Title 16. Board of Pharmacy
DEPARTMENT OF CONSUMER AFFAIRS

Initial Statement of Reasons

Hearing Date: No hearing scheduled.

Subject Matter of Proposed Regulation: Opioid Antagonist Protocol

Section Affected: Amend section 1746.3 to Article 5 of Division 17 of Title 16 of the California Code of Regulations (CCR)

Introduction

The California State Board of Pharmacy (Board) is the state agency vested with the authority to regulate (including licensing, investigating complaints against, and disciplining members and entities in) the pharmacy industry, including pharmacies, pharmacists, pharmacy interns, and pharmacy technicians. The Board's mandate, mission, and statutory priority are to protect the public (Business and Professions Code (BPC) section 4001.1).

The enactment of Assembly Bill (AB) 1535 (Bloom, Chapter 326, Statutes of 2014) authorized pharmacists to furnish the opioid antagonist naloxone hydrochloride in accordance with standardized procedures the Board was to implement through regulations. The Board subsequently developed the regulation and protocol in section 1746.3 of the CCR, in consultation with the entities identified in the statute. This regulation became effective April 10, 2015 through an emergency regulation, and was finalized on January 27, 2016.

With the enactment of Senate Bill 1259 (Laird, Chapter 245, Statutes of 2022), effective January 1, 2023, BPC section 4052.01 was amended to authorize (pharmacists to furnish any federal Food Drug and Administration (FDA) approved opioid antagonist, not just naloxone hydrochloride. Additionally, the Board and the Medical Board of California ("in consultation with the California Society of Addiction Medicine [(CSAM)], the California Pharmacists Association, and other appropriate entities") were authorized to develop and approve regulations implementing standardized procedures or protocols pharmacists are to adhere to when furnishing FDA-approved opioid antagonists. These procedures or protocols must include educating the person to whom the opioid antagonist is furnished (regarding opioid overdose prevention, recognition, and response, safe administration of opioid antagonists, potential side effects/adverse events, seeking emergency medical care, and availability of drug treatment programs), and notifying the recipient's primary care provider—directly, or by updating a patient's information in a database to which their physician has access.

Background and Problems Addressed

The Board's current regulation and protocol is specific to the furnishing of naloxone hydrochloride and must therefore be updated to include standardized procedures or protocols for safely administering any FDA-approved opioid antagonist to prevent opioid overdoses.

This regulatory proposal will implement the statute by amending CCR section 1746.3, updating the current standardized procedures or protocols to regulate the furnishing of any FDA-approved opioid antagonists, not just naloxone hydrochloride. The Board consulted with the California Department of Health Care Services in the development of this proposal. The proposal was provided to CSAM, the Medical Board of California, and the California Pharmacists Association for review prior to approval of the language by the Board. The Board received comments from CSAM and the Medical Board, and neither expressed concerns with the proposed language.

The Board's proposal does the following: replaces "naloxone hydrochloride" with "an opioid antagonist" or "opioid antagonists"; removes specific questions that must be asked of potential recipients; replaces the requirement that the patient receive the naloxone hydrochloride fact sheet with the requirement that the patient receive the FDA-approved medication guide; amends the requirement for the notice to be provided to a patient's primary care provider; and removes another documentation requirement.

Anticipated Benefits from this regulatory action:

The Board has determined that this regulatory proposal will have the following benefits to the health and welfare of California residents.

Implementing this proposal will benefit the health and welfare of California residents by ensuring FDA-approved opioid antagonists are safely furnished. Additionally, implementing this proposal will ensure that the people to whom the opioid antagonists are administered are educated on opioid overdose prevention, recognition, and response, safe administration of opioid antagonists, potential side effects/adverse events, seeking emergency medical care, and availability of drug treatment programs. Finally, implementing this proposal will ensure the patient's primary care provider is notified—directly, or by updating a patient's information in a database to which their physician has access—that an opioid antagonist was furnished to the patient, which will aid the physician and patient with current and future care.

This regulatory proposal does not affect worker safety or the state's environment.

Specific Purpose of, and rational for, each adoption, amendment, or repeal

The Board's proposal makes the following changes:

1. Throughout the proposed regulation text, the phrase “naloxone hydrochloride” has been amended to “an opioid antagonist”, “the opioid antagonist”, “opioid antagonists”, or “opioid antagonist furnished”, depending on the necessary grammatical phrasing.

