



MEMORANDUM

DATE	March 11, 2022
TO	Members of the Dental Board of California
FROM	David Bruggeman, Legislative and Regulatory Specialist Dental Board of California
SUBJECT	Agenda Item 6: Discussion and Possible Action to Initiate an Emergency Rulemaking, Adopt Regulations and a Finding of Emergency, and Initiate a Regular Rulemaking to Adopt California Code of Regulations, Title 16, Section 1066 Relating to Dentists Initiating and Administering Vaccines

Background:

Assembly Bill (AB 526) (Chapter 653 Statutes of 2021) was signed into law on October 8, 2021. The bill amended provisions of the Dental Practice Act to permit dentists to prescribe and administer influenza and COVID-19 vaccinations approved or authorized by the federal Food and Drug Administration to patients 3 years of age and older on a permanent basis. Dentists who would administer these vaccines must biennially complete a vaccination training program offered by the CDC or a provider approved by the Board. They must also comply with all state and federal recordkeeping requirements. This includes documentation for the patient's primary care provider and entering the vaccination information into the appropriate immunization registry designed by the Immunization Branch of the California Department of Public Health.

While AB 526 provides the authority for dentists to initiate and administer influenza and COVID-19 vaccinations, it does not provide specifics on the length of the required training program. AB 526 also does not provide specifics on how dentists are to provide immunization information to their patients' primary care providers or to the state immunization registry. This proposal would establish such standards.

The law indicates that the Board may issue regulations to implement the law. The law provides that such regulations would be deemed to address an emergency (section 1625.6(c)), which would permit the regulations to proceed through the emergency regulations process outlined in Government Code section 11346.1. The law also extends the 180-day duration of an emergency regulation on this subject to 240 days.

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On review of existing immunization practices and procedures for influenza and COVID-19, and in consultation with the California Department of Public Health, Board staff have developed proposed emergency regulations consistent with BPC section 1625.6 and the relevant portions of the Administrative Practice Act concerning emergency regulations. We have drafted an Order of Adoption and Finding of Emergency which is attached to this memo for the Board's consideration and possible action.

The proposed regulations – Title 16 California Code of Regulations, section 1066 – address the training, continuing education, notification, reporting and documentation requirements for dentists to comply with AB 526. They are summarized as follows:

Subsection (a) – Dentists seeking to prescribe and administer vaccinations must comply with all portions of this section and failure to do so is unprofessional conduct.

Subsection (b) – Dentists administering vaccinations must retain documentation of immunization training taken to comply with AB 526. It must be maintained on premises and kept consistent with existing regulation at section 1017 for documenting continuing education coursework.

Subsection (c) – Dentists must complete one hour of vaccination training every two years to comply with AB 526. This training must include vaccine administration, prevention and management of adverse reactions, and maintenance of vaccine records from an approved provider. An approved provider would be the Centers for Disease Control and Prevention (CDC) or a continuing education provider registered and approved by the Board pursuant to section 1016.

Subsection (d) – Dentists must notify a patient's primary care provider or enter the vaccination information in a record system accessible by the patient's primary care provider, within 14 days of administration of the vaccine. If a patient does not have a primary care provider or is unable to provide contact information for his or her primary care provider, the dentist shall advise the patient to consult an appropriate health care provider of the patient's choice.

Subsection (e) – Dentists must submit the required information with the Department of Public Health (currently done through the California Immunization Registry/CAIR) within 14 days of administration of the influenza vaccine or within 24 hours of administration of a COVID-19 vaccine. A dentist must complete the required registration process for reporting this information in the California Immunization Registry via the online CAIR portal designated on the California Department of Public Health's website at: <https://igs.cdph.ca.gov/cair/>. They must notify the patient or patient's guardian of the dentist's information sharing requirements and of the rights of the patient and/or patient's guardian with respect to information shared with the Department of Public Health.

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Subsection (f) – For each vaccine administered, the dentist must provide each patient with a vaccine administration record as specified. A vaccine administration record must also be maintained in an automated data processing or manual record system such that the information required by Federal law (related to the reporting and recordkeeping of vaccine administration) is available during normal operating hours. The record must be maintained for at least 3 years from the date of administration of the vaccine to the patient.

A dentist must provide each patient with a personal vaccine administration record or card at the time of vaccination, which fully documents the vaccines administered by the dentist, including names of vaccines administered and the dates of administration. The dentist's provision of the CDC's "COVID-19 Vaccination Record Card" (Form MLS-319813_r [08/17/2020]) to patients receiving the COVID-19 vaccine, or the California Department of Public Health's Immunization Record and History Form (CDPH-8608P (06/17) to patients receiving the influenza vaccine shall be deemed compliance with the personal vaccine administration record requirement.

Subsection (g) - This proposal would add definitions for the following terms used in this section: (1) "patient vaccine administration record," (2) "Vaccine Information Statement," and the (3) "COVID-19 Vaccine Emergency Use Authorization Fact Sheet or EUA Fact Sheet."

Action Requested:

Staff requests that the Board consider the proposed emergency regulations and make the following motions:

1. Direct staff to take all steps necessary to complete the emergency rulemaking process, including the filing of the emergency rulemaking package with the Office of Administrative Law (OAL), authorize the Executive Officer to make any non-substantive changes to the proposed regulations, and adopt the finding of emergency and the proposed regulatory language as written in the Order of Adoption. If no adverse comments are received and the text is approved by OAL, authorize re-adoption as needed and authorize the staff to take all steps necessary to complete the regular rulemaking process to make the regulations permanent and adopt the proposed regulations at Title 16, CCR Section 1066 as noticed.
2. If OAL or another control agency disapproves the emergency rulemaking, direct staff to submit the proposed text to the Director of the Department of Consumer Affairs and the Business, Consumer Services, and Housing Agency for review and if no adverse comments are received, authorize the Executive Officer to take all steps necessary to initiate the regular rulemaking process, make any non-substantive changes to the package, and set the matter for a hearing, if requested. If no adverse comments are received during the 45-day public

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comment period and no hearing is requested, authorize the Executive Officer to take all steps necessary to complete the rulemaking and adopt the proposed regulations at Title 16, CCR Section 1066 as noticed.

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**TITLE 16. DENTAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS**

ORDER OF ADOPTION

Adopt Section 1066 in Article 9 of Chapter 2 of Division 10 of Title 16 of the California Code of Regulations, as follows:

1066. Dentists Initiating and Administering Vaccines.

(a) A dentist prescribing and administering any vaccine pursuant to section 1625.6 of the Code shall follow the requirements specified in subdivisions (b) through (f) of this section. Failure to comply with this section constitutes unprofessional conduct in accordance with section 1680 of the Code.

(b) Training. A dentist who prescribes and administers any vaccine shall keep documentation of completion of an immunization training program from an approved provider as set forth in subdivision (c). A dentist who prescribes and administers vaccines shall retain certificates of course completion for any approved training program on premises and according to the requirements of section 1017.

(c) Continuing Education. A dentist must complete one hour of continuing education from an approved provider once every two years focused on immunization training that includes, at a minimum, training in vaccine administration, prevention and management of adverse reactions, and maintenance of vaccine records. For the purposes of this section, an "approved provider" means: (1) the federal Centers for Disease Control and Prevention (CDC); or, (2) a continuing education provider registered and approved by the Board pursuant to section 1016.

(d) Notifications: A dentist shall notify each patient's primary care provider of any vaccine administered to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. Primary care provider notification must take place within 14 days of the administration of any influenza or COVID-19 vaccine. If a patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the dentist shall advise the patient to consult an appropriate health care provider of the patient's choice. A dentist shall notify each pregnant patient's prenatal care provider, if known, of any influenza or COVID-19 vaccine administered to the patient within 14 days of the administration of any vaccine.

