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SB-409 Pharmacy practice: testing. (2021-2022)

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Senate Bill No. 409

CHAPTER 604

An act to amend Sections 1206.5, 1209, and 4052.4 of, and to add Section 4119.10 to, the Business and Professions Code, relating to pharmacy.

[Approved by Governor October 06, 2021. Filed with Secretary of State October 06, 2021.]

LEGISLATIVE COUNSEL'S DIGEST

SB 409, Caballero. Pharmacy practice: testing.

Existing law provides for the licensure, registration, and regulation of clinical laboratories and various clinical laboratory personnel by the State Department of Public Health. Existing law prohibits the performance of a clinical laboratory test or examination classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) unless specific criteria are met, including that the test or examination is performed under the overall operation and administration of a laboratory director, as defined.

Existing law, the Pharmacy Law, provides for the licensing and regulation of pharmacists by the California State Board of Pharmacy in the Department of Consumer Affairs. A violation of the Pharmacy Law is a crime. Existing law authorizes a pharmacist to independently initiate and administer any COVID-19 vaccines approved or authorized by the United States Food and Drug Administration (FDA), or vaccines listed on the routine immunization schedules recommended by the federal Advisory Committee on Immunization Practices (ACIP) in compliance with individual ACIP vaccine recommendations and published by the federal Centers for Disease Control and Prevention (CDC) for persons 3 years of age or older.

This bill would also authorize a pharmacist or a pharmacy to perform, in accordance with specified requirements and conditions, any aspect of an FDA-approved or -authorized test that is classified as waived under CLIA if the test is used to detect or screen for certain illnesses, conditions, or diseases identified in the bill or the test is approved by the board, in conjunction with the Medical Board of California and Laboratory Field Services in the State Department of Public Health, by regulation. The bill would make conforming changes in provisions related to clinical laboratories to authorize testing and include pharmacist-in-charge, as specified, in the definition of a laboratory director. The bill would require a pharmacy and a pharmacist-in-charge to maintain documents related to testing and compliance in a specified manner. Because a violation of these provisions would be a crime, 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 to Section 1209 of the Business and Professions Code proposed by AB 526 to be operative only if this bill and AB 526 are enacted and this bill is enacted 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 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 a 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 their 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, if performing skin puncture in the course of performing routine patient assessment procedures in compliance with Section 4052.1, or if performing testing as authorized in Section 4052.4.
- (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.

(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 their 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 the person 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 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 their 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 their 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 their 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 their own patient or from a patient of a group dental practice of which the dentist is a member or an employee.

SEC. 2. Section 1209 of the Business and Professions Code is amended to read:

1209. (a) As used in this chapter, "laboratory director" means any person who is any of the following:

(1) A duly licensed physician and surgeon.

(2) Only for purposes of a clinical laboratory test or examination classified as waived, is any of the following:

(A) A duly licensed clinical laboratory scientist.

(B) A duly licensed limited clinical laboratory scientist.

(C) A duly licensed naturopathic doctor.

(D) A duly licensed optometrist serving as the director of a laboratory that only performs clinical laboratory tests authorized in paragraph (10) of subdivision (d) of Section 3041.

(E) A pharmacist-in-charge of a pharmacy serving as the director of a laboratory that only performs tests waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a), as authorized by the Pharmacy Law (Chapter 9 (commencing with Section 4000)).

(3) Licensed to direct a clinical laboratory under this chapter.

(b) (1) A person defined in paragraph (1) or (3) of subdivision (a) who is identified as the CLIA laboratory director of a laboratory that performs clinical laboratory tests classified as moderate or high complexity shall also meet the laboratory director qualifications under CLIA for the type and complexity of tests being offered by the laboratory.

(2) As used in this subdivision, "CLIA laboratory director" means the person identified as the laboratory director on the CLIA certificate issued to the laboratory by the federal Centers for Medicare and Medicaid Services (CMS).

(c) The laboratory director, if qualified under CLIA, may perform the duties of the technical consultant, technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to persons qualified under CLIA. If the laboratory director reapportions performance of those responsibilities or duties, they shall remain responsible for ensuring that all those duties and responsibilities are properly performed.

(d) (1) The laboratory director is responsible for the overall operation and administration of the clinical laboratory, including administering the technical and scientific operation of a clinical laboratory, the selection and supervision of procedures, the reporting of results, and active participation in its operations to the extent necessary to ensure compliance with this act and CLIA.

They shall be responsible for the proper performance of all laboratory work of all subordinates and shall employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests, and report test results in accordance with the personnel qualifications, duties, and responsibilities described in CLIA and this chapter.

