

**State of California
Office of Administrative Law**

In re:
Board of Pharmacy

Regulatory Action:

Title 16, California Code of Regulations

Adopt sections: 1746.3

Amend sections:

Repeal sections:

**NOTICE OF FILING AND PRINTING ONLY
OF EMERGENCY REGULATION**

**Business and Professions Code Section
4052.01(e); Government Code Section
11343.8**

OAL Matter Number: 2015-0922-01

**OAL Matter Type: Emergency File and Print
Only (EFP)**

The Board of Pharmacy submitted this action for the emergency readoption of title 16, California Code of Regulations, section 1746.3 pursuant to Business and Professions Code section 4052.01(e). Section 1746.3 was originally adopted in OAL file no. 2015-0409-03EFP. Section 1746.3 provides the protocol for pharmacists to furnish naloxone hydrochloride pursuant to Business and Professions Code section 4052.01.

OAL filed this emergency regulation with the Secretary of State and will publish the emergency regulation in the California Code of Regulations.

This emergency regulation is effective on 10/8/2015 and, pursuant to Business and Professions Code section 4052.01(e), will expire on 4/6/2016. The Certificate of Compliance for this action is due no later than 4/5/2016.

Date: September 29, 2015

Richard L. Smith

Richard L. Smith
Senior Attorney

**For: DEBRA M. CORNEZ
Director**

**Original: Virginia Herold
Copy: Lori Martinez**

STD. 400 (REV. 01-2013)

OAL FILE NUMBERS	NOTICE FILE NUMBER Z-	REGULATORY ACTION NUMBER	EMERGENCY NUMBER 2015-0922-01EFP
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For use by Office of Administrative Law (OAL) only

ENDORSED - FILED
In the office of the Secretary of State
of the State of California

SEP 29 2015
2:10 PM

2015 SEP 22 P 3: 06
OFFICE OF
ADMINISTRATIVE LAW

NOTICE

REGULATIONS

AGENCY WITH RULEMAKING AUTHORITY
Board of Pharmacy

AGENCY FILE NUMBER (if any)

A. PUBLICATION OF NOTICE (Complete for publication in Notice Register)

1. SUBJECT OF NOTICE		TITLE(S)	FIRST SECTION AFFECTED	2. REQUESTED PUBLICATION DATE	
3. NOTICE TYPE <input type="checkbox"/> Notice re Proposed Regulatory Action <input type="checkbox"/> Other		4. AGENCY CONTACT PERSON	TELEPHONE NUMBER	FAX NUMBER (Optional)	
OAL USE ONLY	ACTION ON PROPOSED NOTICE <input type="checkbox"/> Approved as Submitted <input type="checkbox"/> Approved as Modified <input type="checkbox"/> Disapproved/Withdrawn		NOTICE REGISTER NUMBER	PUBLICATION DATE	

B. SUBMISSION OF REGULATIONS (Complete when submitting regulations)

1a. SUBJECT OF REGULATION(S) Naloxone hydrochloride	1b. ALL PREVIOUS RELATED OAL REGULATORY ACTION NUMBER(S) <i>per agency request</i> 2015-0409-03 EFP
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2. SPECIFY CALIFORNIA CODE OF REGULATIONS TITLE(S) AND SECTION(S) (Including title 26, if toxics related)	
SECTION(S) AFFECTED (List all section number(s) individually. Attach additional sheet if needed.)	ADOPT Section 1746.3
	AMEND N/A
TITLE(S) 16	REPEAL N/A

3. TYPE OF FILING			
<input type="checkbox"/> Regular Rulemaking (Gov. Code §11346)	<input type="checkbox"/> Certificate of Compliance: The agency officer named below certifies that this agency complied with the provisions of Gov. Code §§11346.2-11347.3 either before the emergency regulation was adopted or within the time period required by statute.	<input checked="" type="checkbox"/> Emergency Readopt (Gov. Code, §11346.1(h))	<input type="checkbox"/> Changes Without Regulatory Effect (Cal. Code Regs., title 1, §100)
<input type="checkbox"/> Resubmittal of disapproved or withdrawn nonemergency filing (Gov. Code §§11349.3, 11349.4)	<i>per agency request</i>	<input checked="" type="checkbox"/> File & Print	<input type="checkbox"/> Print Only
<input type="checkbox"/> Emergency (Gov. Code, §11346.1(b))	<input type="checkbox"/> Resubmittal of disapproved or withdrawn emergency filing (Gov. Code, §11346.1)	<input checked="" type="checkbox"/> Other (Specify) <i>Bus. & Prof. Code sec. 4052.01(e)</i>	

4. ALL BEGINNING AND ENDING DATES OF AVAILABILITY OF MODIFIED REGULATIONS AND/OR MATERIAL ADDED TO THE RULEMAKING FILE (Cal. Code Regs. title 1, §44 and Gov. Code §11347.1)

5. EFFECTIVE DATE OF CHANGES (Gov. Code, §§ 11343.4, 11346.1(d); Cal. Code Regs., title 1, §100)			
<input type="checkbox"/> Effective January 1, April 1, July 1, or October 1 (Gov. Code §11343.4(a))	<input type="checkbox"/> Effective on filing with Secretary of State	<input type="checkbox"/> §100 Changes Without Regulatory Effect	<input checked="" type="checkbox"/> Effective other (Specify) October 8, 2015

6. CHECK IF THESE REGULATIONS REQUIRE NOTICE TO, OR REVIEW, CONSULTATION, APPROVAL OR CONCURRENCE BY, ANOTHER AGENCY OR ENTITY			
<input type="checkbox"/> Department of Finance (Form STD. 399) (SAM §6660)	<input type="checkbox"/> Fair Political Practices Commission	<input checked="" type="checkbox"/> <i>per agency request</i> State Fire Marshal Medical Board of CA	
<input checked="" type="checkbox"/> Other (Specify) Awet Kidane, Director, Department of Consumer Affairs			

7. CONTACT PERSON Lori Martinez	TELEPHONE NUMBER (916) 574-7917	FAX NUMBER (Optional) (916) 574-8618	E-MAIL ADDRESS (Optional) Lori.Martinez@dca.ca.gov
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8. I certify that the attached copy of the regulation(s) is a true and correct copy of the regulation(s) identified on this form, that the information specified on this form is true and correct, and that I am the head of the agency taking this action, or a designee of the head of the agency, and am authorized to make this certification.

SIGNATURE OF AGENCY HEAD OR DESIGNEE <i>Virginia Herold</i>	DATE 9/21/2015
TYPED NAME AND TITLE OF SIGNATORY Virginia Herold, Executive Officer, Board of Pharmacy	

For use by Office of Administrative Law (OAL) only

ENDORSED APPROVED

SEP 29 2015

Office of Administrative Law

BOARD OF PHARMACY

ORDER OF ADOPTION

Add and Adopt §1746.3, which is new regulation text, as follows:

§1746.3 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:

(A) 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).

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

(C) When naloxone hydrochloride is furnished:

- (i.) 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.

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.

- (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.
- (iii.) 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>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>

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.