(e) Immunization Registry: A dentist shall report, in accordance with section 1625.6, subdivision (b)(2) of the Code, the information described in section 120440, subdivision (c), of the Health and Safety Code in the registry designated by the Immunization

Branch of the California Department of Public Health known as the “California Immunization Registry” or “CAIR” within 14 days of the administration of any influenza vaccine and within 24 hours of the administration of any COVID-19 vaccine. A dentist shall complete the required registration process for reporting this information in the California Immunization Registry via the online CAIR portal designated on the California Department of Public Health’s website at: <https://igs.cdph.ca.gov/cair/>. A dentist shall inform each patient or the patient’s guardian of immunization record sharing preferences, detailed in section 120440, subdivision (e), of the Health and Safety Code.

(f) Documentation: For each vaccine administered by a dentist, a patient vaccine administration record shall be maintained for at least 3 years from the date of administration of the vaccine to the patient in an automated data processing or manual record mode such that the information required under section 300aa-25 of title 42 of the United States Code is readily retrievable during normal operating hours. A dentist shall provide each patient with a personal vaccine administration record or card at the time of vaccination, which fully documents the vaccines administered by the dentist, including names of vaccines administered and the dates of administration. The dentist’s provision of the CDC’s “COVID-19 Vaccination Record Card” (Form MLS-319813_r [08/17/2020]) to patients receiving the COVID-19 vaccine, or the California Department of Public Health’s Immunization Record and History Form (CDPH-8608P (06/17) to patients receiving the influenza vaccine shall be deemed compliance with the personal vaccine administration record requirement.

(g) For the purposes of this section, the following definitions apply:

(1) “patient vaccine administration record” shall mean the patient record that fully documents the vaccines administered by the dentist including (A) names of vaccines administered, (B) dates of administration, (C) the dates of the provision of a Vaccine Information Statement (for influenza vaccines) if applicable or a COVID-19 Vaccine Emergency Use Authorization Fact Sheet (EUA Fact Sheet) to the patient (for COVID-19 vaccines), or any other information required to be documented pursuant to section 300aa-25 of title 42 of the United States Code.

(2) “Vaccine Information Statement” means a document produced by the CDC that informs vaccine recipients, or their parents or legal representatives, about the benefits and risks of the influenza vaccine they are receiving as required by 300aa-26 of title 42 of the United States Code.

(3) “COVID-19 Vaccine Emergency Use Authorization Fact Sheet” or “EUA Fact Sheet” means a document, produced by the manufacturer of the particular COVID-19 vaccine and authorized by the federal Food and Drug Administration under authority of the federal Food, Drug and Cosmetic Act pursuant to section 360bbb–3 of title 21 of the United States Code, that informs vaccine recipients, or their parents or legal representatives, about the benefits and risks of a particular COVID-19 vaccine.

Note: Authority cited: Sections 1614 and 1625.6, Business and Professions Code.
Reference: Sections 1625.6, 1645.2 and 1680, Business and Professions Code;
Section 120440, Health and Safety Code; and Sections 300aa-25 and 300aa-26 of Title
42, United States Code.



FINDING OF EMERGENCY
Dental Board of California
Title 16, California Code of Regulations Section 1066
Dentists Initiating and Administering Vaccines

The Dental Board of California (the Board) finds that an emergency exists. The regulations being adopted herewith by the Board as emergency regulations (the Regulations) are, by legislative mandate, necessary for the immediate preservation of the public peace, health and safety, and general welfare. Business and Professions Code (BPC) section 1626.5 allows the Board to adopt regulations by emergency in order to implement that section, which authorizes dentists to 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.

Therefore, the Board proposes to adopt regulations addressing the training, continuing education, notification to a patient's primary care provider, reporting and recordkeeping requirements for dentists to initiate and administer influenza and COVID-19 vaccinations as authorized by 1625.6 of the Business and Professions Code.

AUTHORITY AND REFERENCE

Authority cited: Sections 1614 and 1625.6 of the Business and Professions Code.
Reference: Sections 1625.6, 1645.2 and 1680, Business and Professions Code;
Section 120440, Health and Safety Code; and Sections 300aa-25 and 300aa-26 Title
42, United States Code.

SPECIFIC FACTS DEMONSTRATING THE NEED FOR IMMEDIATE ACTION

Vaccination remains an effective tool against the spread of both COVID-19 and influenza. Ensuring that dentists are authorized to administer vaccines has an immediate impact on the public health, safety and welfare, given the ongoing challenges facing the public with COVID-19, and the fact that having more vaccination providers is a critical need at this time.

In addition, the legislature deemed this proposed action to address an emergency. BPC section 1625.6(c) states (bold added for emphasis):

“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.”

Consistent with that emergency regulation authority, the Board proposes to immediately adopt regulations to make specific the requirements for training, continuing education, notification to the patient’s primary care provider, and reporting and record keeping requirements for dentists seeking to administer influenza and COVID-19 vaccines to their patients.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

The Board is responsible for licensing and regulating dental professionals in California. The Board licenses an estimated 89,000 dental professionals, including approximately 43,500 licensed dentists; 44,500 registered dental assistants (RDAs); and 1,700 registered dental assistants in extended functions (RDAEFs). The Board is also responsible for setting the duties and functions of an estimated 50,000 unlicensed dental assistants.

In early 2021, the Director of the Department of Consumer Affairs issued a public health emergency waiver allowing dentists to administer the COVID-19 vaccines. Assembly Bill (AB 526) (Chapter 653 Statutes of 2021) was signed into law on October 8, 2021. The bill amended provisions of the Dental Practice Act to permit dentists to prescribe and administer influenza and COVID-19 vaccinations approved or authorized by the federal Food and Drug Administration to patients 3 years of age and older on a permanent basis. Dentists who would administer these vaccines must biennially complete a vaccination training program offered by the CDC or a provider approved by the Board. They must also comply with all state and federal recordkeeping requirements. This includes documentation for the patient’s primary care provider and entering the vaccination information into the appropriate immunization registry designed by the Immunization Branch of the California Department of Public Health.

While AB 526 provides the authority for dentists to initiate and administer influenza and COVID-19 vaccinations, it does not provide specifics on the length of the required training program. AB 526 also does not provide specifics on how dentists are to provide immunization information to their patients’ primary care providers or to the state immunization registry. This proposal would establish such standards.

Proposed section 1066 would implement section 1625.6 of the Business and Professions Code (BPC) as enacted by AB 526 and make specific the requirements a dentist must complete when initiating and administering influenza and COVID-19 vaccines to patients. The regulations address the length and frequency of required training, the records that must be kept by the dentist concerning their training and the vaccines they administer, the information dentists must provide to their patients and their patients’ primary care provider, state and federal reporting requirements including reporting vaccine

administration through California’s Immunization Registry (CAIR), and state and federal documentation and recordkeeping requirements.

PURPOSE, ANTICIPATED BENEFITS, AND RATIONALE:

Adopt Section 1066 in in Article 9 of Chapter 2 of Division 10 of Title 16 of the California Code of Regulations – Dentists Administering and Initiating Vaccines

Title

This section would adopt a new section and title in Article 9 of the Board’s regulations entitled “Dentists Initiating and Administering Vaccines” to make it easier for users of the Board's regulations to find and identify information regarding the Board's requirements for initiating and administering vaccines.

Subdivision (a)

This subsection would require a dentist prescribing and administering vaccines to follow the requirements specified in subdivisions (b) through (f) of this section and would provide that failure to comply is considered unprofessional conduct as provided in Business and Professions Code (BPC) section 1680.

