

AMENDED IN SENATE JUNE 22, 2016

AMENDED IN ASSEMBLY APRIL 14, 2016

AMENDED IN ASSEMBLY MARCH 30, 2016

AMENDED IN ASSEMBLY MARCH 28, 2016

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL

No. 2179

Introduced by Assembly Member Gipson

February 18, 2016

An act to amend Section 1206.5 of the Business and Professions Code, and to add Section 122440 to the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

AB 2179, as amended, Gipson. Hepatitis C testing.

Under existing law, the State Department of Public Health licenses, registers, and regulates clinical laboratories and various clinical laboratory personnel. Existing law prohibits a person from performing a clinical laboratory test or examination classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 unless the test or examination is performed under the overall operation and administration of a laboratory director and the test or examination is performed by any one of specified professionals and others, including a licensed physician and surgeon or pharmacist. Existing law establishes the Office of AIDS in the department and defines human immunodeficiency virus (HIV) as the etiologic agent of acquired immunodeficiency syndrome (AIDS). Existing law authorizes an HIV counselor who receives specified training and works in specified

counseling and testing sites to perform HIV, hepatitis C virus (HCV), or combined HIV/HCV tests, including performing skin punctures for purposes of withdrawing blood for purposes of these tests, as specified.

This bill would authorize a hepatitis C counselor who receives specified training and works in described counseling and testing sites to perform HCV tests, and add hepatitis C counselors performing those tests to the specified professionals and others referred to above.

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 1206.5 of the Business and Professions
- 2 Code is amended to read:
- 3 1206.5. (a) Notwithstanding subdivision (b) of Section 1206
- 4 and except as otherwise provided in Sections 1206.6 and 1241, no
- 5 person shall perform a clinical laboratory test or examination
- 6 classified as waived under CLIA unless the clinical laboratory test
- 7 or examination is performed under the overall operation and
- 8 administration of the laboratory director, as described in Section
- 9 1209, including, but not limited to, documentation by the laboratory
- 10 director of the adequacy of the qualifications and competency of
- 11 the personnel, and the test is performed by any of the following
- 12 persons:
- 13 (1) A licensed physician and surgeon holding *a* M.D. or D.O.
- 14 degree.
- 15 (2) A licensed podiatrist, a licensed dentist, or a licensed
- 16 naturopathic doctor, if the results of the tests can be lawfully
- 17 utilized within his or her practice.
- 18 (3) A person licensed under this chapter to engage in clinical
- 19 laboratory practice or to direct a clinical laboratory.
- 20 (4) A person authorized to perform tests pursuant to a certificate
- 21 issued under Article 5 (commencing with Section 101150) of
- 22 Chapter 2 of Part 3 of Division 101 of the Health and Safety Code.
- 23 (5) A licensed physician assistant if authorized by a supervising
- 24 physician and surgeon in accordance with Section 3502 or 3535.
- 25 (6) A person licensed under Chapter 6 (commencing with
- 26 Section 2700).
- 27 (7) A person licensed under Chapter 6.5 (commencing with
- 28 Section 2840).

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

3 (9) A respiratory care practitioner if authorized by and
4 performed in compliance with Chapter 8.3 (commencing with
5 Section 3700).

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

9 (11) A pharmacist, as defined in Section 4036, if ordering drug
10 therapy-related laboratory tests in compliance with paragraph (2)
11 of subdivision (a) of Section 4052.1 or paragraph (2) of subdivision
12 (a) of Section 4052.2, or if performing skin puncture in the course
13 of performing routine patient assessment procedures in compliance
14 with Section 4052.1.

15 (12) A naturopathic assistant, as defined in Sections 3613 and
16 3640.2, if the waived test is performed pursuant to a specific
17 authorization meeting the requirements of Sections 3613 and
18 3640.2.

19 (13) A licensed optometrist as authorized under Chapter 7
20 (commencing with Section 3000).

21 (14) Other health care personnel providing direct patient care.

22 (15) Any other person performing nondiagnostic testing pursuant
23 to Section 1244.

24 (16) A hepatitis C counselor performing a hepatitis C virus
25 (HCV) test pursuant to Section 122440 of the Health and Safety
26 Code.

