

BOARD OF PHARMACY

INITIAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Protocol for Pharmacists Furnishing Naloxone Hydrochloride

Sections Affected: Amend Section 1746.3 of Article 5 of Division 17 of Title 16, California Code of Regulations.

Problems Addressed/Specific Purpose

The California State Board of Pharmacy (Board) is a state agency vested with the authority to regulate the pharmacy industry, including pharmacies, pharmacists, and pharmacy technicians. (Business and Professions Code (BPC) section 4000, et seq.) The Board's mandate and its mission is to protect the public. (BPC section 4001.1)

Specifically, this proposal would:

- Amend 16 CCR Section 1746.3 to authorize the Board's executive officer to approve fact sheets created by licensees for distribution to patients in lieu of the Board's approved fact sheet.
- Authorize the Board's executive officer to approve fact sheets only when they contain, at minimum, the same content as the Board-approved fact sheet. The fact sheet may be formatted or presented in a different manner.
- Require that naloxone hydrochloride fact sheets provided in alternate languages be the current fact sheet approved by the Board of Pharmacy and provided by the Board of Pharmacy.

BPC section 4052.01 states a pharmacist may furnish naloxone hydrochloride in accordance with standardized procedures or protocols developed and approved by both the Board and the Medical Board of California, in consultation with the California Society of Addiction Medicine, the California Pharmacists Association and other appropriate entities. One requirement in this protocol is the requirement that pharmacists distribute a fact sheet approved by the Board to patients receiving naloxone hydrochloride.

Currently, some pharmacists are furnishing the Board-approved fact sheet as well as their pharmacy's own fact sheet. This proposal will allow a pharmacist to furnish either the current Board-approved fact sheet or an alternative fact sheet approved by the Board's executive officer. The Board's executive officer could only approve an alternative fact sheet for furnishing

as long as it contains, at minimum, the information and elements of the current Board-approved fact sheet. This would eliminate the need for pharmacists to provide multiple fact sheets, while ensuring the facts sheets are approved by the executive officer.

This proposal will allow pharmacies to format and present the information and elements required in Board-approved fact sheets in a manner that is specific to their patient populations and computer systems. This regulation would require pharmacies to provide, at a minimum, the same content contained in Board-approved fact sheets, while giving them flexibility to format and present the information in whatever format they choose, provide supplemental information (including information specific to the pharmacy where the naloxone is being furnished), and streamline their business processes for distributing naloxone hydrochloride fact sheets. As one licensee testified at the May 3-4, 2017, Board meeting, some pharmacies currently print their own personalized fact sheets with the other medication-related information provided to the patient in addition to the Board-approved fact sheet to ensure compliance with 16 CCR 1746.3 (c)(6). The addition of the approval process by the Board's executive officer will assist pharmacies in reducing this duplication.

Factual Basis/Rationale

The Board proposes to amend 16 CCR Section 1746.3 (c)(6) as follows: add "or a fact sheet approved by the executive officer. The executive officer may only approve a fact sheet that has all the elements and information that are contained in the current board-approved fact sheet." Additionally, the word "This" at the beginning of the former second sentence was replaced with, "The board-approved". Lastly, a new fourth sentence was added that states, "Fact sheets in alternate languages must be the current naloxone fact sheet approved by the Board of Pharmacy."

This first addition to the regulation text is necessary to enable the executive officer to approve a request from a pharmacy or pharmacist to use a different naloxone hydrochloride fact sheet. The Board wants to provide flexibility to pharmacies and pharmacists in their business operations to present the substantive information in the Board-approved fact sheet in a way that is most convenient to their patients and business, but that still protects public safety. Thus, the Board concluded that any fact sheet approved by the executive officer must contain the exact same information and elements as the fact sheet approved by the Board, but may be formatted differently or have supplemental information added for distribution to a patient upon a pharmacist furnishing naloxone hydrochloride. This addition is necessary to allow a pharmacist to comply with the naloxone hydrochloride fact sheet requirement in 16 CCR 1746.3 while allowing a pharmacist or pharmacy the ability to format the fact sheet in a manner best suiting their individual business and reducing the need for duplicative fact sheets. By requiring

the executive officer to approve the fact sheet, it will ensure that the public is still protected by requiring any fact sheet provided has the same information and elements that the Board has determined is necessary under these circumstances. However, it does also provide flexibility to licensees who would like to provide the information in a different way, or for a chain of pharmacies that may have additional requirements from other states or need additional information on the fact sheets due to the various locations of pharmacies.