(2) Where a point-of-care laboratory testing device is utilized and provides results for more than one analyte, the testing personnel may perform and report the results of all tests ordered for each analyte for which they have been found by the laboratory director to be competent to perform and report.

(e) As part of the overall operation and administration, the laboratory director of a registered laboratory shall document the adequacy of the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory test procedures and examinations. In determining the adequacy of qualifications, the laboratory director shall comply with any regulations adopted by the department that specify the minimum qualifications for personnel, in addition to any CLIA requirements relative to the education or training of personnel.

(f) As part of the overall operation and administration, the laboratory director of a licensed laboratory shall do all of the following:

(1) Ensure that all personnel, prior to testing biological specimens, have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. In determining the adequacy of qualifications, the laboratory director shall comply with any regulations adopted by the department that specify the minimum qualifications for, and the type of procedures that may be performed by, personnel in addition to any CLIA requirements relative to the education or training of personnel. Any regulations adopted pursuant to this section that specify the type of procedure that may be performed by testing personnel shall be based on the skills, knowledge, and tasks required to perform the type of procedure in question.

(2) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to ensure that they are competent and maintain their competency to process biological specimens, perform test procedures, and report test results promptly and proficiently, and, whenever necessary, identify needs for remedial training or continuing education to improve skills.

(3) Specify in writing the responsibilities and duties of each individual engaged in the performance of the preanalytic, analytic, and postanalytic phases of clinical laboratory tests or examinations, including which clinical laboratory tests or examinations the individual is authorized to perform, whether supervision is required for the individual to perform specimen processing, test performance, or results reporting, and whether consultant, supervisor, or director review is required prior to the individual reporting patient test results.

(g) The competency and performance of staff of a licensed laboratory shall be evaluated and documented by the laboratory director, or by a person who qualifies as a technical consultant or a technical supervisor under CLIA depending on the type and complexity of tests being offered by the laboratory.

(1) The procedures for evaluating the competency of the staff shall include, but are not limited to, all of the following:

(A) Direct observations of routine patient test performance, including patient preparation, if applicable, and specimen handling, processing, and testing.

(B) Monitoring the recording and reporting of test results.

(C) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

(D) Direct observation of performance of instrument maintenance and function checks.

(E) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples.

(F) Assessment of problem solving skills.

(2) Evaluation and documentation of staff competency and performance shall occur at least semiannually during the first year an individual tests biological specimens. Thereafter, evaluations shall be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance shall be reevaluated to include the use of the new test methodology or instrumentation.

(h) The laboratory director of each clinical laboratory of an acute care hospital shall be a physician and surgeon who is a qualified pathologist, except as follows:

(1) If a qualified pathologist is not available, a physician and surgeon or a clinical laboratory bioanalyst qualified as a laboratory director under subdivision (a) may direct the laboratory. However, a qualified pathologist shall be available for consultation at suitable intervals to ensure high-quality service.

(2) If there are two or more clinical laboratories of an acute care hospital, those additional clinical laboratories that are limited to the performance of blood gas analysis, blood electrolyte analysis, or both, may be directed by a physician and surgeon qualified as a laboratory director under subdivision (a), irrespective of whether a pathologist is available.

As used in this subdivision, a qualified pathologist is a physician and surgeon certified or eligible for certification in clinical or anatomical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology.

(i) Subdivision (h) does not apply to any director of a clinical laboratory of an acute care hospital acting in that capacity on or before January 1, 1988.

(j) A laboratory director may serve as the director of up to the maximum number of laboratories stipulated by CLIA, as defined under Section 1202.5.

SEC. 2.5. Section 1209 of the Business and Professions Code is amended to read:

1209. (a) As used in this chapter, "laboratory director" means any person who is any of the following:

(1) A duly licensed physician and surgeon.

(2) Only for purposes of a clinical laboratory test or examination classified as waived, is any of the following:

(A) A duly licensed clinical laboratory scientist.

(B) A duly licensed limited clinical laboratory scientist.

(C) A duly licensed naturopathic doctor.

(D) A duly licensed optometrist serving as the director of a laboratory that only performs clinical laboratory tests authorized in paragraph (10) of subdivision (d) of Section 3041.

(E) A duly licensed dentist serving as the director of a laboratory that performs only clinical laboratory tests authorized within the scope of practice of dentistry as delineated under Section 1625.

(F) A pharmacist-in-charge of a pharmacy serving as the director of a laboratory that only performs tests waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a), as authorized by the Pharmacy Law (Chapter 9 (commencing with Section 4000)).

(3) Licensed to direct a clinical laboratory under this chapter.

(b) (1) A person defined in paragraph (1) or (3) of subdivision (a) who is identified as the CLIA laboratory director of a laboratory that performs clinical laboratory tests classified as moderate or high complexity shall also meet the laboratory director qualifications under CLIA for the type and complexity of tests being offered by the laboratory.

