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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

SENATE BILL 493 IMPLEMENTATION COMMITTEE CHAIR REPORT

Stan Weisser, RPh, Board President and Committee Chair
Amy Gutierrez, Pharm D
Debbie Veale, RPh
Victor Law, RPh

Action items and report of the meetings held February 25 and April 13, 2015.

Background:
SB 493 creates a number of new opportunities for pharmacists to provide direct care to patients. There are essentially two levels of additional services authorized – one for all pharmacists, the second to create a new licensure category of advanced practice pharmacist to provide additional duties.

The board has formed this committee to implement the multiple requirements of SB 493. This committee, called simply the Senate Bill 493 Implementation Committee, will work on components to implement the multiple provisions of this bill. The meetings where these deliberations will occur are public, and will be listed on the board's website. We invite interested individuals to attend. The recent enactment of AB 1535 (Bloom) has directed the board to develop a naloxone protocol through an emergency rulemaking process. For expediency, this task has been added to the agenda of this committee.

Copies of the minutes from the February 25 and April 13, 2015, SB 493 Implementation Committee Meetings are provided in **Attachment 4.**

a. <u>Regulations Detailing Licensure Requirements for Advanced Practice Pharmacists</u>

At the January 2015 board meeting, the board approved and moved to initiate a regulation rulemaking on proposed text that specifies the ways and supporting documentation needed to qualify for registration as an advance practice pharmacist. Additionally a fee of $300 was selected as the application and renewal fee for this license.

At the February 2015 committee meeting, the committee made several modifications in the text. At the April meeting, the committee again discussed and made several modifications to the proposed requirements. The board will vote on these proposed changes during this board meeting.

The committee is recommending that the board release the finalized text as it appears

below, and then direct staff to initiate a rulemaking and release the text for the 45 day comment period.

A formal motion needs to be made by the board.

Article 3.5
Advanced Practice Pharmacist

1730 Acceptable Certification Programs

The board recognizes the pharmacy patient care certification programs that are certified by the National Commission for Certification Agencies (NCCA) for purposes of satisfying the requirements in Business and Professions Code section 4210(a)(2)(A).

1730.1 Documentation Requirements for Advanced Practice Pharmacist Licensure

(a) Documentation of possession of a **current** certification as specified in California Business and Professions Code section 4210(a)(2)(A) shall be via:
(1) A ~~notarized~~ copy of the certification award that includes the name of the applicant pharmacist, the area of specialty and date of completion, or
(2) A letter from the certification program attesting the award of the certification that includes the name of the applicant pharmacist, the area of specialty and the date of completion.

(b) Documentation of completion of a postgraduate residency earned **in the United States** through an accredited postgraduate institution as specified in California Business and Professions Code section 4210(a)(2)(B) shall be via either:
(1) A ~~notarized~~ copy of the residency certificate awarded by the postgraduate institution that includes the name of the applicant pharmacist, the area of specialty, and dates of participation and completion, or
(2) A letter of completion of a postgraduate residency signed by the dean or residency program director of the postgraduate institution and sent directly to the board from the postgraduate institution that lists the name of the applicant pharmacist, the dates of participation and completion, and areas of specialty.

(c) ~~**Documentation of**~~ **E**xperience earned under a collaborative practice agreement or protocol **must have been earned within 10 years of the time of application for APP licensure. Additionally, the one year of experience must be comprised of**
~~**for at least one year with**~~ no fewer than 1,500 hours **earned over a period of no longer than four years.** ~~**as specified in California Business and Professions Code section 4210(a)(2)(C) shall be via**~~ **The documentation of this experience that shall be provided to the board shall include both**:
~~(1) A copy of an agreement or protocol under which the applicant pharmacist has provided clinical services to patients, and~~
~~(2)~~(1)~~A letter~~ ~~**An**~~**An attestation from the applicant pharmacist attesting under penalty of perjury that he or she has earned this experience, and:.**

(2) An attestation or letter from the supervising practitioner, program director or health facility administrator attesting under penalty of perjury that the applicant pharmacist has completed at least one year of ~~the~~ experience providing clinical services to patients.

Proposed Amendments to section 1749 (board fees)

(f)**(1)** The fee for the issuance of an original pharmacist license is one hundred fifty dollars ($150).

(2) The fee for application of an advanced practice pharmacist license is three hundred dollars ($300*). If granted, there is no fee for the initial license issued, which will expire at the same time the pharmacist's license expires.*

(g)**(1)** The fee for the biennial renewal of a pharmacist's license is one hundred fifty dollars ($150). The penalty fee for failure to renew is seventy-five dollars ($75).

(2) The fee for the biennial renewal of an advanced practice pharmacist license is three hundred dollars ($300). The penalty fee for failure to renew is one hundred fifty dollars ($150). *The fees in this paragraph are in addition to the fees required to renew the pharmacist's license as specified in paragraph 1.*

b. Regulations to Implement the Protocol for Pharmacists Who Furnish Naloxone

Attachment 1

On April 10, the board's naloxone protocol became effective under emergency provisions that will last 180 days. The board used a subscriber email alert to advise pharmacists and others that pharmacists who possess the one hour of training could provide naloxone to anyone requesting it. A fact sheet was also released that provides patient information about naloxone. These items are also highlighted on the board's web page.

The board now has slightly fewer than 180 days to notice and promulgate a naloxone protocol regulation to replace the emergency adoption version of the protocol. The Medical Board will also need to approve the protocol as well. This is planned for review by the Medical Board on May 8 in Los Angeles, at a hotel near LAX.

During the April SB 493 Implementation Committee's meeting, the committee discussed several modifications to the emergency protocol. The committee clarified that these changes would not affect the emergency rulemaking protocol that has already been filed.

Board researcher Liz McCaman suggested that the board should clarify that the training programs must provide training on *all* routes of administration. The committee was advised that there are some companies that are providing training programs that only promote their products. The committee stated that this type of training would not be sufficient as it does not cover all routes of administration.

Additionally, Ms. Herold noted that the labeling provisions in the emergency protocol involve only directions for use that would be placed on a kit of two doses. When board staff attempted to develop single use labels using common labeling software that is use in California pharmacies referencing the directions in the protocol, it was difficult. Staff expressed concern that standard directions for use regarding "kits" did not translate well onto the labels. Ms. Herold stated she would work on this and bring a solution to the board meeting.

During the meeting, Ms. Freedman stated that she had reformatted the protocol without changing the already approved components. The reformatted protocol was provided to the committee members and is provided in **Attachment 1**.

Discussion during the April committee meeting resulted in proposed amendments to the protocol in addition to the rearrangement of provisions. These are indicated in the proposed new protocol by underscore or strike out.

Ms. Freedman recommended amending subdivsion(c)(4) of the emergency regulation so that the protocol would require the pharmacist to provide advice to the patient on how to choose the formulation which is appropriate for him or her. As the protocol would have to be re-approved by the Medical Board as part of the regular rulemaking process, the committee decided to amend subsection (4) as indicated in the new protocol.

The committee elected to remove references to kits as the product may not always be dispensed as part of a kit.

Ms. Herold suggested that the committee should determine whose name should be on the label, the patient or the recipient.

The committee discussed how best to label the product so that someone could purchase naloxone to use on someone else in an emergency situation; for example, a teacher or law enforcement officer may purchase naloxone to have it ready if an emergency situation arose.

One suggestion was to label the product for Jane or John Doe. President Weisser noted that labeling the product for Jane or John Doe would only work if the person was paying cash and not looking to be reimbursed by insurance. Throughout the protocol, the term "recipient" is used, and is defined as "means the person to whom naloxone hydrochloride is furnished."

Robert Stein, from KGI School of Pharmacy, stated that he would be concerned with creating an electronic medical record for someone who is not the patient. Rebecca Cupp, from Ralph's Pharmacy, clarified that if the pharmacist created a patient profile for John

Doe there would be hundreds of patients under that fictitious profile. The committee agreed that this would be acceptable.

