

Assembly Bill No. 2179

Passed the Assembly August 24, 2016

Chief Clerk of the Assembly

Passed the Senate August 19, 2016

Secretary of the Senate

This bill was received by the Governor this _____ day
of _____, 2016, at _____ o'clock ____M.

Private Secretary of the Governor

CHAPTER _____

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, 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 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 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.

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

SECTION 1. Section 1206.5 of the Business and Professions Code is amended to read:

1206.5. (a) Notwithstanding subdivision (b) of Section 1206 and except as otherwise provided in Sections 1206.6 and 1241, no person shall perform a clinical laboratory test or examination classified as waived under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:

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

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

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

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

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

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

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

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

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

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

(11) A pharmacist, as defined in Section 4036, if ordering drug therapy-related laboratory tests in compliance with paragraph (2)

of subdivision (a) of Section 4052.1 or paragraph (2) of subdivision (a) of Section 4052.2, or if performing skin puncture in the course of performing routine patient assessment procedures in compliance with Section 4052.1.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(11) (A) A person certified or licensed as an “Emergency Medical Technician II” or paramedic pursuant to Division 2.5 (commencing with Section 1797) of the Health and Safety Code while providing prehospital medical care, a person licensed as a psychiatric technician under Chapter 10 (commencing with Section 4500) of Division 2, as a vocational nurse pursuant to Chapter 6.5 (commencing with Section 2840), or as a midwife licensed pursuant to Article 24 (commencing with Section 2505) of Chapter 5, or certified by the department pursuant to Division 5 (commencing with Section 70001) of Title 22 of the California Code of Regulations as a nurse assistant or a home health aide, who provides direct patient care, if the person is performing the test as an adjunct to the provision of direct patient care by the person, is utilizing a point-of-care laboratory testing device at a site for which a laboratory license or registration has been issued, meets the minimum clinical laboratory education, training, and experience requirements set forth in regulations adopted by the department, and has demonstrated to the satisfaction of the laboratory director that he or she is competent in the operation of the point-of-care laboratory testing device for each analyte to be reported.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) Notwithstanding Section 1246.5 of the Business and Professions Code, order and report HCV test results from tests performed pursuant to paragraph (1) to patients without authorization from a licensed health care practitioner or his or her authorized representative. A patient who has an indeterminate or positive test result from tests performed pursuant to paragraph (1)

shall be referred to a licensed health care practitioner whose scope of practice includes the authority to refer a patient for laboratory testing for further evaluation.

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

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

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

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

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

(A) Utilizes hepatitis C counselors who are trained by the State Department of Public Health or its agents to provide hepatitis C counseling and testing. For the purposes of this subparagraph, a training agent may include, but is not limited to, a local health department or its designee, an academic medical center, or a community-based organization.

(B) Has and retains a quality assurance plan and has hepatitis C counseling and testing staff who comply with the quality assurance protocols and guidelines made available by the State Department of Public Health in accordance with Section 122410.

Approved _____, 2016

Governor