

**TITLE 16. PROFESSIONAL AND VOCATIONAL REGULATIONS
DIVISION 10. DENTAL BOARD OF CALIFORNIA**

FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Dentists Initiating and Administering Vaccines

Sections Affected: California Code of Regulations, Title 16, Sections 1066

Updated Information

The Initial Statement of Reasons is included in the file; the information contained therein is updated as follows:

On March 14, 2022, the Board approved a motion to, among other things, approve the emergency rulemaking to adopt regulations and a finding of emergency and initiate a regular rulemaking to adopt California Code of Regulations (CCR) title 16, section 1066 relating to dentists initiating and administering vaccines. At that meeting, the issue of authority to administer vaccine outside of a dental office was discussed and the Board was initially advised that administration of vaccine was limited to the dental office. After that meeting, Board Counsel reviewed the legislative history of AB 526 and other materials related to the administration of COVID-19 vaccines by dentists and determined the statement made at the March 14, 2022 meeting was incorrect. There is no provision in Business and Professions Code (BPC) section 1625.6 limiting the location at which the dentist may prescribe or administer those vaccines. Further, the legislative history of AB 526 supports authority for dentists, who comply with the specified requirements detailed in BPC section 1625.6, to independently prescribe and administer influenza and COVID-19 vaccines in any setting, not just in a dental office.

At the Board's August 25-26, 2022 meeting, the Board further discussed the administration location issue and other Board member concerns related to implementation of the proposed regulations but took no further action to amend the text prior to the close of the public comment period.

The public comment period began on September 2, 2022 and ended on October 18, 2022. During the 45-day comment period, there was no request for a public hearing.

However, during the 45-day comment period the Board received three public comments on proposed section 1066. The comments received and the Board's responses, which

were approved at the November 17-18, 2022 Board meeting, are summarized in the “Objections or Recommendations/Board Responses” section below. Following discussion of those comments, the Board directed staff to take all steps necessary to complete the rulemaking process including the filing of the final rulemaking package with the Office of Administrative Law, authorize the Executive Officer to make any non-substantive changes to the proposed regulation and the rulemaking documents, and adopt the proposed regulations as described in the notice for 16 CCR section 1066.

As a non-substantive change, on January 23, 2023, the proposed text for the last sentence of subdivision (e) was amended to add the phrase “parent or” between the words patient’s and guardian. This was done to align the proposed text with Health and Safety Code section 120440(e).

Local Mandate Determination

A mandate is not imposed on local agencies or school districts.

Small Business Impact:

While the Board does not have, nor does it maintain, data to determine if any of its licensees (dentists) are a “small business,” as defined in Government Code section 11342.610, the Board has determined that the proposed regulations would not affect small businesses. The Board regulates and licenses the individual dental professionals in the State of California.

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.

Anticipated Benefits

This proposal aims to provide guidance to dentists seeking to initiate and administer COVID-19 and influenza vaccines to the public. This proposal benefits the health and welfare of California residents because it seeks to ensure that licensees providing vaccines comply with the necessary training and documentation requirements in relevant state and federal law. These requirements would ensure that state public health agencies are informed about vaccines provided to the public and that individuals who receive vaccines from dentist licensees have the proper records to demonstrate the vaccines they have received.

In addition, 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.

Consideration of Alternatives

No reasonable alternative which was considered or that has otherwise been identified and brought to the attention of the Board as part of public comments received or at the Board's meetings would be more effective in carrying out the purpose for which the regulation is proposed, or would be as effective and less burdensome to affected private persons than the adopted regulation, or would be more cost-effective to affected private

persons and equally effective in implementing the statutory policy or other provision of law. All recommendations provided during this rulemaking were considered by the Board and rejected as discussed herein.

Objections or Recommendations/Board Responses

Comment 1: Email dated September 2, 2022 from Dr. Betty Fong

Comment Summary – The commenter urges the Board to not adopt the regulations. They consider the benefits of allowing dentists to administer vaccines to not outweigh the risks and there are “alternatives that are more effective”. The commenter believes that dentists should not be involved in the “unending and overbearing regulatory demands of on our health and relying on the CDC, which has shown poor decision-making in the covid pandemic.”.