Specific Purpose: Amend section 1736.3 throughout to replace the words “naloxone hydrochloride”, which was the drug specified in the statute prior to its 2022 amendment, with the class of drugs called opioid antagonists, as provided for in the current statute.

Rationale/Necessity: This change throughout makes the language of the regulation consistent with the statute, which allows for the furnishing of any FDA-approved opioid antagonist.

2. Amend section 1746.3, subsection (b).

Specific Purpose: The proposed change relocates the phrase “or equivalent curriculum-based training program completed in a Board recognized school of pharmacy” relocated from the end of the subsection to be directly after the approved continuing education.

Rationale/Necessity: The reordering of the sentence provides clarity and ease of reading to state that the required training program can be completed in a school of pharmacy as part of its curriculum, as well as in an approved continuing education program.

Specific Purpose: Amend this subsection to strike “naloxone hydrochloride in all routes of administration recognized in subsection (c)(4) of this protocol” and replace with “opioid antagonists for overdose reversal.”

Rationale/Necessity: This proposed change provides clarity that the training a pharmacist must receive to employ any protocols before furnishing opioid antagonist are specific to any FDA-approved opioid antagonists used for the purpose of overdose reversal, not just naloxone hydrochloride.

3. Amend section 1746.3, subsection (c)(1)(A) - (c)(1)(C).

Specific Purpose: The proposed changes remove these subsections, which require the pharmacist to screen the potential recipient of naloxone hydrochloride by asking specific questions about their use of and exposure to use of opioids, and their sensitivity to naloxone hydrochloride.

Rationale/Necessity: The Board determined that screening potential recipients for opioid antagonists was not necessary and could hinder someone from obtaining life-saving opioid antagonists. First, these questions could serve as roadblocks that discourage recipients who have legitimate reasons for keeping opioid antagonists on hand from obtaining opioid antagonists and potentially saving a life. Additionally, various state laws have been established in the past few years or are pending in the California Legislature that require various public schools, amusement parks, and private businesses to maintain opioid antagonists on hand for emergency use, rendering the questions

irrelevant. Finally, the risk of dying from a hypersensitivity is lower than the immediate risk of death from an overdose. Therefore, eliminating the screening questions is a benefit to the health and welfare of California residents.

4. As a result of the stricken language in (c)(1), subsections (c)(2) through (c)(5) have been renumbered.

This change is nonsubstantive because it is "renumbering, reordering, or relocating a regulatory provision" within the meaning of Title 1, CCR section 100(a)(1).

This is necessary for structural clarity.

5. Amend section 1746.3, subsection (c)(2) – Now subsection (c)(1).

Specific Purpose: This proposed amendment deletes "antidote naloxone".

Rationale/Necessity: The term is redundant to the phrase opioid antagonist, since an opioid antagonist is an antidote, and the pharmacists are able to furnish more opioid antagonists than naloxone.

6. Amend section 1746.3, subsection (c)(4) – Now subsection (c)(3).

Specific Purpose: This proposed amendment deletes "A pharmacist may supply naloxone hydrochloride as an intramuscular injection, intranasal spray, auto-injector or in another FDA-approved product form."

Rationale/Necessity: This language should be stricken because it applies specifically to naloxone hydrochloride. Additionally, the language is not necessary because the pharmacist is already authorized to advise on choosing a route of administration for any opioid antagonist and, accordingly, can furnish as such under this section.

7. Amend section 1746.3, subsection (c)(5) – Now subsection (c)(4)

Specific Purpose: The proposed amendment adds: "The person to whom the drug is furnished shall also receive the FDA-approved medication guide."

Rationale/Necessity: Medication guides are paper handouts that come with many prescription medicines. The guides address issues that are specific to particular drugs and drug classes, and they contain FDA-approved information that can help patients avoid serious adverse events. The FDA requires that medication guides be issued with certain prescribed drugs and biological products when the FDA determines that certain information is necessary to prevent serious adverse effects, patient decision-making should be informed by information about a known serious side effect with a product, or patient adherence to directions for the use of a product are essential to its effectiveness. Including the requirement for patients to receive the FDA-approved medication guide ensures patients obtain all crucial information and ensures that the pharmacy and pharmacist is compliant with federal requirements (21 CFR Part 208).