Dr. Cupp asked how a pharmacy would handle a recall of naloxone as the fictitious patient profile would not have patient contact information. Ms. Herold stated that the board would not expect the pharmacy to contact recipients that received the naloxone under the fictitious name John Doe.

The committee packet also contained a factsheet on naloxone. Ms. McCaman discussed the requirement for pharmacists to provide translated fact sheets and screening questionnaires. The committee expressed concern that a pharmacist may not dispense the naloxone if he or she did not have a translated fact sheet available or screening questionnaire available.

The committee asked Ms. Freedman to draft the language to say that the pharmacist shall provide the translated information that is provided on the board's website.

> **Motion: SB 493 Implementation Committee:** Direct board staff to use the newly revised protocol [**Attachment 1**], amend it based on the committee discussion and bring it to the April board meeting for approval.

Lisa Kroon noted that there was no time requirement for the naloxone training (example taking the training within the last two years). The committee discussed if they wanted to require the training to be completed recently. The committee decided not to place a time limit on the training as they felt it would create a barrier for a pharmacist who wanted to provide naloxone to a patient in need.

c. <u>Review and Discussion About the Factsheet on Naloxone</u>

The committee packet also contained a factsheet on naloxone. Ms. McCaman discussed the requirement for pharmacists to provide translated fact sheets and screening questionnaires. The committee expressed concern that a pharmacist may not dispense the naloxone if he or she did not have a translated fact sheet available or screening questionnaire available.

The committee asked Ms. Freedman to draft in the language a statement that the pharmacist shall provide the translated information <u>specified in new section that</u> is provided on the board's website.

d. <u>Discussion and Identification of Materials Where Board Guidance is Envisioned:</u>

1. Discussion and Development of Proposed Requirements for Pharmacists who Initiate and Administer Immunizations Pursuant to Recommended Immunizations Schedules by the Federal Advisory Committee of Immunization Practices

Attachment 2

Under Business and Professions Code section 4052.8, immunizations may be provided by pharmacists who possess the required training to provide immunizations. Specifically, to initiate immunizations, a pharmacist must:

- complete an immunization training program endorsed by the CDC,
- be certified in basic life support,
- comply with all state and federal recordkeeping requirements,
- provide information to the patient's primary care physician and into the appropriate immunization registry designated by the immunization branch of the CDPH.

During the February and April committee meetings, the committee discussed certain issues involving immunizations. Based on the discussions during the February meeting, staff drafted language to establish parameters for those pharmacists who provide immunizations. This language is provided in **Attachment 2.**

During the April meeting, the committee made various recommendations to a proposed regulation to specify parameters for pharmacists who provide immunizations.

One requirement is to mandate required reporting into an immunization registry. The committee discussed if they wanted to require pharmacists to report to the state and/or local immunization information system. Dr. Gutierrez stated that reporting the information is important to public health.

Ms. Veale asked if the patient can opt out of having his or her vaccination information placed in the state database. Ms. McCaman explained that for public health reasons, the information is required to be reported to the database; however, the patient can choose not to allow his or her information to be shared with other entities (such as schools).

It was noted that physicians are not required to enter immunization information into the database.

The committee discussed how long the pharmacy should be required to keep the immunization records. Dr. Goad explained that federal law requires the information to be maintained for the life of the patient and recommended that pharmacist follow this standard. President Weisser expressed his concern that requiring a pharmacy to archive the records indefinitely would discourage independent pharmacies from

providing vaccines. The committee decided to leave section (f) unchanged pharmacists as must comply with the federal requirements referenced in the section.

During the April meeting, the committee discussed the training requirements for immunization training as listed in proposed section (b). The committee elected to remove "current" from section (b)(1) as they did not feel that a pharmacist needed to complete intensive immunization training every three years. The committee also decided to remove "current" from section (b)(2) as it was unnecessary.

The committee made no changes to section (c).

Ms. Herold recommended removing the references to 1717 and 1707.1 in section (f). The committee agreed.

Dr. Goad stated that he felt the requirement in section (e) to report to the registry within 15-days is too short of a timeframe for independent pharmacies. The committee decided to change section (e) to require reporting to the registry at least every three months.

2. Development of Proposed Requirements for Pharmacists to Provide Prescription Medications Not Requiring a Diagnosis that Are Recommended by the CDC for Travel Outside the US

Attachment 3

At both the February and April meetings, the committee discussed the parameters for travel medications. The committee has indicated it may wish to establish regulations for some of the travel medication components.

At the April committee meeting, the committee reviewed a draft regulation establishing requirements tor items the committee has discussed in the past. This draft is in **Attachment 3**.

The committee discussed the training requirements for pharmacists who will administer the yellow fever vaccine. The committee determined that it was appropriate for pharmacists practicing travel medicine to take the yellow fever training, even if they will not be administering the vaccine themselves.

Ms. McCaman stated she would bring to the April Board meeting a reformatted regulation proposal that is similar to the regulation style Ms. Freedman used.

3. Requirements for Pharmacists for Ordering and Interpreting Tests to Manage and Monitor Drug Therapies

At the February committee meeting, the committee discussed and determined it did not wish to develop regulation requirements or guidance at this time regarding ordering and interpreting tests.

Minutes for the February 25 and April 13 meetings are provided in **Attachment 4.**

Attachment 1

Title 16. Board of Pharmacy. Adopt §1746.3, as follows:

§1746.3 Protocol for Pharmacists Furnishing Naloxone Hydrochloride

A pharmacist furnishing naloxone hydrochloride pursuant to Section 4052.01 of the Business and Professions Code shall satisfy the requirements of this section.

(a) As used in this section:

(1) ~~"Kit" means _____ and may include optional items, including alcohol pads, rescue breathing masks, and rubber gloves.~~

~~(2)~~ "Opioid" means naturally derived opiates as well as synthetic and semi-synthetic opioids.

(~~3~~ 2) "Recipient" means the person to whom naloxone hydrochloride is furnished.

(b) Training. Prior to furnishing naloxone hydrochloride, pharmacists who use this protocol must have successfully completed a minimum of one hour of an approved continuing education program specific to the use of naloxone hydrochloride, or an equivalent curriculum-based training program completed in a board recognized school of pharmacy.

(c) Protocol for Pharmacists Furnishing Naloxone Hydrochloride.

Before providing naloxone hydrochloride, the pharmacist shall:

(1) Screen the potential recipient by asking the following questions:

(i) Whether the potential recipient currently uses or has a history of using illicit or prescription opioids? (If the recipient answers yes, the pharmacist may skip screening question ii.);

(ii) Whether the potential recipient is in contact with anyone who uses or has a history of using illicit or prescription opioids. If the recipient answers yes, the pharmacist may continue.

(iii) Whether the person to whom the naloxone hydrochloride would be administered has a known hypersensitivity to naloxone. If the recipient answers yes, the pharmacist may not provide the naloxone. If the recipient responds no, the pharmacist may continue.

The screening questions shall be made available by the board on its website in alternate languages for recipients and patients whose primary language is not English.

(2) Provide the recipient training in opioid overdose prevention, recognition, response, and administration of the antidote naloxone.

(3) When naloxone hydrochloride is furnished:

(i) The pharmacist shall provide the recipient with appropriate counseling and information on the product furnished, including dosing, effectiveness, adverse effects, storage conditions, shelf-life, and safety. The recipient is not permitted to waive the required consultation.

(ii) The pharmacist shall provide the recipient with any informational resources on hand and/or referrals to appropriate resources if the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time.

(iii) The pharmacist shall answer any questions the recipient may have regarding naloxone hydrochloride.

