



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

To: Board Members

Subject: Agenda Item VII: DISCUSSION AND POSSIBLE ACTION: Regarding the Emergency Rulemaking Adoption of a Protocol for Pharmacists Who Furnish Naloxone – Update and Next Steps

At the January Board Meeting, the board approved the proposed protocol for pharmacists to provide naloxone. The board directed staff to initiate an emergency rulemaking as the authorizing legislation provides, provided the Medical Board of California approved the protocol during its meeting on January 30.

The Medical Board did approve the protocol during its January 30 meeting. Attachment 1 contains the approved protocol.

Earlier this week DCA Director Awet Kidane and Business, Consumer Services and Housing Secretary Anna Caballero both approved the protocol, the final steps before the board can file the emergency rulemaking with the Office of Administrative Law. As an emergency adoption, the protocol will go into effect upon approval and filing with the Office of Administrative Law.

This filing will occur following this board meeting. At the SB 493 Implementation Committee Meeting, the committee approved a fact sheet that will be available to pharmacists to provide to the public. A copy of this fact sheet is in this tab section following the protocol.

For Board Discussion and Possible Action:

1. One point of clarification for board discussion: the approved protocol contains the directions for use for each of the three forms of naloxone administration. However, as a prescription drug dispensed by a pharmacy, the container will need to be labeled by the pharmacy. As such, all elements of prescription container labeling will be required. This will require a patient name. As such staff recommends that the board develop a short guidance document to explain that the patient name on the container should be that of the individual who secures the naloxone from the pharmacy.
2. At the April board meeting, staff will provide an update on the implementation of the protocol. The board will also be asked to review the protocol for possible changes and to refer the existing protocol to the Medical Board for its review and approval. The goal would be to initiate a formal rulemaking to adopt the protocol after the Medical Board's May board meeting. It typically will take at least 180 days (the initial length of the emergency adoption period) to secure the formal adoption of a regulation.

Attachment 1

Protocol for Pharmacists Furnishing Naloxone Hydrochloride

(a) A pharmacist furnishing naloxone hydrochloride pursuant to Section 4052.01 of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Naloxone Hydrochloride

(1) Authority: Section 4052.01(a) of the California Business and Professions Code authorizes a pharmacist to furnish naloxone hydrochloride in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol in this section satisfies that requirement.

(2) Purpose: To provide access to naloxone hydrochloride via standardized procedures so that pharmacists may educate about and furnish naloxone hydrochloride to decrease harm from opioid¹ overdose.

(3) Procedure: When someone requests naloxone hydrochloride, or when a pharmacist in his or her professional judgment decides to advise of the availability and appropriateness of naloxone hydrochloride, the pharmacist shall complete the following steps:

- Screen for the following conditions:²
 - i. Whether the potential recipient³ currently uses or has a history of using illicit or prescription opioids (If yes, skip question ii and continue with Procedure);
 - ii. Whether the potential recipient is in contact with anyone who uses or has a history of using illicit or prescription opioids (If yes, continue with Procedure);
 - iii. Whether the person to whom the naloxone hydrochloride would be administered has a known hypersensitivity to naloxone? (If yes, do not furnish).
- Provide training in opioid overdose prevention, recognition, response, and administration of the antidote naloxone.
- When naloxone hydrochloride is furnished:
 - 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.
 - The pharmacist shall provide the recipient with any informational resources on hand and/or referrals to appropriate resources if the

¹ For purposes of this protocol, “opioid” is used generally to cover both naturally derived opiates and synthetic and semi-synthetic opioids.

² These screening questions shall be made available in alternate languages for patients whose primary language is not English.

³ For purposes of this protocol, “recipient” means the person to whom naloxone hydrochloride is furnished.

recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time.

- The pharmacist shall answer any questions the recipient may have regarding naloxone hydrochloride.

(4) Product Selection: Naloxone hydrochloride may be supplied as an intramuscular injection, intranasal spray, and auto-injector. Other FDA approved products may be used. Those administering naloxone should choose the route of administration based on the formulation available, how well they can administer it, the setting, and local context.

(5) Suggested Kit Labeling:

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>2ml needleless syringe prefilled with naloxone (1mg/1ml concentration), # 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>

Optional items for the kits include alcohol pads, rescue breathing masks, and rubber gloves.

Kit labels shall include an expiration date for the naloxone hydrochloride furnished. An example of appropriate labeling is available on the Board of Pharmacy 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 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.

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) Training: Prior to furnishing naloxone hydrochloride, pharmacists who participate in 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.

(10) 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.

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Note: Authority cited: Section 4052.01, Business and Professions Code.

Protocol Sources

Scott Burris, et al., “Stopping an Invisible Epidemic: Legal Issues in the Provision of Naloxone To Prevent Opioid Overdose,” DREXEL L. REV. 1(2):273-339, 326 (2009).

This law review article recommends fostering naloxone distribution through pharmacies, and using EC statutes as a model.

Substance Abuse and Mental Health Services Administration, “Opioid Overdose Toolkit,” available at <http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2014/SMA14-4742>.

This resource provides materials to develop policies to prevent opioid overdose.

The Network for Public Health Law, “Legal Interventions To Reduce Overdose Mortality: Naloxone Access and Overdose Good Samaritan Laws” (Aug. 2014), available at https://www.networkforphl.org/_asset/qz5pvn/naloxone_FINAL.pdf.

This article describes naloxone access nationwide.

Harm Reduction Coalition, “Guide to Developing and Managing Overdose Prevention and Take-Home Naloxone Projects” (2012), available at <http://harmreduction.org/issues/overdose-prevention/tools-best-practices/manuals-best-practice/od-manual/>.

This manual outlines the process of developing an overdose prevention program, including with a take-home naloxone component.

Northeast Behavioral Health, “Opioid Overdose Prevention and Reversal via Peer-Administered Narcan” (2012), available at <http://harmreduction.org/wp-content/uploads/2012/02/od-train-the-trainer-parents.pdf>.

This PowerPoint presentation provides information to educate peers on opioid prevention and reversal.

CA Department of Health Care Services, “Pharmacist Protocol for Furnishing Naloxone for the Prevention of Opioid Overdose” (last updated Oct. 29, 2014).

This draft protocol was consulted in development of the Board’s recommended protocol.

World Health Organization, “Community Management of Opioid Overdose” (2014).

This resource provides materials to develop policies to prevent opioid overdose.

Drug Policy Alliance, “What Is Naloxone?” (Aug. 2014), available at <http://www.drugpolicy.org/resource/what-naloxone>.

This fact sheet provides comprehensive information on naloxone.

Massachusetts Department of Health and Human Services, “Dispensing of Naloxone by Standing Order” (2014), available at <http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/dhpl/pharmacy/dispensing-of-naloxone-by-standing-order-.html>.

This site contains a pamphlet recommended as the base for the Board’s factsheet.

N. Zaller, et al., "The Feasibility of Pharmacy-Based Naloxone Distribution Interventions: A Qualitative Study with Injection Drug Users and Pharmacy Staff in Rhode Island," 48 SUBST. USE MISUSE 8 (2013).

This research supports pharmacy-based naloxone intervention, but notes barriers including misinformation and costs.

Traci C. Green, et al., "Responding to Opioid Overdose in Rhode Island: Where the Medical Community Has Gone and Where We Need To Go," R.I. MED. J. 29-33 (Oct. 2014), available at <http://www.rimed.org/rimedicaljournal/2014/10/2014-10-29-dadt-green.pdf>.

This article gives an overview of opioid overdose, provides guidance resources, and emphasizes the importance of Good Samaritan Laws.