

AMENDED IN SENATE JULY 3, 2001
AMENDED IN ASSEMBLY MAY 3, 2001

CALIFORNIA LEGISLATURE—2001–02 REGULAR SESSION

ASSEMBLY BILL

No. 586

Introduced by Assembly Member Nation

February 21, 2001

An act to amend Section 1206.5 of, to add Section 4052.1 to, and to repeal Section 4102 of, the Business and Professions Code, relating to pharmacists.

LEGISLATIVE COUNSEL'S DIGEST

AB 586, as amended, Nation. Pharmacists: performance of routine patient assessments ~~assessments~~ *assessment* procedures and skin puncture.

Existing law prohibits the performance of a clinical laboratory test or examination classified as waived or of moderate complexity 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, including a pharmacist. The Pharmacy Law regulates the practice of pharmacy and authorizes a pharmacist to perform skin puncture in connection with routine patient assessment procedures, defined as including waived or moderate complexity tests, subject to the existing law provisions governing the performance of those tests by a pharmacist. *Existing law requires a pharmacist performing these functions to, at the direction of the patient, report the results obtained from a blood test to the patient and the patient's physician of choice.*

This bill would authorize a pharmacist to perform skin puncture in the course of performing an examination classified as waived. The bill would also delete moderate complexity tests from the definition of patient assessment procedures and would make the performance of those procedures subject to the supervision of a laboratory director. The bill would require a pharmacist performing these functions to report the results from any test to the patient and any physician designated by the patient.

A violation of the Pharmacy Law is a crime. Because a violation of this bill’s requirements regarding disclosure of test results to patients would be a misdemeanor, 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: ~~no~~ yes. State-mandated local program: ~~no~~ yes.

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
- 5 examination classified as waived under CLIA unless the clinical
- 6 laboratory test or examination is performed under the overall
- 7 operation and administration of the laboratory director, as
- 8 described in Section 1209, including, but not limited to,
- 9 documentation by the laboratory director of the adequacy of the
- 10 qualifications and competency of the personnel, and the test is
- 11 performed by any of the following persons:
- 12 (1) A licensed physician and surgeon holding a M.D. or D.O.
- 13 degree.
- 14 (2) A licensed podiatrist or a licensed dentist if the results of the
- 15 tests can be lawfully utilized within his or her practice.
- 16 (3) A person licensed under this chapter to engage in clinical
- 17 laboratory practice or to direct a clinical laboratory.



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

5 (5) A licensed physician assistant if authorized by a supervising
6 physician and surgeon in accordance with Section 3502 or Section
7 3535.

8 (6) A person licensed under Chapter 6 (commencing with
9 Section 2700).

10 (7) A person licensed under Chapter 6.5 (commencing with
11 Section 2840).

12 (8) A perfusionist if authorized by and performed in
13 compliance with Section 2590.

14 (9) A respiratory care practitioner if authorized by and
15 performed in compliance with Chapter 8.3 (commencing with
16 Section 3700).

17 (10) A medical assistant, as defined in Section 2069, if the
18 waived test is performed pursuant to a specific authorization
19 meeting the requirements of Section 2069.

20 (11) A pharmacist, as defined in Section 4036, if ordering drug
21 therapy-related laboratory tests in compliance with clause (ii) of
22 subparagraph (A) of paragraph (5) of, or subparagraph (B) of
23 paragraph (4) of, subdivision (a) of Section 4052, or if performing
24 *skin puncture in the course of performing* routine patient
25 assessment procedures in compliance with Section 4052.1.

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

27 (b) Notwithstanding subdivision (b) of Section 1206, no person
28 shall perform clinical laboratory tests or examinations classified
29 as of moderate complexity under CLIA unless the clinical
30 laboratory test or examination is performed under the overall
31 operation and administration of the laboratory director, as
32 described in Section 1209, including, but not limited to,
33 documentation by the laboratory director of the adequacy of the
34 qualifications and competency of the personnel, and the test is
35 performed by any of the following persons:

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

38 (2) A licensed podiatrist or a licensed dentist if the results of the
39 tests can be lawfully utilized within his or her practice.



