DEPARTMENT OF CONSUMER AFFAIRS
**TITLE 16. BOARD OF PHARMACY**

# NOTICE OF PROPOSED REGULATORY ACTION CONCERNING:
## Opioid Antagonist Protocol

**NOTICE IS HEREBY GIVEN** that the California State Board of Pharmacy (Board) proposes taking the rulemaking action described below under the heading Informative Digest/Policy Statement Overview. Any person interested may present statements or arguments, relevant to the action proposed, in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Persons in this Notice, must be received by the Board at its office by January 29, 2024.

**PUBLIC HEARING**
The Board has not scheduled a public hearing on this proposed action. However, the Board will hold a hearing if it receives a written request for a public hearing from any interested person, or that person's authorized representative, no later than 15 days prior to the close of the written comment period. A hearing may be requested by making such request in writing addressed to the individuals listed under "Contact Persons" in this notice.

The Board may, after holding a hearing if requested and considering all timely and relevant comments, adopt the proposed regulations substantially as described in this notice, or may modify the proposed regulations if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the persons designated in this Notice as the Contact Persons and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

**Authority and Reference:** Pursuant to the authority vested by Business and Professions Code (BPC) section 4052.01, the Board proposes amending section 1746.3 in Division 17 of Title 16 of the California Code of Regulations (CCR).

**INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW**
The Board is a state agency vested with the authority to regulate the pharmacy industry, including pharmacies, pharmacists, interns, and pharmacy technicians. The Board's mandate and mission are to protect the public (BPC § 4001.1).

Existing law at BCP section 4052.01 authorized pharmacists to furnish the opioid antagonist naloxone hydrochloride in accordance with standardized procedures the Board was to implement through regulations.

With the enactment of Senate Bill 1259 ("SB 1259"), BPC section 4052.01 was amended to authorize pharmacists to furnish any Food Drug and Administration (FDA) approved opioid antagonist, not just naloxone hydrochloride. Additionally, the Board and

the Medical Board of California ("in consultation with the California Society of Addiction Medicine [(CSAM)], the California Pharmacists Association, and other appropriate entities") were authorized to develop and approve regulations implementing standardized procedures or protocols pharmacists are to adhere to when furnishing FDA-approved opioid antagonists. These procedures or protocols must include educating the person to whom the opioid antagonist is furnished (regarding opioid overdose prevention, recognition, and response, safe administration of opioid antagonists, potential side effects/adverse events, seeking emergency medical care, and availability of drug treatment programs), and notifying the recipient's primary care provider—directly, or by updating a patient's information in a database to which their physician has access.

This regulatory proposal will implement the statute by amending CCR section 1746.3, updating the current standardized procedures or protocols to regulate the furnishing of any FDA-approved opioid antagonists, not just naloxone hydrochloride. The Board consulted with the California Department of Health Care Services in the development of this proposal. The proposal was provided to CSAM, the Medical Board of California, and the California Pharmacists Association for review prior to approval of the language by the Board. The Board received comments from CSAM and the Medical Board, and neither expressed concerns with the proposed language.

## Anticipated Benefits of Proposal

The Board has determined that this regulatory proposal will have the following benefits to the health and welfare of California residents.

Implementing this proposal will benefit the health and welfare of California residents by ensuring FDA-approved opioid antagonists are safely furnished. Additionally, implementing this proposal will ensure that the people to whom the opioid antagonists are administered are educated on opioid overdose prevention, recognition, and response, safe administration of opioid antagonists, potential side effects/adverse events, seeking emergency medical care, and availability of drug treatment programs. Finally, implementing this proposal will ensure the patient's primary care provider is notified—directly, or by updating a patient's information in a database to which their physician has access—that an opioid antagonist was furnished to the patient, which will aid the physician and patient with current and future care.

This regulatory proposal does not affect worker safety or the state's environment.

## Evaluation of Consistency and Compatibility with Existing State Regulations

During the process of developing this regulatory proposal, the Board conducted a search of any similar regulations on this topic and concluded that these regulations are neither inconsistent nor incompatible with existing state regulations.

## DISCLOSURES REGARDING THIS PROPOSED ACTION

## FISCAL IMPACT ESTIMATES

**Fiscal Impact on Public Agencies Including Costs/Savings to State Agencies or Costs/Savings in Federal Funding to the State:** The proposed regulations do not result in a fiscal impact to the state. The regulations do not result in costs or savings in federal funding or to any state agency. This proposal would implement standardized procedures or protocols for the furnishing of any FDA-approved opioid antagonist. The Board does not anticipate additional workload or costs resulting from the proposed regulations, and if there is any additional workload or costs of implementation, they are the result of current law.

**Nondiscretionary Costs/Savings to Local Agencies:** None

**Cost to Any Local Agency or School District for Which Government Code Sections 17500 – 17630 Require Reimbursement:** None

**Mandate Imposed on Local Agencies or School Districts:** None

**Significant Effect on Housing Costs:** None

## BUSINESS IMPACT ESTIMATES:

The Board has made the initial determination that the proposed regulatory action would not have a significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other States.

