

## BOARD OF PHARMACY

### INITIAL STATEMENT OF REASONS

No hearing is presently planned unless one is requested no later than 15 days before the close of the 45-day comment period.

Subject Matter of Proposed Regulations: Naloxone Hydrochloride.

Section Affected: 16 CCR Section 1746.3.

Specific Purpose of Adoption: Business and Professions Code (“B&P”) Section 4052.01 authorizes pharmacists to furnish naloxone hydrochloride (“naloxone”) under a protocol without a doctor’s prescription. This is presently allowed under emergency regulation 16 CCR Section 1746.3, which went into effect on April 10, 2015, and will expire on October 8, 2015. The purpose of this rulemaking is to convert 16 CCR Section 1746.3 into a permanent regulation through the regular rulemaking process.

The problem to be addressed: People from all walks of life and socio-economic classes are at risk to die from an opioid overdose. The rising death toll has spurred a national movement to make naloxone more widely available to the public. Increased availability of naloxone has the potential to help all people at risk of an opioid overdose, whether heroin addicts and junkies, middle-aged chronic pain sufferers or thrill-seeking young people in their teens and twenties stealing pills out of the family medicine chest. Thus, along with contributing to the general public health and safety, making naloxone more accessible for all will address previous income and class-based discrimination, and will promote fairness and social equity.

Under emergency regulation 16 CCR §1746.3, effective from April 10, 2015 to October 8, 2015, pharmacists can presently furnish naloxone without a doctor’s prescription. To make this situation permanent, a regular regulation allowing pharmacists to furnish naloxone without a doctor’s prescription must be adopted through the regular rulemaking process before October 8, 2015. This revised regulation Section 1746.3 covers the same points as the protocol in the emergency regulation, but in a slightly different order. It also contains additional information, and refers pharmacists to the website of the Board of Pharmacy (“Board”) for examples of package labeling.

The anticipated benefits from this regulatory action: Pharmacists can continue to dispense naloxone to the public without a prescription. Increasing public access to this life-saving drug contributes to public health and safety by preventing opioid overdose and deaths.

#### **Factual Basis/Rationale**

This proposal seeks to adopt proposed 16 CCR Section 1746.01 (which is a revised and simplified version of the emergency regulation in effect) as a permanent regulation. The revised regulation covers the same material as the emergency regulation 16 CCR Section 1746.01, but is arranged in a different order for greater clarity. It also adds an additional translation requirement, and refers pharmacists to the Board’s website for package labeling examples.

Both the emergency regulation protocol and the proposed regulation herein require a pharmacist to provide the recipient with a consultation and a Board-approved Fact Sheet to ensure the education of the person to whom the drug is furnished. The person to whom the drug is furnished may not waive this consultation. The pharmacist must notify the patient's primary care provider, when possible, and must maintain a record for three years of having furnished naloxone. The protocol also requires a pharmacist to complete a training program on the use of opioid antagonists prior to furnishing naloxone pursuant to the protocol.

Naloxone is an "opioid antagonist," that reverses the effects of opioid medications, including oxycodone, oxymorphone, Vicodin, Percocet, methadone, and heroin. It is a low-cost, generic medication and is not a controlled substance, but before the adoption of the emergency regulations, required a doctor's prescription. If an individual with no opioids in his or her system is mistakenly administered naloxone, there are minimal negative effects. Naloxone is active for only a short period of time (between 30 to 80 minutes). While active, naloxone reduces the body's natural pain-lowering endorphins,

Naloxone was developed and patented in the 1960s, when the majority of opioid overdoses resulted from heroin use. While naloxone's life-saving qualities were known in the 1970s and 1980s, at that time, there were no efforts to make naloxone more widely available. Since 1990, drug overdose death rates have more than tripled in the U.S., and this parallels the 300% increase in the sale of prescription opioid pain relievers nationwide. Since 2007, deaths in the U.S. from opioid prescription drugs have outnumbered deaths from cocaine and heroin combined. Grieving friends and families of those who died from an overdose of prescription opioids have pushed to increase public access to naloxone.

In October of 2014, the Legislature enacted, and the Governor signed, Senate Bill 493 (Chapter 469, Statutes of 2013). This statute instructed the Board to address the problem of restricted public access to naloxone via both emergency and regular regulations. Pursuant to B&P §4052.01 (a), the Board worked with the Medical Board and in consultation with the California Society of Addiction Medicine, the California Pharmacists' Association and other entities, to develop the emergency regulation presently in effect at 16 CCR §1746.3. The protocol set out herein is a revision of the emergency regulation protocol and this revised protocol was approved by the Board on April 22, 2015 and by the Medical Board on May 8, 2015.

