

AMENDED IN SENATE AUGUST 16, 2016
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 meets specified requirements to perform an HCV test and to order and report HCV test results. The bill would authorize the State Department of Public Health to implement and administer these provisions by means of a bulletin or similar instructions. The bill would also add hepatitis C counselors performing those tests to the specified professionals and others referred to above: an HCV test to the list of professionals authorized to perform a test or examination classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988, as specified.~~

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 an 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.

- 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 (5) A licensed physician assistant if authorized by a supervising
5 physician and surgeon in accordance with Section 3502 or 3535.
- 6 (6) A person licensed under Chapter 6 (commencing with
7 Section 2700).
- 8 (7) A person licensed under Chapter 6.5 (commencing with
9 Section 2840).
- 10 (8) A perfusionist if authorized by and performed in compliance
11 with Section 2590.
- 12 (9) A respiratory care practitioner if authorized by and
13 performed in compliance with Chapter 8.3 (commencing with
14 Section 3700).
- 15 (10) A medical assistant, as defined in Section 2069, if the
16 waived test is performed pursuant to a specific authorization
17 meeting the requirements of Section 2069.
- 18 (11) A pharmacist, as defined in Section 4036, if ordering drug
19 therapy-related laboratory tests in compliance with paragraph (2)
20 of subdivision (a) of Section 4052.1 or paragraph (2) of subdivision
21 (a) of Section 4052.2, or if performing skin puncture in the course
22 of performing routine patient assessment procedures in compliance
23 with Section 4052.1.
- 24 (12) A naturopathic assistant, as defined in Sections 3613 and
25 3640.2, if the waived test is performed pursuant to a specific
26 authorization meeting the requirements of Sections 3613 and
27 3640.2.
- 28 (13) A licensed optometrist as authorized under Chapter 7
29 (commencing with Section 3000).
- 30 (14) Other health care personnel providing direct patient care.
- 31 (15) Any other person performing nondiagnostic testing pursuant
32 to Section 1244.
- 33 (16) A hepatitis C counselor performing a hepatitis C virus
34 (HCV) test pursuant to Section 122440 of the Health and Safety
35 Code.
- 36 (b) Notwithstanding subdivision (b) of Section 1206, no person
37 shall perform clinical laboratory tests or examinations classified
38 as of moderate complexity under CLIA unless the clinical
39 laboratory test or examination is performed under the overall
40 operation and administration of the laboratory director, as described

1 in Section 1209, including, but not limited to, documentation by
2 the laboratory director of the adequacy of the qualifications and
3 competency of the personnel, and the test is performed by any of
4 the following persons:

5 (1) A licensed physician and surgeon holding an M.D. or D.O.
6 degree.

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

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

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

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

16 (6) A person licensed under Chapter 6 (commencing with
17 Section 2700).

18 (7) A perfusionist if authorized by and performed in compliance
19 with Section 2590.

20 (8) A respiratory care practitioner if authorized by and
21 performed in compliance with Chapter 8.3 (commencing with
22 Section 3700).

23 (9) A person performing nuclear medicine technology if
24 authorized by and performed in compliance with Article 6
25 (commencing with Section 107150) of Chapter 4 of Part 1 of
26 Division 104 of the Health and Safety Code.

27 (10) Any person if performing blood gas analysis in compliance
28 with Section 1245.

29 (11) (A) A person certified or licensed as an “Emergency
30 Medical Technician II” or paramedic pursuant to Division 2.5
31 (commencing with Section 1797) of the Health and Safety Code
32 while providing prehospital medical care, a person licensed as a
33 psychiatric technician under Chapter 10 (commencing with Section
34 4500) of Division 2, as a vocational nurse pursuant to Chapter 6.5
35 (commencing with Section 2840), or as a midwife licensed pursuant
36 to Article 24 (commencing with Section 2505) of Chapter 5, or
37 certified by the department pursuant to Division 5 (commencing
38 with Section 70001) of Title 22 of the California Code of
39 Regulations as a nurse assistant or a home health aide, who
40 provides direct patient care, if the person is performing the test as

1 an adjunct to the provision of direct patient care by the person, is
2 utilizing a point-of-care laboratory testing device at a site for which
3 a laboratory license or registration has been issued, meets the
4 minimum clinical laboratory education, training, and experience
5 requirements set forth in regulations adopted by the department,
6 and has demonstrated to the satisfaction of the laboratory director
7 that he or she is competent in the operation of the point-of-care
8 laboratory testing device for each analyte to be reported.

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

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

29 (13) A pharmacist, if ordering drug therapy-related laboratory
30 tests in compliance with paragraph (2) of subdivision (a) of Section
31 4052.1 or paragraph (2) of subdivision (a) of Section 4052.2.