- 1 (3) A person licensed under this chapter to engage in clinical
2 laboratory practice or to direct a clinical laboratory.
- 3 (4) A person authorized to perform tests pursuant to a
4 certificate issued under Article 5 (commencing with Section
5 101150) of Chapter 2 of Part 3 of Division 101 of the Health and
6 Safety Code.
- 7 (5) A licensed physician assistant if authorized by a supervising
8 physician and surgeon in accordance with Section 3502 or Section
9 3535.
- 10 (6) A person licensed under Chapter 6 (commencing with
11 Section 2700).
- 12 (7) A perfusionist if authorized by and performed in
13 compliance with Section 2590.
- 14 (8) A respiratory care practitioner if authorized by and
15 performed in compliance with Chapter 8.3 (commencing with
16 Section 3700).
- 17 (9) A person performing nuclear medicine technology if
18 authorized by and performed in compliance with Article 6
19 (commencing with Section 107115) of Chapter 4 of Part 1 of
20 Division 104 of the Health and Safety Code.
- 21 (10) Any person if performing blood gas analysis in
22 compliance with Section 1245.
- 23 (11) (A) A person certified as an “Emergency Medical
24 Technician II” or paramedic pursuant to Division 2.5
25 (commencing with Section 1797) of the Health and Safety Code
26 while providing prehospital medical care, a person licensed as a
27 psychiatric technician under Chapter 10 (commencing with
28 Section 4500) of Division 2, as a vocational nurse pursuant to
29 Chapter 6.5 (commencing with Section 2840) of Division 2, or as
30 a midwife licensed pursuant to Article 24 (commencing with
31 Section 2505) of Chapter 5 of Division 2, or certified by the
32 department pursuant to Division 5 (commencing with Section
33 70001) of Title 22 of the California Code of Regulations as a nurse
34 assistant or a home health aide, who provides direct patient care,
35 if the person is performing the test as an adjunct to the provision
36 of direct patient care by the person, is utilizing a point-of-care
37 laboratory testing device at a site for which a laboratory license or
38 registration has been issued, meets the minimum clinical
39 laboratory education, training, and experience requirements set
40 forth in regulations adopted by the department, and has



1 demonstrated to the satisfaction of the laboratory director that he
2 or she is competent in the operation of the point-of-care laboratory
3 testing device for each analyte to be reported.

4 (B) Prior to being authorized by the laboratory director to
5 perform laboratory tests or examinations, testing personnel
6 identified in subparagraph (A) shall participate in a preceptor
7 program until they are able to perform the clinical laboratory tests
8 or examinations authorized in this section with results that are
9 deemed accurate and skills that are deemed competent by the
10 preceptor. For the purposes of this section, a “preceptor program”
11 means an organized system that meets regulatory requirements in
12 which a preceptor provides and documents personal observation
13 and critical evaluation, including review of accuracy, reliability,
14 and validity, of laboratory testing performed.

15 (12) Any other person within a physician office laboratory if
16 the test is performed under the supervision of the patient’s
17 physician and surgeon or podiatrist who shall be accessible to the
18 laboratory to provide onsite, telephone, or electronic consultation
19 as needed, and shall: (A) ensure that the person is performing test
20 methods as required for accurate and reliable tests; and (B) have
21 personal knowledge of the results of the clinical laboratory testing
22 or examination performed by that person before the test results are
23 reported from the laboratory.

24 (13) A pharmacist, if ordering drug therapy-related laboratory
25 tests in compliance with clause (ii) of subparagraph (A) of
26 paragraph (5) of, or subparagraph (B) of paragraph (4) of,
27 subdivision (a) of Section 4052.

28 (c) Notwithstanding subdivision (b) of Section 1206, no person
29 shall perform clinical laboratory tests or examinations classified
30 as of high complexity under CLIA unless the clinical laboratory
31 test or examination is performed under the overall operation and
32 administration of the laboratory director, as described in Section
33 1209, including, but not limited to, documentation by the
34 laboratory director of the adequacy of the qualifications and
35 competency of the personnel, and the test is performed by any of
36 the following persons:

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

39 (2) A licensed podiatrist or a licensed dentist if the results of the
40 tests can be lawfully utilized within his or her practice.