This initial determination is based on the absence of testimony to that effect during the public discussion and development of the proposed amendments to the regulation. Additionally, this proposal would implement standardized procedures or protocols for the furnishing of any FDA-approved opioid antagonist to patients. This would not impact businesses.

**Cost Impact on Representative Private Person or Business:**

The Board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

## RESULTS OF ECONOMIC IMPACT ASSESSMENT/ANALYSIS:

**Impact on Jobs/Businesses:**

The Board concludes that this proposal will not:

(1) create jobs within California;
(2) eliminate jobs within California;

(3) create new businesses within California;
(4) eliminate existing businesses within California; and,
(5) expand businesses currently doing business in the State of California.

**Benefits of Regulation:**

The Board has determined that this regulatory proposal will benefit the health and welfare of California residents because it will ensure that 1) FDA-approved opioid antagonists are safely furnished, 2) the people to whom the opioid antagonists are furnished are educated on opioid overdose prevention, recognition, and response, safe administration of opioid antagonists, potential side effects/adverse events, seeking emergency medical care, and availability of drug treatment programs, and 3) the patient's primary care provider is notified—directly, or by updating a patient's information in a database to which their physician has access—that an opioid antagonist was furnished to the patient, aiding the physician and patient with current and future care.

This proposal will not impact worker safety or the state's environment.

**Business Reporting Requirements**

This regulatory proposal does not require businesses to file a report with the Board.

**Effect on Small Business**:

While the Board does not have, nor does it maintain, data to determine if any of its licensees (pharmacies and clinics) are a "small business", as defined in Government Code section 11342.610, the Board has determined that the proposed regulatory action will not affect small businesses, as the regulations are implementing standardized procedures or protocols for medical professionals to furnish additional FDA-approved opioid antagonists to patients. Small businesses will not be affected.

**CONSIDERATION OF ALTERNATIVES**

In accordance with Government Code section 11346.5(a)(13), the Board must determine that no reasonable alternative it considered to the regulation, or that has otherwise been identified and brought to its attention, would be more effective in carrying out the purpose for which the action is proposed, as effective and less burdensome to affected private persons than the proposal described in this Notice, or more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Any interested person may submit comments—relevant to the above determinations—in writing, at the address listed below for the Contact Persons, during the written comment period, or at the hearing if one is scheduled or requested.

**AVAILABILITY OF INITIAL STATEMENT OF REASONS AND RULEMAKING FILE**

The Board has compiled a record for this regulatory action, which includes the Initial Statement of Reasons (ISOR), proposed regulatory text, and all the information upon which the proposal is based. This material is contained in the rulemaking file and is available for public inspection upon request to the contact persons named in this notice.

## TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations, the Initial Statement of Reasons, and all of the information upon which the proposal is based, may be obtained upon request from the Board of Pharmacy at 2720 Gateway Oaks Drive, Ste. 100, Sacramento, California 95833, or from the Board of Pharmacy's website at http://www.pharmacy.ca.gov/laws_regs/pending_regs.shtml.

## AVAILABILITY OF CHANGED OR MODIFIED TEXT

After considering all timely and relevant comments, the Board, upon its own motion or at the request of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal, with the modifications clearly indicated, will be available for review and written comment for 15 days prior to its adoption from the persons designated in this Notice as the Contact Persons and will be mailed to those persons who submit written comments or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

## AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file, which is available for public inspection by contacting the person named below.

You may obtain a copy of the Final Statement of Reasons once it has been prepared, by making a written request to the Contact Person named below or by accessing the website listed below.

## CONTACT PERSONS

Inquiries or comments concerning the proposed rulemaking action may be addressed to:


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|---|---|
| Name: | Lori Martinez |
| Address: | Board of Pharmacy<br>2720 Gateway Oaks Drive, Ste. 100<br>Sacramento, CA 95833 |
| Phone No.: | (916) 518-3078 |
| Fax No.: | (916) 574-8618 |
| E-Mail Address: | PharmacyRulemaking@dca.ca.gov |

The backup contact person is:

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|---|---|
| Name: | Julia Ansel |
| Address: | Board of Pharmacy<br>2720 Gateway Oaks Drive, Ste. 100<br>Sacramento, CA 95833 |
| Phone No.: | (916) 518-3108 |
| Fax No.: | (916) 574-8618 |
| E-Mail Address: | PharmacyRulemaking@dca.ca.gov |


## AVAILABILITY OF DOCUMENTS ON THE INTERNET

Copies of the Notice of Proposed Action, the Initial Statement of Reasons, and the text of the regulations with modifications noted, as well as the Final Statement of Reasons when completed, and modified text ,if any, can be accessed through the Board of Pharmacy's website at: https://www.pharmacy.ca.gov/laws_regs/pending_regs.shtml.