

## TITLE 16. BOARD OF PHARMACY

NOTICE IS HEREBY GIVEN that the California State Board of Pharmacy (Board) is proposing to take 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 not later than 5:00 p.m. on June 17, 2019.

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 his or her authorized representative, no later than 15 days prior to the close of the written comment period.

The Board may, after 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: Pursuant to the authority vested by section 4052.01 of the Business and Professions Code to implement, interpret, and make specific section 4052.01 of the Business and Professions Code, the Board is proposing to amend Section 1746.3 of Article 5 of Division 17 of Title 16 of the California Code of Regulations as follows:

### **Informative Digest/Policy Statement Overview**

The Board of Pharmacy (Board) proposes to amend Section 1746.3 of Article 5 of Division 17 of Title 16 of the California Code of Regulations (CCR) for the purpose of providing the Board's executive officer the authority to approve alternative fact sheets for distribution to patients after being furnished naloxone hydrochloride by a pharmacist, as long as those fact sheets contain the same elements of the current Board-approved fact sheet. Additionally, the Board proposes to amend 16 CCR 1746.3 to require naloxone hydrochloride fact sheets provided to patients in alternate languages must be the current naloxone fact sheet approved and translated by the Board of Pharmacy.

Business and Professions Code (BPC) section 4001.1 provides that the Board's highest priority shall be the protection of the public while exercising its licensing, regulatory, and disciplinary functions, and further states, that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

Section 4052.01 authorizes a pharmacist to 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 of this protocol is the furnishing of a Board-approved fact sheet. Existing regulations require pharmacists to provide the Board-approved fact sheet. (See Cal. Code Regs, tit. 16, § 16 CCR 1746.3.)

Currently, some pharmacists are furnishing the Board-approved fact sheet as well as their own fact sheet. This proposal will allow a pharmacy to furnish their own fact sheet as long as it contains the Board-approved elements and has been approved by the Board's executive officer, thereby eliminating the duplicative work by the pharmacist, and also ensuring that the fact sheet contains the necessary information.

The proposed regulation would further amend 16 CCR Section 1746.3 by requiring that naloxone hydrochloride fact sheets provided to patients in alternate languages be the current naloxone fact sheet approved by the Board of Pharmacy, and specify that only the Board-approved fact sheet will be posted in alternative languages on the Board's website.

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.

### **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.

### **Consistency and Compatibility with Existing State Regulations**

During the process of developing these regulations and amendments, the Board has conducted a search of any similar regulations on this topic and has concluded that these regulations are neither inconsistent nor incompatible with existing state regulations.

## **Fiscal Impact Estimates**

Fiscal Impact on Public Agencies Including Costs/Savings to State Agencies or Costs/Savings in Federal Funding to the State: The Board estimates that the cost to it to implement this proposal will be less than \$36 per request, which the Board can absorb within its existing resources.

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 an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

This initial determination is based on the fact that the proposed regulation does not impose additional requirements on businesses; rather, the proposed regulation allows for businesses to streamline processes and reduce the need for furnishing duplicate fact sheets at the time naloxone hydrochloride is furnished by a pharmacist under required protocol. Businesses were already required to produce a fact sheet, even prior to this proposal.

### **Cost Impact on Representative Private Person or Business:**

The Board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action. Licensees are already required to produce a fact sheet. Further, the Board has been advised by licensees that this proposal will allow the licensees to streamline their business processes and reduce costs. As one licensee testified at the May 3-4, 2017, Board meeting, the pharmacies within one large retail chain currently print their own personalized fact sheets with other medication-related information 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 allow pharmacies to utilize their own forms and eliminate the need for furnishing duplicative forms.

Effect on Housing Costs: None

Report Requirements: None

**Effect on Small Business:**

While the Board does not have nor does it maintain data to define if any of its licensees (pharmacies) are a “small business” as defined in Government Code section 11342.610, the Board has made an initial determination that the proposed regulatory action would not have a significant adverse economic impact directly affecting small businesses. As previously mentioned, the proposed regulation will assist all businesses including small businesses in streamlining processes and reducing duplication of work when naloxone hydrochloride is furnished by a pharmacist.

**Results of Economic Impact Assessment/Analysis:**

Impact on Jobs/New Businesses:

The Board has determined that this regulatory proposal will not have a significant impact on the creation or elimination of jobs or new businesses or the expansion of businesses in the State of California. This initial determination is based on the fact that pursuant to 16 CCR 1746.3, a pharmacist is currently required to provide a Board-approved naloxone hydrochloride fact sheet upon furnishing of naloxone hydrochloride. This proposal does not add a requirement for a pharmacist furnishing naloxone hydrochloride, rather, the proposed regulation will allow for the licensees to streamline business processes and reduce duplicative work when naloxone hydrochloride is furnished by a pharmacist.

Benefits of Regulation:

The Board has determined that this regulatory proposal will benefit the health and welfare of California residents as the proposed regulation will allow for Board licensees to format the required naloxone hydrochloride fact sheet for their specific patient population which may provide for increased patient education as intended by the fact sheet. This regulatory proposal may benefit the state’s environment because there may be less paper products used and related waste as pharmacies will be able to provide only one fact sheet rather than the two facts sheets currently being provided by some pharmacies, the Board-approved and pharmacy specific fact sheets. The proposed regulation will not benefit worker safety.

**Consideration of Alternatives**

The Board must determine that no reasonable alternative 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.

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.

**Initial Statement of Reasons and Information**

The Board of Pharmacy has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

**Text of Proposal**

Copies of the exact language of the proposed regulations, any document incorporated by reference, of 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 1625 N. Market Blvd., N219, Sacramento, California 95834, 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:

Name:	Debbie Damoth
Address:	1625 N. Market Blvd., N219 Sacramento, CA 95834
Phone No.:	(916) 574-7935
Fax No.:	(916) 574-8618
E-Mail Address:	Debbie.Damoth@dca.ca.gov

The backup contact person is:

Name:	Lori Martinez
Address:	1625 N. Market Blvd., N219 Sacramento, CA 95834
Phone No.:	(916) 574-7917
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**Website Access**

Materials regarding this proposal can be found at the Board of Pharmacy's website:  
[www.pharmacy.ca.gov](http://www.pharmacy.ca.gov).