BPC section 1670 permits the Board to discipline a licensee for unprofessional conduct. Section 1680 defines unprofessional conduct as conduct that includes “but is not limited to” a list of prescribed acts, but does not presently include violation of this regulatory provision as one of those acts constituting unprofessional conduct; the addition of this conduct to this definition is therefore necessary for compliance and enforcement of these provisions. Defining violations of this section as unprofessional conduct ensures that dentists meet the minimum requirements set forth in section 1625.6 of the Business and Professions Code and as specified in this section by making it a violation to fail to comply with the provisions of this section and subjecting noncompliant dentists to possible citation or discipline (see Bus. & Prof. Code, § 1670 and tit.16, Calif. Code Reg., § 1023).

Subdivision (b)

Business and Professions Code section 1625.6(b)(2) requires dentists, as a condition of prescribing or administering vaccine, to comply with all state and federal recordkeeping and reporting requirements. Under this proposal dentists will be required to take specified training (see subdivision (c)) and maintain records of that training according to the requirements in this subdivision.

This section would require a dentist who prescribes and administers a vaccine to keep documentation of completion of an immunization training program from an approved provider as specified in subdivision (c). Further a dentist who prescribes and administers vaccines must retain certificates of course completion for any approved training program on premises according to the requirements of section 1017 of the Board’s regulations.

These provisions will help the Board verify that the dentist who is administering or prescribing a vaccine has completed the required training, is able to provide proof of the required training (certificates of completion), has the information readily available to any Board inspector on premises and complies with the existing recordkeeping requirements of the Board relative to this compliance as set forth in section 1017.

Subdivision (c)

Business and Professions Code section 1625.6(b)(1) requires dentists as a condition of prescribing or administering a vaccine to complete an immunization training program biennially that is either offered by the federal Centers for Disease Control and Prevention (CDC) or taken through a registered provider approved by the Board and includes minimum requirements for training including vaccine administration, prevention and management of adverse reactions, and maintenance of vaccine records. Existing regulation does not set forth the recommend length of training, the content of training or the process for obtaining this training from a from a Board-approved education provider. This proposal is necessary to establish those requirements.

This section would require a dentist to complete one hour of continuing education from an approved provider once every two years focused on immunization training that includes, at a minimum training in vaccine administration, prevention and management of adverse reactions, and maintenance of vaccine records. An “approved provider” would be defined as: (1) the federal Centers for Disease Control and Prevention (as required by Section 1625.6), or (2) a continuing education provider registered and approved by the Board pursuant to section 1016 of the Board’s regulations.

This provision is necessary to ensure that dentists are adequately placed on notice that the Board will require one hour of continuing education once every two years that is focused on immunization training in accordance with the requirements of subsection (b)(1) of section 1625.6 of the Business and Professions Code. Dentists are professionals with experience in injecting various medications into patients and many dentists have already been administering COVID-19 vaccines under the emergency waiver granted by this Department. Therefore, the Board believes that one-hour training every two years should be sufficient to instruct dentists on the required subject areas outlined in BPC section 1625.6(b)(1) and such training would prepare dentists to administer vaccine with safety to the public.

In accordance with BPC section 1625.6(b)(1), the regulation further specifies that the approved provider of such education includes the CDC or a continuing education provider registered and approved by the Board pursuant to section 1016. Section 1016 sets forth the Board’s existing requirements for approval of continuing education courses and providers. These proposed provisions are consistent with the requirements in section 1625.6(b)(1) to allow CDC to provide training and also with the current processes for approving education providers set forth in section 1016. Use of the continuing education provider approval process outlined in section 1016 will also quickly and efficiently provide a method for approving these types of educational training programs to prepare dentists to administer vaccine in compliance with this section.

Subdivision (d)

Business and Professions Code section 1625.6(b)(2) requires as a condition for a dentist to prescribe and administer a vaccine that the dentists comply with all state and federal requirements for providing documentation to the patient's primary care provider, if applicable.

Under this proposal, dentists must notify a patient's primary care provider of any vaccine administered to the patient (in some health systems this is done in through a shared patient record system). Physicians are often requested by parents of patients or patients to provide patient immunization records for schools, day care centers and other organizations that need this information. The regulation requires timely notification of the patients' physicians (primary care or prenatal provider, as applicable) (within 14 days of the administration of any influenza or COVID-19 vaccine) so that this important information remains up-to-date in physician records, as physicians already maintain this information and respond to requests for patient immunization records. To help ensure follow-up or continuity of care for the patient, the Board proposes to add a requirement that if the patient does not have a primary care provider, or is unable to provide contact information for their provider, the dentist advises the patient to consult an appropriate health care provider of the patient's choice.

Subdivision (e)

Business and Professions Code (BPC) section 1625.6(b)(2) requires, as a condition for a dentist to prescribe and administer a vaccine, that the dentist enter the vaccine administration information for each patient in the appropriate immunization registry designated by the Immunization Branch of the State Department of Public Health. As a result, this subdivision would set forth the requirements for reporting to the designated California Department of Public health immunization registry the information required by Health and Safety Code section 120440 and the process for registering and submitting information through the California immunization registry in accordance with the California Department of Public Health's registry requirements.

This subdivision is necessary to implement the requirements of subdivision BPC section 1625.6 and to provide adequate notice to dentists of the procedures for reporting information in accordance with section 120440 of the Health and Safety Code. According to Health and Safety Code ("H&S") section 120440(c) vaccine providers must report into one or more state and/or local immunization information systems the administration of any vaccine, and must inform the patient of immunization record sharing preferences as set out in H&S Code section 120440(e). H&S Code section 120440 sets out the information that is to be gathered and shared, and what must be explained to the patient to obtain an informed consent to provide information to an immunization registry. Many dentists already provide COVID-19 vaccines and thus are already familiar with and follow the guidelines in H&S Code section 120440. The Board believes that referring to the relevant sections of H&S Code 120440 within this regulation will provide sufficient guidance to dentists on the required procedures.

In addition, the California Department of Public Health has designated the California Immunization Registry or “CAIR” as its designated registry for submitting the vaccine information set forth in Health and Safety Code 120440. Registry reporting is contingent upon registration within the California Department of Public Health’s on-line portal registry website at <https://igs.cdph.ca.gov/cair/>. The Board’s staff have also conferred with representatives from the California Department of Public Health (CDPH) in the development of this regulation and these representatives have confirmed that the 14-day reporting requirement is sufficient notice for reporting such information to this registry for influenza vaccines and the 24-hour reporting requirement for COVID-19 administration (a standard established by the CDC). As a result, this proposal is necessary to make specific to dentists the process for complying with state and federal vaccine administration reporting requirements.

Subdivision (f)

Business and Professions Code section 1625.6(b)(2) requires that as a condition of prescribing and administering vaccine, a dentist must comply with all state and federal reporting and recordkeeping requirements. Federal law requires health care providers to record certain information in a patient’s medical record after administering a vaccine. This record can be in electronic or paper form.

This subdivision would specify that dentists must keep a copy of the patient vaccine administration record (as defined in subdivision (g)) for at least three (3) years from the date of the vaccination (either in automated data processing or manual mode) such that the vaccine information required to be reported by health care providers under federal law under section 300aa-25 of Title 42 of the United States Code is readily retrievable during normal operating hours. This provision is necessary to establish notice of and a method for verifying compliance with reporting and recordkeeping requirements in Section 300aa-25, which establishes the federal reporting and recordkeeping requirements for vaccine administration under federal law.

This subdivision would also require retention of the patient vaccine administration record for at least 3 years. This is necessary to implement the record retention guidance provided by the CDPH and to allow the Board sufficient time to investigate and prosecute violations of this section.

