  
24 compliance with Section 2590.

25 (8) A respiratory care practitioner ~~when~~ *if* authorized by and  
26 performed in compliance with Chapter 8.3 (commencing with  
27 Section 3700).

28 (9) A person performing nuclear medicine technology ~~when~~ *if*  
29 authorized by and performed in compliance with Article 6  
30 (commencing with Section 107115) of Chapter 4 of Part 1 of  
31 Division 104 of the Health and Safety Code.

32 (10) Any person ~~when~~ *if* performing blood gas analysis in  
33 compliance with Section 1245.

34 (11) (A) A person certified as an “Emergency Medical  
35 Technician II” or paramedic pursuant to Division 2.5  
36 (commencing with Section 1797) of the Health and Safety Code  
37 while providing prehospital medical care, a person licensed as a  
38 psychiatric technician under Chapter 10 (commencing with  
39 Section 4500) of Division 2, as a vocational nurse pursuant to  
40 Chapter 6.5 (commencing with Section 2840) of Division 2, or as



1 a midwife licensed pursuant to Article 24 (commencing with  
2 Section 2505) of Chapter 5 of Division 2, or certified by the  
3 department pursuant to Division 5 (commencing with Section  
4 70001) of Title 22 of the California Code of Regulations as a nurse  
5 assistant or a home health aide, who provides direct patient care,  
6 ~~so long as~~ *if* the person is performing the test as an adjunct to the  
7 provision of direct patient care by the person, is utilizing a  
8 point-of-care laboratory testing device at a site for which a  
9 laboratory license or registration has been issued, meets the  
10 minimum clinical laboratory education, training, and experience  
11 requirements set forth in regulations adopted by the department,  
12 and has demonstrated to the satisfaction of the laboratory director  
13 that he or she is competent in the operation of the point-of-care  
14 laboratory testing device for each analyte to be reported.

15 (B) Prior to being authorized by the laboratory director to  
16 perform laboratory tests or examinations, testing personnel  
17 identified in subparagraph (A) shall participate in a preceptor  
18 program until they are able to perform the clinical laboratory tests  
19 or examinations authorized in this section with results that are  
20 deemed accurate and skills that are deemed competent by the  
21 preceptor. For the purposes of this section, a “preceptor program”  
22 means an organized system that meets regulatory requirements in  
23 which a preceptor provides and documents personal observation  
24 and critical evaluation, including review of accuracy, reliability,  
25 and validity, of laboratory testing performed.

26 (12) Any other person within a physician office laboratory  
27 ~~when~~ *if* the test is performed under the supervision of the patient’s  
28 physician and surgeon or podiatrist who shall be accessible to the  
29 laboratory to provide onsite, telephone, or electronic consultation  
30 as needed, and shall: (A) ensure that the person is performing test  
31 methods as required for accurate and reliable tests; and (B) have  
32 personal knowledge of the results of the clinical laboratory testing  
33 or examination performed by that person before the test results are  
34 reported from the laboratory.

35 (13) A pharmacist, ~~when~~ *if* ordering drug therapy-related  
36 laboratory tests in compliance with clause (ii) of subparagraph (A)  
37 of paragraph (5) of ~~subdivision (a) of~~, or ~~paragraph (6)~~  
38 *subparagraph (B) of paragraph (4) of*, subdivision (a) of, Section  
39 4052.



1 (c) Notwithstanding subdivision (b) of Section 1206, no person  
2 shall perform clinical laboratory tests or examinations classified  
3 as of high complexity under CLIA unless the clinical laboratory  
4 test or examination is performed under the overall operation and  
5 administration of the laboratory director, as described in Section  
6 1209, including, but not limited to, documentation by the  
7 laboratory director of the adequacy of the qualifications and  
8 competency of the personnel, and the test is performed by any of  
9 the following persons:

10 (1) A licensed physician and surgeon holding a M.D. or D.O.  
11 degree.

12 (2) A licensed podiatrist or a licensed dentist ~~when~~ *if* the results  
13 of the tests can be lawfully utilized within his or her practice.

14 (3) A person licensed under this chapter to engage in clinical  
15 laboratory practice or to direct a clinical laboratory ~~when~~ *if* the test  
16 or examination is within a specialty or subspecialty authorized by  
17 the person's licensure.

18 (4) A person authorized to perform tests pursuant to a  
19 certificate issued under Article 5 (commencing with Section  
20 101150) of Chapter 2 of Part 3 of Division 101 of the Health and  
21 Safety Code ~~when~~ *if* the test or examination is within a specialty  
22 or subspecialty authorized by the person's certification.

23 (5) A licensed physician assistant ~~when~~ *if* authorized by a  
24 supervising physician and surgeon in accordance with Section  
25 3502 or Section 3535.

26 (6) A perfusionist ~~when~~ *if* authorized by and performed in  
27 compliance with Section 2590.

28 (7) A respiratory care practitioner ~~when~~ *if* authorized by and  
29 performed in compliance with Chapter 8.3 (commencing with  
30 Section 3700).

31 (8) A person performing nuclear medicine technology ~~when~~ *if*  
32 authorized by and performed in compliance with Article 6  
33 (commencing with Section 107115) of Chapter 4 of Part 1 of  
34 Division 104 of the Health and Safety Code.

35 (9) Any person ~~when~~ *if* performing blood gas analysis in  
36 compliance with Section 1245.

37 (10) Any other person within a physician office laboratory  
38 ~~when~~ *if* the test is performed under the onsite supervision of the  
39 patient's physician and surgeon or podiatrist who shall: (A) ensure  
40 that the person is performing test methods as required for accurate



1 and reliable tests; and (B) have personal knowledge of the results  
2 of clinical laboratory testing or examination performed by that  
3 person before the test results are reported from the laboratory.

4 (d) Clinical laboratory examinations classified as  
5 provider-performed microscopy under CLIA may be personally  
6 performed using a brightfield or phase/contrast microscope by one  
7 of the following practitioners:

8 (1) A licensed physician and surgeon using the microscope  
9 during the patient's visit on a specimen obtained from his or her  
10 own patient or from a patient of a group medical practice of which  
11 the physician is a member or employee.

12 (2) A nurse midwife holding a certificate as specified by  
13 Section 2746.5, a licensed nurse practitioner as specified in  
14 Section 2835.5, or a licensed physician assistant acting under the  
15 supervision of a physician pursuant to Section 3502 using the  
16 microscope during the patient's visit on a specimen obtained from  
17 his or her own patient or from the patient of a clinic, group medical  
18 practice, or other health care provider of which the certified nurse  
19 midwife, licensed nurse practitioner, or licensed physician  
20 assistant is an employee.

21 (3) A licensed dentist using the microscope during the patient's  
22 visit on a specimen obtained from his or her own patient or from  
23 a patient of a group dental practice of which the dentist is a member  
24 or an employee.