Board Response

Reject Comment. Dentists are currently authorized to independently prescribe and administer vaccines based on Business and Professions Code section 1625.6, and whether or not the Board adopts regulations will not change that authorization. Further, refusing to adopt regulations would only serve to create confusion and compliance issues for those dentists who choose to provide such services to the public. Regulations are the only legally prescribed method under the laws of this state (California Administrative Procedure Act) for setting the minimum training, recordkeeping and reporting requirements referenced in this proposal for all dentists that choose to administer vaccines.

Comment 2 – Email dated September 6, 2022, from Dr. Wai Chan.

Comment Summary – The commenter applauds the Dental Board’s response to AB 526 by considering making changes to its regulations. The commenter raises a concern that the language of the proposed rule has not taken into consideration dentists who are volunteering their services in the Medical Reserve Corps (MRC) and retirees. The commenter thinks the reporting and record keeping requirements will have undue burden on retired dentists and employee dentists who volunteer the vaccination services as a community service. The commenter would like volunteer dentists to be exempted from the vaccine recordkeeping requirements if the vaccinations are done in public health facilities or sponsored by educational, public safety, and public health organizations and public health organizations and that the sponsored facilities/organizations are responsible for the reporting and record keeping.

Board Response

Reject Comment. The Board has no jurisdiction to require the organizations mentioned in this comment to report on or maintain vaccination records or to make the recommended exemption as suggested. BPC section 1625.6(b) requires the dentist to comply with all state and federal recordkeeping and reporting requirements and contains no exemptions. The Board's current regulatory proposal is consistent with that mandate. The Board notes, however, that this proposal does not prohibit a dentist from making whatever arrangements they deem necessary with any organization to assist them with meeting the proposed regulations in Section 1066 (d), (e), and (f) covering vaccine reporting and recordkeeping requirements.

Comment 3 – Email dated September 8, 2022, from Dr. Antonio Bistrain.

Comment Summary – Commenter points out the costs of data storage and maintenance should be considered for dentists who administer vaccines. Commenter also urges Board to hold off on issuing regulations until lawsuits contesting the liability of vaccine administration are settled as the outcome of those suits could present a negative impact to all dentists due to increases in liability insurance.

Board Response

Reject Comment. The costs related to vaccines would represent a minimal increase to the data storage and maintenance costs dentists already incur. As noted in the response to Comment 1, holding off on regulations would not affect the ability of dentists to administer vaccinations and refusing to adopt regulations would only serve to create confusion and compliance concerns within the regulated community. In addition, vaccine administration is a service that dentists may or may not choose to provide to patients.

Finding of Necessity

The proposed regulations impose additional reporting or other compliance requirements, as follows.

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, proposed subdivision (e) of this proposal would set forth the requirements for dentists to report 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.

The Board hereby finds that it is necessary for the public health, safety, and welfare of the people of California that this regulation apply to business. The Board believes that adopting a regulation that specifies that dentists administering vaccine must comply with relevant sections of Health and Safety Code section 120440 is necessary to provide guidance to dentists on the required procedures for reporting vaccine administration information in compliance with state law, and also documenting that information required under federal law pursuant to Section 300aa-25 of Title 42 of the United States Code. These laws have been enacted to ensure accurate recordkeeping of patient medical histories and monitoring of safe administration of vaccine with the overall goal of providing for the healthcare of the affected patients and general public. Consequently, the Board's proposal is necessary to help further those public policy objectives.

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 section 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/>. No current law or regulation specifies how a dentist must comply with documenting or reporting vaccine administration according to state or federal law, which can lead to confusion and noncompliance with documentation and reporting requirements under these laws. As a result, this proposal is necessary to make specific to dentists the process for complying with state and federal vaccine administration recordkeeping and reporting requirements.