B&P Code §4001.1 mandates that the protection of the public shall be the highest priority for the Board and that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public comes first. Adopting this regulation as a permanent guide for pharmacists furnishing naloxone will benefit public health and safety by increasing public access to this life-saving drug.

### **Necessity for proposed Section 1746.3**

B&P section 4052.01, Senate Bill 493 (Chapter 469, Statutes of 2013) authorized the Board to adopt emergency regulations to establish standardized procedures or protocols for furnishing naloxone. 16 CCR Section 1746.3, the emergency regulation now in effect, will expire on October 8, 2015. Since the adoption of the emergency regulation, the Board has worked with

the Medical Board and consulted with the California Society of Addiction Medicine, the California Pharmacists' Association and other entities to revise the emergency regulation into the final form of the proposed regulation herein. The changes made consist primarily of re-arranging the language in the emergency regulation for greater clarity, removing footnotes, and suggested kit labeling instructions.

Proposed CCR Section 1746.3, in section (a) defines two terms used within the regulation, and then in section (b) sets out screening requirements which pharmacists are required to complete before they may furnish naloxone. The vast majority of medications pharmacists dispense are done so pursuant to a doctor's prescription. In those situations, the pharmacist may presume that the physician has screened the patient as to whether the particular medicine is appropriate, and on when and how to administer the drug, how the drug works, and any potential side effects. While pharmacists have a corresponding responsibility to exercise their judgment and provide a consultation for medications they dispense pursuant to a doctor's prescription, patients are free to waive a pharmacist's consultation. Under both the emergency regulation presently in effect and this proposed regulation, naloxone will be furnished directly by the pharmacist, acting as a health care provider (B&P section 4050), without a doctor's prescription. This means the pharmacist may well be the only health care provider a recipient interacts with who can train and counsel that person on the use and effects of naloxone. The regulation sets out numerous tasks pharmacists must complete before furnishing naloxone, including screening all recipients; providing recipients with training in overdose prevention, recognition, and response; and the administration of naloxone; and this consultation cannot be waived by the recipient. Given the importance of properly fulfilling these requirements in the regulation, the Board finds the public interest is best served by requiring all pharmacists who choose to furnish naloxone to first undergo one hour of training specific to the proper use of naloxone, or to have received an equivalent curriculum-based training in a Board recognized school of pharmacy.

The proposed regulation at section (c) sets out the protocol for pharmacists to follow to when furnishing naloxone to the public. Subsection (c)(1) sets out three medical screening questions the pharmacist must ask. Potential recipients are asked if they use or have a history of using opioids to determine whether they are at risk of an opioid overdose, and if so, the pharmacist can then emphasize to the individual the need to educate those around them as to overdose recognition, response and the administration of naloxone, because in the event of an overdose, that individual will not be in a position to self-administer the drug. Potential recipients who are not opioid users are asked if they are in contact with anyone who uses or has a history of using opioids so that the pharmacist can determine why the recipient needs the naloxone, and can shape their consultation accordingly, or decline to furnish. Potential recipients, whether opioid users or not, are asked whether the individual to whom the naloxone would be administered has a known sensitivity to naloxone, and if the recipient replies "yes," the pharmacist will decline to furnish naloxone. The Board will make available on its website the screening questions translated into five alternate languages to assist pharmacist in screening recipients whose primary language is not English. The availability of these translations is the only additional information added to the proposed regulation that is not found in the emergency regulation.

Subsection (c)(1)(B) requires pharmacists to train recipients in opioid overdose prevention, recognition, response, and the administration of naloxone prior to furnishing naloxone. Naloxone is a pure opioid antagonist used to prevent opioid overdose deaths. A person seeking naloxone is either an individual who is prescribed high doses of opioids, abuses opioids or has a history of opioid drug abuse, or they are in contact with such people. Because some opioid overdoses can be avoided with training in opioid overdose prevention, pharmacists dispensing naloxone are in the best position to educate opioid abusers, and thereby reduce the incidence of opioid overdose. In Subsection (c)(2)(B), if a recipient expresses interest in addiction treatment, recovery services or medication disposal resources, pharmacists must provide information resources and/or referrals.

All recipients under subsection (c)(1)(B) must be trained how to recognize an opioid overdose, how to respond to it, and how to administer naloxone. Naloxone is a temporary drug that wears off between 30 to 90 minutes after administration, and the effects of opioids can last much longer. Because of this, naloxone may need to be given a second time to keep a patient alive until medical treatment arrives. Recipients need to be taught to call 911 so that trained medical personnel arrive to assess the overdose victim, as there may be other medical problems occurring, and a person who overdoses is at risk of experiencing other health complications from the overdose. Naloxone works only on opioids, and does not reverse overdose of cocaine, amphetamines, methamphetamine, alcohol, or other non-opioid drugs.