(2) As used in this subdivision, "CLIA laboratory director" means the person identified as the laboratory director on the CLIA certificate issued to the laboratory by the federal Centers for Medicare and Medicaid Services (CMS).

(c) The laboratory director, if qualified under CLIA, may perform the duties of the technical consultant, technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to persons qualified under CLIA. If the laboratory director reapportions performance of those responsibilities or duties, they shall remain responsible for ensuring that all those duties and responsibilities are properly performed.

(d) (1) The laboratory director is responsible for the overall operation and administration of the clinical laboratory, including administering the technical and scientific operation of a clinical laboratory, the selection and supervision of procedures, the reporting of results, and active participation in its operations to the extent necessary to ensure compliance with this act and CLIA. They shall be responsible for the proper performance of all laboratory work of all subordinates and shall employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests, and report test results in accordance with the personnel qualifications, duties, and responsibilities described in CLIA and this chapter.

(2) Where a point-of-care laboratory testing device is utilized and provides results for more than one analyte, the testing personnel may perform and report the results of all tests ordered for each analyte for which they have been found by the laboratory director to be competent to perform and report.

(e) As part of the overall operation and administration, the laboratory director of a registered laboratory shall document the adequacy of the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory test procedures and examinations. In determining the adequacy of qualifications, the laboratory director shall comply with any regulations adopted by the department that specify the minimum qualifications for personnel, in addition to any CLIA requirements relative to the education or training of personnel.

(f) As part of the overall operation and administration, the laboratory director of a licensed laboratory shall do all of the following:

(1) Ensure that all personnel, prior to testing biological specimens, have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. In determining the adequacy of qualifications, the laboratory director shall comply with any regulations adopted by the department that specify the minimum qualifications for, and the type of procedures that may be performed by, personnel in addition to any CLIA requirements relative to the education or training of personnel. Any regulations adopted pursuant to this section that specify the type of procedure that may be performed by testing personnel shall be based on the skills, knowledge, and tasks required to perform the type of procedure in question.

(2) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to ensure that they are competent and maintain their competency to process biological specimens, perform test procedures, and report test results promptly and proficiently, and, whenever necessary, identify needs for remedial training or continuing education to improve skills.

(3) Specify in writing the responsibilities and duties of each individual engaged in the performance of the preanalytic, analytic, and postanalytic phases of clinical laboratory tests or examinations, including which clinical laboratory tests or examinations the individual is authorized to perform, whether supervision is required for the individual to perform specimen processing, test performance, or results reporting, and whether consultant, supervisor, or director review is required prior to the individual reporting patient test results.

(g) The competency and performance of staff of a licensed laboratory shall be evaluated and documented by the laboratory director, or by a person who qualifies as a technical consultant or a technical supervisor under CLIA depending on the type and complexity of tests being offered by the laboratory.

(1) The procedures for evaluating the competency of the staff shall include, but are not limited to, all of the following:

(A) Direct observations of routine patient test performance, including patient preparation, if applicable, and specimen handling, processing, and testing.

(B) Monitoring the recording and reporting of test results.

(C) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

(D) Direct observation of performance of instrument maintenance and function checks.

(E) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples.

(F) Assessment of problem solving skills.

(2) Evaluation and documentation of staff competency and performance shall occur at least semiannually during the first year an individual tests biological specimens. Thereafter, evaluations shall be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance shall be reevaluated to include the use of the new test methodology or instrumentation.

(h) The laboratory director of each clinical laboratory of an acute care hospital shall be a physician and surgeon who is a qualified pathologist, except as follows:

(1) If a qualified pathologist is not available, a physician and surgeon or a clinical laboratory bioanalyst qualified as a laboratory director under subdivision (a) may direct the laboratory. However, a qualified pathologist shall be available for consultation at suitable intervals to ensure high-quality service.

(2) If there are two or more clinical laboratories of an acute care hospital, those additional clinical laboratories that are limited to the performance of blood gas analysis, blood electrolyte analysis, or both, may be directed by a physician and surgeon qualified as a laboratory director under subdivision (a), irrespective of whether a pathologist is available.

As used in this subdivision, a qualified pathologist is a physician and surgeon certified or eligible for certification in clinical or anatomical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology.

(i) Subdivision (h) does not apply to any director of a clinical laboratory of an acute care hospital acting in that capacity on or before January 1, 1988.

(j) A laboratory director may serve as the director of up to the maximum number of laboratories stipulated by CLIA, as defined under Section 1202.5.

