

**California State Board of Pharmacy**

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

April 23, 2015

To: Board Members
Medical Board of California

From: California State Board of Pharmacy

Subject: Request for Review and Approval of Protocol to Permit Pharmacists to Provide
Naloxone Hydrochloride

At this meeting, representatives of the California State Board of Pharmacy will attend to present a protocol for Medical Board approval under which pharmacists may provide naloxone hydrochloride to patients or recipients who may need to reverse an opioid overdose.

Attending from the Board of Pharmacy will be:

- Stan Weisser, Board President
- Virginia Herold, Board Executive Officer
- Liz McCaman, Researcher

The naloxone protocol was authorized by AB 1535 (Bloom, Chapter 346, Statutes of 2014). A copy of this law appears at the back of this information packet.

On April 10, the board's emergency rulemaking took effect, putting into effect a protocol approved by both the Medical Board and Board of Pharmacy earlier this year. The emergency rulemaking version of the naloxone protocol is available online at http://www.pharmacy.ca.gov/licensing/naloxone_info.shtml.

The Board of Pharmacy now has slightly fewer than 180 days to promulgate the naloxone protocol through the traditional rulemaking process while the emergency rulemaking is in process. Again the Medical Board is required to review and approve the future protocol. Thus, the purpose of this agenda item for the Medical Board is for you to review, and ideally approve, the protocol. The Board of Pharmacy reviewed this version of the protocol during its board meeting on April 22.

The Board of Pharmacy has a new DCA attorney, and the protocol has been reorganized to reflect her preferences for presentation. The provisions are the same, except:

- the board has moved the labeling instructions for kits from the protocol to online, which will be matched with labeling examples for kits and unit doses.
- translations of the screening criteria (in section (c)(1)) will be added to the board's

website in the future.

- the requirements for the minimum of one hour of continuing education have been amended to require training in all routes of administration specified in the protocol (section (c)(4)).

A copy of the fact sheet that is provided to patients follows the protocol in this packet, and is available from the board's website:

http://www.pharmacy.ca.gov/publications/naloxone_fact_sheet.pdf. The fact sheet was developed by Philip Coffin, MD, San Francisco Department of Public Health. The board will ensure translations are made of this fact sheet in the top five languages spoken in California.

Thank you for your collaborative work on this important public health issue.

Title 16. Board of Pharmacy. Adopt §1746.3, ~~which is new regulation text~~, as follows:

§1746.3 Protocol for Pharmacists Furnishing Naloxone Hydrochloride

A pharmacist furnishing naloxone hydrochloride pursuant to ~~se~~Section 4052.01 of the Business and Professions Code shall satisfy the requirements of this section.

(a) As used in this section:

~~(1) "Kit" means _____ and may include optional items, including alcohol pads, rescue breathing masks, and rubber gloves.~~

~~(12)~~ "Opioid" means naturally derived opiates as well as synthetic and semi-synthetic opioids.

~~(23)~~ "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 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 Naloxone Hydrochloride. Before providing naloxone hydrochloride, the pharmacist shall:

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

~~(A*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 ~~B*ii*~~);

~~—(B*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.

~~—(C*iii*)~~ Whether the person to whom the naloxone hydrochloride would be administered has a known hypersensitivity to ~~n~~Naloxone. If the recipient answers yes, the pharmacist may not provide the ~~n~~Naloxone. If the recipient responds no, the pharmacist may continue.

~~The screening questions shall be made available in alternate languages for recipients and patients whose primary language is not English.~~

These screening questions shall be made available on the Board of Pharmacy's website in alternate languages for patients whose primary language is not English.

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

—(3) When naloxone hydrochloride is furnished:

(A~~ii~~) 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~~ii~~) 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~~ii~~) The pharmacist shall answer any questions the recipient may have regarding naloxone hydrochloride.

(4) ___ Product Selection: A pharmacist shall advise the recipient to how to choose the ~~kit and~~ route of administration based on the formulation available, how well it can likely be administered, the setting, and local context. ~~A~~The pharmacists may supply naloxone hydrochloride as an intramuscular injection, intranasal spray, auto-injector, or in another FDA approved product forms. The pharmacist may also recommend optional items when appropriate, including alcohol pads, rescue breathing masks, and rubber gloves.

(5) ___ ~~Kit~~-Labeling: A pharmacist shall label the ~~kit-naloxone hydrochloride~~ 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.

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

(7) ___ 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.

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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.

- (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 ~~processing~~ 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.
- (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.

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

For the Board of Pharmacy's website:

Naloxone

Suggested ~~Kit~~ Labeling (by route of administration):

| Intramuscular | Intranasal | Auto-Injector |
|--|---|---|
| <p>Naloxone 0.4mg/1ml single dose vial, # 2 vials SIG: Inject 1 ml intramuscularly upon signs of opioid overdose. Call 911. May repeat x 1.</p> <p>Syringe 3ml 25G X 1" # 2 SIG: Use as directed for naloxone administration.</p> <p>Kit should contain 2 vials and 2 syringes.</p> | <p>Naloxone needleless prefilled syringe (1mg/1ml concentration) 2ml, # 2 syringes SIG: Spray one-half (1ml) of the naloxone into each nostril upon signs of opioid overdose. Call 911. May repeat x 1.</p> <p>Mucosal Atomization Device (MAD) # 2 SIG: Use as directed for naloxone administration.</p> <p>Kit should contain 2 prefilled needleless syringes and 2 atomizers.</p> | <p>Naloxone 0.4 mg/0.4 ml #1 twin pack SIG: Use one auto-injector upon signs of opioid overdose. Call 911. May repeat x 1.</p> <p>Kit is commercially available as a twin pack with directions for administration included.</p> |

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California Business and Professions Code: 4052.01.

(a) Notwithstanding any other provision of law, a pharmacist may furnish naloxone hydrochloride in accordance with standardized procedures or protocols developed and approved by both the board and the Medical Board of California, in consultation with the California Society of Addiction Medicine, the California Pharmacists Association, and other appropriate entities. In developing those standardized procedures or protocols, the board and the Medical Board of California shall include the following:

(1) Procedures to ensure education of the person to whom the drug is furnished, including, but not limited to, opioid overdose prevention, recognition, and response, safe administration of naloxone hydrochloride, potential side effects or adverse events, and the imperative to seek emergency medical care for the patient.

(2) Procedures to ensure the education of the person to whom the drug is furnished regarding the availability of drug treatment programs.

(3) Procedures for the notification of the patient's primary care provider with patient consent of any drugs or devices furnished to the patient, or entry of appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider, and with patient consent.

(b) A pharmacist furnishing naloxone hydrochloride pursuant to this section shall not permit the person to whom the drug is furnished to waive the consultation required by the board and the Medical Board of California.

(c) Prior to performing a procedure authorized under this section, a pharmacist shall complete a training program on the use of opioid antagonists that consists of at least one hour of approved continuing education on the use of naloxone hydrochloride.

(d) The board and the Medical Board of California are each authorized to ensure compliance with this section. Each board is specifically charged with enforcing this section with respect to its respective licensees. This section does not expand the authority of a pharmacist to prescribe any prescription medication.

(e) The board may adopt emergency regulations to establish the standardized procedures or protocols. The adoption of regulations pursuant to this subdivision shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The emergency regulations authorized by this subdivision are exempt from review by the Office of Administrative Law. The emergency regulations authorized by this subdivision shall be submitted to the Office of Administrative Law for filing with the Secretary of State and shall remain in effect until the earlier of 180 days following their effective date or the effective date of regulations adopted pursuant to subdivision (a).