



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

XI. Proposed Regulations to Add Title 16 California Code of Regulations (CCR) section 1746.5, Related to Travel Medications

At the June 2015 Board Meeting, the board approved proposed text to add Section 1746.5 of Title 16 CCR, related to Travel Medications. The 45 day comment period began on September 25, 2015 and ended November 9, 2015. At the January 19, 2016 Board meeting, in response to the comments received during the 45 day comment period, the board approved a modified text and initiated a 15 day comment period, which began January 27, 2016 and ended February 11, 2016. At the March 28, 2016 Board meeting, in response to the comments received during the 15 day comment period, the board approved a modified text and initiated a second 15 day comment period, which began March 28, 2016 and ended April 12, 2016.

The Board received one comment during the comment period.

At this Meeting

The board will have the opportunity to discuss the regulation, the comment received and determine what course of action it wishes to pursue. Among its options:

1. Adopt the regulation as approved at the March 2016 Board meeting
2. Amend the regulation to address the concerns expressed by stakeholders and notice the modified text for a third 15 day comment period.

The Attachment contains the proposed regulation text as noticed on March 28, 2016 and a copy of the comment received during the second 15 day comment period.

**Travel Medications -
1746.5**

Travel Medications
Second
15-day Comment

Martinez, Lori@DCA

From: Goad, Jeffery Allen <goad@chapman.edu>
Sent: Monday, April 04, 2016 12:35 PM
To: Martinez, Lori@DCA
Subject: modification of Travel Medication Text

Hi Lori,

Some suggested changes and rationale:

(a) For purposes of Business and Professions Code section 4052(a)(10)(A)(3), prescription medications "not requiring a diagnosis" means a prescription medication that is either:

(1) For a condition that is both self-diagnosable and recognized as self-treatable by the federal Center for Disease Control and Prevention's (CDC) Health Information for International Travel (commonly called the Yellow Book), or

(2) A prophylactic for prophylaxis of a condition recognized by the CDC Health Information for International Travel

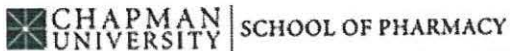
Rationale: The first option mentions specifically the CDC Yellow Book, but the 2nd does not. The CDC Yellow Book does adequately cover medications used for prophylaxis and self-diagnosis/self-treatment. Not putting parameters around "prophylactic" might indicate that medications beyond what the CDC recommends for travel related prophylaxis could be furnished.

(c) Training: A pharmacist who furnishes travel medications shall keep documentation of the following on site and available for inspection by the Board:

(1) Completion of an immunization certification certificate program that meets the requirements of Business and Professions Code section 4052.8(b)(1),

(±2) Completion of an approved travel medicine training program, which must consist of at least 10 ±0 hours of training and cover each medication and vaccination related element of the International Society of Travel Medicine's Body of Knowledge for the Practice of Travel Medicine (2012),

Rationale: This section requires that the pharmacist have taken an immunization training program. A traditional immunization certificate program that meets the requirements of this section does NOT include all travel related vaccines. The ISTM Body of Knowledge does include all vaccines that are travel related. Thus, since this section already mentions immunization training, adding "vaccination" related elements to the training requirement is imperative.



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Travel Medications - Modified Text

BOARD OF PHARMACY

Second Modified Text

Changes made to the originally proposed language are shown by ~~single strikethrough~~ for deleted language and single underline for added language. (Additionally, the modified text is listed in red for color printers.)

Changes made to the modified proposed language are shown by ~~double strikethrough~~ for deleted language and bold and double underline for added language. (Additionally, the modified text is listed in blue for color printers.)

Add §1746.5 to Article 5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§1746.5 Pharmacists Furnishing Travel Medications.

(a) For purposes of Business and Professions Code section 4052(a)(10)(A)(3), prescription medications “not requiring a diagnosis” means a prescription medication that is either:

(1) For a condition that is both self-diagnosable and recognized as self-treatable by the federal Center for Disease Control and Prevention’s (CDC) Health Information for International Travel (commonly called the Yellow Book), or

(2) A prophylactic.

(b) A pharmacist furnishing prescription medications not requiring a diagnosis that are recommended by the CDC for individuals traveling outside the 50 states and the District of Columbia pursuant to section 4052(a)(10) of the Business and Professions Code shall follow the requirements of this section.

(c) Training: A pharmacist who furnishes travel medications shall keep documentation of the following on site and available for inspection by the Board:

(1) Completion of an immunization ~~certification~~ certificate program that meets the requirements of Business and Professions Code section 4052.8(b)(1),

~~(12)~~ Completion of an approved travel medicine training program, which must consist of at least 10 ~~20~~ hours of training and cover each medication related element of the International Society of Travel Medicine’s Body of Knowledge for the Practice of Travel Medicine (2012),

~~(23)~~ Completion of the CDC Yellow Fever Vaccine Course, and

~~(34)~~ Current basic life support certification.

(d) Continuing Education: Pharmacists must complete two hours of ongoing continuing education focused on travel medicine, separate from continuing education in immunizations and vaccines, from an approved provider once every two years.

(e) Prior to furnishing travel medication, a pharmacist shall perform a good faith evaluation of the patient, including evaluation of a patient travel history using destination-specific travel criteria. The travel history must include all the information necessary for a risk assessment during pre-travel consultation, as identified in the CDC Yellow Book. An example of an appropriate and comprehensive travel history is available on the Board's website.

(f) Notifications: The pharmacist shall notify the patient's primary care provider of any drugs and/or devices furnished to the patient within 30 days of the date of ~~dispense~~furnishing, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with written record of the drugs and/or devices furnished and advise the patient to consult a physician of the patient's choice.

(g) Documentation: For each travel medication furnished by a pharmacist, a patient medication record shall be maintained and securely stored in physical or electronic manner such that the information required by title 42, section 300aa-25 of the United States Code and 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. A pharmacist shall provide the patient with a progress note, which fully documents the clinical assessment and travel medication plan. An example of an appropriate and comprehensive progress note is available on the Board's website.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4052 and 4052.8, Business and Professions Code.