(4) Product Selection: The pharmacist may supply naloxone hydrochloride as an intramuscular injection, intranasal spray, auto-injector, or as another FDA approved products. A pharmacist shall provide advice to ~~advise~~ the recipient to how to choose the ~~kit and~~ route of administration of naloxone based on the formulation available, how well it can likely be administered, the setting, and local context.

(5) ~~Kit~~ Product Labeling: A pharmacist shall label ~~the kit~~ each container consistent with law and regulations. Labels shall include an expiration date for the naloxone hydrochloride furnished. An example of appropriate labeling is available on the Board of Pharmacy's website.

(6) Fact Sheet: The pharmacist shall provide the recipient with a copy of the current naloxone fact sheet approved by the Board of Pharmacy. This fact sheet shall be made available in alternate languages for patients whose primary language is not English and made available on the board's website.

(7) Notifications: If the recipient of the naloxone hydrochloride is also the person to whom the naloxone hydrochloride would be administered, then the naloxone recipient is considered a patient for purposes of this protocol and notification may be required under this section.

If the patient gives verbal or written consent, then the pharmacist shall notify the patient's primary care provider of any drug(s) and/or device(s) furnished, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the patient and that primary care provider.

If the patient does not have a primary care provider, or chooses not to give notification consent, then the pharmacist shall provide a written record of the drug(s) and/or device(s) furnished and advise the patient to consult an appropriate health care provider of the patient's choice.

(8) Documentation: Each naloxone hydrochloride product furnished by a pharmacist pursuant to this protocol shall be documented in a medication record

for the naloxone recipient, and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispensing. The 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.

(9) Privacy: All pharmacists furnishing naloxone hydrochloride in a pharmacy or health care facility shall operate under the pharmacy or facility's policies and procedures to ensure that recipient confidentiality and privacy are maintained.

Authority and Reference: Section 4052.01, Business and Professions Code.

<u>For the Board of Pharmacy's website: (not formally part or regulation any longer)</u>

Naloxone
Suggested Kit Labeling (by route of administration):

Intramuscular	Intranasal	Auto-Injector
Naloxone 0.4mg/1ml single dose vial, # 2 vials SIG: Inject 1 ml intramuscularly upon signs of opioid overdose. Call 911. May repeat x 1. Syringe 3ml 25G X 1" # 2 SIG: Use as directed for naloxone administration. Kit should contain 2 vials and 2 syringes.	Naloxone needleless prefilled syringe (1mg/1ml concentration) 2ml, # 2 syringes SIG: Spray one-half (1ml) of the naloxone into each nostril upon signs of opioid overdose. Call 911. May repeat x 1. Mucosal Atomization Device (MAD) # 2 SIG: Use as directed for naloxone administration. Kit should contain 2 prefilled needleless syringes and 2 atomizers.	Naloxone 0.4 mg/0.4 ml #1 twin pack SIG: Use one auto-injector upon signs of opioid overdose. Call 911. May repeat x 1. Kit is commercially available as a twin pack with directions for administration included.

Attachment 2

Title 16. Board of Pharmacy. Adopt §1746.X, which is new regulation text, as follows:

§1746.X Pharmacists Initiating and Administering Vaccines

(a) A pharmacist initiating and/or administering vaccines pursuant to Section 4052.8 of the Business and Professions Code shall follow the requirements specified in subdivisions (b) through (f) of this section.

(b) Training: A pharmacist who initiates and/or administers any vaccine shall keep documentation of:

(1) ~~Current c~~ Completion of an approved immunization training program;

(2) ~~Current b~~ Basic life support certification.

This documentation shall be kept on site and available for inspection.

(c) Continuing Education: A pharmacists must complete one hour of ongoing continuing education focused on immunizations and vaccines from an approved provider once every two years.

(d) Notifications: The pharmacist shall notify the patient's primary care provider of any vaccines administered to the patient, 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 a vaccine administration record and advise the patient to consult an appropriate health care provider of the patient's choice.

(e) Immunization Registry: A pharmacist shall fully report the information described in Section 120440(c) of the Health and Safety Code into one or more state and/or local immunization information systems within ~~15~~ 90 days of the administration of any vaccine. The pharmacist shall inform the patient or the patient's guardian of immunization record sharing preferences, as detailed in Section 120440(e) of the Health and Safety Code.

(f) Documentation: For each vaccine administered by a pharmacist, a patient medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 42, section 300aa-25 of the United States Code~~, and 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.

Authority and Reference: Sections 4052(a)(11), 4052.8, Business and Professions Code.

Attachment 3

Title 16. Board of Pharmacy. Adopt §1746.X, which is new regulation text, as follows:

§1746.X Pharmacists Furnishing Travel Medications

(a) For purposes of section 4052(a)(10)(A)(3), "not requiring a diagnosis" means either
(1) a self-diagnosable and self-treatable condition under the federal Centers 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 specified in subdivisions (c) through (f) of this section.

(c) Training: A pharmacist who initiates and/or administers any vaccine shall keep documentation of:
(1) Current completion of an approved immunization training program, which must consist of at least 30 hours and cover the International Society of Travel Medicine's body of knowledge;
(2) Completion of the CDC Yellow Fever Vaccine Course;
(3) Current basic life support certification.
This documentation shall be kept on site and available for inspection.

(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 examination, though not necessary a physical examination, of the patient, including evaluation of a patient travel history form using a destination-specific travel database. The travel history form 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 form is available on the Board of Pharmacy's website.

(f) Notifications: The pharmacist shall notify the patient's primary care provider of any drugs and/or devices furnished to the patient, 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 an automated data processing or manual record mode such that the required information under title 42, section 300aa-25 of the United States Code, and 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.

A pharmacist shall provide the patient with a progress note, which fully documents the clinical assessment and travel plan. An example of an appropriate and comprehensive progress note is available on the Board of Pharmacy's website.

Authority and Reference: Sections 4052(a)(10)(A)(3), 4052(a)(10)(B), Business and Professions Code.

Date:_____

Travel History Form

Name:_____ DOB:_____ Sex (circle): M F

Telephone: Home: _____ Work: _____ Mobile:_____

Home Address:_____

City:_____ State:_____ ZIP:_____ Email: _____

Who is your primary care physician?_____ Telephone: _____

Primary Insurance: _____ Insurance ID: _____

Does your insurance cover: Health care overseas? ❑ Yes ❑ No ❑ Not sure Medical evacuation? ❑ Yes ❑ No ❑ Not sure

Travel Plans

(list additional information on back of form if needed)

Purpose of Trip (check all that apply): ❑ Vacation ❑ Business ❑ Study ❑ Other: _____

Planned activities: _____

Will you be:	Yes	No	
	❑	❑	Visiting ONLY urban areas? If no, explain:_____
	❑	❑	Visiting friends and/or family?
	❑	❑	Ascending to high altitudes (8,000 feet or higher)?
	❑	❑	Working with potential exposure to bodily fluids (e.g., medical or dental work)?
	❑	❑	Working with exposure to animals?
	❑	❑	Potentially having new sexual partners?

Countries and Cities in order of visit	Arrival Date	Departure Date

Accommodations: (Check all that apply.)
_____Resorts or large hotels ____Small hotels ____Cruise Ship ____Private Home ____Camp ____Dormitory
____Youth Hostel _____Other (list)_____

Have you traveled outside the United States before? ❑ Yes ❑ No
If yes, when and where? _____

Health History

Medical Conditions (such as heart disease, stroke, cancer, arthritis, diabetes, hypertension, psychiatric illnesses, etc) _____

_____

Surgical History:

Allergies (include medications, foods (incl. eggs), environmental allergens such as ragweed):_____
_____

Intolerances or other reactions (include side effects from previous medications, such as nausea, constipation, sleepiness, dizziness, stomach upset, etc.):_____
_____

Date:_____

Vaccination History

Were you born in the United States? ❑ Yes ❑No If no, where? _____

Have you received the following immunizations?