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 described
32 in Section 1209, including, but not limited to, documentation by
33 the laboratory director of the adequacy of the qualifications and
34 competency of the personnel, and the test is performed by any of
35 the following persons:

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

38 (2) A licensed podiatrist or a licensed dentist if the results of
39 the 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 certificate
4 issued under Article 5 (commencing with Section 101150) of
5 Chapter 2 of Part 3 of Division 101 of the Health and Safety Code.
- 6 (5) A licensed physician assistant if authorized by a supervising
7 physician and surgeon in accordance with Section 3502 or 3535.
- 8 (6) A person licensed under Chapter 6 (commencing with
9 Section 2700).
- 10 (7) A perfusionist if authorized by and performed in compliance
11 with Section 2590.
- 12 (8) A respiratory care practitioner if authorized by and
13 performed in compliance with Chapter 8.3 (commencing with
14 Section 3700).
- 15 (9) A person performing nuclear medicine technology if
16 authorized by and performed in compliance with Article 6
17 (commencing with Section 107150) of Chapter 4 of Part 1 of
18 Division 104 of the Health and Safety Code.
- 19 (10) Any person if performing blood gas analysis in compliance
20 with Section 1245.
- 21 (11) (A) A person certified or licensed as an “Emergency
22 Medical Technician II” or paramedic pursuant to Division 2.5
23 (commencing with Section 1797) of the Health and Safety Code
24 while providing prehospital medical care, a person licensed as a
25 psychiatric technician under Chapter 10 (commencing with Section
26 4500) of Division 2, as a vocational nurse pursuant to Chapter 6.5
27 (commencing with Section 2840), or as a midwife licensed pursuant
28 to Article 24 (commencing with Section 2505) of Chapter 5, or
29 certified by the department pursuant to Division 5 (commencing
30 with Section 70001) of Title 22 of the California Code of
31 Regulations as a nurse assistant or a home health aide, who
32 provides direct patient care, if the person is performing the test as
33 an adjunct to the provision of direct patient care by the person, is
34 utilizing a point-of-care laboratory testing device at a site for which
35 a laboratory license or registration has been issued, meets the
36 minimum clinical laboratory education, training, and experience
37 requirements set forth in regulations adopted by the department,
38 and has demonstrated to the satisfaction of the laboratory director
39 that he or she is competent in the operation of the point-of-care
40 laboratory testing device for each analyte to be reported.

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

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

21 (13) A pharmacist, if ordering drug therapy-related laboratory
22 tests in compliance with paragraph (2) of subdivision (a) of Section
23 4052.1 or paragraph (2) of subdivision (a) of Section 4052.2.

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

33 (1) A licensed physician and surgeon holding a *an* M.D. or D.O.
34 degree.

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

37 (3) A person licensed under this chapter to engage in clinical
38 laboratory practice or to direct a clinical laboratory if the test or
39 examination is within a specialty or subspecialty authorized by
40 the person’s licensure.

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

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

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

10 (7) A respiratory care practitioner if authorized by and
11 performed in compliance with Chapter 8.3 (commencing with
12 Section 3700).

13 (8) A person performing nuclear medicine technology if
14 authorized by and performed in compliance with Article 6
15 (commencing with Section 107150) of Chapter 4 of Part 1 of
16 Division 104 of the Health and Safety Code.

17 (9) Any person if performing blood gas analysis in compliance
18 with Section 1245.

19 (10) Any other person within a physician office laboratory if
20 the test is performed under the onsite supervision of the patient's
21 physician and surgeon or podiatrist who shall: (A) ensure that the
22 person is performing test methods as required for accurate and
23 reliable tests; and (B) have personal knowledge of the results of
24 clinical laboratory testing or examination performed by that person
25 before the test results are reported from the laboratory.

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

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

34 (2) A nurse midwife holding a certificate as specified by Section
35 2746.5, a licensed nurse practitioner as specified in Section 2835.5,
36 or a licensed physician assistant acting under the supervision of a
37 physician pursuant to Section 3502 using the microscope during
38 the patient's visit on a specimen obtained from his or her own
39 patient or from the patient of a clinic, group medical practice, or
40 other health care provider of which the certified nurse midwife,

1 licensed nurse practitioner, or licensed physician assistant is an
2 employee.

