

BOARD OF PHARMACY

INITIAL STATEMENT OF REASONS

Hearing Date: No hearing is presently planned unless one is requested no later than 15 days before the close of the 45-day comment period.

Subject Matter of Proposed Regulation: Travel Medications

Section Affected: 16 CCR Section 1746.5

Specific Purpose of Adoption: Business & Professions Code (B&P) section 4052 authorizes pharmacists to furnish travel medications to the public. The Board of Pharmacy (Board) has developed and approved 16 CCR Section 1746.5 as the standards pharmacists must follow in order to furnish travel medications. The proposed regulation defines travel medications as medications not requiring a diagnosis that are recognized as self-treatable by the federal Centers for Disease Control (CDC) for individuals traveling outside the 50 states and the District of Columbia. The proposed regulation establishes both the training and continuing education requirements for a pharmacist to dispense travel medications. The proposed regulation also establishes standards a pharmacist must follow to evaluate a patient and a patient's travel plans in a pre-travel consultation; requires notification of the patient's primary care provider or requires the pharmacist to provide a written record of drugs and/or devices furnished to the patient; and requires that the pharmacy or facility maintain the documents concerning the patient medication record for three (3) years.

The problem to be addressed by this regulation is that in the past a doctor's visit was required to obtain travel medications, making obtaining travel medications costly and inconvenient. B&P section 4052(a)(10)(A)(3) authorized pharmacists to furnish travel medications without a doctor's prescription. The Board has developed 16 CCR Section 1746.5 to establish standards for pharmacists who furnish travel medications. The proposed regulation establishes the type and amount of additional education pharmacists must have to furnish travel medications. The proposed regulation establishes standards for evaluating a patient and the patient's travel plans in a pre-travel consultation; requires notification of the patient's primary care provider or requires the pharmacist to provide a written record of drugs and/or devices furnished to the patient; and requires the pharmacy or facility maintain the documents concerning the patient medication record for three (3) years.

The anticipated benefits from this regulatory action are that individuals will have greater access to travel medications and more information about travel health issues, thus benefiting public health. Pharmacists will be able to follow the standards set out in the proposed regulation and furnish travel medications to the public without a doctor's prescription. It is anticipated that this will result in more individuals obtaining travel medications and information about travel health at pharmacies, which will have both a positive impact on public health and a corresponding reduction in physicians' workloads.

Factual Basis/Rationale

This proposal seeks to add and adopt 16 CCR Section 1746.5, which establishes standards for pharmacists to furnish travel medications. In 2013, the Legislature enacted and the Governor signed Senate Bill 493 (Hernandez, Chapter 469, Statutes of 2013) which declared that pharmacists are health care providers to the public and authorized pharmacists to furnish travel medications (in B&P section 4052(a)(10)(A)(3)). The adoption of this proposed regulation is necessary to effectuate B&P section 4052(1)(10)(A)(3). The Board developed the proposed standards for furnishing travel medications and approved this proposed regulatory language on June 4, 2015.

By following the standards proposed in this regulation, pharmacists will be able to furnish travel medications without a doctor's prescription. While there are other medications individuals should take with them when they travel (daily medications for blood pressure, cholesterol, diabetes, allergies, etc.), those items are not "travel medications" as defined in this proposed regulation. As used here, "travel medications" refers to medications not requiring a diagnosis that are recognized as self-treatable by the CDC for individuals traveling outside the 50 states and the District of Columbia. Additionally, prophylactic is a commonly used term in the industry and refers to a medication or treatment used to prevent a disease from occurring.

The proposed standards require a pharmacist to complete a Board- approved travel medicine training program that consists of at least twenty (20) hours and covers each element of the International Society of Travel Medicine's (ISTM) Body of Knowledge for the Practice of Travel Medicine (2012), completion of the CDC's Yellow Fever Vaccine Course, and obtain current basic life support certification prior to furnishing travel medications pursuant to the standards. The ISTM is the largest organization of professionals dedicated to the advancement of travel medicine. In 16 CCR Section 1732.05, 1732.1, 1732.2, and 1732.3, the Board defines the approved accreditation agencies and providers. Any courses approved by those agencies or providers are considered Board-approved courses. Additionally, the Board heard testimony and consulted with experts before deciding upon the required Board-approved travel medicine training program, and that it was determined that it would take at least twenty (20) hours of training to adequately cover the material. The Board believes the CDC's Yellow Fever Vaccine Course to be an excellent training tool for educating pharmacists on conducting appropriate pre-travel consultations, teaching best practices when offering travel advice and related Yellow Fever vaccines.

