California State Board of Pharmacy
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STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
PUBLIC BOARD MEETING
MINUTES

DATE: March 28, 2016

LOCATION:

Staff Location
Department of Consumer Affairs
1625 North Market Blvd., First Floor Hearing Room
Sacramento, CA 95834

Additional Teleconference Locations
313 N. Figueroa, Room 607
Los Angeles, CA 90012

Redlands Community Hospital
350 Terracina
Redlands, Ca 92373

1418 S. San Gabriel Blvd., Suite A
San Gabriel, CA 91776

1695 Eastshore Highway
Berkeley, CA 94710

Renaissance Providence Downtown Hotel
5 Ave. of the Arts
Providence, RI 02903

1215 Avila Beach Drive
San Luis Obispo, CA 93405

388 9th Street, #108
Oakland, CA 94607

25949 Belle Porte Ave.
Harbor City, CA 90710

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Laura Freedman, DCA Staff Counsel
Lori Martinez, Staff Manager
Laura Hendricks, Staff Analyst

BOARD MEMBERS PRESENT:	Amy Gutierrez, PharmD, President Deborah Veale, RPh, Vice President Victor Law, RPh, Treasurer Gregory Lippe, Public Member Stanley Weisser, RPh Ryan Brooks, Public Member Albert Wong, PharmD Allen Schaad, RPh Lavanza Butler, RPh
BOARD MEMBERS NOT PRESENT:	Ramon Castellblanch, Public Member Gregory Murphy, Public Member Ricardo Sanchez, Public Member

Monday, March 28, 2016

Call to Order 1:03 p.m.

I. Call to Order, Establishment of Quorum and General Announcements

President Gutierrez called the meeting to order at 1:03 p.m. Board members present: Amy Gutierrez, Debbie Veale, Gregory Lippe, Victor Law, Ryan Brooks, Albert Wong, Stanley Weisser, Allen Schaad and Lavanza Butler.

Laura Freedman, staff counsel, asked if there were any members of the public at the teleconference locations. Members of the board confirmed there were no members of the public in attendance at the any of the teleconference locations.

Note: This meeting was not webcast.

II. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings.

President Gutierrez asked if there were any comments from any of the meeting locations. There were no comments from board members or the public at any of the meeting locations.

III. Proposed Regulation to Add Title 16 California Code of Regulations section 1746.1, Related to Self-Administered Hormonal Contraception

Virginia Herold explained that the Office of Administrative Law (OAL) required the board to update the Initial Statement of Reasons, which is one of the required rulemaking documents needed to create or modify a regulation. The board then issued a 15-day notice comment period which closed March 24 to add this information.

Ms. Herold reported that the board had received only one comment during the 15-day

comment period. A copy of the comment is provided immediately following these minutes.

The board elected not to modify the regulation language based on the comment.

Motion: Approve the language as provided in the board meeting materials (do not modify based on the comment received during the comment period).

Note: A copy of the language is provided following these minutes.

M/S: Weisser/Lippe

Support: 9 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	x			
Butler	x			
Castellblanch				x
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

IV. Proposed Regulation to Add Title 16 California Code of Regulations section 1746.5 Related to Travel Medications

Laura Freedman reported that at the February 2016 Board meeting, the board reviewed the comment that was submitted by Dr. Jeff Goad during the comment period. Ms. Freedman explained that the board did not modify the language in response to his comment, and adopted the language as noticed.

Ms. Freedman stated that upon further consideration staff is recommending that the board reconsider the comment submitted by Dr. Goad. She explained that staff is recommending modifying the language as suggested by Dr. Goad in his comment. The recommended modified language is provided below.

(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),

Note: Dr. Goad's comment is provided following these minutes.

The board agreed that the language should be modified to use the term "certificate

program" as suggested by Dr. Goad.

Motion: Modify the language as provided below and initiate a 15-day comment period.

(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),

M/S: Weisser/Veale

Support: 9 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	x			
Butler	x			
Castellblanch				x
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

Motion: For both the hormonal contraception and travel medicine regulations - Delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Office of Administrative Law or the Department of Consumer Affairs to complete the rulemaking files.

M/S: Lippe/Weisser

Support: 9 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	x			
Butler	x			
Castellblanch				x
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

The board asked when the hormonal contraception regulation would be approved and implemented. Ms. Herold explained that staff would submit the rulemaking file for final review by Friday. She added that the Office of Administrative Law has six weeks to review and approve the file.

Ms. Freedman noted that the Office of Administrative Law is aware that this regulation is very important to the board and has been asked to expedite their review.

