

BOARD OF PHARMACY

FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Naloxone Hydrochloride.

Section Affected: Adopt Title 16 of the California Code of Regulations (CCR) Section 1746.3.

Updated Information

When a Notice of Availability of Language was sent out by email to the 102 individuals who had signed up for email notice of any regulatory action by the Board of Pharmacy (Board), the May 22, 2015, Notice of Proposed Action was not sent out electronically as required. One week later on May 29, 2015, the Board extended the comment period by an additional week and re-sent a Notice of Availability of Language (setting out the ending date of the extended comment period), the Notice of Proposed Action and the text of the proposed regulation to all individuals who had signed up for notice of the Board's regulatory actions by US mail and email, sent out a Subscriber Alert concerning the extension of the comment period, and posted the extension of the 45-day comment period to the Board's website.

The Initial Statement of Reasons is included in this rulemaking file. The information contained therein is updated as follows:

The 45-day comment period began on May 22, 2015, and ended on July 13, 2015. The Board's notice indicated that the Board did not intend to hold a hearing on the matter, unless requested. No request for hearing was received by the Board during the 52-day comment period. The Board received one comment during the 45-day comment period. Additionally, staff and legal counsel recommended clarifying changes be made to the proposed text. The Board accepted the staff and legal counsels recommendations at its April 2015 Board meeting. These changes were inadvertently not included in the proposed text, noticed on May 22, 2015.

The 15-day comment period began on September 5, 2015, and ended on September 19, 2015. The Board received one comment, which was addressed at the September 30, 2015 Board meeting. No changes were made to the modified text based on the comment received.

In the proposed regulation text for 16 CCR Section 1746.3, there was a typographical error in the introduction so that it read "Article 5 of Division 7 of Title 16 ..." which should be corrected to read "Article 5 of Division 17 of Title 16 ..." This typographical error has been corrected in the final version which is marked to indicate how changes are being made to the emergency regulations presently in effect at 16 CCR Section 1746.3.

In the proposed regulation text, subdivision (b) was amended during the 15-day comment period to add "in all routes of administration recognized in subsection (c)(4) of this protocol." This statement was added to clarify that, in order to dispense naloxone, a pharmacist must be trained in all routes of administration. This ensures that the pharmacist has sufficient training on naloxone to select the method of administration that best fits a recipient's need.

In the proposed regulation text, the subsections of subdivision (c) were renumbered for clarity and to maintain compliance with the Administrative Procedures Act. Additionally, “by the board” was amended to “the Board of Pharmacy’s” to specify where the alternate language screening questions can be located. Finally, “recipients and” was removed from the proposed text. The Board determined that the information should be provided in alternate languages for the patients. A pharmacist can use their judgment and provide the information in multiple languages should he or she wish to do so; however, this is not being mandated.

In the proposed regulation text, subdivision (c)(4), previous subdivision (c)(3) was reworded for grammatical clarity. Additionally, “A pharmacist may also recommend optional items when appropriate, including alcohol pads, rescue breathing masks, and rubber gloves” was added to allow a pharmacist the use of their professional judgment when offering additional items to those purchasing naloxone hydrochloride. Finally, “provide advice to” was amended to “advise” and “to” was amended to “on” for grammatical clarity.

Subdivision (c)(5), previous subdivision (c)(4), was amended from “Product Labeling” to “Labeling” and “each container” was amended to “the naloxone hydrochloride” to provide clarity and be more specific about what must be labeled.

Subdivision (c)(6), previous subdivision (c)(5), was reworded for grammatical clarity by adding “on the Board of Pharmacy’s website” after “made available” and removing “and made available on the board’s website” from the end of the subdivision.

Subdivision (c)(8), previous subdivision (c)(7), was amended for grammatical and order clarity in that “dispensing” was amended to “dispense” and sections “1717 and 1707.1” were reordered to “1707.1 and 1717.”

Information Supplementing the Initial Statement of Reasons

In the Initial Statement of Reasons, under the heading “Factual Basis/Rationale” (on page 2 in the 4th paragraph), there was an error, which read “and the Governor signed, Senate Bill 493 (Chapter 469, Statutes of 2013)” and should have read, “and the Governor signed, Assembly Bill 1535 (Bloom, Chapter 326, Statutes of 2014)” which is corrected herein. In the Initial Statement of Reasons, in the “Underlying Data” section (on page 5, first item) this error is repeated as the entry incorrectly reads “Senate Bill 493 (Bloom, Chapter 469, Statutes of 2013), and should have read, “Assembly Bill 1535 (Bloom, Chapter 326, Statutes of 2014)” and is corrected herein. Copies of both bills are provided in the rulemaking binder.

Under the heading “Necessity for proposed Section 1746.3” (on page 3), there is an erroneous reference to Senate Bill 493 (Chapter 469, Statutes of 2013). The first sentence in that section has an error, as it reads “In B&P section 4052.01, Senate Bill 493 (Chapter 469, Statutes of 2013) and it should have read: “In B&P section 4052.01, Assembly Bill 1535 (Bloom, Chapter 326, Statutes of 2014) “ and is corrected herein.

Under the heading “Necessity for proposed Section 1746.3 (on page 3 at the end of the 2nd paragraph) it is mentioned that the Board chose to require one hour of training specific to the use of Naloxone Hydrochloride (naloxone), but it was inadvertently omitted that the one hour of

training requirement follows the recommendation made in the draft protocol developed by the California Department of Health Care Services in the “Pharmacist Protocol for Furnishing Naloxone for the Prevention of Opioid Overdose” (last revised October 2014).

