MEDICAL BOARD STAFF REPORT

DATE REPORT ISSUED:	January 26, 2023 (updated February 8, 2023)
ATTENTION:	Members, Medical Board of California
SUBJECT:	Discussion and Possible Action to Approve Proposed Regulations Pursuant to SB 1259 (Chapter 245, Statutes of 2022)
STAFF CONTACT:	Aaron Bone, Chief of Legislation and Public Affairs

REQUESTED ACTION

To approve updated regulatory language proposed by the California State Board of Pharmacy (Pharmacy Board) related to the authority of a licensed pharmacist to furnish opioid antagonists to the public without a prescription.

Background

Under prior law, since 2015, pursuant to Business and Professions Code (BPC) section 4052.01, a pharmacist has been authorized to independently furnish naloxone hydrochloride to an individual, in accordance with protocols jointly developed by the Pharmacy Board and the Medical Board of California (Board). In 2015, the Board reviewed and approved the current protocols which were drafted by Pharmacy Board.

According to the Pharmacy Board, since 2015, additional access points have been established for patients to access naloxone hydrochloride, including authority for pharmacies to furnish naloxone hydrochloride to law enforcement agencies and to school districts, county office of education, or charter schools under specified conditions. The California Department of Public Health issued a standing order that allows libraries and other community organizations to obtain and distribute naloxone to a person at risk of an opioid related overdose or to a family member, friend, or other person in a position to assist; and allow for the administration of the naloxone. In April 2021, the FDA announced its approval of higher dose of naloxone hydrochloride nasal spray. The FDA has approved naloxone hydrochloride nasal spray products in 2mg, 4 mg, and 8 mg amounts and noted that naloxone is a medicine that can be administered by individuals with or without medical training to help reduce opioid overdose deaths.

SB 1259 of 2022 updated the authorizing statute to allow a pharmacist to independently furnish any opioid antagonist (not just the product naloxone hydrochloride) approved by the federal Food and Drug Administration. Accordingly, the related protocols must be updated.

Analysis

During their meeting on January 24, 2023, the Licensing Committee of the Pharmacy Board approved the proposed amendments to the current protocols. The proposed amendments were approved by the full Pharmacy Board during their meeting on February 6-7, 2023.

The Executive Officer of the Pharmacy Board, Ms. Anne Sodergren, will be present to discuss these proposed changes and respond to any questions. The proposed regulatory text was developed with the assistance of James Gasper, PharmD, BCPP, Psychiatric and Substance Use Disorder Pharmacist, California Department of Health Care Services. Further, the proposed text was reviewed by the California Society of Addiction Medicine. Thus far, the Pharmacy Board has not received negative comments regarding the proposed changes.

In summary, the proposed changes would do the following:

- Replace the term “naloxone hydrochloride” with the generic term “opioid antagonist.”
- Update the training requirement to allow for completion of training completed in a school of pharmacy recognized by the Pharmacy Board.
- Removes the screening criteria. Any individual seeking an opioid antagonist would have access similar to what is provided to schools and libraries.
- Allows product selection to be determined by the pharmacist.
- Updates labeling requirements to be consistent with other prescription medications dispensed.
- Replaces a requirement to provide a Pharmacy Board-approved fact sheet with an FDA-approved medication guide.
- Updates the requirement to notify the patient’s physician to be effective upon the request of the patient.
- Removes unnecessary documentation and privacy language so that these requirements are aligned with any other product dispensed by the pharmacy.

Proposed Amendments to Current Protocol Regulatory Language

16 CCR § 1746.3

§ 1746.3. Protocol for Pharmacists Furnishing Opioid Antagonists ~~Naloxone Hydrochloride~~.