Specific Purpose: Finally, the proposed amendment strikes the last two sentences of the subsection, which read: “Labels shall include an expiration date for the naloxone hydrochloride furnished. An example of appropriate labeling is available on the Board of Pharmacy's website.”

Rationale/Necessity: The Board determined that including the expiration date of the naloxone hydrochloride on the label was duplicative and not necessary as the expiration date is already required to be listed directly on the product. Further, all labels must comply with several laws and regulations, including BPC sections 4076, 4076.5, and 4076.7, and 16 CCR section 1707.5. Accordingly, language referencing a Board-posted sample is not necessary, as all prescription labels must meet all the same requirements.

8. Delete section 1746.3, subsection (c)(6).

Specific Purpose: The proposed amendment deletes the subsection, as it is duplicative. It reads: “Fact Sheet: The pharmacist shall provide the recipient a copy of the current naloxone fact sheet approved by the Board of Pharmacy 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. The board-approved fact sheet shall be made available on the Board of Pharmacy's website in alternate languages for patients whose primary language is not English. Fact sheets in alternate languages must be the current naloxone fact sheet approved by the Board of Pharmacy.”

Rationale/Necessity: The fact sheet provided by the pharmacist would contain the same information that is found in the medication guide, required in the new subsection (c)(4). Additionally, the prior approved fact sheets are specific to naloxone hydrochloride and would not be helpful when a different opioid antagonist is furnished.

9. As a result of the stricken language in (c)(6), subsection (c)(7) has been renumbered.

This change is nonsubstantive because it is “renumbering, reordering, or relocating a regulatory provision” within the meaning of Title 1, CCR section 100(a)(1).

This is necessary for structural clarity.

10. Amend section 1746.3, subsection (c)(7) – Now subsection (c)(5).

Specific Purpose: The first proposed amendments strike the first and second sentences related to Notifications, which: (1) deem the recipient of the naloxone hydrochloride to be a patient for purposes of the protocol if he or she is also the person to whom the naloxone hydrochloride would be administered; and (2) require the pharmacist to notify the patient's primary care provider of any drug(s) and/or device(s) furnished and to enter the appropriate information in a patient record system upon consent.

Rationale/Necessity: The first sentence is stricken, as it is not a requirement to identify whether the recipient of the opioid antagonist is the intended user of the product. As

such, identifying whether is person is a “patient” for the purposes of the protocol is not necessary, and could serve as an unnecessary roadblock that prevents a life from being saved. Ultimately, the receipt of the opioid antagonist within the pharmacy would be considered the patient as the opioid antagonist is being furnished to them, even if they intend to have it for use by another individual.

Specific Purpose: The second sentence is stricken and rewritten for clarity as the new first sentence of this subsection. This new first sentence reads as follows: “At the request of the patient, a pharmacist shall notify the identified primary care provider, if any, of the product furnished or enter appropriate information in a shared patient record system as permitted by the primary care provider.”

Rationale/Necessity: Previously, the subsection required the patient to give verbal or written consent. With the proposed amendments, however, the pharmacist is no longer required to request consent to notify the primary care provider or to enter the information into a patient record system. The amended language now requires that the primary care provider be notified at that the patient’s request. Further, the Board determined that, as the opioid antagonist is being furnished to the patient at their request, consent has been provided for the pharmacist to provide training, counseling, and informational resources, and to answer questions.

Specific Purpose: The proposed amendments to the (second and) last sentence, which requires the pharmacist to provide a record of the drug(s) provided, adds “or does not identify” after “If the patient does not have” and before “a primary care provider.” It also strikes “or chooses not to give notification consent, then ….”

Rationale/Necessity: This proposed language makes the sentence consistent with the notification requirement being *upon request*, rather than upon obtaining specific consent.

Specific Purpose: Additionally, the proposed amendments strike “and/or devices” from the last sentence.

Rationale/Necessity: An opioid antagonist is a drug and not a device for which there would be a written record of the furnishing, so this inclusion is being removed to avoid confusion.

