



XIV. Possible Reconsideration of the Adoption of Title 16 CCR section 1746.4 related to Immunizations

The board was recently asked a question about the board's immunization regulations that are nearing completion of the administration review process. This question is being brought to the board for clarification of the board's intent.

The issue is 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.

This issue is whether the board wishes to have two standards of care for patients who receive immunizations from pharmacists, or whether it intended that all pharmacists who provide immunizations would be required to comply with the terms of proposed regulation section 1746.4.

The board's immunization regulation is provided below. If the board intended to have the protocol apply to all pharmacist-provided immunizations, the regulation would need to be amended and released for a 15-day comment period.

§1746.4 Pharmacists Initiating and Administering Vaccines.

- (a) A pharmacist initiating and/or administering vaccines pursuant to section 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 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 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 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 vaccines administered by the pharmacist. An example of an appropriate vaccine administration record is available on the Board of Pharmacy's website.

Authority cited: Section 4005, Business and Professions Code.

Reference: Sections 4052 and 4052.8, Business and Professions Code.

Proposed Modification:

- (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.