A pharmacist furnishing an opioid antagonist ~~naloxone hydrochloride~~ pursuant to section 4052.01 of the Business and Professions Code shall satisfy the requirements of this section.
(a) As used in this section:

(1) “Opioid” means naturally derived opiates as well as synthetic and semi-synthetic opioids.
(2) “Recipient” means the person to whom ~~naloxone hydrochloride~~ an opioid antagonist is furnished.
(b) Training. Prior to furnishing ~~naloxone hydrochloride~~ an opioid antagonist, pharmacists who use this protocol must have successfully completed a minimum of one hour of an approved continuing education program or equivalent-based training program completed in a board recognized school of pharmacy specific to the use of opioid antagonists for overdose reversal. ~~naloxone hydrochloride such products including in all routes of administration recognized in subsection (c)(4) of this protocol, or an equivalent curriculum-based training program completed in a board recognized school of pharmacy.~~
(c) Protocol for Pharmacists Furnishing Opioid Antagonists ~~Naloxone Hydrochloride~~. Before providing an opioid antagonist ~~naloxone hydrochloride~~, the pharmacist shall:
~~(1) Screen the potential recipient by asking the following questions:~~ Make a reasonable inquiry to determine:
~~(A) Whether the potential recipient currently uses or has a history of using illicit or prescription opioids. (If the recipient answers yes, the pharmacist may skip screening question B.);~~
~~(B) Whether the potential recipient is in contact with anyone who uses or has a history of using illicit or prescription opioids. (If the recipient answers yes, the pharmacist may continue.);~~
~~(C) Whether the person to whom the naloxone hydrochloride would be administered has a known hypersensitivity to naloxone. (If the recipient answers yes, the pharmacist may not provide naloxone. If the recipient responds no, the pharmacist may continue.)~~
~~The screening questions shall be made available on the Board of Pharmacy's website in alternate languages for patients whose primary language is not English.~~
(~~2~~1) Provide the recipient training in opioid overdose prevention, recognition, response, and administration of the opioid antagonist ~~antidote naloxone~~.
(~~3~~2) When an opioid antagonist ~~naloxone hydrochloride~~ is furnished:
(A) The pharmacist shall provide the recipient with appropriate counseling and information on the product furnished, including dosing, effectiveness, adverse effects, storage conditions, shelf-life, and safety. The recipient is not permitted to waive the required consultation.
(B) The pharmacist shall provide the recipient with any informational resources on hand and/or referrals to appropriate resources if the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time.
(C) The pharmacist shall answer any questions the recipient may have regarding ~~naloxone hydrochloride~~ the opioid antagonist.
(~~4~~3) Product Selection: A pharmacist shall advise the recipient on how to choose the route of administration based on the formulation available, how well it can likely be administered, the setting, and local context. ~~A pharmacist may supply naloxone hydrochloride as an intramuscular injection, intranasal spray, auto-injector or in another FDA-approved product form.~~ A pharmacist may also recommend optional items when appropriate, including alcohol pads, rescue breathing masks, and rubber gloves.

(~~5~~4) Labeling: A pharmacist shall label the ~~naloxone hydrochloride~~ product consistent with law and regulations. The patient shall also receive the FDA approved medication guide. ~~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~~.

~~(6) 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.~~

(~~7~~5) Notifications: ~~If the recipient of the naloxone hydrochloride is also the person to whom the naloxone hydrochloride would be administered, then the naloxone recipient is considered a patient for purposes of this protocol and notification may be required under this section.~~

~~If the patient gives verbal or written consent, then the pharmacist shall notify the patient's primary care provider of any drug(s) and/or device(s) furnished, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the patient and that primary care provider.~~

~~If the patient does not have a primary care provider, or chooses not to give notification consent, then the pharmacist shall provide a written record of the drug(s) and/or device(s) furnished and advise the patient to consult an appropriate health care provider of the patient's choice.~~ At the request of the patient, a pharmacist shall notify to the identified primary care provider of the product furnished or enter appropriate information in a shared patient record system as permitted by the primary care provider. If the patient does not have or does not identify a primary care provider, the pharmacist shall provide the recipient a written record of the drug furnished along with a recommendation to consult with an appropriate health care provider of the patient's choice.

~~(8) Documentation: Each naloxone hydrochloride~~ A product ~~furnished by a pharmacist pursuant to this protocol shall be documented in~~ the pharmacy's ~~a medication record for the naloxone recipient, and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense in compliance with . The medication record shall be maintained in an automated data or manual record mode such that the required information under title 16, sections 1707.1 and 1717 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours.~~

~~(9) Privacy: All pharmacists furnishing naloxone hydrochloride in a pharmacy or health care facility shall operate under the pharmacy or facility's policies and procedures to ensure that recipient confidentiality and privacy are maintained.~~

Credits

NOTE: Authority cited: Section 4052.01, Business and Professions Code. Reference: Section 4052.01, Business and Professions Code.