- 1 (3) A person licensed under this chapter to engage in clinical
2 laboratory practice or to direct a clinical laboratory if the test or
3 examination is within a specialty or subspecialty authorized by the
4 person’s licensure.
- 5 (4) A person authorized to perform tests pursuant to a
6 certificate issued under Article 5 (commencing with Section
7 101150) of Chapter 2 of Part 3 of Division 101 of the Health and
8 Safety Code if the test or examination is within a specialty or
9 subspecialty authorized by the person’s certification.
- 10 (5) A licensed physician assistant if authorized by a supervising
11 physician and surgeon in accordance with Section 3502 or Section
12 3535.
- 13 (6) A perfusionist if authorized by and performed in
14 compliance with Section 2590.
- 15 (7) A respiratory care practitioner if authorized by and
16 performed in compliance with Chapter 8.3 (commencing with
17 Section 3700).
- 18 (8) A person performing nuclear medicine technology if
19 authorized by and performed in compliance with Article 6
20 (commencing with Section 107115) of Chapter 4 of Part 1 of
21 Division 104 of the Health and Safety Code.
- 22 (9) Any person if performing blood gas analysis in compliance
23 with Section 1245.
- 24 (10) Any other person within a physician office laboratory if
25 the test is performed under the onsite supervision of the patient’s
26 physician and surgeon or podiatrist who shall: (A) ensure that the
27 person is performing test methods as required for accurate and
28 reliable tests; and (B) have personal knowledge of the results of
29 clinical laboratory testing or examination performed by that
30 person before the test results are reported from the laboratory.
- 31 (d) Clinical laboratory examinations classified as
32 provider-performed microscopy under CLIA may be personally
33 performed using a brightfield or phase/contrast microscope by one
34 of the following practitioners:
 - 35 (1) A licensed physician and surgeon using the microscope
36 during the patient’s visit on a specimen obtained from his or her
37 own patient or from a patient of a group medical practice of which
38 the physician is a member or employee.
 - 39 (2) A nurse midwife holding a certificate as specified by
40 Section 2746.5, a licensed nurse practitioner as specified in



1 Section 2835.5, or a licensed physician assistant acting under the
2 supervision of a physician pursuant to Section 3502 using the
3 microscope during the patient’s visit on a specimen obtained from
4 his or her own patient or from the patient of a clinic, group medical
5 practice, or other health care provider of which the certified nurse
6 midwife, licensed nurse practitioner, or licensed physician
7 assistant is an employee.

8 (3) A licensed dentist using the microscope during the patient’s
9 visit on a specimen obtained from his or her own patient or from
10 a patient of a group dental practice of which the dentist is a member
11 or an employee.

12 SEC. 2. Section 4052.1 is added to the Business and
13 Professions Code, to read:

14 4052.1. Notwithstanding Section 2038 or any other provision
15 of law, a pharmacist may perform *skin puncture in the course of*
16 *performing* routine patient assessment ~~procedures and may~~
17 ~~perform skin puncture in the course of performing those~~
18 *procedures or in the course of performing any procedure*
19 *authorized under Section 1206.5.* For purposes of this section,
20 “routine patient assessment procedures” means: (a) procedures
21 that a patient could, with or without a prescription, perform for
22 himself or herself, or (b) clinical laboratory tests that are classified
23 as waived pursuant to the federal Clinical Laboratory
24 Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the
25 regulations adopted thereunder by the federal Health Care
26 Financing Administration, as authorized by paragraph (11) of
27 subdivision (a) of Section 1206.5. A pharmacist performing these
28 functions shall, ~~at the direction of the patient,~~ report the results
29 obtained from a ~~blood~~ test to the patient and ~~the patient’s physician~~
30 ~~of choice~~ *any physician designated by the patient.* Any pharmacist
31 who performs the service authorized by this section shall not be in
32 violation of Section 2052.

33 SEC. 3. Section 4102 of the Business and Professions Code
34 is repealed.

35 SEC. 4. *No reimbursement is required by this act pursuant to*
36 *Section 6 of Article XIII B of the California Constitution because*
37 *the only costs that may be incurred by a local agency or school*
38 *district will be incurred because this act creates a new crime or*
39 *infraction, eliminates a crime or infraction, or changes the penalty*
40 *for a crime or infraction, within the meaning of Section 17556 of*



- 1 *the Government Code, or changes the definition of a crime within*
- 2 *the meaning of Section 6 of Article XIII B of the California*
- 3 *Constitution.*

O

