

Assembly Bill No. 586

CHAPTER 501

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.

[Approved by Governor October 4, 2001. Filed with Secretary of State October 4, 2001.]

LEGISLATIVE COUNSEL'S DIGEST

AB 586, Nation. Pharmacists: performance of routine patient 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.

This bill would incorporate additional changes in Section 1206.5 of the Business and Professions Code proposed by SB 1174, that would become operative only if SB 1174 and this bill are both chaptered and become effective on or before January 1, 2002, and this bill is chaptered last.

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, 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 a 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 Section 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 clause (ii) of subparagraph (A) of paragraph (5) of, or subparagraph (B) of paragraph (4) of, subdivision (a) of Section 4052, or if performing skin puncture in the course of performing routine patient assessment procedures in compliance with Section 4052.1.

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

(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 a 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 Section 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 107115) 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 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) of Division 2,



or as a midwife licensed pursuant to Article 24 (commencing with Section 2505) of Chapter 5 of Division 2, 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 clause (ii) of subparagraph (A) of paragraph (5) of, or subparagraph (B) of paragraph (4) of, subdivision (a) of Section 4052.

(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 a 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 Section 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 107115) 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. 1.5. 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 Section 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 a 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 Section 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 clause (ii) of subparagraph (A) of paragraph (5) of , or subparagraph (B) of paragraph (4) of, subdivision (a) of Section 4052, or if performing skin puncture



in the course of performing routine patient assessment procedures in compliance with Section 4052.1.

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

(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 a 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 Section 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 107115) 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) of Division 2, or as a midwife licensed pursuant to Article 24 (commencing with Section 2505) of Chapter 5 of Division 2, 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 clause (ii) of subparagraph (A) of paragraph (5) of, or subparagraph (B) of paragraph (4) of, subdivision (a) of Section 4052.

(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 a 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 Section 3535.

(6) A perfumist 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 107115) 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 4052.1 is added to the Business and Professions Code, to read:

4052.1. Notwithstanding Section 2038 or any other provision of law, a pharmacist may perform skin puncture in the course of performing routine patient assessment procedures or in the course of performing any procedure authorized under Section 1206.5. For purposes of this section, "routine patient assessment procedures" means: (a) procedures that a patient could, with or without a prescription, perform for himself or herself, or (b) clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration, as authorized by paragraph (11) of subdivision (a) of Section 1206.5. A pharmacist performing these functions shall report the results obtained from a test to the patient and any physician designated by the patient. Any pharmacist who performs the service authorized by this section shall not be in violation of Section 2052.

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

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

SEC. 5. Section 1.5 of this bill incorporates amendments to Section 1206.5 of the Business and Professions Code proposed by both this bill and SB 1174. It shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2002, (2) each bill amends Section 1206.5 of the Business and Professions Code, and (3) this bill is enacted after SB 1174, in which case Section 1 of this bill shall not become operative.