President Gutierrez stated that she would intervene to help expedite the approval if necessary.

President Gutierrez adjourned the meeting at 1:16 p.m.

Self-Administered Hormonal Contraception

15-day Comment

Martinez, Lori@DCA

From: starship1980s@aol.com
Sent: Wednesday, March 09, 2016 5:01 PM
To: Martinez, Lori@DCA
Subject: Title 16 CCR § 1746.1, related to Self-Administered Hormonal Contraceptio

Pharmacists should not be allowed to administer or prescribe self administered hormonal contraceptives

Self-Administered Hormonal Contraception

Adopted Text

BOARD OF PHARMACY
Department of Consumer Affairs

ORDER OF ADOPTION

Adopt §1746.1 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1746.1 Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraception.

(a) A pharmacist furnishing self-administered hormonal contraception pursuant to Section 4052.3 of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraception

(1) Authority: Section 4052.3(a)(1) of the California Business and Professions Code authorizes a pharmacist to furnish self-administered hormonal contraceptives in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol in this section satisfies that requirement.

(2) Purpose: To provide timely access to self-administered hormonal contraception medication and to ensure that the patient receives adequate information to successfully comply with therapy.

(3) Definition of Self-Administered Hormonal Contraception: Hormonal contraception products with the following routes of administration are considered self-administered:

(A) Oral;
(B) Transdermal;
(C) Vaginal;
(D) Depot Injection.

(4) Procedure: When a patient requests self-administered hormonal contraception, the pharmacist shall complete the following steps:

(A) Ask the patient to use and complete the self-screening tool;
(B) Review the self-screening answers and clarify responses if needed;
(C) Measure and record the patient's seated blood pressure if combined hormonal contraceptives are requested or recommended;
(D) Before furnishing self-administered hormonal contraception, the pharmacist shall ensure that the patient is appropriately trained in

administration of the requested or recommended contraceptive medication.

(E) When a self-administered hormonal contraceptive is furnished, the patient shall be provided with appropriate counseling and information on the product furnished, including:

(1) Dosage;
(2) Effectiveness;
(3) Potential side effects;
(4) Safety;
(5) The importance of receiving recommended preventative health screenings;
(6) That self-administered hormonal contraception does not protect against sexually transmitted infections (STIs).

(5) Self-Screening Tool: The pharmacist shall provide the patient with a self-screening tool containing the list of questions specified in this protocol. The patient shall complete the self-screening tool, and the pharmacist shall use the answers to screen for all Category 3 and 4 conditions and characteristics for self-administered hormonal contraception from the current United States Medical Eligibility Criteria for Contraceptive Use (USMEC) developed by the federal Centers for Disease Control and Prevention (CDC). The patient shall complete the self-screening tool annually, or whenever the patient indicates a major health change.

A copy of the most recently completed self-screening tool shall be securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense.

This self-screening tool should be made available in alternate languages for patients whose primary language is not English.

Fact Sheets:

(A) The pharmacist should provide the patient with a copy of a current, consumer-friendly, comprehensive birth control guide such as that created by the FDA. Examples of appropriate guides are available on the Board of Pharmacy's website.

(B) The pharmacist shall provide the patient with the FDA-required patient product information leaflet included in all self-administered hormonal contraception products, as required by the Business and Professions Code Section 4052.3(c). The pharmacist shall answer any questions the patient may have regarding self-administered hormonal contraception.

(C) The pharmacist should provide the patient with a copy of an administration-specific factsheet. Examples of appropriate factsheets are available on the Board of Pharmacy's website.

(7) Follow-Up Care: Upon furnishing a self-administered hormonal contraceptive, or if it is determined that use of a self-administered hormonal contraceptive is not recommended, the pharmacist shall refer the patient for appropriate follow-up care to the patient's primary care provider or, if the patient does not have a primary care provider, to nearby clinics. A patient who is determined not to be an appropriate candidate for self-administered hormonal contraception shall be advised of the potential risk and referred to an appropriate health care provider for further evaluation.

(8) Notifications: The pharmacist shall notify the patient's primary care provider of any drug(s) or device(s) furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that 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 a written record of the drug(s) or device(s) furnished and advise the patient to consult an appropriate health care professional of the patient's choice.

(9) Referrals and Supplies: If self-administered hormonal contraception services are not immediately available or the pharmacist declines to furnish pursuant to a conscience clause, the pharmacist shall refer the patient to another appropriate health care provider.

The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.