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

7 SEC. 2. Section 122440 is added to the Health and Safety Code,
8 to read:

9 122440. (a) A hepatitis C counselor who meets the
10 requirements of subdivision (d) may do all of the following:

11 (1) Perform any hepatitis C virus (HCV) test that is classified
12 as waived under the federal Clinical Laboratory Improvement Act
13 (CLIA) (42 U.S.C. Sec. 263a et seq.) if all of the following
14 conditions exist:

15 (A) The performance of the HCV test meets the requirements
16 of CLIA and Chapter 3 (commencing with Section 1200) of
17 Division 2 of the Business and Professions Code.

18 (B) Notwithstanding Section 1246 of the Business and
19 Professions Code, a hepatitis C counselor may perform skin
20 punctures for the purpose of withdrawing blood for waived HCV
21 testing, upon specific authorization from a licensed physician and
22 surgeon, provided that the person meets both of the following
23 requirements:

24 (i) He or she works under the direction of a licensed physician
25 and surgeon.

26 (ii) He or she has been trained in rapid test proficiency for skin
27 puncture blood tests and in universal infection control precautions,
28 consistent with best infection control practices established by the
29 Division of Occupational Safety and Health in the Department of
30 Industrial Relations and the federal Centers for Disease Control
31 and Prevention.

32 (C) The person performing the HCV test meets the requirements
33 for the performance of waived laboratory testing pursuant to
34 subdivision (a) of Section 1206.5 of the Business and Professions
35 Code. ~~For purposes of this subdivision and subdivision (a) of~~
36 ~~Section 1206.5 of the Business and Professions Code, a hepatitis~~
37 ~~C counselor who meets the requirements of subdivision (d) shall~~
38 ~~be "other health care personnel providing direct patient care" as~~
39 ~~referred to in paragraph (13) of subdivision (a) of Section 1206.5~~
40 ~~of the Business and Professions Code.~~

1 (D) The patient is informed that the preliminary result of the
2 test is indicative of the likelihood of HCV exposure and that the
3 result must be confirmed by an additional more specific test, or,
4 if approved by the federal Centers for Disease Control and
5 Prevention for that purpose, a second, different rapid HCV test.
6 This subdivision does not allow a hepatitis C counselor to perform
7 any HCV test that is not classified as waived under CLIA.

8 (2) Notwithstanding Section 1246.5 of the Business and
9 Professions Code, order and report HCV test results from tests
10 performed pursuant to paragraph (1) to patients without
11 authorization from a licensed health care practitioner or his or her
12 authorized representative. A patient who has an indeterminate or
13 positive test result from tests performed pursuant to paragraph (1)
14 shall be referred to a licensed health care practitioner whose scope
15 of practice includes the authority to refer a patient for laboratory
16 testing for further evaluation.

17 (b) A hepatitis C counselor who meets the requirements of this
18 section with respect to performing any HCV test that is classified
19 as waived under CLIA may not perform any other test unless that
20 person meets the statutory and regulatory requirements for
21 performing that other test.

22 (c) Compliance with this section does not fulfill any
23 requirements for certification as a phlebotomy technician or a
24 limited phlebotomy technician, unless the hepatitis C counselor
25 has otherwise satisfied the certification requirements imposed
26 pursuant to Section 1246 of the Business and Professions Code.

27 (d) A hepatitis C counselor shall meet one of the following
28 criteria:

29 (1) Is trained by the Office of AIDS and working in an HIV
30 counseling and testing site funded by the department through a
31 local health jurisdiction, or its agents.

32 (2) Is working in an HIV counseling and testing site that meets
33 both of the following criteria:

34 (A) Utilizes HIV counseling staff who are trained by the Office
35 of AIDS or its agents to provide both HIV counseling and testing
36 and hepatitis C counseling and testing.

37 (B) Has and retains a quality assurance plan approved by the
38 local health department in the jurisdiction where the site is located
39 and has HIV counseling and testing staff who comply with the

1 quality assurance requirements as specified by the State Department
2 of Public Health.

3 (3) Is working at a site approved by the local health department
4 to provide hepatitis C rapid testing and counseling, and has been
5 trained using a curriculum approved by the local health department,
6 and retained by the site, or approved by the State Department of
7 Public Health, which, at a minimum, provides training in universal
8 precautions, safe working conditions, proper running and reading
9 of hepatitis C rapid test kit technology, and providing accurate
10 information to clients including the importance of confirmatory
11 tests, linkages to medical care, and the prevention of hepatitis C
12 transmission.

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