This subdivision would also require the dentist to provide the patient with a personal vaccination record or card at the time of vaccination which fully documents the vaccines administered by the dentist, including names of vaccines administered and the dates of administration. Since vaccination may be required for certain jobs, travel abroad, or a school registration, the CDC and CDPH recommend that patients be provided, at the time of vaccination, a vaccination record or card that documents vaccine administration by the health care provider. After consultation with the CDPH, the Board proposes the following documents that would be deemed compliant personal vaccination records to the patient: for COVID-19 vaccinations: CDC’s “COVID-19 Vaccination Record Card” (Form MLS-319813_r [08/17/2020]); and, for influenza vaccinations: the California Department of Public Health’s Immunization Record and History Form (CDPH-8608P (06/17)).

These provisions are therefore necessary to implement these guidelines specific to dentists administering vaccine according to BPC section 1625.6, and to establish that the aforementioned forms would be presumed compliant with the requirements of this section for the provision of a personal vaccination record at the time of vaccination.

Subdivision (g)

Business and Professions Code section 1625.6(b)(2) requires that as a condition of prescribing and administering vaccine, a dentist must comply with all state and federal reporting and recordkeeping requirements. This proposal would add definitions for the following terms used in this section to implement the federal reporting and recordkeeping requirements specific to dentists administering influenza and COVID-19 vaccines and further clarify the requirements in subdivision (e) of this section: (1) “patient vaccine administration record,” (2) “Vaccine Information Statement,” and the (3) “COVID-19 Vaccine Emergency Use Authorization Fact Sheet or EUA Fact Sheet.”

As explained further below, these definitions are derived from the following recordkeeping and reporting obligations.

Under Section 300aa-25 of Title 42 of the United States Code, health care providers who administer vaccines are required to ensure that the permanent medical record of the patient indicates:

- (1) the date of administration of the vaccine,
- (2) the vaccine manufacturer and lot number of the vaccine,
- (3) the name and address and, if appropriate, the title of the health care provider administering the vaccine, and,
- (4) any other identifying information on the vaccine required by federal regulations promulgated by the Secretary of Health and Human Services.

Under Section 300aa-26 of Title 42 of the United States Code, all vaccine providers must give the applicable VIS to the patient (or parent or legal representative) prior to every dose of specific vaccines, including influenza. In addition, COVID-19 Emergency Use Authorization requirements developed by the federal Food and Drug Administration mandate under the emergency use authorization provisions of the federal Food, Drug and Cosmetic Act specify that patients receiving a COVID-19 vaccine be provided an EUA Fact Sheet at the time of vaccination.

Consistent with those requirements, the Board proposes to define “patient vaccine administration record” under proposed subdivision (g)(1) as: the patient record that fully documents the vaccines administered by the dentist including (A) names of vaccines administered, (B) dates of administration, (C) the dates of the provision of a Vaccine Information Statement (for influenza vaccines) or a COVID-19 Vaccine Emergency Use Authorization Fact Sheet (EUA Fact Sheet) to the patient (for COVID-19 vaccines), or any other information required to be documented pursuant to section 300aa-25 of title 42 of the United States Code.

This proposal would also define “Vaccine Information Statement” under proposed subsection (g)(2) as a document produced by CDC that informs vaccine recipients, or their parents or legal representatives, about the benefits and risks of the influenza vaccine they are receiving as required by 300aa-26 of title 42 of the United States Code.

Finally, under proposed subdivision (g)(3), this proposal would define (4)(3) “COVID-19 Vaccine Emergency Use Authorization Fact Sheet” or “EUA Fact Sheet” as a document, produced by the manufacturer of the particular COVID-19 vaccine and authorized by the federal Food and Drug Administration under authority of the federal Food, Drug and Cosmetic Act pursuant to section 360bbb–3 of title 21 of the United States Code, that informs vaccine recipients, or their parents or legal representatives, about the benefits and risks of a particular COVID-19 vaccine.

Anticipated Benefits of the Proposal

Having dentists initiate and/or administer vaccinations will make obtaining vaccinations more convenient. When it is more convenient and less expensive to obtain vaccinations, Californians are more likely to vaccinate, raising vaccination rates and improving public health. Having individuals obtain vaccinations from dentists may result in a proportionate reduction in physician and other health care workers’ workloads, freeing them to focus on patients with more serious medical issues requiring their attention.

BPC Code section 1601.2 mandates that the protection of the public shall be the highest priority for the Board and that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. The proposed standard provides protection for the public by setting out training, notification, reporting and record retention procedures for dentists who will now be able to offer the public broader access to vaccinations, thus increasing California’s vaccination rates, and improving the health of all Californians.

Consistency and Compatibility with Existing State Regulations

The Board has evaluated this proposal and determined that these proposed regulations are neither inconsistent nor incompatible with existing state regulations.

Fiscal Impact Estimates

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State:

The regulations help to provide additional guidance to dentists related to training, continuing education, notification to a patient’s primary care provider, reporting and record keeping requirements for dentists to initiate and administer influenza and COVID-19 vaccinations as required by 1625.6 of the Business and Professions Code. Implementation of these requirements does not result in a fiscal impact to the state in the form of federal funding or any cost or savings to any state agency. Any additional workload or costs related to increased inspection or enforcement of these standards are expected to be minor and absorbable within existing budgets.

Nondiscretionary Costs/Savings to Local Agencies: None.

Local Mandate: None.

Cost to Any Local Agency or School District for Which Government Code Section 17561 Requires Reimbursement: None.

Documents Relied Upon

1. "Reporting Doses Administered, California COVID-19 Vaccination Program," published by the California Department of Public Health (Form No. IMM-1328 (10/1/2021)).
2. Senate Committee on Business, Professions and Economic Development Analysis of AB 526, dated July 12, 2021.
3. CDC on-line advisory entitled "COVID-19 Vaccine Emergency Use Authorization (EUA) Fact Sheets for Recipients and Caregivers" (<https://www.cdc.gov/vaccines/covid-19/eua/index.html>)
4. Vaccine Information Statement entitled, "Influenza (Flu) Vaccine (Inactivated or Recombinant): What you need to know," published by the U.S. Department of Health and Human Services, CDC dated 8/6/2021.
5. CDC's "COVID-19 Vaccination Record Card" (Form MLS-319813_r [08/17/2020]) (<https://stacks.cdc.gov/view/cdc/112473>)
6. California Department of Public Health's Immunization Record and History Form (CDPH-8608P (06/17)) (https://www.pharmacy.ca.gov/forms/immunization_record.pdf)

DOCUMENTS RELIED UPON

Reporting Doses Administered

California COVID-19 Vaccination Program



Reporting is critical for the state to optimize allocations statewide. COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and report administration data daily to their local immunization registry (CAIR2, SDIR, or RIDE).

Program Requirements

- Within 24 hours of administering a dose of COVID-19 vaccine and adjuvant (if applicable), Organization must record in the vaccine recipient's record and report required information to the relevant state, local, or territorial public health authority. Details of required information (collectively, Vaccine Administration Data) for reporting can be found on CDC's website.
- Organization must submit Vaccine Administration Data through either (1) the immunization information system (IIS) of the state and local or territorial jurisdiction or (2) another system designated by CDC according to CDC documentation and data requirements.
- Organization must preserve the record for at least 3 years following vaccination, or longer if required by state, local, or territorial law. Such records must be made available to any federal, state, local, or territorial public health department to the extent authorized by law.
- Request and report recipient mobile number and email to the California Immunization Registry (see [Health Officer Order](#)).

Reporting Race and Ethnicity

As part of California's commitment to [ensure that COVID-19 vaccine is equitably available](#), providers who wish to administer COVID-19 vaccines in California are [required to record the race or ethnicity](#) of everyone who receives COVID-19 vaccine. Please ensure that all clinic staff record this information by whichever method is being used to submit data to your local immunization registry.

Reporting Recipient Mobile and Email

All immunization providers administering COVID-19 vaccinations within California must request from the recipient their mobile phone number and email address.