Hepatitis A	❑ Yes	When? _____	❑ No	❑ Not sure
Hepatitis B	❑ Yes	When? _____	❑ No	❑ Not sure
Meningococcal Meningitis	❑ Yes	When? _____	❑ No	❑ Not sure
Measles/Mumps/Rubella	❑ Yes	When? _____	❑ No	❑ Not sure
Polio	❑ Yes	When? _____	❑ No	❑ Not sure
Tetanus	❑ Yes	When? _____	❑ No	❑ Not sure
Typhoid	❑ Yes	When? _____	❑ No	❑ Not sure
Yellow Fever	❑ Yes	When? _____	❑ No	❑ Not sure
Japanese Encephalitis	❑ Yes	When? _____	❑ No	❑ Not sure
Influenza	❑ Yes	When? _____	❑ No	❑ Not sure

Other: _____

Have you ever had an adverse reaction to an immunization? ❑ Yes Explain: _____ ❑ No

Medications

Are you currently using corticosteroids, receiving cancer treatment, or other immunosuppressive therapy? ❑ Yes ❑ No

Prescription medications: List all current prescription medications and condition treated. (include birth control pills):

Prescription Medication	Reason for Use/Medical Condition

Nonprescription products: List all over-the-counter, herbal, homeopathic products, vitamins, supplements etc.)

Nonprescription medications	Reason for Use/Medical Condition

Women Only

Are you pregnant now, or do you suspect that you might be pregnant? ❑ Yes ❑ No
Do you have plans to become pregnant in the next 3 months ❑ Yes ❑ No
Date of your last menstrual period: _____

Questions/Concerns:

List any additional questions or concerns you have about your travel: _____
_____
_____

PROGRESS NOTE ***INTERNATIONAL TRAVEL HEALTH CLINIC***

PT NAME (*last, first*):				**DOB:**		**MRN:**
BP:	**P:**	**WT:**	**HT:**	**TEMP:**	**SEX:**	**ALLERGIES:**

SUBJECTIVE/OBJECTIVE:

Destination:

_____ Departure Date (from U.S.) _____ Return Date_____

Details of Itinerary:_____

_____

_____

Past Medical History: _____

Medications:_____

Immunization hx (date completed): Hep A_____ Hep B_____ Td/Tdap _____ Polio_____ Other: _____

ASSESSMENT: *Per patient's itinerary, at risk for…*

PLAN:

✓	Vaccine	Recommended by: (Date)	Administered on: (Date)	Administration Details (Vaccine Name; Manufacturer; Lot number; Expiration Date; VIS; Dose; Route; Location)	Administered by:
	Hepatitis A # 1 , 2				
	Hepatitis B # 1, 2, 3				
	Hepatitis A + B combo # 1, 2, 3				
	Influenza (Inactivated)				
	Influenza (Live Intranasal)				
	Japanese Encephalitis				
	Meningococcal				
	Pneumococcal				
	Polio (IPV)				
	Rabies				
	TD or Tdap (circle one)				
	Typhoid Injection / PO				
	Yellow Fever				
	Int'l Certificate of Immunization				

✓		Date
	General Advice (Including: Accident and Risk Awareness)	
	Food/Water Precautions	
	Traveller's Diarrhea (written information provided), Loperamide & BSS use	
	Vector Borne Disease Precautions	
	HIV / Hepatitis B / Hepatitis C Precautions: □ Sexual Activity □ Risk Avoidance □ Contraceptive Foam & Condoms from USA	
	Malaria Prophylaxis (written information provided), DEET & permethrin use	
	Rabies: Animal Bites and Scratches	

✓	Medications	QTY
	Ciprofloxacin 500 mg Sig: Take 1 tablet BID x 3 days for traveler's diarrhea Take 2 tabs one time for traveler's diarrhea. May repeat dose.	
	Levofloxacin 500 mg Sig: Take 1 tablet QD x 3 days for traveler's diarrhea	
	Azithromycin 500 mg Sig: □ Take 1 tab QD x 3 days for traveler's diarrhea □ Take 2 tabs one time for traveler's diarrhea **Alternate dosing: Azithromycin** _____	
	Chloroquine phosphate 500 mg (eq 300mg base) Sig: Take 1 table weekly starting 1 week before entering malarious area, continue weekly during the stay and continue for 4 weeks after leaving area. Take with food.	
	Mefloquine 250 mg Sig: take one tablet weekly starting 1 week before entering malarious area, continue weekly during the stay and continue for 4 weeks after leaving area.	
	Doxycycline 100 mg Sig: Take 1 tab QD starting 1 day before entering malarious area, during stay, and for 4 weeks after leaving area.	
	Malarone (atovaquone-proguanil) 250 mg / 100 mg Sig: Take 1 tab QD 1 day before arrival in malarious area, take 1 tab QD while there, then take 1 tablet daily for 7 days after leaving area. Take with food.	
	Malarone (atovaquone-proguanil) 250 mg / 100 mg ~ SELF TREATMENT~ Sig: Take 4 tab daily as a single dose for 3 days for treatment of malaria.	**12**
	Acetazolamide 125 mg BID Sig: Take 1 tablet BID the day before ascent, then take 1 tablet BID during ascent, and then 1 tablet BID for 2 days while at altitude	
	Transderm Scop (Scopolamine) 0.5 mg/24hr. patch Sig: Apply 1 disc (0.5 mg delivered over 3 days) to skin behind the ear 4 hours before antiemetic effect is needed. The disc may be left in place for three days.	
	Typhoid Vaccine Live Oral Ty21a Sig: Take 1 capsule PO once daily for 4 alternate days (days 1, 3, 5 and 7), taken 1 hour before meals with cold or lukewarm water.	**4**

Additional Notes: _____

_____

_____

_____

Pharmacist Name and Signature:_____ Date: _____

Attachment 4

California State Board of Pharmacy
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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
SB 493 IMPLEMENTATION COMMITTEE MEETING
MINUTES

DATE: February 25, 2015

LOCATION: County of Los Angeles - Department of Health Services
313 N. Figueroa Street
1st Floor Auditorium
Los Angeles, CA 90012

COMMITTEE MEMBERS PRESENT:
Stanley C. Weisser, President, Committee Chair
Deborah Veale, RPh
Amy Gutierrez, PharmD.
Victor Law, RPh

COMMITTEE MEMBERS NOT PRESENT:

STAFF PRESENT:
Virginia Herold, Executive Officer
Laura Hendricks, Staff Analyst
Liz McCaman, SB 493 Researcher

Call to Order

Dr. Gutierrez called the meeting to order at 10:15 a.m. in President Weisser's absence.

Dr. Gutierrez conducted a roll call. Committee members present: Stanley Weisser (arrived at 10:16 a.m.), Amy Gutierrez, Victor Law and Deborah Veale.

a. Discussion and Identification of Materials Where Board Guidance Is Envisioned, Discussion of the Requirements: For Prescription Medications Not Requiring a Diagnosis that Are Recommended by the CDC for Travel Outside the US

Dr. Jeff Goad, from Chapman University, provided a presentation on how a pharmacist would effectively practice travel medicine. The presentation can be found immediately following these minutes. Below is a summary of the presentation.

Dr. Goad explained that the CDC travel guide is published in hard copy annually, and is continually updated electronically.

Dr. Goad noted that "not requiring a diagnosis" can be broken into two categories:

1) **Self-treatable conditions**
   - Traveler's diarrhea
   - Altitude sickness
   - Jet lag
   - Motion sickness
   - URI
   - UTI
   - Bacterial skin infections
   - Vaginal yeast infections
   - HIV PEP
   - Malaria SBET

2) **To prevent illness**
   - IGIM (Hep A protection)
   - Influenza prophylaxis
   - Leptospirosis
   - Malaria
   - Travelers' diarrhea

Dr. Goad explained that pharmacists must ensure that they are providing a comprehensive or are part of a comprehensive Travel Health Service. They must also ensure that they have received the proper training and are current on emerging issues for people traveling abroad.