SEC. 3. Section 4052.4 of the Business and Professions Code is amended to read:

4052.4. (a) 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 or 1206.6. For purposes of this section, "routine patient assessment procedures" means: (a) procedures that a patient could, with or without a prescription, perform for themselves, 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 or Section 1206.6. 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.

(b) A pharmacist may perform any aspect of any FDA-approved or -authorized test that is 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, under all of the following conditions:

(1) The test meets the criteria in subparagraph (A) or (B) and does not require the use of specimens collected by vaginal swab, venipuncture, or the collection of seminal fluid.

(A) The test is used to detect or screen for any of the following illnesses, conditions, or diseases:

(i) SARS-CoV-2 or other respiratory illness, condition or disease.

(ii) Mononucleosis.

(iii) Sexually transmitted infection.

(iv) Strep throat.

(v) Anemia.

(vi) Cardiovascular health.

(vii) Conjunctivitis.

(viii) Urinary tract infection.

(ix) Liver and kidney function or infection.

(x) Thyroid function.

(xi) Substance use disorder.

(xii) Diabetes.

(B) Other tests classified as waived under 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 and approved by the board by regulation, in conjunction with the Medical Board of California and Laboratory Field Services in the State Department of Public Health.

(2) The pharmacist completes the testing in a pharmacy laboratory that is appropriately licensed in California as a laboratory pursuant to Section 1265, unless otherwise authorized in law.

(3) The pharmacist has completed necessary training as specified in the pharmacy's policies and procedures maintained pursuant to subdivision (b) of Section 4119.10, and that allows the pharmacist to demonstrate sufficient knowledge of the illness, condition, or disease being tested, as applicable.

SEC. 4. Section 4119.10 is added to the Business and Professions Code, to read:

4119.10. A pharmacy located in the state may use pharmacists to perform FDA-approved or -authorized 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, under all of the following conditions:

(a) The pharmacy is appropriately licensed as a laboratory under Section 1265.

(b) The pharmacy maintains policies and procedures that do all of the following:

(1) Establish the initial training requirements, including specimen collection techniques relevant to a test being performed at the pharmacy, and ongoing training.

(2) Establish safety precautions necessary to protect pharmacy staff and consumers and to reduce the risk of transmission, consistent with Cal-OSHA and CDC requirements, including, but not limited to, provisions for the use of personal protective equipment, cleaning and sanitizing procedures, appropriate biohazard waste requirements, and space requirements for pharmacy staff and consumers.

(3) Ensure the availability of dedicated physically distanced space or other segregated space that provides for privacy during the testing process and private consultation with the pharmacist, and limits potential contamination of other consumers in the pharmacy.

(4) Establish requirements for providing test results to the patient in a nonverbal manner, complying with mandatory reporting requirements to local and state reporting systems, and notifying the patient's health care providers if consent is provided, and referral to licensed sources of care for confirmation, diagnosis, and treatment as appropriate for followup to positive test results. A health care provider shall not be held personally liable for test results, or for any actions or inactions related to test results they did not receive, have knowledge of, or otherwise have access to.

(5) Establish requirements for the pharmacist-in-charge serving as the pharmacy laboratory director to report any reportable disease or condition identified in Section 120130 of the Health and Safety Code or the regulations adopted under that section.

(6) Ensure documentation of testing equipment maintenance and calibration.

(7) Ensure appropriate storage and handling of specimens, testing reagents, and other supplies or equipment that require specialized storage or handling. Specimen collection shall not include vaginal swab, venipuncture, or the collection of seminal fluid.

(c) The test is authorized to be administered by a pharmacist pursuant to paragraph (1) of subdivision (b) of Section 4052.4.

(d) The pharmacist-in-charge does both of the following:

(1) Annually reviews the policies and procedures maintained pursuant to subdivision (b), assesses the pharmacy's compliance with its policies, and documents corrective actions to be taken when noncompliance is found.

(2) Maintains documentation of the annual review and assessment in a readily retrievable format for a period of three years from the date of completion.

(e) The pharmacy maintains documentation related to performing tests that demonstrates compliance with this section, which shall include the name of the pharmacist performing the test, the results of the test, and communication of results to a patient's primary medical provider, and is maintained in a readily retrievable format for a period of three years from the date of creation.

SEC. 5. 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. 6. Section 2.5 of this bill incorporates amendments to Section 1209 of the Business and Professions Code proposed by this bill and Assembly Bill 526. That section of this bill shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2022, (2) each bill amends Section 1209 of the Business and Professions Code, and (3) this bill is enacted after Assembly Bill 526, in which case Section 1209 of the Business and Professions Code, as amended by Assembly Bill 526, shall remain operative only until the operative date of this bill, at which time Section 2.5 of this bill shall become operative, and Section 2 of this bill shall not become operative.