32 (c) Notwithstanding subdivision (b) of Section 1206, no person
33 shall perform clinical laboratory tests or examinations classified
34 as of high complexity under CLIA unless the clinical laboratory
35 test or examination is performed under the overall operation and
36 administration of the laboratory director, as described in Section
37 1209, including, but not limited to, documentation by the laboratory
38 director of the adequacy of the qualifications and competency of
39 the personnel, and the test is performed by any of the following
40 persons:

- 1 (1) A licensed physician and surgeon holding an M.D. or D.O.
2 degree.
- 3 (2) A licensed podiatrist or a licensed dentist if the results of
4 the tests can be lawfully utilized within his or her practice.
- 5 (3) A person licensed under this chapter to engage in clinical
6 laboratory practice or to direct a clinical laboratory if the test or
7 examination is within a specialty or subspecialty authorized by
8 the person’s licensure.
- 9 (4) A person authorized to perform tests pursuant to a certificate
10 issued under Article 5 (commencing with Section 101150) of
11 Chapter 2 of Part 3 of Division 101 of the Health and Safety Code
12 if the test or examination is within a specialty or subspecialty
13 authorized by the person’s certification.
- 14 (5) A licensed physician assistant if authorized by a supervising
15 physician and surgeon in accordance with Section 3502 or 3535.
- 16 (6) A perfusionist if authorized by and performed in compliance
17 with Section 2590.
- 18 (7) A respiratory care practitioner if authorized by and
19 performed in compliance with Chapter 8.3 (commencing with
20 Section 3700).
- 21 (8) A person performing nuclear medicine technology if
22 authorized by and performed in compliance with Article 6
23 (commencing with Section 107150) of Chapter 4 of Part 1 of
24 Division 104 of the Health and Safety Code.
- 25 (9) Any person if performing blood gas analysis in compliance
26 with Section 1245.
- 27 (10) Any other person within a physician office laboratory if
28 the test is performed under the onsite supervision of the patient’s
29 physician and surgeon or podiatrist who shall: (A) ensure that the
30 person is performing test methods as required for accurate and
31 reliable tests; and (B) have personal knowledge of the results of
32 clinical laboratory testing or examination performed by that person
33 before the test results are reported from the laboratory.
- 34 (d) Clinical laboratory examinations classified as
35 provider-performed microscopy under CLIA may be personally
36 performed using a brightfield or phase/contrast microscope by one
37 of the following practitioners:
 - 38 (1) A licensed physician and surgeon using the microscope
39 during the patient’s visit on a specimen obtained from his or her

1 own patient or from a patient of a group medical practice of which
2 the physician is a member or employee.

3 (2) A nurse midwife holding a certificate as specified by Section
4 2746.5, a licensed nurse practitioner as specified in Section 2835.5,
5 or a licensed physician assistant acting under the supervision of a
6 physician pursuant to Section 3502 using the microscope during
7 the patient's visit on a specimen obtained from his or her own
8 patient or from the patient of a clinic, group medical practice, or
9 other health care provider of which the certified nurse midwife,
10 licensed nurse practitioner, or licensed physician assistant is an
11 employee.

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

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

18 122440. (a) A hepatitis C counselor who meets the
19 requirements of subdivision (d) may do all of the following:

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

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

27 (B) Notwithstanding Section 1246 of the Business and
28 Professions Code, a hepatitis C counselor may perform skin
29 punctures for the purpose of withdrawing blood for waived HCV
30 testing, upon specific authorization from a licensed physician and
31 surgeon, provided that the person meets both of the following
32 requirements:

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

35 (ii) He or she has been trained in rapid test proficiency for skin
36 puncture blood tests and in universal infection control precautions,
37 consistent with best infection control practices established by the
38 Division of Occupational Safety and Health in the Department of
39 Industrial Relations and the federal Centers for Disease Control
40 and Prevention.

1 (C) The person performing the HCV test meets the requirements
2 for the performance of waived laboratory testing pursuant to
3 subdivision (a) of Section 1206.5 of the Business and Professions
4 Code.

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

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

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

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

31 (d) A hepatitis C counselor shall meet one of the following
32 criteria:

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

36 *(1) Is authorized to perform an HCV test in accordance with*
37 *paragraph (1) of subdivision (a) of Section 120917.*

38 (2) Is working in ~~an HIV~~ a hepatitis C counseling and testing
39 site that meets both of the following criteria:

1 (A) Utilizes ~~HIV counseling staff~~ *hepatitis C counselors* who
2 are trained by the ~~Office of AIDS~~ *State Department of Public*
3 *Health* or its agents to provide ~~both HIV counseling and testing~~
4 ~~and~~ *hepatitis C counseling and testing*. *For the purposes of this*
5 *subparagraph, a training agent may include, but is not limited to,*
6 *a local health department or its designee, an academic medical*
7 *center, or a community-based organization.*

8 (B) Has and retains a quality assurance plan ~~approved by the~~
9 ~~local health department in the jurisdiction where the site is located~~
10 ~~and has HIV and has hepatitis C counseling and testing staff who~~
11 ~~comply with the quality assurance requirements as specified by~~
12 ~~the State Department of Public Health.~~ *protocols and guidelines*
13 *made available by the State Department of Public Health in*
14 *accordance with Section 122410.*

15 (3) ~~Is working at a site approved by the local health department~~
16 ~~to provide hepatitis C rapid testing and counseling, and has been~~
17 ~~trained using a curriculum approved by the local health department,~~
18 ~~and retained by the site, or approved by the State Department of~~
19 ~~Public Health, which, at a minimum, provides training in universal~~
20 ~~precautions, safe working conditions, proper running and reading~~
21 ~~of hepatitis C rapid test kit technology, and providing accurate~~
22 ~~information to clients including the importance of confirmatory~~
23 ~~tests, linkages to medical care, and the prevention of hepatitis C~~
24 ~~transmission.~~