Dr. Goad provided an example of a "travel history form" that must be used for each patient and shared with a primary health care provider.

Dr. Goad reviewed different software (both through the CDC and commercially) that is available to pharmacists that allow them to research current travel guidelines based on the area of travel.

Dr. Goad noted that 95% of the public does not see a health care provider before they travel. Dr. Steve Gray noted that most seniors do not see a health care provider before they travel and they often have existing conditions that could affect their health while traveling.

Dr. Goad warned the committee not to make the same mistake as Public Health and only allow pharmacists to administer vaccines and ignore other travel medicines.

Dr. Gutierrez asked what the cost is for commercial travel medicine software. Dr. Goad responded that it ranges from $300 to $800 per year. The committee also discussed the CDC software, which is free, but is not as user friendly as other commercial software. Dr. Gray noted that some health systems have their own software.

Dr. Gutierrez asked if the CDC software or commercial software is more up-to-date. Dr. Goad explained that the commercial software allow doctors to provide current information on outbreaks. The CDC will also receive this information; however, they must vet it before they put it online, so it will be slightly delayed.

Liz McCaman asked if a pharmacist should require the traveler to provide proof of travel (flight itinerary). Ms. Veale asked if Dr. Goad had ever had someone make up a trip to obtain medication. Dr. Goad responded that in his many years of experience in travel medicine he has never had this problem.

At the request of the committee, Dr. Goad explained the process for obtaining a yellow fever stamp. He explained that in California only a physician can apply for a stamp with the California Department of Public Health; however, they can delegate it to other health care providers.

Liz McCaman asked if a pharmacist, who has been delegated a yellow fever stamp, would have to take the CDC yellow fever training. Dr. Goad responded that anyone who has the stamp or has been delegated must take the training.

Dr. Gray asked if a traveler should go to a travel clinic if they are visiting a United States territory (Guam, Puerto Rico, etc.). Ms. Herold responded that from a legal perspective they are treated as part of the United States. Dr. Goad noted that while they are part of the United States they often do not have the same standards for water and food sanitation.

Dr. Gutierrez asked if the law currently allows a pharmacist to *furnish* or *prescribe* travel medicine. It was confirmed that a pharmacist could furnish travel medicine.

Dr. Goad explained that the travel history form could be modified by a clinic to fit their needs. Liz McCaman noted that the CDC has guidelines for what information should be gathered from the traveler.

Mr. Law asked if members of a group of travelers would each have to be counseled individually. Dr. Goad explained that some of the information could be given to an entire group, but each traveler would have to meet with the pharmacist to discuss their individual medical history.

The committee discussed proofing of travel (itinerary). It was determined that the travel history form would adequately gather enough information that a copy of an itinerary would be unnecessary.

President Weisser asked if there was a possibility for the Department of Public Health to allow pharmacists to obtain their own yellow fever stamp. Michael Santiago responded that there is a federal regulation (42 CFR 71.3) that delegates that authority to issue stamps to the Department of Public Health. The federal regulation specifically states that the stamps can only be issued to physicians or health facilities. Dr. Gutierrez asked if other states interpret the federal regulations the same way that California does. Dr. Goad explained that a protocol with a doctor is required for yellow fever, so either way a pharmacist would need to be involved.

The committee discussed the required travel medicine training and continuing education. Liz McCaman provided the following draft language.

> Prior to furnishing prescription travel medication not requiring a diagnosis, pharmacists must complete the American Pharmacy Association's pharmacy-based travel health services training or an equivalent training program of at least 30 hours, which covers the International Society of Travel Medicine's body of knowledge.

Ms. Herold noted that in the regulation the board would have to be specific on the definition of "equivalent."

Dr. Goad noted that the ISTM is a good place to start for anyone who wants to develop a training program.

Lisa Kroon, from the University of California, San Francisco outlined how the schools of pharmacy teach travel medicine. Mr. Law asked if the students are given a certificate when they complete the training. Dr. Croon confirmed that they do receive a certificate.

The committee asked Ms. McCaman to draft regulation language for travel medicine training based on the committee's discussion.

Ms. Veale asked Ms. McCaman to be sure that any pharmacist who will be providing travel medicine has completed immunization training.

The committee moved the discussion from training to the requirements for the practice of travel medicine. Ms. McCaman provided the following draft language:

> Prior to furnishing prescription travel medication not requiring a diagnosis, a pharmacist shall preform a good faith evaluation, though not necessarily a physical examination, of the patient including the

> evaluation of the travel history form. The travel history form must include all of the information necessary for a risk assessment during pre-travel consultation as identified in the CDC yellow book. An example of an appropriate, comprehensive travel history form is available on the Board of Pharmacy's website.

Ms. Veale asked to modify the draft language to say the good faith evaluation must be documented and be based on the travel history form. Ms. McCaman noted that the statute requires the pharmacist to report to the primary care provider.

The committee then discussed continuing education requirements for travel medicine.

Dr. Goad reported that there are many places to receive continuing education.

The committee determined that as part of the 30 hours of required continuing education, a pharmacist practicing travel medicine must take two hours of travel medicine and one hour of immunization continuing education. Jon Roth, of the California Pharmacist's Association, supported this recommendation.

Ms. Herold asked if the committee wanted to require the use of certain travel software. Dr. Goad did not recommend specific software, only that their information be based on the CDC yellow book. Ms. Herold stated that the language must mention the CDC and the yellow book, but should allow for the use of other software based on the CDC. Ms. McCaman noted that she would draft the language to reflect this.

Dr. Steve Gray and Dr. Besinque warned the committee not to be too prescriptive in the requirements for SB 493. President Weisser responded that as this is a new area of practice the board needs to provide adequate guidance. Ms. Veale stated that as there is not a standard of practice for pharmacists in this area, they are being more prescriptive so pharmacists understand the expectations. Dr. Gutierrez agreed with Ms. Veale and President Weisser.

Ms. Herold and Mr. Santiago noted that the Office of Administrative Law is requiring regulation language to be very specific before they approve it.

Ms. Herold asked how long a pharmacist has to notify the primary healthcare provider. Ms. McCaman noted that the other protocols do not have a specific time period. The committee decided not to include a certain time frame but to leave it to the pharmacist's professional judgment.

The committee recessed for a break at 11:52 a.m. and resumed at 11:58 a.m.

b. <u>Protocol For Pharmacists Who Furnish Self-Administered Hormonal Contraceptives</u>

President Weisser reported that at the January Board Meeting, the board approved the proposed protocol for hormonal contraception. The board also moved to regulation hearing the approved protocol if the Medical Board of California approved the protocol during its meeting on January 30.

The Medical Board approved the protocol with a small change. The approved protocol, with the Medical Board suggested change, immediately follows these minutes.

President Weisser stated that, the American Congress of Obstetricians and Gynecologists (ACOG), who under SB 493 the board is required to consult in developing the protocol, appeared at the Medical Board meeting to request changes in the protocol. The Medical Board did not incorporate ACOG's recommendations into the protocol when it modified and approved the protocol.

President Weisser noted that if additional changes are made to the protocol, the Board of Pharmacy and the Medical Board will both need to approve the modifications.

Liz McCaman commented that one of ACOG's concerns was the inclusion of depo-injections in the protocol. Ms. McCaman explained that the board decided to include it based on information from the CDC, USMEC and multiple studies showing its safety and effectiveness.

Ms. Veale asked if depo-injections were included in the protocol approved by the Medical Board. Ms. McCaman confirmed that the Medical Board approved the protocol with depo-injections included.

Mr. Law commented that he was pleased that the Medical Board approved the protocol with only a minimal change.