The California Department of Public Health has created a system to allow Californians to access their Digital COVID-19 Vaccine Record (DCVR) to replace lost or otherwise unavailable paper records and provide an additional form of portable and reliable vaccine verification. The DCVR is generated using patient data from the California Immunization Registry (CAIR).

The DCVR system grants an individual access to their COVID-19 vaccine records using the name and date of birth, in combination with either a mobile phone number or email address. To ensure the system remains secure, individuals are required to verify their identity either by email or text message to the email address or mobile phone number provided at the time of vaccination. Once confirmed, the system then generates a QR code and digital copy of the individual's COVID-19 vaccination record. ([Read more.](#))

Reporting Options

Providers may use My Turn, or an EHR/EMR connected to CAIR2, RIDE, or SDIR. (Providers already manually entering data into CAIR may continue to do so.)

My Turn provides vaccinators an all-in-one application that manages clinics, dose accountability and reporting, public eligibility and scheduling, and walk-in registration for vaccine clinics. ([Read more.](#))

CDC's Required Data Elements

These data elements must be reported. They are standard fields for reporting vaccinations. (See CDC's [Comprehensive Vaccine Data Requirements.](#))

Required Data elements

- Administered at location: facility name/ID
- Administered at location: type
- Administration address (including county)
- Administration date
- CVX
- Dose number
- Extract type
- Lot number
- MVX
- NDC
- Recipient address*
- Recipient date of birth*
- Recipient ethnicity
- Recipient ID*
- Recipient name*
- Recipient race
- Recipient sex
- Responsible organization
- Vaccine administering provider suffix
- Vaccine administering site
- Vaccine expiration date
- Vaccine route of administration
- Vaccination series complete
- Vaccination event ID
- VTrckS provider PIN

Optional data elements

- Comorbidity status (Y/N)
- Recipient missed vaccination appointment (Y/N)
- Serology results (presence of positive result, Y/N)
- Vaccination refusal (Y/N)

*Identifiable information will be used to facilitate deduplication of data

**SENATE COMMITTEE ON
BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT**
Senator Richard Roth, Chair
2021 - 2022 Regular

Bill No:	AB 526	Hearing Date:	July 12, 2021
Author:	Wood		
Version:	May 25, 2021		
Urgency:	Yes	Fiscal:	Yes
Consultant:	Dana Shaker		

Subject: Dentists and podiatrists: clinical laboratories and vaccines

SUMMARY: Authorizes a dentist or doctor of podiatric medicine (DPM), if the dentist or DPM 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 (FDA) for persons 3 years of age or older, as specified. Counts vaccine training provided through the federal CDC toward the fulfillment of a dentist or DPM's continuing education (CE) requirements. Expands 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.

Existing law:

- 1) Establishes the Dental Board of California (DBC) to regulate the practice of dentistry. (Business and Professions Code (BPC) §§ 1600 *et seq.*)
- 2) 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 such diagnosis or treatment may include all necessary related procedures as well as the use of drugs, anesthetic agents, and physical evaluation. (BPC § 1625)
- 3) Establishes the Podiatric Medical Board of California (PMBC) and vests the PMBC with regulation of podiatric medicine. (BPC §§ 2460 *et seq.*)
- 4) Defines "podiatric medicine" as 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. (BPC § 2472)
- 5) Provides that a licensed dentist or licensed podiatrist, among other providers, may perform a clinical laboratory test or examination classified as waived under the federal Clinical Laboratory Improvement Amendments (CLIA) Program, provided that the laboratory test or examination is performed under the overall operation and administration of a qualified laboratory director. (BPC § 1206.5)
- 6) Defines "laboratory director" as including the following professions: physician and surgeons, or anyone licensed to direct a clinical laboratory, as specified. (BPC § 1209)

- 7) Defines “laboratory director” as additionally including, for the purposes of waived tests or examinations: clinical laboratory scientist, limited clinical laboratory scientist, naturopathic doctor, optometrist serving as the director of a laboratory that only performs clinical laboratory tests authorized in paragraph (10) of subdivision (d) of Section 3041. (BPC § 1209)

This bill:

- 1) Authorizes a dentist or DPM, if the dentist or DPM complies with specified requirements, to independently prescribe and administer influenza and COVID-19 vaccines approved or authorized by the FDA for persons 3 years of age or older, as specified.
- 2) Authorizes DBC and PMBC to adopt regulations to implement these provisions, as provided.
- 3) Counts vaccine training provided through the federal Centers for Disease Control and Prevention (CDC) toward the fulfillment of a DPM’s continuing education requirements.
- 4) Counts vaccine training provided through the CDC or the California Pharmacists Association toward the fulfillment of a dentist’s or dental hygienist’s continuing education requirements, as specified.
- 5) Expands 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.

FISCAL EFFECT: According to the Assembly Committee on Appropriations, costs to the DBC and PMBC are expected to be minor and absorbable (fee-supported special funds).

COMMENTS:

1. **Purpose.** The California Dental Association is the Sponsor of this bill. According to the Author, this bill has two parts:

“Part 1. To protect the public from the COVID-19 pandemic, the health care system must be ready to vaccinate the residents of California at the fastest rate possible. To do this, we must allow all appropriate trained health care providers to vaccinate patients. With millions of individuals needing vaccination, authorizing the nearly 27,000 dentists and 2,200 podiatrists the workforce expands significantly to achieve full vaccination in the state of California much more quickly.

Part 2. In order to perform “waived tests” dentists are required to obtain both federal CLIA Certificates of Waivers through CMS and state registrations through DPH’s Lab Field Services (LFS). Dentists can obtain the federal CLIA certificate but are not currently eligible under state law to obtain an LFS registration despite there being no federal qualification for lab directors that have Certificate of Waivers.

Dentists need to have the ability acquire state lab licenses in order to conduct waived tests that are within their scope of practice.”

2. **Background.**

DBC. The DBC is responsible for licensing and regulating dental professionals in California. Today, the DBC licenses an estimated 89,000 dental professionals, of which approximately 43,500 are fully licensed dentists; 44,500 are registered dental assistants (RDAs); and 1,700 are registered dental assistants in extended functions (RDAEFs). The DBC is also responsible for setting the duties and functions of an estimated 50,000 unlicensed dental assistants. Dental hygienists are licensed and regulated by a separate and distinct regulatory body, the Dental Hygiene Board of California.

Statute 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 such diagnosis or treatment may include all necessary related procedures as well as the use of drugs, anesthetic agents, and physical evaluation.” Dentists are health care practitioners authorized to write and issue prescriptions for controlled substances. Oral and maxillofacial surgeons are a surgically trained specialty of dentistry that have completed additional residency requirements. The DBC’s regulation of dental professionals includes licensing, regulatory, and disciplinary responsibilities. The DBC reviews and approves applications for initial or renewed licensure, determining whether an applicant has sufficient education and training to possess a license, certification, or permit. The DBC also engages in disciplinary activities through its own enforcement division, investigating potential violations of the Act and taking action against professional misconduct. The DBC additionally monitors licensees who have been placed on probation and manages a diversion program for licensees whose practice may be impaired due to abuse of drugs or alcohol. Currently, neither dentists nor dental hygienists have the authority in their practice act to administer any type of vaccine.

PMBC. The Podiatric Medical Board of California (PMBC) is tasked with oversight of practitioners of podiatric medicine (DPMs or podiatrists) and administers and enforces the laws relating to licensure. Podiatric medicine focuses on the foot and ankle. In California, it is defined as “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” (Business and Professions Code [BPC] § 2472(b)). It is unlawful to practice podiatric medicine without a license and licensed podiatrists are known as Doctors of Podiatric Medicine (DPMs). Currently, podiatrists do not have the authority in their practice act to administer any type of vaccine.

