TITLE 16: BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS

FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Opioid Antagonist Protocol

Sections Affected: Title 16, California Code of Regulations (CCR) section 1746.3

Updated Information

The Initial Statement of Reasons is included in this rulemaking file. The information contained therein accurately reflects the position of the Board of Pharmacy (Board) regarding the amendment of the above section. The Initial Statement of Reasons (ISR) is updated as follows:

The 45-day public comment period began on December 15, 2023, and ended on January 29, 2024. The Board's notice stated that the Board did not intend to hold a hearing on the matter unless requested. The Board did not receive a request for a hearing during the comment period and one was not held.

During the 45-day comment period, the Board received two comments. At the February 8, 2024 Board meeting, the Board reviewed the comments received and amended the regulation text. The Board voted to initiate a 15-day public comment period, which commenced on March 1, 2024, and concluded on March 16, 2024. Additionally, no comments were received after the March 16, 2024.

During the 15-day comment period, the Board received one comment, which only thanked the Board for accepting and implementing their recommendation from the prior comment period and provided no additional comment. On May 24, 2024, per the delegated authority granted to the Executive Officer (EO) at the February 8, 2024 Board meeting, the EO adopted the regulation as noticed for public comment on March 1, 2024.

The changes for the modified text comment period are as follows:

This first sentence of the regulation text was amended to add "for overdose reversal" after opioid antagonist. The purpose of this addition is to specify that this protocol applies to opioid antagonists used for overdose reversal. This addition is necessary to ensure clarity to pharmacists furnishing opioid antagonists that the protocol is specific to those antagonists used for overdose reversal, consistent with the legislative intent of Senate Bill 493 (Chapter 469, Statutes of 2013).

Subdivision (c)(4) was amended to remove the requirement for the person receiving the opioid antagonist to receive that FDA-approved medication guide. The purpose of this amendment is to remove the proposed requirement that the FDA-approved medication

guide be provided to the person receiving the opioid antagonist. This amendment is necessary because medication guides do not currently exist for the two approved opioid antagonists available for overdose reversal. Additionally, the Board did not add commenter's suggested language to subdivision (c)(4) (which would require pharmacists to provide patients with the "manufacturers package insert if available"). The language in the manufacturers' package inserts can be highly technical in nature and not intended for consumers. However, the Board notes that nothing in the language prohibits the pharmacist from providing the manufacturers' package insert to patients should the pharmacist wish to do so. Thus, removing the proposed requirement to provide FDA-approved medication guides and not adding a requirement that pharmacists provide patients with manufacturers' package inserts (if available) will not impact consumer safety.

The Board consulted with the California Department of Health Care Services, California Society of Addiction Medicine, and the Medical Board of California in the development of this proposal.

Local Mandate

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

Small Business Impact

While the Board does not have nor does it maintain data to determine if any of its licensees are "small businesses", as defined in Government Code section 11342.610, the Board determined that the proposed regulatory action will not have a significant adverse economic impact on small businesses. The proposed regulation will establish flexibility for pharmacists to furnish additional opioid antagonists.

Consideration of Alternatives

No reasonable alternative considered by the agency would be more effective in carrying out the purpose for which the regulation is proposed, as effective and less burdensome to affected private persons than the adopted regulation, or more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

The Board considered requiring a specific area for furnishing to ensure patient privacy and confidentiality; however, the Board determined that alternative was not reasonable, as requiring a specific space may result in some pharmacy's being unable to comply and therefore participate in furnishing FDA-approved opioid antagonists. Additionally, the Board considered alternatives proposed by commenters during the public comment periods. The proposed alternatives and the Board's determinations are in the comment responses below.

Objections or Recommendations/Responses to Comments

45-Day Comment Period

During the 45-day comment period, which began on December 15, 2023 and ended on January 29, 2024, the Board received several comments. At the February 8, 2024 Board meeting, the Board reviewed the comments received and amended the regulation text to address changes proposed in some of the comments. The Board voted to initiate a 15-day public comment period.