(10) Product Selection: The pharmacist, in consultation with the patient, may select any hormonal contraceptive listed in the current version of the USMEC for individuals identified as Category 1 or 2, based on the information reported in the self-screening tool and the blood pressure (if recorded by the pharmacist). The USMEC shall be kept current and maintained in the pharmacy or health care facility, and shall be available on the Board of Pharmacy's website.

Generic equivalent products may be furnished.

(11) Documentation: Each self-administered hormonal contraceptive furnished by a pharmacist pursuant to this protocol shall be documented in a patient medication record and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense. A patient medication record shall be maintained in an automated data processing or manual record mode

such that the required information under title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours.

(12) Training: Prior to furnishing self-administered hormonal contraception, pharmacists who participate in this protocol must have completed a minimum of one hour of a board-approved continuing education program specific to self-administered hormonal contraception, application of the USMEC, and other CDC guidance on contraception. An equivalent, curriculum-based training program completed on or after the year 2014 in an accredited California school of pharmacy is also sufficient training to participate in this protocol.

(13) Patient Privacy: All pharmacists furnishing self-administered hormonal contraception in a pharmacy or health care facility shall operate under the pharmacy or facility's policies and procedures to ensure that patient confidentiality and privacy are maintained.

(14) Self-Screening Tool Questions

HORMONAL CONTRACEPTION SELF-SCREENING TOOL QUESTIONS

1	What was the first date of your last menstrual period?	/ /	
2a	Have you ever taken birth control pills, or used a birth control patch, ring, or shot/injection? (If no, go to question 3)	Yes ☐	No ☐
2b	Did you ever experience a bad reaction to using hormonal birth control?	Yes ☐	No ☐
2c	Are you currently using birth control pills, or a birth control patch, ring, or shot/injection?	Yes ☐	No ☐
3	Have you ever been told by a medical professional not to take hormones?	Yes ☐	No ☐
4	Do you smoke cigarettes?	Yes ☐	No ☐
5	Do you think you might be pregnant now?	Yes ☐	No ☐
6	Have you given birth within the past 6 weeks?	Yes ☐	No ☐
7	Are you currently breastfeeding an infant who is less than 1 month of age?	Yes ☐	No ☐
8	Do you have diabetes?	Yes ☐	No ☐
9	Do you get migraine headaches, or headaches so bad that you feel sick to your stomach, you lose the ability to see, it makes it hard to be in light, or it involves numbness?	Yes ☐	No ☐
10	Do you have high blood pressure, hypertension, or high cholesterol?	Yes ☐	No ☐
11	Have you ever had a heart attack or stroke, or been told you had any heart disease?	Yes ☐	No ☐
12	Have you ever had a blood clot in your leg or in your lung?	Yes ☐	No ☐
13	Have you ever been told by a medical professional that you are at a high risk of developing a blood clot in your leg or in your lung?	Yes ☐	No ☐
14	Have you had bariatric surgery or stomach reduction surgery?	Yes ☐	No ☐

15	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	Yes ☐	No ☐
16	Do you have or have you ever had breast cancer?	Yes ☐	No ☐
17	Do you have or have you ever had hepatitis, liver disease, liver cancer, or gall bladder disease, or do you have jaundice (yellow skin or eyes)?	Yes ☐	No ☐
18	Do you have lupus, rheumatoid arthritis, or any blood disorders?	Yes ☐	No ☐
19a	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?	Yes ☐	No ☐
19b	If yes, list them here:		
20a	Do you have any other medical problems or take regular medication?	Yes ☐	No ☐
20b	If yes, list them here:		

Authority: Sections 4005 and 4052.3, Business and Professions Code.
Reference: Sections 4052, 4052.3, and 4103, Business & Professions Code.

Travel Medications - 15-Day Comments Comment Period Closed February 11, 2016

Martinez, Lori@DCA

From: Goad, Jeffery Allen <goad@chapman.edu>
Sent: Wednesday, January 27, 2016 5:30 PM
To: Martinez, Lori@DCA
Subject: Travel Med comment
Attachments: Modified Text Travel Meds.pdf - Adobe Acrobat Pro.pdf

Hi Lori,
Attached are some minor modifications. I made them directly on the draft, but they are also listed below:

(c)(1) "...an immunization certificate program..." – there are no certification programs for immunization, just certificate

(c)(2) "...of training and cover at least each medication related" – programs that only train on medications are not adequate.

Thanks!
Jeff

CHAPMAN UNIVERSITY | SCHOOL OF PHARMACY
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Travel Medications

Staff Recommended 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),

(~~1~~2) 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),

(~~2~~3) Completion of the CDC Yellow Fever Vaccine Course, and

(~~3~~4) 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.