Specific Purpose: Finally, “along with a recommendation for the patient” to consult “with” an appropriate health care provider has been added.

Rationale/Necessity: These proposed amendments are for ease of reading and to clarify that the pharmacist is only required to make a recommendation to the recipient of the product.

11. Delete section 1746.3, subsection (c)(8).

Specific Purpose and Rationale/Necessity: This proposed amendment strikes the requirement related to documentation of the furnishing of naloxone hydrochloride. This is necessary because this inclusion is duplicative. Medication record documentation and storage requirements are specified within other areas of pharmacy law, including BPC sections 4081, 4105, 4119.8, 4119.9, and 4332, and CCR sections 1707.1 and 1717.

12. Delete section 1746.3, subsection (c)(9).

Specific Purpose and Rationale/Necessity: This proposed amendment strikes the privacy requirements, as they are unnecessary to include. This is necessary because their inclusion is duplicative of the confidentiality and privacy requirements of the Health Insurance Portability and Accountability Act (HIPAA), which requires appropriate safeguards to protect the privacy of protected health information and sets limits and conditions on the uses and disclosures that may be made of such information without an individual's authorization.

Underlying Data

1. Assembly Bill 1535 (Bloom, Chapter 326, Statutes of 2014).
2. Senate Bill 1259 (Laird, Chapter 245, Statutes of 2022).
3. Relevant Meeting Materials and Meeting Minutes from the Licensing Committee Meeting held October 18, 2022 (Meeting Materials (Agenda item V, Pages 1, 3-5), Minutes Pages (1, 14-16)).
4. Relevant Meeting Materials and Meeting Minutes from Board of Pharmacy Meeting held October 25-26, 2022 (Meeting Materials (Licensing Committee, Pages 1, 4-6), Minutes Pages (1, 49-50)).
5. Relevant Meeting Materials and Excerpt of Meeting Minutes from the Licensing Committee Meeting held January 24, 2023 (Meeting Materials (Agenda item IV, Pages 1-3, and Attachment 2), Excerpt from Minutes).
6. Relevant Meeting Materials and Meeting Minutes from Board of Pharmacy Meeting held February 6-7, 2023 (Meeting Materials (Licensing Committee, Pages 1-3, and Attachment 1), Excerpt from Minutes).
7. Comments on the Proposed Text from the California Society of Addiction Medicine received January 3, 2023.

Business Impact

The Board has made the initial determination that the proposed regulations will not have a 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 absence of testimony to that effect during the public discussion and development of the proposed regulation. The proposal establishes flexibility within the Board’s regulation for pharmacists to furnish additional opioid antagonists.

Economic Impact Assessment:

The Board has determined that this proposal will not:
(1) create jobs within California;
(2) eliminate jobs within California;
(3) create new businesses within California;
(4) eliminate existing businesses within California;
(5) expand businesses currently doing business in the State of California.

This proposal will not create or eliminate jobs or businesses within California. Additionally, this proposal will not expand businesses because this regulatory proposal ensures consistency between the statute and regulation and provides standardized procedures for the furnishing of additional opioid antagonists by licensed pharmacists, and this does not lead to an increase or decrease in the number jobs or businesses.

The Board has determined that this regulatory proposal will have the following benefits to the health and welfare of California residents.

Implementing this proposal will benefit the health and welfare of California residents by ensuring FDA-approved opioid antagonists are safely furnished. Additionally, implementing this proposal will ensure that the people to whom the opioid antagonists are administered are educated on opioid overdose prevention, recognition, and response, safe administration of opioid antagonists, potential side effects/adverse events, seeking emergency medical care, and availability of drug treatment programs. Finally, implementing this proposal will ensure the patient's primary care provider is notified—directly, or by updating a patient's information in a database to which their physician has access—that an opioid antagonist was furnished to the patient, which will aid the physician and patient with current and future care.

This regulatory proposal does not affect worker safety or the state's environment.

Fiscal Impact Assessment:

The Board has determined that the proposed regulations do not result in a fiscal impact to the state.

The Board does not anticipate an increase in enforcement activity. Additionally, compliance will be verified through routine pharmacy inspections.

The regulations do not result in costs or savings in federal funding to the state.

Specific Technologies or Equipment

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

Consideration of Alternatives

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or 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 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.