AB-526 Dentists and podiatrists: clinical laboratories and vaccines. (2021-2022)

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Assembly Bill No. 526

CHAPTER 653

An act to amend Section 1209 of, and to add Sections 1625.6, 1645.2, 2473, and 2496.5 to, the Business and Professions Code, relating to healing arts, and declaring the urgency thereof, to take effect immediately.

[Approved by Governor October 08, 2021. Filed with Secretary of State October 08, 2021.]

LEGISLATIVE COUNSEL'S DIGEST

AB 526, Wood. Dentists and podiatrists: clinical laboratories and vaccines.

Existing law provides for the certification and regulation of podiatrists by the Podiatric Medical Board of California within the Department of Consumer Affairs. Under existing law, the certificate to practice podiatric medicine authorizes the holder to practice podiatric medicine and defines “podiatric medicine” to mean the diagnosis, medical, surgical, mechanical, manipulative, and electrical treatment of the human foot, including the ankle and tendons that insert into the foot and the nonsurgical treatment of the muscles and tendons of the leg governing the functions of the foot.

Existing law, the Dental Practice Act, provides for the licensure and regulation of persons engaged in the practice of dentistry by the Dental Board of California. Existing law defines dentistry as the diagnosis or treatment, by surgery or other method, of diseases and lesions and the correction of malpositions of the human teeth, alveolar process, gums, jaws, or associated structures, and provides that diagnosis or treatment may include all necessary related procedures as well as the use of drugs, anesthetic agents, and physical evaluation. Existing law provides that a person practices dentistry if the person performs various specified acts. Existing law also provides for the registration and regulation of registered dental hygienists by the Dental Hygiene Board of California within the Department of Consumer Affairs.

This bill would additionally authorize a dentist or podiatrist, if the dentist or podiatrist complies with specified requirements, to independently prescribe and administer influenza and COVID-19 vaccines approved or authorized by the United States Food and Drug Administration for persons 3 years of age or older, as specified. The bill would authorize the board to adopt regulations to implement these provisions, as provided. The bill would count vaccine training provided through the federal Centers for Disease Control and Prevention toward the fulfillment of a podiatrist’s continuing education requirements, and would count vaccine training provided through the federal Centers for Disease Control and Prevention or the California Pharmacists Association toward the fulfillment of a dentist’s or dental hygienist’s continuing education requirements, as specified.

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 requires a clinical laboratory test or examination classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 to be performed under the overall operation and administration of a laboratory director, which is defined to include certain licensees.

This bill would expand the definition of “laboratory director” to include a duly licensed dentist serving as the director of a laboratory that performs only authorized clinical laboratory tests, as specified.

This bill would incorporate additional changes to Section 1209 of the Business and Professions Code proposed by SB 409 to be operative only if this bill and SB 409 are enacted and this bill is enacted last.

This bill would declare that it is to take effect immediately as an urgency statute.
Vote: 2/3 Appropriation: no Fiscal Committee: yes Local Program: no

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. 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.

(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. 1.5. 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. 2. Section 1625.6 is added to the Business and Professions Code, to read:

1625.6. (a) In addition to the actions authorized under Section 1625, a dentist may independently prescribe and administer influenza and COVID-19 vaccines approved or authorized by the United States Food and Drug Administration in compliance with the individual federal Advisory Committee on Immunization Practices (ACIP) influenza and COVID-19 vaccine recommendations, and published by the federal Centers for Disease Control and Prevention (CDC) to persons 3 years of age or older.

(b) In order to prescribe and administer a vaccine described in subdivision (a), a dentist shall do all of the following:

(1) Complete an immunization training program biennially that is either offered by the CDC or taken through a registered provider approved by the board that, at a minimum, includes vaccine administration, prevention and management of adverse

reactions, and maintenance of vaccine records.

(2) Comply with all state and federal recordkeeping and reporting requirements, including providing documentation to the patient's primary care provider, if applicable, and entering in the information in the appropriate immunization registry designated by the Immunization Branch of the State Department of Public Health.