Ms. Veale asked why the committee was reviewing the protocol again if the Medical Board had already approved it. Ms. Herold responded that ACOG wanted the opportunity to address their concerns with the protocol as approved. President Weisser again stated that if any modifications were made at today's committee meeting the protocol would have to be approved again by the full board and the Medical Board.

Dr. Laura Sirott, practicing obstetrician and Vice Chairman for California, ACOG, commented that per their national policy ACOG is in support of over-the-counter access of oral contraceptives. Dr. Sirott noted that they define oral contraceptives as the pill, patch or ring and exclude the depo-injection.

Dr. Sirott stated that ACOG understands the desire to increase accessibility to the depo-injection; however, they are concerned with patients self-administering an intramuscular

injection as they are deep and painful. Dr. Sirott encouraged the committee to limit the protocol to subcutaneous injections with adequate training provided to the patient.

Dr. Sirott asked the committee to consider changing the language to say "offer to measure blood pressure." ACOG is of the opinion that most patients will know their blood pressure or could measure it themselves using the blood pressure stations available in most pharmacies. Dr. Sirott explained that ACOG is concerned that having the pharmacist take the patient's blood pressure could be a barrier to access.

Dr. Gutierrez asked if in a doctor's office contraceptives would be prescribed without taking the patient's blood pressure. Dr. Sirott responded that she would not prescribe contraceptives without first taking blood pressure as it is the standard of care.

Dr. Sirott asked the committee to consider changing the term "primary care provider" to "primary health care provider" because the federal definition of primary care provider does not include OBGYNs. Liz McCaman responded that the governing statute uses the term "primary care provider," so the committee could not change the term.

Dr. Sirott expressed ACOG's opinion that the self-screening tool is overly complicated and could be simplified.

Dr. Kathy Hill-Besinque stated that pharmacists already dispense intramuscular injections to patients and the self-administered depo injections are already used worldwide. She added that the protocol specifically states that the patient must be trained by the pharmacist.

Dr. Hill-Besinque commented that most pharmacists would not feel comfortable dispensing hormonal contraceptives without first taking the patient's blood pressure. Dr. Hill-Besinque stated that a pharmacist should be following the same standard of care as a doctor or other health care professional.

Dr. Hill-Besinque noted that the language allows the questionnaire to be modified as long as it contains the same content.

Mr. Law asked how students are being trained for injections. Dr. Hill-Besinque responded that they receive extensive injection training and would be qualified to train the patient.

A member of the public commented that limiting the protocol to subcutaneous injections would limit patient access.

Dr. Sirott comments that ACOG's primary goal is to increase access to contraception.

Ms. McCaman stated that the author of one of the studies used as a reference for the creation of the protocol indicated that verifying normal blood pressure is essential to good,

clinical decision making. Dr. Gutierrez added that the board would be holding the pharmacist responsible for their clinical decisions.

The committee did not take any action to modify the protocol based on ACOG's concerns. President Weisser thanked Dr. Sirott for attending the meeting and providing comments.

Ms. Herold noted that ACOG would have another opportunity to voice their concerns during regulation process during the 45-day comment period.

c. <u>Update on the Status of Requirements for Licensure as Advanced Practice Pharmacists</u>

President Weisser reported that at the January 2015 Board Meeting, the board approved and moved to initiate a regulation rulemaking that specifies the ways and supporting documentation needed to qualify for registration as an advance practice pharmacist. Additionally a fee of $300 was selected as the application and renewal fee for this license. Board staff will very soon be noticing this language to initiate the rulemaking process.

As a review:
California Business and Professions Code section 4210 provides that applicants:

Satisfy any two of the following criteria:

(A) Earn certification in a relevant area of practice, including, but not limited to, ambulatory care, critical care, geriatric pharmacy, nuclear pharmacy, nutrition support pharmacy, oncology pharmacy, pediatric pharmacy, pharmacotherapy, or psychiatric pharmacy, from an organization recognized by the Accreditation Council for Pharmacy Education or another entity recognized by the board.

(B) Complete a postgraduate residency through an accredited postgraduate institution where at least 50 percent of the experience includes the provision of direct patient care services with interdisciplinary teams.

(C) Have provided clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system.

President Weisser noted that since the language has not yet been released, the committee may wish to discuss questions on the language. He added that any modification would need to be returned to the board for its review at the March 9 meeting.

Below is the draft language.

<u>Article 3.5</u>
<u>Advanced Practice Pharmacist</u>

<u>1730 Acceptable Certification Programs</u>

<u>The board recognizes the pharmacy patient care certification programs that are certified by the</u>

National Commission for Certification Agencies (NCCA) for purposes of satisfying the requirements in Business and Professions Code section 4210(a)(2)(A).

1730.1 Documentation Requirements for Advanced Practice Pharmacist Licensure

(a) Documentation of possession of a certification as specified in California Business and Professions Code section 4210(a)(2)(A) shall be via:
  (1) A notarized copy of the certification award that includes the name of the applicant pharmacist, the area of specialty and date of completion, or
  (2) A letter from the certification program attesting the award of the certification that includes the name of the applicant pharmacist, the area of specialty and the date of completion.

(b) Documentation of completion of a postgraduate residency earned through an accredited postgraduate institution as specified in California Business and Professions Code section 4210(a)(2)(B) shall be via either:
  (1) A notarized copy of the residency certificate awarded by the postgraduate institution that includes the name of the applicant pharmacist, the area of specialty, and dates of participation and completion, or
  (2) A letter of completion of a postgraduate residency signed by the dean or residency program director of the postgraduate institution and sent directly to the board from the postgraduate institution that lists the name of the applicant pharmacist, the dates of participation and completion, and areas of specialty.

(c) Documentation of experience earned under a collaborative practice agreement or protocol for at least one year with no fewer than 1,500 hours as specified in California Business and Professions Code section 4210(a)(2)(C) shall be via:
  (1) A copy of an agreement or protocol under which the applicant pharmacist has provided clinical services to patients, and
  (2) A letter from the supervising practitioner attesting under penalty of perjury that the applicant pharmacist has completed at least one year of the experience providing clinical services to patients.

Ms. Herold explained that she placed this item on the agenda because she wanted the committee to clarify how they would like to handle clinical experience that was gained many years ago. Documenting the experience may be difficult for some of the more experienced pharmacists.

Dr. Gutierrez asked what the definition of clinical would be in the language. Ms. Herold responded that California Business and Professions Code section 4210 defines clinical as: providing clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system.

Dr. Besinque commented that many pharmacists work under institutional protocols, which would make it difficult to get the signature of a supervising physician, especially if they no longer work at the institution. Dr. Besinque recommended allowing the pharmacist to

attest to their own experience and provide the board with the information on the setting in which they gained the experience rather than requiring a letter from the supervising practitioner.

Dr. Besinque commented that she also did not see the value of collecting the protocols as the board staff would be unable to validate them.

Jon Roth agreed with Dr. Besinque's recommendation to allow the pharmacist to attest to their own experience. If the attestation is subsequently found to be false, enforcement action would then follow.

Pharmacist Sara McBane stated that she agreed with the self-attestation approach and noted that North Carolina uses this method.

Ms. Veale expressed concern with not collecting documentation from someone else besides the applicant him or herself. Ms. Herold added that self-attestation would essentially be allowing people to submit resumes to the board as proof of experience.

Mr. Law noted that an institution should have someone who could at least verify that a pharmacist worked at the institutions for a certain time period.

Jon Roth suggested that the board handle the APP experience in the same way it currently handles continuing education requirements. The board could simply do spot checks on the documentation of experience.

Ms. Herold explained that when the board issues a license they are doing so in the interest of protecting the public and essentially stating that the licensee meets the minimum standards to practice. The applicants need to prove that he or she possesses the experience set out in the law.

