DEPARTMENT OF CONSUMER AFFAIRS
Title 16. Board of Pharmacy

Modified Regulatory Language
Opioid Antagonist Protocol

Legend: Added text is indicated with an underline.
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Modified Text Legend: Added text is indicated with a double underline.
Deleted text is indicated by ~~double strikeout~~.

Amend section 1746.3 to Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

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

A pharmacist furnishing an opioid antagonist for overdose reversal ~~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 curriculum-based training program, completed in a Board recognized school of pharmacy, specific to the use of opioid antagonists for overdose reversal. ~~naloxone hydrochloride 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:~~
~~(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 furnished ~~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 furnished.

(~~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~~ opioid antagonist consistent with law and regulations. ~~The person to whom the drug is furnished 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.~~

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. If the patient does not have or does not identify a primary care provider, ~~or chooses not to give notification consent, then~~ the pharmacist shall provide the patient a written record of the drug~~(s) and/or device(s)~~ furnished ~~and advise the patient~~ along with a recommendation for the patient to consult with an appropriate health care provider of the patient's choice.

~~(8) 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 dispense. 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.~~

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