The deletion of “This” and the addition of “The Board-approved” is necessary to explain that only the Board-approved fact sheet will be made available in alternative languages on the Board’s website. Since the proposed rule would allow alternatives to the Board-approved fact sheet, the Board wants to clarify that only its fact sheet needs to be on its website.

Similarly, the Board determined that the executive officer should not approve alternative fact sheets that are in languages other than English. Pharmacists furnishing naloxone pursuant to BPC 4052.01 in an alternate language must use the Board-approved fact sheet available on the Board’s website. This ensures that the Board has control over the translation of the fact sheet to ensure accuracy and consistency of translation. Currently, the Board does not have the resources for the executive officer to be able to approve fact sheets that are not in English.

Anticipated Benefits of Proposal

This proposal will authorize the Board’s executive officer to approve alternative naloxone hydrochloride fact sheets as long as they contain the same elements and information required in the Board-approved fact sheet. These fact sheets may be developed and submitted by individual pharmacies for approval and therefore they can be formatted in a different manner or contain additional information than the Board-approved fact sheet. Allowing the Board’s executive officer the authority to approve such fact sheets, will allow pharmacies to streamline their work processes by eliminating the need to furnish more than one fact sheet at the time naloxone hydrochloride is furnished. Additionally, this will allow pharmacies to format and present the same subject matter for their specific patient populations. The proposal will also ensure that patients receive fact sheets that contain the information required by the Board.

Underlying Data:

1. Relevant Meeting Materials and Minutes from Board of Pharmacy’s Communication and Public Education Committee Meeting held March 23, 2017.
2. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held May 3-4, 2017.

3. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held March 27, 2018.
4. License Type Totals for the California State Board of Pharmacy (Updated 9/1/17)

Business Impact

This regulation will not have a significant adverse economic impact on businesses. This initial determination is based on the fact that the proposed regulation does not impose an additional requirement on businesses. Pursuant to 16 CCR 1746.3, pharmacists are currently required to provide a Board-approved fact sheet upon furnishing of naloxone hydrochloride to a patient. The proposed regulation may assist pharmacy licensees in streamlining the delivery of the naloxone hydrochloride fact sheet required to be distributed at time of furnishing naloxone hydrochloride to a patient. However, there are no additional requirements for businesses.

Economic Impact Assessment Results:

This regulatory proposal will have the following effects:

- It will not create or eliminate jobs in the State of California because pursuant to 16 CCR 1746.3, pharmacists are currently required to provide the Board-approved naloxone hydrochloride fact sheet upon furnishing naloxone hydrochloride to a patient.
- It will not create new businesses or eliminate existing businesses within California because pursuant to 16 CCR 1746.3, pharmacists are currently required to provide the Board-approved naloxone hydrochloride fact sheet upon furnishing naloxone hydrochloride to a patient.
- It would not affect the expansion of businesses currently operating in California because pursuant to 16 CCR 1746.3, pharmacists are currently required to provide the Board-approved naloxone hydrochloride fact sheet upon furnishing naloxone hydrochloride to a patient.
- This regulatory proposal benefits the health and welfare of California residents because it would allow pharmacies licensed by the Board to format the naloxone hydrochloride fact sheet in a manner that assists their patient population which may increase the patient's review and familiarity of the information regarding naloxone hydrochloride while maintaining the required elements of the fact sheet specified in 16 CCR 1746.3.
- This regulatory proposal will have no impact worker safety. It does not involve worker safety.
- This regulatory proposal may impact the state's environment by reducing paper waste from one fact sheet being printed rather than two fact sheets being printed.

Specific Technologies or Equipment

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

Consideration of Alternatives

No reasonable alternative to the regulatory proposal would either be 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 only alternative to this proposal is to not amend the requirements. This alternative was rejected because the change in regulation can increase patient education and medication adherence and assist licensees in streamlining business processes.