Under the heading “Necessity for proposed Section 1746.3” (on page 4), it is mentioned that the Board found the suggested kit labeling instructions unnecessary. This was decided based on the Board determining that most naloxone obtained from pharmacists will not be furnished as a part of a kit. At present, a handful of naloxone products are available that use different administration routes (injection and nasal spray). More states are allowing pharmacists to dispense naloxone and some states are requiring first responders to carry it. This will create a far bigger market, which may result in more companies stepping up to produce it. The Board doesn’t want to limit pharmacists to just the products that exist at the time of the adoption of this regulation. Additionally, exactly how insurance will cover naloxone obtained by a concerned 3rd party will need to be worked out in the marketplace, and the Board does not wish to hamper that by putting suggested labeling in the regulation.

Under the heading “Necessity for proposed Section 1746.3” (on pages 4 and 5), it is mentioned that on the Board’s website are translations of the fact sheet into five other languages to assist patients whose primary language is not English. The availability of these translations is additional information which was not found in the emergency regulation, and was added in the proposed regulation. If the ultimately overdosing individual speaks Spanish, it is likely that the people around that person also speak Spanish. In educating the recipient and providing the training required in 16 CCR Section 1746.3(c)(1)(B), pharmacists must exercise their discretion, and may hand out fact sheets in English and other languages. The fact sheets contain pictorial instructions for administering naloxone, so there is less impact to the problem of the Board not having a fact sheet available in every recipient’s preferred language.

Under the heading “Necessity for proposed Section 1746.3” (on page 5), the notification requirements of this regulation are discussed. In drafting this regulation, as required in Business and Professions Code (B&P) section 4052.01, the Board worked with the Medical Board and other appropriate entities to develop the standardized procedure and protocol. The notification paragraph in the regulation insures notice to primary care providers in the same way as required for other medications pursuant to B&P section 4052(a)(10)(B). Including this language within the regulation protects both the interests of physicians and increases patient safety. A patient’s primary care provider needs to be fully informed of all prescription medications the patient is receiving, and this requirement that pharmacists notify health care providers, where possible, best achieves this goal. Given that some patients will not have a regular primary care provider, yet would still benefit from naloxone, 16 CCR Section 1746.3(c)(6) of this regulation mirrors the steps required in B&P section 4052(a)(10)(B), which pertains to other medications furnished by a pharmacist. Under this regulation, pharmacists providing patients who cannot provide contact information for, or do not have, a primary care provider can still be furnished naloxone, but they are also given a written record of the prescription drug and/or device, and advised to consult the appropriate health care provider of their choice.

Under the heading “Necessity for proposed Section 1746.3” (on page 5), the documentation required in this regulation is briefly discussed. 16 CCR Section 1746.3(c)(7) of the regulation reiterates established pharmacy practice, which is set out in B&P section 4081, which requires pharmacists to maintain documentation of the sale of all dangerous drugs and/or dangerous devices (defined in B&P section 4022 as any medication or device that requires a prescription to obtain).

Local Mandate

A mandate is not imposed on local agencies or school districts.

Small Business Impact

This action will not have a significant adverse economic impact on small businesses. Naloxone Hydrochloride was already dispensed to individuals with a doctor’s prescription before April 10, 2015, and has been dispensed to individuals without a doctor’s prescription after April 10, 2015, when the emergency regulation at 16 CCR section 1746.3 was adopted. The Board has determined, based on the absence of substantive comments and the lack of any requests for a hearing during this rulemaking process, that this regulation will not have a significant adverse economic impact on businesses.

Consideration of Alternatives

No reasonable alternative which was considered or that has otherwise been identified and brought to the attention of the Board would be more effective in carrying out the purpose for which it was proposed or would be as effective and less burdensome to affected private persons than the adopted regulation or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Objections or Recommendations/Responses to Comments

During the extended 52-day comment period from May 22, 2015, to July 13, 2015, one comment was received from Jody Jacobson who wrote from University of California, Irvine. This comment was presented to the Board in the meeting materials provided for the July 28-29, 2015 Board meeting. The comment contained two inquires, one about allergy screening, and the other asking how a person getting naloxone hydrochloride (naloxone) for themselves would be able to self-administer, given they are overdosing when the need for naloxone arises.

The Board rejected these comments. First, it was noted that there is a low incidence of allergic reaction to naloxone. Once a patient receives naloxone during an overdose, they are to seek emergency medical attention. Although there is a low incidence of allergies to naloxone, should there be an allergic reaction, emergency medical assistance can treat any allergic reaction. In regards to the second issue, it was noted that the regulation is set up for the patient or another person to obtain naloxone for use by the patient. The patient may educate whomever they hope will use it to revive them. If the naloxone is being provided to a third party, the pharmacist can use their judgement and provide fact sheets as necessary. In either case, the person administering the naloxone will have access to the appropriate information.

During the 15-day comment period from September 5, 2015, to September 19, 2015, one comment was received from Mark Chew, Pharm.D. at County of Orange Health Disaster Management. This comment indicated that the term “rubber gloves” should be changed to “protective gloves” because rubber gloves can include dishwashing gloves.

This Board rejected this comment as the protocol is designed for use by a pharmacist and a pharmacist will know the appropriate types of gloves they can recommend.