Dr. Besinque stated that the requirement to have the documents notarized is onerous and unnecessary. She again expressed her opinion that getting a letter from a supervising practitioner will be very difficult for many pharmacists.

Ms. Veale asked if the supervising practitioner had to be a physician. Ms. Herold clarified that it did not have to be physician, it could be a pharmacist.

Ms. Veale asked if the committee could strike (c)(1) and only require the letter attesting to one year of clinical experience. The committee agreed to eliminate (c)(1).

The committee modified the language to read "~~A letter~~ An attestation from the supervising practitioner or director…"

Dr. Gutierrez asked if the residency program director could sign the letter of completion of a postgraduate residency (required in (b)(2)) and have it also count towards the one year of clinical experience required in (c)(2). Ms. Veale commented that the committee previously discussed this and wanted them to be two separate requirements. Ms. Herold noted that there is nothing in the statute that separates them, so the board would have to build it in.

Dr. Grey recommended removing the "supervisor" requirement as some pharmacists may not have a direct supervisor. Ms. Herold recommended that the committee keep the supervisor requirement.

Rebecca Cupp, from Ralph's Pharmacy, asked if a program director leaves a program if the new director could attest to experience gained prior to them taking over the program. Ms. Herold confirmed that the current director could attest.

Sara McBane recommended removing the notarization requirement. The committee agreed to remove the notary requirement.

Dr. Besinque and Sara McBane asked for clarification on the application and renewal fees. Ms. Herold explained that it would be $300 for the initial application and $300 for each renewal. She noted that $300 covers the cost to run the program.

Dr. Gutierrez expressed concern with the competency of someone whose experience was earned 20 years ago. Ms. Herold responded that the committee could add in a certain time frame in which the experience must have been earned. Ms. Veale agreed with Dr. Gutierrez's concern.

Jon Roth recommended adding "health facility administrator" to the list of those who could sign a letter of attestation.

Motion: Approve the draft 1730 language with the modifications made by the committee (below).

Article 3.5
Advanced Practice Pharmacist

1730 Acceptable Certification Programs

The board recognizes the pharmacy patient care certification programs that are certified by the National Commission for Certification Agencies (NCCA) for purposes of satisfying the requirements in Business and Professions Code section 4210(a)(2)(A).

1730.1 Documentation Requirements for Advanced Practice Pharmacist Licensure

(a) Documentation of possession of a certification as specified in California Business and

Professions Code section 4210(a)(2)(A) shall be via:

(1) A ~~notarized~~ copy of the certification award that includes the name of the applicant pharmacist, the area of specialty and date of completion, or

(2) A letter from the certification program attesting the award of the certification that includes the name of the applicant pharmacist, the area of specialty and the date of completion.

(b) Documentation of completion of a postgraduate residency earned through an accredited postgraduate institution as specified in California Business and Professions Code section 4210(a)(2)(B) shall be via either:

(1) A ~~notarized~~ copy of the residency certificate awarded by the postgraduate institution that includes the name of the applicant pharmacist, the area of specialty, and dates of participation and completion, or

(2) A letter of completion of a postgraduate residency signed by the dean or residency program director of the postgraduate institution and sent directly to the board from the postgraduate institution that lists the name of the applicant pharmacist, the dates of participation and completion, and areas of specialty.

(c) Documentation of experience earned under a collaborative practice agreement or protocol for at least one year with no fewer than 1,500 hours as specified in California Business and Professions Code section 4210(a)(2)(C) shall be via:

~~(1) A copy of an agreement or protocol under which the applicant pharmacist has provided clinical services to patients, and~~

~~(2)~~(1)~~A letter~~ An attestation from the supervising practitioner or program director or health facility administrator attesting under penalty of perjury that the applicant pharmacist has completed at least one year of the experience providing clinical services to patients.

M/S: Veale/Law

Support: 3 Oppose: 0 Abstain: 1

Ms. Veale asked if the committee wanted to address the issue of earning their postgraduate experience (b) and clinical experience (c) concurrently. The committee decided not to amend the language as they felt that the experience could be gained concurrently.

Lisa Croon explained that due to a lag in licensure time many residents will have earned 1,500 hours of experience, but would have only have been licensed for 10 months. The committee noted that the language does not state that they have been licensed for one year, only that they are earning experience under a collaborative practice agreement for one year.

Dr. Gutierrez again expressed her concern with licensing APP's who gained their experience 20 or more years ago.

The committee recessed for a lunch break at 1:23 pm. and resumed at 2:00 p.m.

d. Protocol for Pharmacists Who Furnish Nicotine Replacement Products

President Weisser reported that at the January Board of Pharmacy Meeting, the board approved the proposed protocol for nicotine replacement products. The board also moved to initiate the rulemaking process if the Medical Board of California approved the protocol during its meeting on January 30.

President Weisser stated that the Medical Board did approve the protocol, a copy of which was provided in the meeting materials. President Weisser noted that the protocol will be noticed for public comment as a regulation in the near future.

e. Protocol for Pharmacists Who Furnish Naloxone

President Weisser reported that at the January Board Meeting, the board approved the proposed protocol for pharmacists to provide naloxone, a copy of which was provided in the meeting materials. The Medical Board of California approved the protocol during its meeting on January 30.

President Weisser explained that the naloxone protocol was authorized by AB 1535 (Bloom, Chapter 346, Statutes of 2014). This bill contained a provision that specifies:

> The board may adopt emergency regulations to establish the standardized procedures or protocols. The adoption of regulations pursuant to this subdivision shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The emergency regulations authorized by this subdivision are exempt from review by the Office of Administrative Law. The emergency regulations authorized by this subdivision shall be submitted to the Office of Administrative Law for filing with the Secretary of State and shall remain in effect until the earlier of 180 days following their effective date or the effective date of regulations adopted pursuant to subdivision (a).

Ms. Herold stated that the board is ready to file the protocol as an emergency regulation following this meeting.

f. Review and Discussion About the Factsheet on Naloxone

President Weisser explained that staff has reviewed various factsheets for patients describing the use of naloxone. Recently, staff has identified a factsheet that provides information of value to consumers. At least those who have reviewed the factsheet support use of this specific document. President Weisser stated that the factsheet was developed by Phillip O. Coffin, MD, MIA, Director of Substance Use Research, San Francisco Department of Public Health and was provided in the meeting materials.

Ms. Herold noted that Dr. Coffin has granted the board permission to use this factsheet so that it may be placed on the board's website for use by pharmacies.

Mr. Roth, from CPHA, commented that the third mechanism for administration on the fact sheet (auto-injector) does not stand out as much as the other two options. Ms. McCaman noted that this fact sheet is only given out after the patient has chosen the form of administration they will be using.

Amy Swartz, from Kaleo Pharm the manufacturer of the auto-injector, provided the committee with sample auto-injectors. She noted that it is the only administration designed for take-home use; the other options are really designed for use by health care providers.

g. <u>Review and Discussion About the Factsheet on Self-Administered Hormonal Contraception</u>

Ms. McCaman briefly reviewed the examples of factsheets on various forms of hormonal contraception that were provided in the meeting materials.

President Weisser noted that some of the numbers provided for the effectiveness of birth control do not add up. Dr. Besinque explained that with contraception everything is described in two ways: "perfect use" and "typical use" and there will always be a discrepancy between the two numbers.

President Weisser noted that there was a grammatical error on the fact sheet. Ms. McCaman noted that she would work with the author of the fact sheet to correct any such errors.

Ms. McCaman stated that the author plans to translate the fact sheets into two or three new languages per year. Ms. Herold added that the board will assist with translations.

h. <u>Review and Discussion About a Factsheet on Nicotine Replacement Products</u> President Weisser explained that most of the patient care elements enacted by SB 493 require the development of a fact sheet. However, the provision of nicotine replacement products does not require such a document.

