

TITLE 16. BOARD OF PHARMACY

NOTICE IS HEREBY GIVEN that the Board of Pharmacy (“Board”) is proposing to take the action described in the Informative Digest. 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 Person in this Notice, must be received by the Board of Pharmacy at its office not later than 5:00 p.m. on July 6, 2015.

The Board does not intend to conduct a regulation hearing on the matter, unless requested. Any interested person may submit a written request for a public hearing no later than 15 days prior to the close of the 45-day written comment period.

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 will be available for 15 days prior to its adoption from the person designated in this Notice as contact person 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: Under the authority conferred by Business and Professions Code (“B&P”) sections 4005 and 4052.01, in order to implement, interpret and make specific B&P section 4052.01, the Board is proposing to amend Article 5 of Division 17 of Title 16 of the California Code of Regulations (“CCR”), as follows:

INFORMATIVE DIGEST/ POLICY STATEMENT OVERVIEW

The Board proposes to adopt Section 1746.3 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to permanently set out requirements pharmacists must follow to furnish naloxone hydrochloride (“naloxone”) without a doctor’s prescription. Naloxone is an “opioid antagonist,” that reverses the effects of opioid medications, including oxycodone, oxymorphone, Vicodin, Percocet, methadone, and heroin. Senate Bill 493 (Chapter 469, Statutes of 2013) authorized the Board to address the problem of restricted public access to naloxone. The Board, following the instructions set out in B&P section 4052.01(e), promulgated an emergency regulation to allow pharmacists to furnish naloxone to the public. The emergency regulation went into effect on April 10, 2015 and will expire on October 8, 2015.

Since the adoption of the emergency regulation, the Board, again following the instructions set out in B&P section 4052.01(a), worked with the Medical Board and consulted with the California Society of Addiction Medicine, the California Pharmacists’ Association and other entities, to revise the emergency regulation found at 16 CCR Section 1746.3 and created the version submitted herein.

The practice of pharmacy is authorized, regulated and enforced in California by the Board. Because the federal government does not authorize or regulate practice in California, there are no existing federal regulations comparable to this rulemaking.

Specific Benefits Anticipated: Increasing the public's access to naloxone will contribute to public health and safety by preventing opioid overdose deaths.

Consistency and Compatibility with Existing State Regulation: During the collaborative process of reviewing and revising this regulation, the Board conducted a search of similar regulations on this topic. Presently, emergency regulation 16 CCR Section 1746.3 is quite similar and is in effect. However, 16 CCR Section 1746.3 was adopted as an emergency regulation. This proposed regulation, while substantially similar to 16 CCR Section 1746.3, is neither inconsistent nor incompatible with it or any other existing state regulations. Aside from the existing emergency naloxone regulation, the Board has concluded that the only other California statute concerning naloxone is Assembly Bill 635 (Chapter 707, Statutes of 2013), which insulates physicians from civil liability when they prescribe naloxone to a family member, friend, or other person in a position to assist a person experiencing or suspected of experiencing an opioid overdose (adopted as Civil Code section 1714.22).

Mandate on Local Agencies or School Districts: This regulatory action does not impose a mandate on local agencies or school districts.

FISCAL IMPACT:

- A. Cost or Savings to any state agency: NONE
- B. Cost to any local agency required to be reimbursed under Part 7 (commencing with Section 17500) of Division 4: NONE
- C. Cost to any school district required to be reimbursed under Part 7 (commencing with Section 17500) of Division 4: NONE
- D. Other nondiscretionary cost or savings imposed on local agencies: NONE
- E. Cost or savings in federal funds to the state: NONE

Effect on Housing Costs: NONE

Business Impact: The Board has made an initial determination that the proposed regulatory action will have no significant statewide adverse economic impact on directly affected businesses, including the ability of California businesses to compete with businesses in other states.

Results of Economic Impact Assessment: Pharmacists wishing to dispense naloxone must take one (1) hour of continuing education (CE) before dispensing. However, pharmacists presently complete thirty (30) hours of CE each renewal cycle, and the one (1) hour of CE on self-administered hormonal contraception can be applied to meet the existing CE requirement. Thus, while this regulatory proposal affects pharmacists, it will not have a significant statewide adverse economic impact directly affecting business, or businesses' ability to compete.

Impact on Jobs/New Businesses: The Board has determined that the regulatory proposal herein will not have any impact on the creation of jobs or new businesses or the elimination of jobs or existing businesses or the expansion of businesses in the State of California.

Benefits of the Regulations: This regulatory proposal benefits the health and welfare of California residents because pharmacies furnishing naloxone to the general public will increase the availability of naloxone. Increased public access to naloxone will contribute to public health and safety by preventing opioid overdose deaths. Improved access to this life-saving drug will help eliminate some of the previous income and class-based discrimination that has existed and thus, also promotes fairness and social equity.

The Board has determined that this regulation has no impact on worker safety.

This regulatory proposal does not affect the state's environment because it simply allows pharmacists to dispense naloxone to family, friends, and other persons in a position to assist a person experiencing or suspected of experiencing an opioid overdose. Pharmacists have been dispensing naloxone to the public with a doctor's prescription for several decades, and since April (under the emergency regulation) without a doctor's prescription, and the Board has not received any information about measureable environmental effects.

Cost Impacts: 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.

Business Report: The proposed regulations do not require a new report to be made. Until the emergency regulations were adopted, naloxone was only dispensed by prescription, and pharmacies were and are required to maintain patient medication records for three (3) years. This proposed regulation makes permanent the requirement of the existing emergency regulation, under which pharmacies are to keep records of dispensing naloxone for three (3) years.

Effect on Small Businesses: The Board has determined that the proposed regulation would not affect small businesses. Before the emergency regulations were enacted, pharmacists already furnished naloxone to those presenting a doctor's prescription. While there might have been a slight uptick in demand for naloxone once members of the public could obtain it without a doctor's prescription, the Board has concluded that making this regulation permanent will have a negligible effect on small businesses.

CONSIDERATION OF ALTERNATIVES: The Board must determine that no reasonable alternative considered by the Board, or otherwise identified and brought to the Board's attention, would either be more effective in carrying out the purpose for which the action is proposed, or would be as effective and less burdensome to affected private persons than the regulation described herein, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policies or other provision of law.

Any interested person may present statements or arguments in writing relevant to the above determinations to the Board at the address listed for the Contact Person.

INITIAL STATEMENT OF REASONS AND INFORMATION: The Board has prepared an initial statement of the reasons for the proposed actions and has available all the information upon which the proposals are based.

TEXT OF PROPOSAL: Copies of the exact language of the proposed regulation and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained upon request from the person designated below as contact person, or by accessing the Board of Pharmacy's Web site at www.pharmacy.ca.gov.

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE: All of the information upon which the proposed regulation is based is contained in the rulemaking file which is available for public inspection by contacting the contact person named below. Any interested person 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 Board of Pharmacy's Web site www.pharmacy.ca.gov.

CONTACT PERSON: Materials regarding this proposal can be found at www.pharmacy.ca.gov. Inquiries or comments concerning the proposed rulemaking actions may be addressed to:

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