

TITLE 16: BOARD OF PHARMACY
FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Administering Vaccines

Section Affected: Amend Title 16 California Code of Regulations (CCR) section 1746.4

Updated Information

The Initial Statement of Reasons is included in this rulemaking file. The information contained therein accurately reflects the position of the Board of Pharmacy (board) regarding the amendment of the above section. The Initial Statement of Reasons (ISR) is updated as follows:

The 45-day public comment period began on October 8, 2021 and ended on November 22, 2021. The board's notice indicated that the board did not intend to hold a hearing on the matter, unless requested. No request for a hearing was received by the board during the 45-day comment period.

During the 45-day comment period two comments were received. At its December 2, 2021 board meeting, the board adopted the regulation text as noticed on October 8, 2021.

Local Mandate

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 (pharmacies and clinics) are a "small business," as defined in Government Code section 11342.610, the board has made a determination that the proposed regulatory action will not have a significant adverse economic impact on small businesses. This determination is based upon the following facts. Although the proposed regulation will directly affect businesses statewide, which may include small businesses, the board does not anticipate any adverse economic impact. No costs were identified because the board determined that eliminating the mandatory 14-day reporting requirement would ease some of the administrative burden on pharmacists which will increase the availability of the pharmacists to provide patient-centered care, which may result in a minor cost savings to licensees.

Consideration of Alternatives

No reasonable alternative considered by the agency would be more effective in carrying out the purpose for which the regulation is proposed, 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.

The board considered not removing the mandatory 14-day reporting requirement; however, the board determined that easing the administrative burden and more closely aligning the board's regulation with other licensed healthcare professionals was a benefit to patient safety. The board also considered a recommendation received during the 45-day public comment period to change this proposal by removing the existing requirement to notify a patient's prenatal care provider, if known, but rejected that recommendation for the reasons set forth below.

Objections or Recommendations/Responses to Comments

During the public comment period from October 8, 2021 to November 22, 2021, the board received two comments. The comments were provided in the meeting materials for the December 2, 2021 board meeting, and the board reviewed and considered them.

Summarized 45-day Comments Regarding Inventory Reconciliation:

Written Comments from Nasiba Makarem, Pharm.D.

Comment 1: The commenter requests that the Board remove the requirement to notify a patient's prenatal care provider, if known, as vaccinations must be reported to the California Immunization Registry and practitioners should be checking there. Additionally, the commenter expressed concern that a patient may not disclose they are pregnant or provide the contact information of their OB to the pharmacist.

Response to Comment 1: The Board reviewed this comment and did not make any changes to the text based thereon. The Board notes that the language requires reporting if the patient's prenatal care provider is known. If the patient has not disclosed that they are pregnant or is unable or unwilling to provide the contact information for their prenatal care provider, then the pharmacist would not be required to report to the prenatal care provider.

Written Comments from Steven Anderson, FASAE, CAE, IOM, National Association of Chain Drug Stores

Comment 2: The commenter expressed support for the proposed regulation language as they feel it will reduce some of the administrative burden for duplicative reporting to the primary care provider and the California Immunization Registry.

Response to Comment 2: The Board acknowledges the commenter's support of the proposed regulation language.

At its December 2, 2021 meeting, the board voted to adopt the regulation text as it was noticed on October 8, 2021.