The regulation also require pharmacists to obtain basic life support certification, which is a class that takes just a few hours and is provided by the Red Cross, American Heart Association, or other medical associations such as the American Medical Association. In basic life support certification, people are trained to help revive, resuscitate, or sustain a person having cardiac arrest or respiratory failure (whenever a person's heartbeat or breathing is not working properly). Provided that the basic life support certification training program has obtained accreditation from one of approved accreditation agencies or providers, the Board does not deem it necessary to specify the number of required course hours.

After completion of the initial training, pharmacists who wish to continue dispensing travel medications must complete two (2) hours of continuing education from a Board-approved provider focused on travel medicine. This additional education must be completed biennially with their pharmacist license renewal, separate from continuing education on immunizations and vaccines. The Board believes that two (2) hours of continuing education will provide a sufficient review of the material. Per 16 CCR 1732.5, pharmacists are required to complete 30 hours of continuing education every 24 months. The two (2) hours required for travel medications can be counted towards that 30 hour requirement.

Under the proposed standards, before furnishing travel medications, a pharmacist will evaluate and educate the patient during a pre-travel consultation (as discussed in the CDC Yellow Book). During the good faith evaluation, the pharmacist will fill out a patient travel history using destination-specific travel criteria so that the pharmacist can make a risk assessment. A good faith evaluation is a common term used in the industry and encompasses a sincere intention to fairly and honestly evaluate the patient. The proposed regulation also specifies that examples of an appropriate and comprehensive travel history form are available on the Board's website.

The proposed standards require a pharmacist who furnishes travel medications to notify the patient's primary care provider within 30 days of furnishing any drugs or devices. If the patient does not have a primary care provider, the pharmacist must provide a written record of drugs and/or devices furnished to the patient and advise the patient to consult with a physician of their choice per B&P 4052(a)(10)(B). Additionally, if the patient is unable to provide contact information for their primary care provider, the pharmacist must provide a written record of drugs and/or devices furnished to the patient and advise the patient to consult with a physician of their choice. This was added to ensure that patients are provided with a record should they not have their primary care providers contact information readily available. A pharmacist must also provide the patient with a progress note that fully documents the clinical assessment and travel plan. The Board determined that the 30 day reporting requirement was necessary to prevent duplicate doses being administered by a primary care provider. Additionally, some treatments may require booster injections at specific time intervals (i.e. 4-8 weeks). If the primary care provider is not notified timely, the patient may not receive the necessary booster injections. The proposed regulation states that examples of appropriate progress notes are available on the Board's website.

Specific Benefits Anticipated: 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.

Pneumococcal disease and Influenza are serious diseases that are spread through coughing, sneezing, and close contact with infected persons. Meningococcal disease is a serious bacterial illness that is contracted by close contact with an infected person. Malaria, Yellow Fever, and Japanese Encephalitis are all serious diseases which are contracted by mosquito bites. If a traveler, who is sick, returns to California and is bitten by a mosquito, the risk increases that the next California resident to be bitten by that mosquito will develop the disease. All of these serious diseases are preventable via pre-travel vaccinations. Malaria chemoprophylaxis (an oral medication taken before, during, and after travel depending on the person and the country or region of travel), may be an appropriate preventative treatment to start taking prior to traveling. In the pre-travel consultation, patients are educated about how to avoid traveler's diarrhea, altitude illness, other vector-borne diseases, environmental hazards, and will be cautioned about personal safety and sexual health and blood-borne pathogens as appropriate to their planned destinations.

When individuals obtain travel medications from a pharmacist without a doctor's prescription, the necessary but time-consuming pre-travel consultation process is done by the patient's pharmacist, not the patient's physician. It is anticipated that this will proportionately reduce physician workloads. The proposed regulation will reduce the cost and inconvenience of obtaining travel medications, increase the number of travelers undergoing pre-travel consultations and obtaining travel medications, and lighten the workload of primary care physicians. Taken together, these benefits will improve public health.

B&P section 4001.1 mandates that the protection of the public is the highest priority for the Board and that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public comes first. The proposed travel medications standards provide protection to the public by setting out the training, notification and record retention procedures required of pharmacists who wish to furnish travel medications without a doctor's prescription.

