



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.

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.

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. 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.

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 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.

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.

This proposal establishes continuing education requirements related to administering vaccines for licensees, as specified, and does not increase the total number of continuing education hours required. As a result, the Board does not anticipate an increase in workload or costs.

The Board will ensure compliance with the proposed regulations through its existing continuing education and enforcement activities and does not anticipate a significant number of violations.

However, in the event a licensee is out of compliance with the regulations and is subject to formal discipline, the Board estimates enforcement-related costs of \$5,000 per case.

The regulations do not result in a fiscal impact to the state in the form of federal funding or any cost or savings.

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))