Section (c)(2) sets out the information the pharmacist must provide when furnishing naloxone which, along with the addiction treatment information mentioned above, includes information on dosing, effectiveness, adverse effects, storage conditions, shelf-life and safety. The pharmacist must also answer any questions the recipient has about naloxone. Section (c)(3) specifies for pharmacists the naloxone products that are presently available, which are muscular injection, nasal spray and auto-injection, and allows pharmacists to furnish any new FDA-approved products that become available after this regulation goes into effect. Pharmacists are instructed to provide advice to recipients about how to choose between the various routes of administration based on the when and how the product is likely to be used. Frequently such a discussion as to what version of a particular medication would be best utilized by a patient is held between a doctor and patient when the medication is prescribed. While pharmacists are highly skilled at drug consultations and do many every day, these regulations specify in detail what must be covered because naloxone is furnished to the recipient without that person first seeing a doctor to discuss the drug in the course of obtaining a prescription.

Section (c)(4) provides instructions on product labeling. Normally, the person who will take the medicine is the person to whom the medicine is dispensed and that person's name is placed on the label, but naloxone can be furnished to third parties, such as relatives, friends, persons in a position to witness an overdose. This section directs pharmacists to the Board's website for an example of appropriate labeling. This is a change from the emergency regulation, which had "Suggested Kit Labeling" which the Board found to be unnecessary. Section (c)(5) requires a pharmacist who furnishes naloxone to provide all recipients with a Board-approved fact sheet, available on the Board's website. That fact sheet is translated into five other languages to

assist recipients whose primary language is not English and made available on the Board's website.

Section (c)(6) sets out the notification requirement, which applies if the person who is receiving the naloxone is the same person who is expecting to receive the naloxone. In that case, with that person's verbal or written consent, the pharmacist must notify that person's primary care provider of any drug or device furnished, or enter it into a patient record system shared with the primary care provider. If that person doesn't have a primary care provider or chooses not to consent to notification, then the pharmacist must provide that person with a written record of the drug and/or device furnished and advise the person to consult a health care provider of their choice. Section (c)(7) requires pharmacists to document and store a medication record for each person furnished naloxone for three (3) years from the date of dispensing, maintained in an automated data or manual record in the usual way. Section (c)(8) essentially reminds pharmacists that the pharmacy's or facility's privacy policies and procedures still apply to maintain recipient confidentiality and privacy, even though naloxone will be sometimes furnished to third parties and not to the person who will ultimately be administered the drug.

When administered correctly in a timely fashion, naloxone can resuscitate individuals who have overdosed on opioids. With the adoption of B&P section 4052.01, the legislature made it possible for the Board to adopt emergency regulations to facilitate greater public access to naloxone. The proposed regulation would put in place a clearer, reorganized set of standardized procedures for pharmacists to follow in furnishing this life-saving drug to the public.

**Specific Benefits Anticipated:** Increasing the public's access to naloxone will contribute to public health and safety by preventing opioid overdose deaths.

Naloxone has been available by prescription since the late 1960s, when the majority of opioid abusers were addicted to heroin and morphine. Powerful new opioid pain medications have increased the rate of opioid addiction in people from all walks of life and socio-economic classes. Thus, along with contributing to the general public health and safety, making naloxone more accessible will address previous income and class-based discrimination which promotes greater fairness and social equity in California.

**Underlying Data:**

1. Senate Bill 493 (Bloom, Chapter 469, Statutes of 2013).
2. Emergency regulation 16 CCR §1746.3.
3. Relevant Meeting Materials and Minutes from the Board of Pharmacy, held April 21-22, 2015, March 9, 2015, and January 27-28, 2015.
4. Relevant Meeting Materials and Minutes from the SB 493 Implementation Committee, held April 13, 2015, February 25, 2015, December 16, 2014, and November 5, 2014.
5. Economic Impact Assessment.
6. Scott Burris, et al., "Stopping an Invisible Epidemic: Legal Issues in the Provision of Naloxone To Prevent Opioid Overdose," DREXEL L. REV. 1(2):273-339, 326 (2009). (*This*