(c) The board may adopt regulations to implement this section. The adoption, amendment, repeal, or readoption of a regulation authorized by this section is deemed to address an emergency, for purposes of Sections 11346.1 and 11349.6 of the Government Code, and the board is hereby exempted for this purpose from the requirements of subdivision (b) of Section 11346.1 of the Government Code. For purposes of subdivision (e) of Section 11346.1 of the Government Code, the 180-day period, as applicable to the effective period of an emergency regulatory action and submission of specified materials to the Office of Administrative Law, is hereby extended to 240 days.

SEC. 3. Section 1645.2 is added to the Business and Professions Code, to read:

1645.2. Any vaccine training program provided through the federal Centers for Disease Control and Prevention or the California Pharmacists Association, including courses that were completed by a licensed dentist or a registered dental hygienist on or after January 4, 2021, pursuant to the Department of Consumer Affairs public health emergency order DCA-20-104, DCA-21-111, DCA-21-113, or any subsequent waivers that supersede these waivers, and Section 1625.6 shall count toward the fulfillment of the continuing education requirements governed by Sections 1645 and 1936.1.

SEC. 4. Section 2473 is added to the Business and Professions Code, to read:

2473. (a) A doctor of podiatric medicine may independently prescribe and administer influenza and COVID-19 vaccines approved or authorized by the United States Food and Drug Administration in compliance with the individual federal Advisory Committee on Immunization Practices (ACIP) influenza and COVID-19 vaccine recommendations, and published by the federal Centers for Disease Control and Prevention (CDC) to persons three years of age or older.

(b) In order to prescribe and administer a vaccine described in subdivision (a), a doctor of podiatric medicine shall do all of the following:

(1) Complete an immunization training program biennially that is either offered by the CDC or taken through a registered provider approved by the board that, at a minimum, includes vaccine administration, prevention and management of adverse reactions, and maintenance of vaccine records.

(2) Comply with all state and federal recordkeeping and reporting requirements, including providing documentation to the patient's primary care provider, if applicable, and entering in the information in the appropriate immunization registry designated by the Immunization Branch of the State Department of Public Health.

(c) The board may adopt regulations to implement this section. The adoption, amendment, repeal, or readoption of a regulation authorized by this section is deemed to address an emergency, for purposes of Sections 11346.1 and 11349.6 of the Government Code, and the board is hereby exempted for this purpose from the requirements of subdivision (b) of Section 11346.1 of the Government Code. For purposes of subdivision (e) of Section 11346.1 of the Government Code, the 180-day period, as applicable to the effective period of an emergency regulatory action and submission of specified materials to the Office of Administrative Law, is hereby extended to 240 days.

SEC. 5. Section 2496.5 is added to the Business and Professions Code, to read:

2496.5. Any vaccine training program provided through the federal Centers for Disease Control and Prevention, including courses that were completed by a licensed doctor of podiatric medicine on or after January 4, 2021, pursuant to the Department of Consumer Affairs public health emergency order DCA-21-115, or any subsequent waivers that supersede this waiver, and Section 2473 shall count toward the fulfillment of the continuing education requirements governed by Section 2496.

SEC. 6. Section 1.5 of this bill incorporates amendments to Section 1209 of the Business and Professions Code proposed by both this bill and Senate Bill 409. That section of this bill shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2022, but this bill becomes operative first, (2) each bill amends Section 1209 of the Business and Professions Code, and (3) this bill is enacted after Senate Bill 409, in which case Section 1209 of the Business and Professions Code, as amended by Section 1 of this bill, shall remain operative only until the operative date of Senate Bill 409, at which time Section 1.5 of this bill shall become operative.

SEC. 7. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the California Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order to address the public health need to provide as many points of care for the administration of testing and vaccines for influenza and COVID-19 in order to test and vaccinate the greatest amount of people at the fastest rate possible and as soon as possible, it is necessary that this act take effect immediately.