



California State Board of Pharmacy
2720 Gateway Oaks Drive, Ste 100
Sacramento, CA 95833
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www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor



To: Board Members

Subject: Agenda Item VI. Discussion and Consideration of Adoption of Board Approved Regulation, Title 16, California Code of Regulations Section 1746.4 Related to Administering Vaccines and Discussion and Consideration of Public Comments received during the 45-day comment period

Background:

At the July 28, 2021 Board meeting, the Board approved proposed regulation text to amend Section 1746.4 related to administering vaccines. This proposal amends the vaccination reporting requirements to the primary care physician to upon patient request.

As required by the Administrative Procedure Act, Board staff released the proposed text for the 45-day comment period on October 8, 2021, which ended on November 22, 2021. Two comments were received during the comment period. Attached following this memo are the following:

1. The proposed text released for 45-day public comment.
2. Board staff prepared summarized comments with recommendations
3. Comments received during the 45-day comment period

At this Meeting:

The Board will have the opportunity to discuss the regulation and determine what course of action it wishes to pursue. Among its options:

1. Adopt the regulation text as noticed on October 8, 2021 for the 45-day comment period.
2. Amend the regulation to address concerns expressed by stakeholders and notice the modified text for a 15-day comment period.

Possible Adoption Language:

Accept the Board staff recommended comment responses and adopt the regulation language as noticed on October 8, 2021. Additionally, authorize the Executive Officer to take all steps necessary to complete the rulemaking and delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.

**Administering
Vaccines
16 CCR § 1746.4
Proposed Text
Released for 45-Day
Comment**

**Title 16. Board of Pharmacy
Proposed Text**

Amend Section 1746.4 to Title 16 of the California Code of Regulations, to read as follows:

§ 1746.4. Pharmacists Initiating and Administering Vaccines.

- (a) A pharmacist initiating and/or administering any vaccine pursuant to section 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: A pharmacist must complete one hour of ~~engaging~~ continuing education focused on immunizations and vaccines from an approved provider once every two years.
- (d) Notifications: At the request of a patient, A a pharmacist shall notify, each patient's primary care provider of any vaccine 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 a 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. A pharmacist shall notify each pregnant patient's prenatal care provider, if known, of any vaccine administered to the patient within 14 days of the administration of any vaccine.
- (e) Immunization Registry: A pharmacist shall report, in accordance with section 4052.8, subdivision (b)(3), of the Business and Professions Code, the information described in section 120440, subdivision (c), of the Health and Safety Code within 14 days of the administration of any vaccine. A pharmacist shall inform each patient or the patient's guardian of immunization record sharing preferences, detailed in section 120440, subdivision (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 information required under section 300aa-25 of title 42 of the United States Code is readily retrievable during the pharmacy or facility's normal operating hours. A pharmacist shall provide each 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.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052, 4052.8 and 4081, Business and Professions Code; Section 120440, Health and Safety Code; and Section 300aa-25, Title 42, United States Code.

**Administering
Vaccines
16 CCR § 1746.4
Board Staff
Comment
Recommendations**



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Proposed Regulation to Amend Title 16 CCR Section 1746.4, Administering Vaccinations

Summarized 45-day Comments Regarding Inventory Reconciliation with Board Staff Recommendations:

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: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff note 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: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff acknowledges the commenter's support of the proposed regulation language.

**Administering
Vaccines
16 CCR § 1746.4
45-Day Public
Comment**

From: Makarem, Nasiba <nmakarem@Cerritos.edu>
Sent: Thursday, November 4, 2021 4:16 PM
To: Martinez, Lori@DCA <Lori.Martinez@dca.ca.gov>
Subject: NOTICE OF PROPOSED REGULATORY ACTION CONCERNING: ADMINISTERING VACCINES

[EXTERNAL]: nmakarem@Cerritos.edu

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DO NOT: click links or open attachments unless you know the content is safe.
NEVER: provide credentials on websites via a clicked link in an Email.

Hello,

Below is my comment regarding the proposed regulation:

Title 16, California Code of Regulations
Section 1746.4

“Notably, the reporting requirement to notify a pregnant patient's prenatal care provider, if known, of the administered vaccine, will remain due to the time sensitive nature of the medical treatment for pregnant patients.”

Will the board consider removing or replacing this statement as we are required to report all vaccinations to the CAIR2 program and thus all practitioners should get into the habit of checking CAIR for updated vaccination record or their patients.

Keep in mind that many patients who arrive to a community pharmacy might not disclose that they are pregnant and might not disclose the name and contact information of their current OB/ physician.

Regards,

Nasiba Makarem, Pharm.D.

November 22, 2021

Lori Martinez
California State Board of Pharmacy
2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833
via email: Lori.Martinez@dca.ca.go

Re: Proposed Rule Changes to 16 CCR §1746.4. Pharmacists Initiating and Administering Vaccines

Ms. Martinez:

On behalf of our members operating chain pharmacies in the state of California, the National Association of Chain Drug Stores (NACDS) appreciates the opportunity to comment to the California State Board of Pharmacy in support of the proposed rule revising 16 CCR §1746.4 pertaining requirements for notification to patients' primary care provider following vaccine administration. In modifying the notification provisions of the rule to apply only when requested by a patient, the proposed rule change would reduce the administrative burden of preparing and forwarding potentially redundant information that is not always needed or desired by every primary care provider, especially considering that pharmacies also report administered vaccines to the California Immunization Registry. In light of pharmacist and pharmacy workload demands having amplified during the COVID-19 pandemic, eliminating unnecessary administrative requirements free up pharmacy personnel to focus on meeting public demand for increased pharmacy services.

NACDS represents traditional drug stores, supermarkets, and mass merchants with pharmacies. Chains operate nearly 40,000 pharmacies, and NACDS' 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit NACDS.org

NACDS thanks the Board for considering our support for this proposed rule. We appreciate the Board's efforts to help ensure that pharmacists and pharmacies work and operate in an environment focused on meeting the needs of patients to support health and wellness and to improve outcomes from appropriate medication use. If we can provide further assistance, please contact NACDS' Sandra Guckian at sguckian@nacds.org.

Sincerely,



Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer
National Association of Chain Drug Stores