Continuing Education Requirements for Dentists and DPMs. Like most professions, dentists and DPMs have to fulfill certain continuing education requirements in order to maintain their licensure. Dentists must complete a basic life support course, a California Infection Control course, and a California Dental Practice Act course, for a total of 8 units of CE coursework. DPMs must complete 50 hours of approved CE,

including a minimum of 12 hours in subjects related to the lower extremity muscular skeletal system, and one of the continuing competence pathways specified in BPC Section 2496(a) through (h), during each two (2) year renewal period. Each doctor of podiatric medicine renewing his or her license under the provisions of Section 2423 of the code may be required to submit proof satisfactory to the board of compliance with the provisions of this article every two (2) years. Both boards require that courses be taken from an approved course provider or program.

COVID-19 Pandemic and Responsive Legislation. The COVID-19 pandemic brought about a scientific race to the cure. Scientists around the world began testing for medical treatments including vaccines, plasma therapies, and other medicines and biologics. In an effort to respond to the pandemic last year, Assemblymember Wood carried AB 1710 (Wood, Chapter 123, Statutes of 2020). Originally, this bill would have authorized a pharmacist to independently initiate and administer vaccines approved by the FDA under certain circumstances. However, because the intention of the bill was specific to COVID-19, and because at that time no vaccine or other therapeutic was available to the public to prevent COVID-19, Assemblymember Wood narrowed the bill at the Committee's suggestion to expand pharmacists' authority to be able to administer COVID-19 vaccines. AB 1710 (Wood, Chapter 123, Statutes of 2020) expanded pharmacist's scope of practice in this area, permitting pharmacist to independently initiate and administer any COVID-19 vaccines approved and authorized by the FDA under certain circumstances.

In early 2021, the Department of Consumer Affairs issued a waiver allow dentists and DPMs to administer the COVID-19 vaccines. Since then, more professions have sought statutory authority to administer to COVID-19 vaccines and other immunizations. In addition to this bill, AB 691 (Chau, 2021) would codify authorization for optometrists to administer the COVID-19 vaccine and perform waived tests for COVID-19. AB 1064 (Fong, 2021) seeks to authorize a pharmacist to independently initiate and administer any vaccine approved or authorized by the FDA for persons three years of age and older.

Laboratory Director. Current law provides for the licensure, registration, and regulation of clinical laboratories and various clinical laboratory personnel by the State Department of Public Health. Current law also 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 the following licensees: physician and surgeons, or anyone licensed to direct a clinical laboratory, as specified. For the purposes of waived tests or examinations, the following professionals also can be laboratory directors: clinical laboratory scientist, limited clinical laboratory scientist, naturopathic doctor, optometrist serving as the director of a laboratory that only performs clinical laboratory tests authorized in paragraph (10) of subdivision (d) of Section 3041.

- 3. Arguments in Support.** The Association of Dental Support Organizations writes in support: "As we all know, dentists in California have been approved to administer COVID-19 vaccinations to those over 16 years of age pursuant to the Department of Consumer Affairs' public health emergency waiver. Enactment of AB 526 will make

permanent this waiver and further permit California dentists to inoculate patients with other influenza vaccines approved by the FDA.

Dental professionals administer injections to patients throughout every day of their practice, and after the requisite immunization training requirements set forth in the bill, dentists across the state will be in the position significantly augment California's response to any number of public health concerns."

The California Association of Orthodontists (CAO) writes in support: "To protect the public from the COVID-19 pandemic, the health care system must be ready to vaccinate the residents of California at the fastest rate possible. Allowing all appropriately trained health care providers to provide these critical vaccinations will add access and speed to the process.

Orthodontists are dentists who have completed additional training in the specialty of orthodontics. In that capacity, we know that dentists are well equipped to administer vaccines because they routinely provide injections to particularly sensitive areas of the mouth that are in a dark, wet environment, navigate around major blood vessels, nerves, and other complex and important structures like bone, ligaments, joints, and a moving tongue. Dentists also have extensive training in microbiology, autoimmune response, and general anatomy, pharmacology (ability to respond to drug interactions/allergic reactions) and starting IVs.

It is crucial that vaccines be offered at every entry point to the health care system. Offering a vaccine at every opportunity will help turn immunization into a concerted, coordinated health care effort."

The California Dental Association (CDA) writes in support: "This bill seeks to codify the current DCA waiver and federal PREP act authority that allows dentists to administer COVID-19 vaccines during the current public health emergency. Specifically, it would allow a dentist to independently prescribe and administer FDA-approved or -authorized influenza and COVID-19 vaccines in compliance with the federal vaccine schedules published by the CDC to persons 3 years of age or older.

Additionally, this bill will align California laboratory registration statute with federal law so that dentists can obtain the appropriate state registration alongside their federal licensure in order to conduct simple, reliable, waived tests within their scope of practice. Dentists are not currently able to register as a laboratory director to oversee waived tests under California law. Although screening for COVID-19 is within a dentist's scope of practice, current COVID-19 tests are considered "high-complexity" tests that required specialized laboratory technology and would not be performed in a dental office. However, as soon as there is an FDA-approved "waived test" for screening asymptomatic patients that is reliable, affordable and readily available, dentists will need to be able to use it in their dental offices. Dentists need to be able to rapidly screen all patients before dental treatment to protect the dental team from COVID-19 exposure and to help direct asymptomatic patients to appropriate care."

The California Podiatric Medical Association writes in support: "Doctors of podiatric medicine undergo education and training similar to their allopathic and osteopathic

physician colleagues and possess more than enough experience to prescribe and administer the influenza and COVID-19 vaccine. Not only do doctors of podiatric medicine have the training, but podiatrists often treat patients with multiple comorbidities and chronic conditions such as diabetes. These patients frequently see their podiatrists more often and more consistently than their primary care providers, and because of that ongoing relationship, have a high level of trust in their podiatrists. Moreover, doctors of podiatric medicine have many opportunities to interact with their patients as they are on staff in a variety of health-care settings, such as hospitals, nursing homes, wound care centers, and outpatient surgical centers. Facing a shortage of medical personnel, hospitals and other health-care facilities called upon doctors of podiatric medicine and podiatric residents to provide care to patients diagnosed with COVID-19, and doctors of podiatric medicine are ready to serve again.

Relevant to the training needed to support this request, podiatric education follows the same rigorous 4-4-3 model as MDs and DOs – 4 years of undergraduate education followed by 4 years of podiatric medical school and 3 years of residency training. Their education includes courses in human anatomy, biochemistry, physiology, pharmacology, pathology, public health, general medicine, pediatrics, trauma, and numerous hospital rotations. Upon graduation from a four-year podiatric medical school, podiatrists complete three-year, comprehensive, hospital-based residency programs which incorporate rotations in anesthesia, general medicine, emergency medicine, surgery, and dermatology. In practice, podiatrists frequently give injections to provide local anesthetic blocks for procedures and to relieve pain related to inflammation. Significantly, to be able to do so, they are trained and experienced in the management of allergic responses to injected medications through their rotations in emergency medicine, anesthesia, and general medicine.”

The California Society of Health-System Pharmacists (CSHP) writes in support that it “has respectfully adopted a position of support on AB 526 (Wood), which would allow dentists and podiatrists to provide influenza and COVID-19 immunizations.

As an association that represents providers and experts in medication management, CSHP recognizes the value of ensuring that preventative healthcare is available to all patients. As such, CSHP applauds your efforts to increase the accessibility of vaccines to the community.”

The Dental Board of California writes in support: “At its quarterly meeting last week, the Dental Board of California (Board) voted to SUPPORT AB 526 which permanently authorizes dentists to order and administer the COVID-19 and influenza vaccines approved or authorized by the United States Food and Drug Administration for persons 3 years of age or older.”

4. **Policy Considerations.**

Granting Dentists and Podiatrists the Authority to Administer Vaccines. Dentists and DPMs do not currently have any statutory authority to administer vaccines. They were authorized through waivers issued by DCA but, unlike other professions

extending vaccine and testing waiver authority (pharmacists and optometrists), the provisions of this bill would include new practice ability.

