

**Board of Pharmacy**  
**Initial Statement of Reasons**

Subject Matter of Proposed Regulation: Administering Vaccines

Section Affected: California Code of Regulations (CCR), Title 16, Division 17, Amend Section 1746.4

Hearing Date: None unless requested, see Notice of Proposed Action

**Background**

The California State Board of Pharmacy (board) is a state agency vested with the authority to regulate the pharmacy industry, including pharmacies, pharmacists, pharmacy interns, and pharmacy technicians. The board's mandate and its mission is to protect the public (Business and Professions Code (BPC) section 4001.1).

**Problems Addressed**

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.

### **Specific Purpose of Proposed Changes and Rationale**

Section 1746.4(c) has been amended to remove the term "ongoing" prior to continuing education. The board determined that the term is not appropriate as the pharmacist must complete one hour of continuing education focused on immunizations and vaccines every two years. Further, the term "ongoing" could cause confusion as to the meaning and requirements of completing a course, as a course would not be considered completed if it was ongoing.

Subdivision (d) of Section 1746.4 adds the phrase "At the request of a patient" at the beginning of the first section after the title "Notifications", and makes the capital A, lowercase. This change eliminates the requirement that pharmacists must notify the PCP of each patient to whom a vaccination is administered and only requires that the pharmacist notify the PCP of the patient's vaccination if the patient requests notification to their PCP. The board determined that this change was appropriate as the pharmacist must report the vaccination(s) to the immunization registry, to which all physicians have access. The board concluded the mandatory reporting was duplicative and created unnecessary workload for the pharmacist. The board determined that by removing this requirement, the board's regulation will more closely align with the reporting

requirements of other healthcare providers and will increase the availability of pharmacists to provide more patient-centered care.

### **Underlying Data**

1. Relevant Public Board Meeting Materials and Draft Minutes (Excerpt) from Board Meeting held July 28-29, 2021

### **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.

### **Economic Impact Assessment:**

The board has determined 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;
- (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 proposal removes the mandatory reporting requirements to each patient's PCP, which eases the administrative burden for the pharmacist and pharmacy.

The board 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.

### **Fiscal Impact Assessment:**

The proposed regulation does not result in a fiscal impact to the state. The board currently ensures compliance with its regulation through its inspection and enforcement programs. The board does not anticipate any added workload associated with this regulatory change.

### **Specific Technologies or Equipment**

This regulation does not mandate the use of specific technologies or equipment.

### **Consideration of Alternatives**

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific.

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.