

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 written statements or arguments relevant to the action proposed. Written comments, including those sent by mail, facsimile, or email 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 November 9, 2015.

The Board does not intend to conduct a regulation hearing on the matter, unless one is timely 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 section 4005 in order to implement, interpret and make specific Business and Professions Code sections 4052(a)(10)(A)(3), the Board is proposing to amend Article 5 of Division 17 of Title 16 of the California Code of Regulations, as follows:

Informative Digest/ Policy Statement Overview

The Board proposes to add and adopt Section 1746.5 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to set out a standard for pharmacists to follow to furnish travel medications without a doctor's prescription. This regulation is necessary to implement provisions of B&P section 4052(a)(10)(A)(3). This proposed rulemaking would increase public access to and reduce the cost of obtaining travel medications and proportionately reduce physician workloads.

Business and Professions Code section 4005 generally authorizes the board to amend rules and regulations pertaining to the practice of pharmacy.

Business and Professions Code section 4052(a)(10)(A)(3) authorizes pharmacists to furnish travel medications to the public.

Anticipated Benefits of Proposal:

Having pharmacists furnish travel medications will reduce the cost and increase the convenience of obtaining travel medications. A crucial part of the process of furnishing travel medications is the pre-travel consultation. In a pre-travel consultation, a pharmacist goes over the patient's travel plan, and educates the patient about what diseases are prevalent where they are going, how the diseases can be contracted, ways to avoid getting sick, symptoms to watch

for, and when and how local diseases must be treated. Only after a pre-travel consultation does the pharmacist furnish vaccinations and other medications as appropriate. Consumers will be better educated about travel health and safety, and thus public health will be improved. Californians who obtain travel medications are less likely to cut their travels short due to illness or other conditions, thus improving the health and welfare of Californians who travel. Easing access to travel medications should contribute to the public health by increasing public education about the risks associated with foreign travel and by reducing the number of sick travelers returning home and potentially spreading diseases in California. These various benefits, when taken together, will improve public health.

Consistency and Compatibility with Existing State Regulation

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

Incorporation by Reference

1. International Society of Travel Medicine: Body of Knowledge for the Practice of Travel Medicine - 2012

Fiscal Impact Estimates

Fiscal Impact on Public Agencies Including Costs/Savings to State Agencies or Costs/Savings in Federal Funding to the State: None

Nondiscretionary Costs/Savings to Local Agencies: None

Local Mandate: None

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

Business Impact:

The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states as the regulation only affects individual licensed pharmacists that elect to dispense travel medications.

Pharmacists wishing to dispense travel medications must first complete an approved travel medicine training program, which must consist of at least twenty (20) hours and cover each element of the International Society of Travel Medicine's (ISTM) Body of Knowledge for the Practice of Travel Medicine (2012). Additionally, the Centers for Disease Control Yellow Fever Vaccine Course, and current basic life support certification. Pharmacists are not required to furnish travel medications, and will only do so if they believe it to be worth the cost of

completing the required training and meeting the record storage and notification requirements.

After the initial training, pharmacists must biennially complete two (2) hours of continuing education (CE) focused on travel medicine, separate from CE in immunizations and vaccines. However, pharmacists presently complete thirty (30) hours of CE each renewal cycle, and the two (2) hours of CE on focused on travel medicine, separate from CE in immunizations and vaccines, can be applied to meet the existing CE requirement. Thus, while this regulatory proposal affects pharmacies, it will not have a significant statewide adverse economic impact directly affecting businesses, or businesses' ability to compete.

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 unless that individual is licensed by the board and subject to disciplinary action by the board.

Effect on Housing Costs: None

Effect on Small Business

The Board has determined that the proposed regulation will not affect small businesses, as the regulation only affects individual licensed pharmacists that elect to dispense travel medications.

Results of Economic Impact Assessment

Impact on Jobs/New Businesses:

The Board has determined that this regulatory proposal 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 having pharmacists dispense travel medications will make obtaining travel medications easier and less expensive, benefitting the health and welfare of California residents. When individuals do not need to see a physician in order to obtain travel medications, there should be a corresponding reduction on physicians' workloads.

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 travel medications without a doctor's prescription. Pharmacists have long dispensed travel medications with a doctor's prescription and the Board has not received any information about measureable environmental effects.

Business Report

The proposed regulations do not require a new report to be made. Prior to B&P section 4052(a)(10)(A)(3), Pharmacists could dispense travel medications with a doctor's prescription and those records were maintained for three (3) years. That record-keeping requirement remains unchanged, as the proposed regulation simply allows pharmacists who obtain the necessary training and follow the standards, as defined in the regulation, to dispense travel medications without a doctor's prescription.

Consideration of Alternatives

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; or would be as effective and less burdensome to affected private persons than the proposal described in this Notice, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy 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 action and has available all of the information upon which the proposal is based.

Text of Proposal

Copies of the exact language of the proposed regulation, 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 website at <http://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.

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 Board of Pharmacy's website at <http://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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