Expanding “laboratory director.” Currently physician and surgeons, or anyone licensed to direct a clinical laboratory, as specified, are permitted to be laboratory directors. For the purposes of waived tests or examinations, the following professionals also can be laboratory directors: clinical laboratory scientist, limited clinical laboratory scientist, naturopathic doctor, optometrist serving as the director of a laboratory that only performs clinical laboratory tests authorized in paragraph (10) of subdivision (d) of Section 3041. This bill will add dentists to this list.

What is interesting is that dentists neither have vaccination authority nor laboratory director authority—where optometrists have both, and under this section pharmacists have one. However, according to Sponsors, the purpose of this provision is to eventually enable dental professionals to administer certain COVID-19 tests to test patients who come to receive dental care, in order to determine whether an appointment should be rescheduled and for the overall protection of the staff.

CE Requirements. This bill would count vaccine training provided through the CDC toward the fulfillment of CE requirements. It also counts vaccine training provided through the CDC or the California Pharmacists Association toward the fulfillment of a dentist’s or dental hygienist’s continuing education requirements, as specified.

Given that dentists must complete a basic life support course, a California Infection Control course, and a California Dental Practice Act course, it would be helpful to know which requirements these courses will fulfill.

SUPPORT AND OPPOSITION:

Support:

Association of Dental Support Organizations
 California Association of Orthodontists
 California Dental Association
 California Podiatric Medical Association
 California Society of Health-system Pharmacists
 Department of Consumer Affairs, Dental Board of California

Opposition:

None received

-- END --

Vaccines & Immunizations

EUA

For each COVID-19 vaccine authorized under an Emergency Use Authorization (EUA), the Food and Drug Administration (FDA) requires that vaccine recipients or their caregivers are provided with certain vaccine-specific EUA information to help make an informed decision about vaccination. This is accomplished by providing an EUA Fact Sheet for Recipients and Caregivers. The Fact Sheet is similar in purpose and content to vaccine information statements (VISs) for licensed vaccines but differs in that the EUA Fact Sheet is specific to each authorized COVID-19 vaccine, is developed by the manufacturer of the vaccine, and is authorized by the FDA.


There is no VIS for COVID-19 vaccines authorized under an EUA. Instead, the FDA-issued EUA Fact Sheet for Recipients and Caregivers for each COVID-19 vaccine must be used.

To help facilitate documentation of having provided the EUA Fact Sheet in electronic medical records/immunization information systems, CDC is leveraging the existing [VIS Code Set](#) infrastructure, barcoding, and URLs to provide the information needed for various systems, analogous to electronic system and workflow documentation of VISs.



It is important to note again that although CDC’s VIS Code Set files are used to convey the codes for EUA Fact Sheets for Recipients and Caregivers, these Fact Sheets are distinct from VISs. VISs will become available when there are licensed COVID-19 vaccines.

Thus far, the codes and URL links to access the EUA Fact Sheet documents have been developed for the following current and potential COVID-19 EUA vaccines:

- [COVID-19 Pfizer BioNTech Vaccine EUA Fact Sheet for Recipients](#)
- [COVID-19 Pfizer BioNTech Vaccine EUA Fact Sheet for individuals 5 though 11 years of age](#) 
- [COVID-19 Moderna Vaccine EUA Fact Sheet for Recipients](#)
- [COVID-19 AstraZeneca Vaccine EUA Fact Sheet for Recipients](#)
- [COVID-19 Janssen Vaccine EUA Fact Sheet for Recipients](#)

Note: URL links cited in the codes for the EUA Fact Sheets are not active until after the FDA provides Emergency Use Authorization for the vaccine.

Page last reviewed: August 6, 2021

COVID-19 Vaccination

Product Info by U.S. Vaccine

Pfizer-BioNTech Vaccines 

EUI

Interim Clinical Considerations



Clinical Care



Provider Requirements and Support



Training and Education



Vaccine Recipient Education



Health Departments



Planning & Partnerships



Vaccine Effectiveness Research

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Influenza (Flu) Vaccine (Inactivated or Recombinant): *What you need to know*

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

Influenza vaccine can prevent **influenza (flu)**.

Flu is a contagious disease that spreads around the United States every year, usually between October and May. Anyone can get the flu, but it is more dangerous for some people. Infants and young children, people 65 years and older, pregnant people, and people with certain health conditions or a weakened immune system are at greatest risk of flu complications.

Pneumonia, bronchitis, sinus infections, and ear infections are examples of flu-related complications. If you have a medical condition, such as heart disease, cancer, or diabetes, flu can make it worse.

Flu can cause fever and chills, sore throat, muscle aches, fatigue, cough, headache, and runny or stuffy nose. Some people may have vomiting and diarrhea, though this is more common in children than adults.

In an average year, **thousands of people in the United States die from flu**, and many more are hospitalized. Flu vaccine prevents millions of illnesses and flu-related visits to the doctor each year.

2. Influenza vaccines

CDC recommends everyone 6 months and older get vaccinated every flu season. **Children 6 months through 8 years of age** may need 2 doses during a single flu season. **Everyone else** needs only 1 dose each flu season.

It takes about 2 weeks for protection to develop after vaccination.

There are many flu viruses, and they are always changing. Each year a new flu vaccine is made to protect against the influenza viruses believed to be likely to cause disease in the upcoming flu season.

Even when the vaccine doesn't exactly match these viruses, it may still provide some protection.

Influenza vaccine **does not cause flu**.

Influenza vaccine may be given at the same time as other vaccines.

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of influenza vaccine**, or has any **severe, life-threatening allergies**
- Has ever had **Guillain-Barré Syndrome** (also called "GBS")

In some cases, your health care provider may decide to postpone influenza vaccination until a future visit.

Influenza vaccine can be administered at any time during pregnancy. People who are or will be pregnant during influenza season should receive inactivated influenza vaccine.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting influenza vaccine.

Your health care provider can give you more information.



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

4. Risks of a vaccine reaction

- Soreness, redness, and swelling where the shot is given, fever, muscle aches, and headache can happen after influenza vaccination.
- There may be a very small increased risk of Guillain-Barré Syndrome (GBS) after inactivated influenza vaccine (the flu shot).

Young children who get the flu shot along with pneumococcal vaccine (PCV13) and/or DTaP vaccine at the same time might be slightly more likely to have a seizure caused by fever. Tell your health care provider if a child who is getting flu vaccine has ever had a seizure.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at www.vaers.hhs.gov or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

6. The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at www.hrsa.gov/vaccinecompensation or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at www.fda.gov/vaccines-blood-biologics/vaccines.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call **1-800-232-4636** (1-800-CDC-INFO) or
 - Visit CDC's website at www.cdc.gov/flu.



COVID-19 Vaccination Record Card



Please keep this record card, which includes medical information about the vaccines you have received.

Por favor, guarde esta tarjeta de registro, que incluye información médica sobre las vacunas que ha recibido.

Last Name

First Name

MI

Date of birth

Patient number (*medical record or IIS record number*)

Vaccine	Product Name/Manufacturer	Date	Healthcare Professional or Clinic Site
	Lot Number		
1 st Dose COVID-19		___/___/___ <i>mm dd yy</i>	
2 nd Dose COVID-19		___/___/___ <i>mm dd yy</i>	
Other		___/___/___ <i>mm dd yy</i>	
Other		___/___/___ <i>mm dd yy</i>	

Reminder! Return for a second dose!

¡Recordatorio! ¡Regrese para la segunda dosis!

Vaccine	Date / Fecha
COVID-19 vaccine Vacuna contra el COVID-19	____/____/____ mm dd yy
Other Otra	____/____/____ mm dd yy

Bring this vaccination record to every vaccination or medical visit. Check with your health care provider to make sure you are not missing any doses of routinely recommended vaccines.