B&P section 4005 generally authorizes the board to amend rules and regulations pertaining to the practice of pharmacy.

B&P section 4052(a)(10)(A)(3) authorizes pharmacists to furnish travel medications to the public.

Underlying Data:

1. Senate Bill 493, Statutes 2013, Chapter 469
2. Relevant pages from Minutes of the Board of Pharmacy Meeting held June 3-4, 2015.
3. Relevant pages of the Minutes from Board of Pharmacy Meeting held April 21-22, 2015, and pages 7-8 (Attachment 3) of the Senate Bill 493 Implementation Committee Chair Report within the Meeting Materials.

4. Relevant pages of the Minutes and pages 5, 56-60 (Attachment 7) from the Meeting Materials for SB 493 Implementation Committee Meeting held April 13, 2015.
5. Pages 1-5 of the Minutes of the SB 493 Implementation Committee Meeting held February 25, 2015, and pages 48-60 (Attachment 8) of the Meeting Materials for the February 25, 2015 meeting.
6. Pages 21-22 from Minutes of Board of Pharmacy Meeting held January 27-28, 2015, and pages 3-5 of the Senate Bill 493 Implementation Committee Report (within the Meeting Materials there was no relevant Attachment).
7. Relevant Meeting Materials pages 179-186 (Attachment 5) and pages 9-10 of the Minutes from SB 493 Implementation Committee Meeting held December 16, 2014.
8. Relevant Meeting Materials pages 2-3 and 30-38 (Attachment 3), and pages 5-7 of the Minutes from SB 493 Implementation Committee Meeting held November 5, 2014.
9. Relevant Meeting Materials pages 3-5 and pages 18-19 of the Minutes from Board of Pharmacy Meeting held October 29-30, 2014.
10. Relevant Meeting Materials pages 2-5 and 31-41 (no relevant Attachment) and pages 6-7 of the Minutes from SB 493 Implementation Committee Meeting held August 6, 2014.
11. Relevant Meeting Materials page 4-11 and 102-123 (Attachment 3) and page 29 of the Minutes from Board of Pharmacy Meeting held July 30-31, 2014.
12. Relevant Meeting Materials pages 109-127 (Attachment 4) and pages 4-14 of the Minutes from SB 493 Implementation Committee Meeting held June 4, 2014.

Business Impact:

The Board has determined that this regulation will not have a significant adverse economic impact on businesses. Adopting this regulation simply provides pharmacists who choose to furnish travel medications without a doctor's prescription with a protocol to follow.

Economic Impact Assessment:

This regulatory proposal will have the following effects:

- It will not create or eliminate jobs in the State of California because pharmacists already dispense travel medications with a doctor's prescription; pharmacists can chose whether or not to get trained to furnish travel medications; the proposed regulation simply sets out standards pharmacists must follow to furnish travel medications.
- It will not create new businesses or eliminate existing businesses within California because pharmacists already dispense travel medications with a doctor's prescription; pharmacists can chose whether or not to get trained to furnish travel medications; the proposed regulation simply sets out standards pharmacists must follow to furnish travel medications.
- It would not affect the expansion of businesses currently operating in California because pharmacists already dispense travel medications with a doctor's prescription; pharmacists can choose whether or not to get trained to furnish

travel medications; the proposed regulation simply sets out standards pharmacists must follow to furnish travel medications.

- This regulatory proposal benefits the health and welfare of California residents because it makes it easier and less expensive to obtain travel medications, which should increase the number of travelers undergoing pre-travel consultations and being educated about travel health and safety, and thereby improving the health of Californians.
- This regulatory proposal will have no impact on worker safety because prior to SB 493, pharmacists dispensed travel medications with a doctor's prescription, and the Board has not received any comments during numerous Board and Committee meetings about impacts on worker safety.
- This regulatory proposal will have no impact on the state's environment because prior to SB 493, pharmacists dispensed travel medications with a doctor's prescription, and the Board has not received any comments during numerous Board and Committee meetings about possible environmental impacts.

Specific Technologies or Equipment

This regulation would not mandate the use of specific technologies or equipment.

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 actions are proposed, or would be as effective and less burdensome to affected private persons than the proposals described herein, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provisions of law. The Board believes taking no action to be an unacceptable alternative in the face of B&P section 4052 (a)(10)(A)(3) which authorizes pharmacists to furnish travel medications. This proposed regulation implements B&P section 4052(a)(10)(A)(3).