



**Title 16, Dental Board of California  
DEPARTMENT OF CONSUMER AFFAIRS**

**INITIAL STATEMENT OF REASONS**

**Hearing Date:** No Hearing Has Been Scheduled

**Subject Matter of the Proposed Regulations:** Dentists Initiating and Administering Vaccines

**Sections Affected:** Section 1066 of Article 9 of Chapter 2 of Division 10 of Title 16 of the California Code of Regulations.

**Specific Purpose of Each Adoption:**

**1. Background/Statement of the Problem:**

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 designated by the Immunization Branch of the California Department of Public Health.

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.

The Dental Board of California (the Board) is seeking to make permanent the emergency regulations (the Regulations) in Section 1066 approved by the Office of Administrative Law on June 23, 2022. The Regulations authorize 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. The Board is now submitting the adopted Emergency rulemaking, rulemaking file, and certificate of compliance in accordance with the requirements of Government Code section 11346.1, subdivision (e) and Business and Professions Code section 1625.6 to permanently establish these standards.

## **2. Problem Being Addressed:**

Business and Professions Code (BPC) section 1614 authorizes the Board to adopt, amend, or repeal such rules and regulations as may be reasonably necessary to enable the Board to carry into effect the provisions of the Dental Practice Act. BPC section 1625.6 authorizes the Board to adopt regulations to implement BPC section 1625.6. That section 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. While BPC section 1625.6 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. BPC 1625.6 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 permanently establish such standards, as follows.

The Board proposes to permanently adopt Section 1066 to:

- Require that dentists seeking to provide vaccines pursuant to BPC section 1626.5 comply with Section 1066. Noncompliance would be considered unprofessional conduct subject to discipline.
- Require dentists that initiate and administer vaccines complete an immunization training program and retain documentation of said training.
- Require dentists to complete one hour in immunization training every two years. The training must come from an approved provider (either the CDC or a provider registered and approved by the Board), and contain, at a minimum, vaccine administration, prevention and management of adverse reactions, and maintenance of vaccine records.

- Require dentists to notify the patient’s primary care provider of an administered vaccine within 14 days of the vaccine being administered. If there is no primary care provider or they cannot be contacted, the dentist must advise the patient to contact a primary care provider of their choice. If the patient is pregnant, the dentist must contact their prenatal care provider within 14 days of administering the vaccine.
- Require dentists to enter the vaccine in the California Immunization Registry (CAIR) within 14 days of administration for a flu vaccine and within 24 hours for a COVID-19 vaccine. The dentist must inform patients (or patients’ guardians) of immunization record sharing preferences per section 120440(e) of the Health and Safety Code.
- Require dentists to maintain vaccine records for at least 3 years from the date of vaccine administration, either in an electronic or manual format. Dentists must also provide patient vaccine administration records or cards to patients who receive vaccinations.

This proposal would make permanent 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.

### **3. Anticipated Benefits of the Regulations**

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 and public safety. 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. Such benefits are difficult to quantify.

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.

Making these regulations permanent will help provide notice and guidance to dentists who wish to provide vaccines to their patients of the measures necessary to administer and initiate these vaccines in a manner consistent with the law and accepted vaccination practices.

#### **Specific purpose of, and rationale for, each adoption:**

The Board proposes to:

- **Adopt Section 1066, Dentists 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.

Adoption of this subsection is necessary to ensure compliance with the Board's minimum standards for safe vaccination administration and practice. 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.

BPC section 1625.6 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 as described in that section. These provisions will help the Board verify that the dentist who is administering or prescribing a vaccine has completed the required training in compliance with Section 1625.6, 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. Existing regulation at section 1017 includes a requirement that a licensee retain, for a period of three renewal periods, the certificates of course completion issued to him or her at the time he or she attended a continuing

education course and to forward such certifications to the Board upon request by the Board for audit purposes. Cross-referencing to Section 1017 therefore also ensures consistency in recordkeeping and compliance requirements for all continuing education required by the Board.

### **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. This requirement is a minimum requirement and would not preclude a dentist from taking more than one hour in continuing education on this topic every two years.

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.