For more information about COVID-19 and COVID-19 vaccine, visit [cdc.gov/coronavirus/2019-ncov/index.html](https://www.cdc.gov/coronavirus/2019-ncov/index.html).

You can report possible adverse reactions following COVID-19 vaccination to the Vaccine Adverse Event Reporting System (VAERS) at vaers.hhs.gov.

Lleve este registro de vacunación a cada cita médica o de vacunación. Consulte con su proveedor de atención médica para asegurarse de que no le falte ninguna dosis de las vacunas recomendadas.

Para obtener más información sobre el COVID-19 y la vacuna contra el COVID-19, visite [espanol.cdc.gov/coronavirus/2019-ncov/index.html](https://www.espanol.cdc.gov/coronavirus/2019-ncov/index.html).

Puede notificar las posibles reacciones adversas después de la vacunación contra el COVID-19 al Sistema de Notificación de Reacciones Adversas a las Vacunas (VAERS) en vaers.hhs.gov.

MEETING MATERIALS Page 469 of 471

Immunization Record and History

PATIENT NAME (Last Name, First Name, Middle Initial)			NUMBER
BIRTHDATE	<input type="checkbox"/> Male <input type="checkbox"/> Female	KNOWN REACTIONS TO VACCINES/ALLERGIES	PRACTICE NAME/ADDRESS
VACCINES FOR CHILDREN (VFC) ELIGIBILITY (check one)		Under-insured (insurance does not cover immunizations) may be vaccinated with VFC vaccines only at federally qualified and rural health centers	
<input type="checkbox"/> CHDP/Medi-Cal eligible	<input type="checkbox"/> No health insurance	<input type="checkbox"/> American Indian/Alaskan Native	<input type="checkbox"/> Not eligible

If a combination vaccine (e.g., DTaP+IPV+HepB or DTaP+IPV+Hib) is used, record dose in each section.

VACCINE	DOSE	DATE GIVEN*	TRADE NAME/MANUFACTURER AND LOT NUMBER	ADMINISTERED BY	SITE** VIS I.D.†	VACCINE	DOSE	DATE GIVEN*	TRADE NAME/MANUFACTURER AND LOT NUMBER	ADMINISTERED BY	SITE** VIS I.D.†
HepB	1				<i>IM</i>	PCV	1				<i>IM</i>
HepB	2				<i>IM</i>	PCV	2				<i>IM</i>
HepB	3				<i>IM</i>	PCV	3				<i>IM</i>
HepB					<i>IM</i>	PCV	4				<i>IM</i>
RV	1				<i>oral</i>	IPV	1				<i>IM or SC</i>
RV	2				<i>oral</i>	IPV	2				<i>IM or SC</i>
RV	3				<i>oral</i>	IPV	3				<i>IM or SC</i>
DTaP	1				<i>IM</i>	IPV	4				<i>IM or SC</i>
DTaP	2				<i>IM</i>	MMR	1				<i>SC</i>
DTaP	3				<i>IM</i>	MMR	2				<i>SC</i>
DTaP	4				<i>IM</i>	VAR	1				<i>SC</i>
DTaP	5				<i>IM</i>	VAR	2				<i>SC</i>
HIB	1				<i>IM</i>	HepA	1				<i>IM</i>
HIB	2				<i>IM</i>	HepA	2				<i>IM</i>
HIB	3				<i>IM</i>						
HIB	4				<i>IM</i>						

Abbreviation Trade Name & Manufacturer
DTaP Daptacel (sanofi); Infanrix (GlaxoSmithKline [GSK]);
DTaP-HepB-IPV Pediarix (GSK)
DTaP-IPV/Hib Pentacel (sanofi)
DTaP-IPV Kinrix (GSK); Quadracel (sanofi)
HepB Engerix-B (GSK); Recombivax HB (Merck)
Hib ActHIB (sanofi); Hiberix (GSK); PedvaxHIB (Merck)
IPV Ipol (sanofi)
PCV13 Prevnar 13 (Pfizer)
RV1 Rotarix (GSK)
RV5 RotaTeq (Merck)
Tdap Adacel (sanofi); Boostrix (GSK)
MMR M-M-R_{II} (Merck)
MMRV ProQuad (Merck)
VAR Varivax (Merck)
HepA Havrix (GSK); Vaqta (Merck)
www.cdc.gov/vaccines/hcp/vis/index.html

* **Date Given** is the date you gave the patient the Vaccine Information Statement (VIS) and you administered the vaccine.

** **Site:** Abbreviations are LD=left deltoid or left outer upper arm, LT=left thigh, RD=right deltoid or right outer upper arm, RT=right thigh. Proper route indicated by italics: IM=intramuscular, SC=subcutaneous.

† **VIS**—Vaccine Information Statement. Each VIS has an issue date in the lower corner; record the VIS issue date here. The VIS should be given to the patient/parent before each dose of vaccine is administered. Each VIS can be downloaded from www.immunize.org/vis.

Note: If you are recording a vaccine given elsewhere, record date dose was given, write in "elsewhere" or "transcribed" and name of provider.

Immunization Record and History, continued

VACCINE/DOSE	DATE GIVEN*	TRADE NAME/MANUFACTURER AND LOT NUMBER	ADMINISTERED BY	SITE** VS I.D.†	VACCINE	DOSE	DATE GIVEN*	TRADE NAME/MANUFACTURER AND LOT NUMBER	ADMINISTERED BY	SITE** VS I.D.†
IIV/LAIV (Flu)				IM/Nasal	HPV	1				IM
IIV/LAIV (Flu)				IM/Nasal	HPV	2				IM
IIV/LAIV (Flu)				IM/Nasal	HPV	3				IM
IIV/LAIV (Flu)				IM/Nasal	MCV4/ MenACWY	1				IM
IIV/LAIV (Flu)				IM/Nasal	MCV4/ MenACWY	2				IM
IIV/LAIV (Flu)				IM/Nasal	MenB	1				IM
IIV/LAIV (Flu)				IM/Nasal	MenB	2				IM
IIV/LAIV (Flu)				IM/Nasal	MenB					IM
IIV/LAIV (Flu)				IM/Nasal	Tdap	1				IM
IIV/LAIV (Flu)				IM/Nasal	Tdap					IM
IIV/LAIV (Flu)				IM/Nasal	Tdap					IM
IIV/LAIV (Flu)				IM/Nasal						
IIV/LAIV (Flu)				IM/Nasal						
IIV/LAIV (Flu)				IM/Nasal						
IIV/LAIV (Flu)				IM/Nasal						
IIV/LAIV (Flu)				IM/Nasal						
IIV/LAIV (Flu)				IM/Nasal						
IIV/LAIV (Flu)				IM/Nasal						
IIV/LAIV (Flu)				IM/Nasal						
IIV/LAIV (Flu)				IM/Nasal						
IIV/LAIV (Flu)				IM/Nasal						
IIV/LAIV (Flu)				IM/Nasal						
IIV/LAIV (Flu)				IM/Nasal						
IIV/LAIV (Flu)				IM/Nasal						
IIV/LAIV (Flu)				IM/Nasal						

Abbreviation Trade Name & Manufacturer

HPV2 Cervarix (GSK)
HPV4 Gardasil (Merck)
HPV9 Gardasil9 (Merck)
LAIV (Live attenuated influenza vaccine) FluMist (MedImmune)
IIV (Inactivated influenza vaccine)
 For latest formulations, see: eziz.org/assets/docs/IMM-895.pdf
MCV4/MenACWY Menactra (sanofi pasteur); Menveo (Novartis)
MenB Bexsero (GSK/Novartis)
 Trumenba (Pfizer)