- law review article recommends fostering naloxone distribution through pharmacies, and using EC statutes as a model).*
7. Substance Abuse and Mental Health Services Administration, “Opioid Overdose Toolkit,” available at <http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2014/SMA14-4742>. (*This resource provides materials to develop policies to prevent opioid overdose*)
  8. The Network for Public Health Law, “Legal Interventions To Reduce Overdose Mortality: Naloxone Access and Overdose Good Samaritan Laws” (Aug. 2014), available at <https://www.networkforphl.org/asset/qz5pvn/naloxone-FINAL.pdf>. (*This article describes naloxone access nationwide*).
  9. Harm Reduction Coalition, “Guide to Developing and Managing Overdose Prevention and Take-Home Naloxone Projects” (2012), available at <http://harmreduction.org/issues/overdose-prevention/tools-best-practices/manuals-best-practice/od-manual/> (*This manual outlines the process of developing an overdose prevention program, including with a take-home naloxone component*).
  10. Northeast Behavioral Health, “Opioid Overdose Prevention and Reversal via Peer-Administered Narcan” (2012), available at <http://harmreduction.org/wp-content/uploads/2012/02/od-train-the-trainer-parents.pdf>. (*This PowerPoint presentation provides information to educate peers on opioid prevention and reversal*).
  11. CA Department of Health Care Services, “Pharmacist Protocol for Furnishing Naloxone for the Prevention of Opioid Overdose” (last updated Oct. 29, 2014). (*This draft protocol was consulted in development of the Board’s recommended protocol*).
  12. World Health Organization, “Community Management of Opioid Overdose” (2014). (*This resource provides materials to develop policies to prevent opioid overdose*).
  13. Drug Policy Alliance, “What Is Naloxone?” (Aug. 2014), available at <http://www.drugpolicy.org/resource/what-naloxone>. (*This fact sheet provides comprehensive information on naloxone*).
  14. Massachusetts Department of Health and Human Services, “Dispensing of Naloxone by Standing Order” (2014), available at <http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/dhpl/pharmacy/dispensing-of-naloxone-by-standing-order-.html>. (*This site contains a pamphlet recommended as the base for the Board’s factsheet*).
  15. N. Zaller, et al., “The Feasibility of Pharmacy-Based Naloxone Distribution Interventions: A Qualitative Study with Injection Drug Users and Pharmacy Staff in Rhode Island,” 48 SUBST. USE MISUSE 8 (2013). (*This research supports pharmacy-based naloxone intervention, but notes barriers including misinformation and costs*).
  16. Traci C. Green, et al., “Responding to Opioid Overdose in Rhode Island: Where the Medical Community Has Gone and Where We Need To Go,” R.I. MED. J. 29-33 (Oct. 2014), available at <http://www.rimed.org/rimedicaljournal/2014/10/2014-10-29-dadt-green.pdf>. (*This article gives an overview of opioid overdose, provides guidance resources, and emphasizes the importance of Good Samaritan Laws*).

**Business Impact:** The Board does not believe this regulation will have a significant adverse economic impact on businesses. Adopting this regulation simply provides pharmacists, who

choose to dispense naloxone without a doctor's prescription, with a revised and simplified protocol to follow.

**Economic Impact Assessment:**

This regulatory proposal will have the following effects:

- It will not create or eliminate jobs in California because pharmacists are already dispensing naloxone without a prescription under the emergency regulation, and pharmacists were previously dispensing naloxone with a prescription. The proposed regulation simply sets out a revised and simplified protocol for furnishing naloxone without a prescription.
- It will not create new businesses or eliminate existing businesses within California because pharmacists already dispense naloxone without a prescription under the emergency regulation, and pharmacists were previously dispensing naloxone with a prescription. The proposed regulation simply sets out a revised and simplified protocol for furnishing naloxone without a prescription.
- It will not affect the expansion of businesses currently operating in California because pharmacists already dispense naloxone without a prescription under the emergency regulation, and pharmacists were previously dispensing naloxone with a prescription. The proposed regulation simply sets out a revised and simplified protocol for furnishing naloxone without a prescription.
- This regulatory proposal benefits the health and welfare of California residents because it increases public access to naloxone, a life-saving drug, and contributes to public health and safety by preventing opioid overdose deaths.
- This regulatory proposal will have no impact on worker safety, because pharmacists have dispensed doctor-prescribed naloxone for decades, and have been able to furnish naloxone without a prescription since April 10, 2015, and the Board has not received any information about impacts on worker safety.
- This regulatory proposal will have no impact on the state's environment, because pharmacists have dispensed doctor-prescribed naloxone for decades, and have been able to furnish naloxone without a prescription since April 10, 2015, and the Board has not received any information about environmental impacts.

**Specific Technologies or Equipment:** This regulation does not mandate the use of specific technologies or equipment.

**Consideration of Alternatives:** The Board has determined that no reasonable alternative considered by the Board, or otherwise identified and brought to the Board's attention, would be more effective in carrying out the purpose for which the regulation is proposed; would be as effective and less burdensome to affected private persons than the proposals described herein; would be more cost-effective to affected private persons; and equally effective in implementing the statutory policy or other provisions of law. The Board found taking no action an unacceptable alternative in the face of the specific charge in the law that the Board must

enforce B&P section 4052.01 for its licensees. This proposed regulation implements B&P section 4052.01.