



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

To: Board Members

Subject: Agenda Item III - Consideration and Possible Adoption of Proposed Regulation to Add Title 16 California Code of Regulations section 1746.4, Related to Immunizations

Attachment 1

Background

The board was recently asked a question about the board's immunization regulations that are nearing completion of the administration review process. During the June 8, 2016 board meeting, the question was brought to the board to clarify the board's intent.

The issue was whether the board intended to draft the regulation to apply to all immunizations provided by pharmacists, or only those provided under the provisions of CA Business and Professions Code section 4052.8. As you know, pharmacists have been able to provide immunizations under a protocol with a physician under CA Business and Professions Code section 4052(a)(11). Any requirements on pharmacists providing immunizations under a physician's protocol would be established in the protocol.

The board clarified that the protocol should apply to all pharmacist-provided immunizations. The board voted to amend the protocol language for clarity and released the amended text for a 15-day comment period.

During the 15-day comment period, no comments were received.

At this Meeting

The board will have the opportunity to discuss the regulation a final time and adopt the regulation as approved at the June 2016 Board meeting.

Attachment 1 contains the proposed regulation text as noticed on June 10, 2016.

Staff Recommendation: Adopt the regulatory language as noticed on June 10, 2016, and delegate to the executive officer the authority to make technical or non-substantive changes as may be required by Office of Administrative Law or the Department of Consumer Affairs to complete the rulemaking file.

Immunizations –

1746.4

Title 16. BOARD OF PHARMACY

Third Modified Text

Changes made to the originally proposed language are shown by ~~double strikethrough~~ for deleted language and **bold and dashed underline** for added language. (Additionally, the modified text is listed in red for color printers.)

Changes made to the modified proposed language are shown by ~~double strikethrough and bold underline~~ for deleted language and **bold and double underline** for added language. (Additionally, the modified text is listed in blue for color printers.)

Changes made to the modified proposed language are shown by **bold wavy underline** for added language. (Additionally, the modified text is listed in purple for color printers.)

Proposal to add §1746.4 of Article 5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§1746.4 Pharmacists Initiating and Administering Vaccines.

(a) A pharmacist initiating and/or administering vaccines pursuant to sections **4052 or** 4052.8 of the Business and Professions Code shall follow the requirements specified in subdivisions (b) through (f) of this section.

(b) Training: A pharmacist who initiates and/or administers any vaccine shall keep documentation of:

- (1) Completion of an approved immunization training program, and
- (2) Basic life support certification.

This documentation shall be kept on site and available for inspection.

(c) Continuing Education: Pharmacists must complete one hour of ongoing continuing education focused on immunizations and vaccines from an approved provider once every two years.

(d) Notifications: The pharmacist shall notify the patient's primary care provider of any vaccines 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 ~~30~~ **14** days of the administration of any vaccine. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall advise the patient to consult an appropriate health care provider of the patient's choice. ~~If known, notification to the~~

prenatal care provider of immunizations provided to pregnant women must take place within 14 days of the administration of any vaccine.

(e) Immunization Registry: A pharmacist shall fully report the information described in Section 120440(c) of the Health and Safety Code into one or more state and/or local immunization information systems within ~~30~~ 14 days of the administration of any vaccine. The pharmacist shall inform the patient or the patient's guardian of immunization record sharing preferences, detailed in Section 120440(e) of the Health and Safety Code.

(f) Documentation: For each vaccine administered by a pharmacist, a patient vaccine administration medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 42, section 300aa-25 of the United States Code is readily retrievable during the pharmacy or facility's normal operating hours. A pharmacist shall provide the patient with a vaccine administration record, which fully documents the initiation and administration of any vaccine administered by the pharmacist. An example of an appropriate vaccine administration record is available on the Board of Pharmacy's website.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.8, Business and Professions Code.