

Board of Pharmacy
Proposed Regulation

Adopt §1746.3 of Article 5 of Division 7 of Title 16 of the California Code of Regulations to read as follows:

§1746.3 Protocol for Pharmacists Furnishing Naloxone Hydrochloride

A pharmacist furnishing 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 is furnished.

(b) Training. Prior to furnishing naloxone hydrochloride, pharmacists who use this protocol must have successfully completed a minimum of one hour of an approved continuing education program specific to the use of naloxone hydrochloride, or an equivalent curriculum-based training program completed in a board recognized school of pharmacy.

(c) Protocol for Pharmacists Furnishing Naloxone Hydrochloride.

(1) Before providing naloxone hydrochloride, the pharmacist shall:

(A) Screen the potential recipient by asking the following questions:

- (i) 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 ii.);
- (ii) 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.
- (iii) 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 the naloxone. If the recipient responds no, the pharmacist may continue.

The screening questions shall be made available by the board on its website in alternate languages for recipients and patients whose primary language is not English.

(B) Provide the recipient training in opioid overdose prevention, recognition, response, and administration of the antidote naloxone.

(2) When 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.

(3) Product Selection: The pharmacist may supply naloxone hydrochloride as an intramuscular injection, intranasal spray, auto-injector, or any other FDA-approved products. A pharmacist shall provide advice to the recipient to how to choose the route of administration of naloxone based on the formulation available, how well it can likely be administered, the setting, and local context.

(4) Product Labeling: A pharmacist shall label each container consistent with law and regulations. 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.

(5) Fact Sheet: The pharmacist shall provide the recipient with a copy of the current naloxone fact sheet approved by the Board of Pharmacy. This fact sheet shall be made available in alternate languages for patients whose primary language is not English and made available on the board's website.

(6) 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.

(7) Documentation: Each naloxone hydrochloride product furnished by a pharmacist pursuant to this protocol shall be documented in 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 dispensing. The medication record shall be maintained in an automated data or manual record mode such that the required information under title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours.

(8) 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.

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