

TITLE 16. BOARD OF PHARMACY

NOTICE OF PROPOSED REGULATORY ACTION CONCERNING: ADMINISTERING VACCINES

NOTICE IS HEREBY GIVEN that the California State Board of Pharmacy (board) proposes taking the rulemaking action described below under the heading Informative Digest/Policy Statement Overview. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the board at its office by November 22, 2021.

The board has not scheduled a public hearing on this proposed action. The board will, however, hold a hearing if it receives a written request for a public hearing from any interested person, or that person's authorized representative, no later than 15 days prior to the close of the written comment period.

The board may, after holding a hearing if requested and considering all timely and relevant comments, adopt the proposed regulations substantially as described in this notice, or may modify the proposed regulations if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as the Contact Person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Section 4005 of the Business and Professions Code (BPC) authorizes the board to adopt this regulation. The proposed regulation implements, interprets, and makes specific sections 4052, 4052.8, and 4081 of the Business and Professions Code, Section 120440, Health and Safety Code; and, Section 300aa-25, Title 42, United States Code.

Informative Digest/Policy Statement Overview

The board is a state agency vested with the authority to regulate the pharmacy industry, including pharmacies, pharmacists, interns, and pharmacy technicians. The board's mandate and its mission is to protect the public (BPC § 4001.1).

Existing pharmacy law establishes the authority for a pharmacist to initiate and administer vaccines as specified (BPC 4052.8). Additionally, California Code of Regulations (CCR) Title 16, section 1746.4 specifies the conditions under which a pharmacist may administer vaccines. The regulation currently requires a pharmacist to notify each patient's primary care provider (PCP) of any vaccine administered to the patient as specified. Further, a pharmacist must report vaccine administration to California's vaccine immunization registry.

As part of both the state and national responses to the COVID-19 pandemic, pharmacists and pharmacies have served as a primary access point for patients to receive their COVID-19 vaccines. This access point was possible, in part, because the board approved a waiver effective December 17, 2020 (and available on the Board's web site) to the mandatory notification requirement in section 1746.4(d) to each patient's PCP during the recently declared COVID-19 related statewide emergency declaration. Under the conditions of the waiver a pharmacist is not required to notify each patient's PCP if specified conditions are met, including that the pharmacist continue reporting vaccinations administered to a vaccination registry. As BPC 4052.8(b)(3) requires compliance with state and federal recordkeeping and reporting requirements (Title 42, United States Code, section 300aa-25), including reporting vaccinations in the immunization registry developed and maintained by the California Department of Public Health, physicians, including PCPs, currently have access to vaccine administration records for their patients without the additional notification from pharmacists.

Additionally, other health care providers, specifically, optometrists (BPC 3041(g)(1)), have the authority to administer certain vaccinations but are not obligated to notify the patient's PCP within 14 days. Optometrists are required to provide documentation of the immunization to the patient's PCP if the patient provides the PCP's information. Further, Assembly Bill 526 (Wood, Statutes of 2021), is under committee discussion with the California Legislature, and will grant authority to dentists and podiatrists to provide certain vaccinations without any requirement to notify the patient's PCP within 14 days of administration.

This proposal will permanently remove the 14-day mandatory reporting requirement to each patient's PCP as the notification is duplicative and creates additional workload for the pharmacist and pharmacy when the vaccination information is readily available to the patient's PCP through the immunization registry of the California Department of Public Health. Instead, the proposal will require reporting to the patient's PCP, only if requested by the patient as the patient has the right to request such notification. 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.

Anticipated Benefits of the Proposed Regulations

By eliminating the current, mandatory 14-day reporting requirement, imposed only on pharmacists, the board is more closely aligning its regulation with the statutory reporting requirements in BPC 4052.8 as well as the reporting requirements for other health care providers. Additionally, making the reporting requirement mandatory only when requested by the patient, will ease some of the administrative burden for pharmacists. Reducing some of the administrative burden will increase the availability of the pharmacists to provide patient-centered care, which is a benefit to public health. In addition, eliminating the word "ongoing" from the continuing education requirement in subsection (c) of Section 1746.4 will help avoid confusion for the regulated public regarding the board's continuing education completion requirements.

Consistency and Compatibility with Existing State Regulations

While developing these regulations and amendments, the board conducted a search of similar regulations on this topic and concluded that these regulations are neither inconsistent nor incompatible with existing state regulations. As noted above, these amendments make state law more consistent with federal law.

Fiscal Impact and Related Estimates

Fiscal Impact on Public Agencies Including Costs/Savings to State Agencies or Costs/Savings in Federal Funding to the State: None

Nondiscretionary Costs/Savings to Local Agencies: None

Local Mandate: None

Cost to Any Local Agency or School District for Which Government Code Sections 17500 – 17630 Require Reimbursement: None

Business Impact:

The board has made the initial determination that the proposed regulations will not have a significant statewide adverse economic impact directly affecting businesses including the inability of California businesses to compete with businesses in other States.

This initial determination is based on the following facts:

This initial determination is based on the absence of testimony to that effect during the public discussion and development of the proposed amendments to the regulation. 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.

Cost Impact on Representative Private Person or Business:

The board is not aware of any negative cost impacts that a representative private person or business would necessarily incur in reasonable compliance with proposed action. 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

Effect on Housing Costs: None

Effect on Small Business:

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 an initial determination that the proposed regulatory action will not affect small businesses. 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.

Results of Economic Impact Assessment/Analysis:

Impact on Jobs/New Businesses:

The Board concludes that:

- (1) this proposal will not create jobs within California;
- (2) this proposal will not eliminate jobs within California;
- (3) this proposal will not create new businesses within California;
- (4) this proposal will not eliminate existing businesses within California; and,
- (5) this proposal will not expand businesses currently doing business in the State of California.

The board determined that this proposal will not cause any of the foregoing because these changes are not of sufficient magnitude to create those impacts. This proposal simply eliminates a single reporting requirement for pharmacists and strikes a confusing word from the continuing education provisions, which may result in minor cost savings to the licensees.

Additionally, the board determined that this regulatory proposal will not impact worker safety, or the state’s environment as these changes do not involve worker safety or the environment. The board has determined that this regulatory proposal benefits the health and welfare of California residents by increasing the availability of the pharmacists to provide patient-centered care.

Consideration of Alternatives

The Board determined that no reasonable alternative that it considered to the regulation, or that has otherwise been identified and brought to its attention, would either be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposal described in this Notice, 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.

Any interested person may present statements or arguments in writing relevant to the above determinations at the address listed for the Contact Person during the written comment period.

Availability of Text of Proposal and Initial Statement of Reasons

The Board has prepared an Initial Statement of Reasons for the proposed action and has available all the information upon which the proposal is based. Copies of the exact language of the proposed regulations, the Initial Statement of Reasons, and all of the information upon which the proposal is based, may be obtained upon request from the Board of Pharmacy at 2720 Gateway Oaks Drive, Ste. 100, Sacramento, California 95833, or from the Board of Pharmacy's website at <http://www.pharmacy.ca.gov>.

Availability and Location of the Final Statement of Reasons and Rulemaking File

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the website listed below.

Contact Person

Inquiries or comments concerning the proposed rulemaking action may be addressed to:

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The backup contact person is:

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Website Access

Materials regarding this proposal can be found at the Board of Pharmacy's website:
https://www.pharmacy.ca.gov/laws_regs/pending_regs.shtml.