Additionally, this subsection requires, if known, notification to the prenatal care provider of any influenza or COVID-19 vaccine administered within 14 days of administration for pregnant women. This change is necessary to ensure prenatal providers are informed of immunizations as well. Often, pregnant women will not see their primary care provider during the duration of their pregnancy and will see their prenatal provider for all medical issues. For this reason, it is important that the prenatal provider be notified as well. The Board included "if known" in case the dentist does not know who the prenatal provider is or the patient doesn't provide that information. Notification is required within 14 days for the same reasons that the primary care doctor must be notified in 14 days, as well as for consistency.

### **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 patient 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 patient vaccination records for 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 documents are necessary to provide the regulated community with exemplary methods of compliance, although the dentist would not be required to use these forms in every case to meet the Board’s standards. The standards for the content of every patient vaccination record are set forth in the second sentence of this subsection: “A dentist shall provide each patient with a patient 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.”

In consultation with the CDPH, it is the Board’s understanding that the above-referenced forms are widely used to meet state and federal standards for providing a patient vaccination record. They are referenced in the proposed text so that the dentists can properly identify the documents if they would like to use these documents to meet the Board’s patient vaccination record or card requirement and included in the rulemaking file as underlying data.

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 patient 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.” These definitions are necessary to accurately communicate the meaning and purpose of these documents so that dentists clearly understand their recordkeeping and compliance obligations for vaccine administration under federal and state law.

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), and 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.

## **Underlying Data**

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](https://www.pharmacy.ca.gov/forms/immunization_record.pdf))
7. Minutes of the March 14, 2022 Dental Board of California Board Meeting

**Business Impact:**

The Board has made the initial determination that the proposed regulations would not have a significant, statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other States. This initial determination is based on the following facts.

The Board does not believe this regulation will have a significant adverse economic impact on businesses. Adopting this regulation simply provides dentists, who choose to initiate and/or administer vaccinations without a doctor’s prescription, as authorized by Business and Professions Code (BPC) section 1625.6, with the training, recordkeeping and reporting requirements to ensure that the dentists have the appropriate training and are in compliance with federal and state laws governing vaccine administration. Allowing dentists the ability to initiate and/or administer vaccinations will reduce the cost and increase the convenience of obtaining vaccinations. By making vaccines more readily available, dentists may experience an increase in business from patients electing to use their dentist for these services instead of their doctor. In addition, unless a dentist already has the capacity for vaccine storage in their dental office, dentists seeking to administer these vaccines are more likely to do so in other settings that have that storage capacity and the ability to deal with any adverse reactions to the vaccinations. These settings would include clinics, hospitals, and sites set up to handle mass vaccinations. Such settings would likely be able to address and support the documentation and notification requirements of these proposed regulations.

**Economic Impact Assessment:**

This regulatory proposal will have the following effects:

- o It will not create or eliminate jobs in the State of California because dentists already administer vaccines to the public under the waivers granted by this

Department; dentists can choose whether to get trained to initiate and/or administer vaccines; the proposed regulation simply sets out the standard for initiating and/or administering vaccinations for dentists to follow.

o It will not create new businesses or eliminate existing businesses within California because dentists already administer vaccines to the public under waivers granted by this Department; dentists can choose whether to get trained to initiate and/or administer vaccines; the proposed regulation simply sets out the standard for initiating and/or administering vaccinations for dentists to follow.

o It would not affect the expansion of businesses currently operating in California because dentists already administer vaccines to the public under waivers granted by this Department; dentists can choose whether to get trained to initiate and/or administer vaccines; the proposed regulation simply sets out the standard for initiating and/or administering vaccinations for dentists to follow.

o This regulatory proposal benefits the health and welfare of California residents because by making vaccinations less expensive and easier to obtain, more Californians will get vaccinated, and a rising vaccination rate among Californians benefits public health.

o This regulatory proposal will have no impact on worker safety because dentists have dispensed some vaccines to the public for some time, and the Board has not received any information about impacts on worker safety.

o This regulatory proposal will have no impact on the state's environment because it is not relevant to the State's environment. This proposal relates to standards for dentists administering or initiating influenza or COVID-19 vaccines to dental patients.

### **Specific Technologies or Equipment**

This regulation does not mandate the use of specific technologies or equipment.

### **Consideration of Alternatives:**

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific.

No such alternatives have been proposed, however, the Board welcomes comments from the public.

### **Description of reasonable alternatives to the regulation that would lessen any adverse impact on small business:**

No such alternatives have been proposed, however, the Board welcomes comments from the public.