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To: Board Members

Subject: Agenda Item IV – Discussion and Consideration of Proposed Regulations to Amend Title 16, California Code of Regulations, Section 1746.3, Related to the Naloxone Fact Sheet

Attachment 1

Relevant Sections:
Title 16, California Code of Regulations (CCR) section 1746.3 specifies the protocol requirements for pharmacists furnishing naloxone hydrochloride. Included in this regulation is the requirement for a board-approved fact sheet that the pharmacist is required to give the patient upon furnishing naloxone hydrochloride.

Business and Professions Code (BPC) section 4052.01 authorizes a pharmacist to furnish naloxone hydrochloride in accordance with protocols developed and approved by both the board and the Medical Board of California. A copy of BPC section 4052.01 may be found in **Attachment 1**.

Summary of Regulation:
This regulation will provide the board's executive officer the authority to approve alternate fact sheets that contain the same content as the board's required fact sheet but are formatted or presented in a different manner.

Regulation Timeline:

May 3-4, 2017	Approved by Board
May 31, 2017	Board staff prepared rulemaking file for DCA for pre-review
Jan. 18, 2018	DCA pre-review comments received
Feb. 27, 2018	Recommendation to return to Board for discussion

Recent Update:
During DCA pre-review, concerns were raised that the language require alternative fact sheets to contain the same content as the board-approved fact sheet. Additionally, there was a concern the regulation language does not address fact sheets in other languages.

At this Meeting:
The board will have the opportunity to review and discuss changes in the regulation language proposed to address the issues raised during the DCA pre-review. **Attachment 1** includes a copy of the revised proposed language for CCR 1746.3. For ease of reading, changes made to the approved language are shown by ~~double strikethrough~~ for deleted language and double underline for added language.

Staff Recommendation:
Should the board agree with the proposed changes, the following motion could be used to initiate the rulemaking process.

Motion: Approve the proposed modification to Title 16 CCR Section 1746.3 and initiate the formal rulemaking process. Further, delegate to the executive officer the authority to make any nonsubstantive changes and clarifying changes consistent with the board's policy direction upon recommendations of the control agencies.

Attachment 1

4052.01. Furnishing of Naloxone Hydrochloride; Permitted Procedures by Pharmacist

(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).

Proposal to amend § 1746.3 in Article 5 of Division 17 of Title 16 of the California Code of Regulations to read:

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

(3) 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.

(4) 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) Labeling: A pharmacist shall label the 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 or ~~substantially similar~~ 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 is contained in the current board-approved fact sheet. ~~This~~ 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) 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 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.