Summary and Response to 45-day Comments:

Written Comments from Lorri Walmsley, Walgreens

Comment 1: The commenter indicates that FDA-approved medication guides are not currently available for all available opioid antagonist products. Commenter requests that subdivision (c)(4) be amended to change "FDA-approved medication guide" to "manufacturers package insert if available" to allow pharmacists to provide the manufacturers' package insert to patients.

Response to Comment 1: The Board reviewed the comment and voted to amend the regulation text to remove the requirement to provide FDA-approved medication guides. Additionally, the Board notes that nothing in the language prohibits the pharmacist from providing the manufacturers' package insert to patients should the pharmacist wish to do so. The Board notes that there are versions of naloxone available over the counter and this protocol would not apply to those products.

Written Comments from Lucas Evensen, California Medical Association

Comment 2: The commenter recommends that the regulation text be split into two different protocols, one for Naloxone and one for all other opioid antagonists. Commenter states that medications beyond Naloxone require "*a thorough evaluation based on the clinical context, patient needs, and the balance of risks and benefits*." Additionally, commenter states that "*coordination with the patient's primary care provider is crucial to ensure they are informed about the furnished medication and its management to monitor its effectiveness and any adverse effects*."

Response to Comment 2: The Board reviewed the comment and did not make any changes to the text based upon the comment. The Board notes pharmacists are healthcare professions, who are appropriately trained to use clinical judgement when evaluating a patient's needs. Additionally, pharmacists must provide the recipient with appropriate counseling, that cannot be waived, and information on the product furnished, including dosing, effectiveness, adverse effects, storage conditions, shelf-life, and safety.

With respect to Nalmefene referenced in the commenters letter, the Board notes that, according to the FDA, Nalmefene is an opioid receptor antagonist which is used to treat acute opioid overdose. Its approval was supported by safety and pharmacokinetic studies, as well as a study in people who use opioids recreationally to assess how quickly the drug worked.

With respect to Naltrexone referenced in the commenter's letter, pursuant to BPC section 4052(a)(14) a pharmacist may provide medication-assisted treatment, consistent with a standardized protocol, which would include Naltrexone. The Board notes that, according to the FDA, Naltrexone administration is usually started after a patient has been off alcohol or opioids for about 7 to 10 days.

Comment 3: Commenter also recommends limiting the opioid antagonists which may be furnished to those indicated for reversal of respiratory depression associated with opioid overdose.

Response to Comment 3: The Board reviewed the comment and voted to amend the regulation text to specify overdose reversal as the regulation text is directly related to opioid overdose reversal, consistent with the legislative intent. The Board amended the first sentence to add "for overdose reversal" consistent with prior policy discussions.

Comment 4: Commenter also recommends that the term "patient" be defined to clarify when notification is appropriate.

Response to Comment 4: The Board reviewed the comment and did not make any changes to the text based upon the comment. The Board notes that the term "patient" is used in one context within the subdivision (c)(5) with respect to the notification of the patient's primary care provider. The Board did not believe it necessary to define this term as its meaning is clear within the context of the regulation text.

Comment 5: Commenter also recommends adding language to clarify that the protocol does not apply in situations where a pharmacist is recommending an FDA approved over-the-counter opioid antagonist.

Response to Comment 5: The Board reviewed the comment and did not make any changes to the text based upon the comment. The Board notes that providing an over-the-counter medication is not subject to the Board's regulations, as such the protocol would not apply. Further, the Board notes that there are versions of Naloxone available over the counter and this protocol would not apply to those products.

15-Day Comment Period

During the 15-day comment period, which began on March 1, 2024 and ended on March 16, 2024, the Board received one comment.

Summary and Response to 15-day Comment:

Written Comment from Lucas Evensen, California Medical Association

Comment 6: The commenter thanked the Board for reviewing their comments and narrowing the protocol to overdose reversal opioid antagonists. The commenter provided no additional comments.

Response to Comment 6: No action is necessary is response to this comment.

On May 24, 2024, per the delegated authority granted to the Executive Officer (EO) at the February 8, 2024 Board meeting, the EO adopted the regulation as noticed for public comment on March 1, 2024