President Weisser noted that this agenda item was added simply to affirm that the committee does not wish to develop such a factsheet. The committee agreed that no factsheet would be developed.

i. <u>For Pharmacists Who Initiate and Administer Immunizations Pursuant to Recommended Immunization Schedules by the Federal Advisory Committee of Immunization Practices</u>

President Weisser explained that according to section 4052.8, immunizations may be provided by pharmacists who possess the required training to provide immunizations. Specifically, to initiate immunizations, a pharmacist must:

- complete an immunization training program endorsed by the CDC,
- be certified in basic life support,
- comply with all state and federal recordkeeping requirements,

– provide information to the patient's primary care physician and into the appropriate immunization registry designated by the immunization branch of the CDPH.

President Weisser stated that during this meeting, the committee needs to address certain issues, and determine if it wishes to create requirements for these components. If so, regulations will need to be drafted if the board desires the provisions to be enforceable.

The first item the committee discussed was the mandatory reporting to an immunization registry.

President Weisser reported that at prior committee meetings, the committee discussed various aspects of immunizations, including required reporting into an immunization registry. President Weisser stated that the committee needs to identify whether it will make reporting of vaccinations into the CDPH Immunization Registry mandatory, and whether patients can opt out. If so, there are some issues to resolve, including:

- How long from the time of immunization must the pharmacy/pharmacist input the information into the registry?
- Will patients be provided with written information document the immunization(s) they receive?
- How long does the pharmacist have to provide immunization information to the primary care provider? In what form?
- What documentation must the pharmacist maintain?

Dr. Gutierrez stated that she supports the mandatory reporting to the immunization registry.

Lauren Dunning, from the Los Angeles Department of Public Health, explained how a pharmacist would enter and search information into the California Immunization Registry (CAIR).

Ms. Veale asked if there is more than one databank in California. Dr. Dunning explained that while some counties have their own system, the information is shared with CAIR.

Mr. Law asked how a pharmacist could differentiate between someone with the same name and date of birth. Dr. Dunning responded that there are other data elements, such as mother's maiden name that can be used to differentiate.

Mr. Law asked if patients have access to CAIR. Ms. Dunning responded that patients do not have access to CAIR, but the information could be shared with them to use on the "yellow cards." Dr. Dunning noted that the new version being developed will allow patients to access information.

Dr. Gutierrez stated that the more people who use the system the better the information will be.

Rebecca Cupp, from Ralphs,' asked the committee to make reporting mandatory. The attorney's for Ralph's allow reporting to databases in states where it is mandatory. However in states where reporting isn't they view it as a HIPPA violation and do not allow pharmacist to report.

A pharmacist commented that a pharmacist should have the option to report to CAIR rather than making it mandatory.

Dr. Grey recommended checking with counsel to ensure that mandatory reporting would not violate any privacy laws.

Ms. McCaman read the Business and Professions Code section that states that in order to initiate and administer an immunization a pharmacist is required to enter the information into the appropriate immunization registry designated by the state department of public health. The committee concluded that this gives the board the authority to require entry to the immunization databank.

The committee discussed the time frame in which the pharmacist must report to the databank. Ms. McCaman reported that the shortest reporting timeframe in other states was 15 days. The committee decided to require reporting at least every 15 days.

The committee discussed if a pharmacist must report to the primary healthcare provider. Ms. Veale indicated that chain stores do report. Ms. McCaman noted that the statute requires reporting. The committee elected to use the same 15 day time frame as the immunization databank reporting.

President Weisser asked how pharmacies record the patient's immunization. Ms. Veale indicated that in most pharmacies the information becomes part of the patient profile. The committee concluded that this was adequate record keeping.

President Weisser explained that the law (section 4052.8(b)(1) of the B&P Code) requires that a pharmacist complete an immunization training program endorsed by the CDC (this would seem to be the APhA Pharmacy-Based Immunization Delivery Program), that at a minimum includes hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines, and shall maintain that training.

President Weisser asked if the committee wished to be more specific in what it will require under this category (i.e., APHA's Pharmacy-Based Immunization Delivery Program).

Ms. Veale indicated that she would prefer not to list a specific program. Dr. Gutierrez noted that the committee should also consider out of state pharmacists. The committee determined not to make any changes to this section.

President Weisser reminded the committee that earlier in the meeting they had already decided to require one hour of immunization continuing education for each renewal cycle.

President Weisser asked what information was kept in the patient profile. Ms. Veale answered that the record would contain the NDC of the immunization, how much the patient was charged and date of administration. A pharmacist added that the pharmacist would also record the administration site (which arm) and lot number, although this information is kept separately from the patient profile.

Dr. Grey recommended the committee specifically state in the language how long the records must be kept because some of the information will not be kept in the patient profile and not all patients would have a patient profile. Dr. Gutierrez recommended looking at current pharmacy practice regarding immunization reporting so that the committee does not reinvent the wheel.

Ms. McCaman provided the following draft language:

> Each vaccine initiated and or administered by a pharmacist shall be documented in a patient medication record and shall be stored in the originating pharmacy or health care facility for a period of at least three years from the date of administration. A patient medication record shall be maintained in an automated data processing or manual record mode such that the required information under Title 16 section 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the pharmacy or facility's regular operating hours.

Dr. Grey noted that the National Vaccine Injury Compensation Program already requires certain records to be kept per federal law. He encouraged the committee to look at these requirements to ensure that they are not creating duplicate requirements.

President Weisser asked if the committee wanted to bring this language before the board or back to the committee. The committee decided to bring it to the next board meeting on March 9, 2015.

j. <u>For Ordering and Interpreting Tests to Monitor and Manage Drug Therapies</u>

President Weisser explained that:

- All pharmacists can:
  Order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies. A pharmacist who orders and interprets tests

pursuant to this paragraph shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescription, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by the prescriber. (CA B&P Code section 4052(a)(12)

- APP licensed pharmacists can:
  Order and interpret drug-therapy related tests, and initiate or modify therapy

President Weisser reported that at prior meetings, comments made on this topic included that during creation of the legislation, doctors stated that they wanted pharmacists to have the ability to order tests to make recommendations on the patient's care based on actual data.

President Weisser stated that the language in SB 493 states that pharmacists may order tests to improve patient safety and access to care. However, at a prior committee meeting it was noted that in the future, the standard of care could evolve to a point where a pharmacist must order a test prior to dispensing a certain medication.

CPhA drafted a guidance document for pharmacists ordering and managing tests. This document has been provided in the meeting materials.

Dr. Gutierrez asked why there is a differentiation between regular pharmacists and APP pharmacists. Ms. Herold explained that APP pharmacists have an additional level of autonomy. Jon Roth added that for regular pharmacists the tests are limited to efficacy and toxicity, an APP pharmacist would be eligible to initiate a larger range of tests.

Dr. Gutierrez stated that she did not think the language indicated different types of testing; rather an APP pharmacist could use the results to modify or initiate therapy. Dr. Grey commented that the language was intended to give all pharmacists specific authority to order tests. Dr. Grey added that currently, all pharmacists practicing in a hospital or under a collaborative practice agreement could modify or initiate therapy based on the test results.

For clarity Dr. Gutierrez recommended changing the language to state:

- APP licensed pharmacists can:
  In addition to the above, initiate or modify therapy.

k. <u>General Discussion Concerning Implementation of SB 493</u>

President Weisser asked if there were any general comments from the public or the committee on the Implementation of SB 493.

Dr. Kroon noted that the committee has voted to accept certification programs accredited

by the NCCA. Ms. Herold responded that if there are other programs that should be considered then they should be submitted to the committee for review at a future meeting.

Dr. Grey commented that many other states are looking to implement similar programs and are looking to California for leadership.

Dr. Gutierrez asked if there was any news on whether a pharmacist will be able to submit claims for Medicare reimbursement. Dr. Grey responded that HR 4190 has been reintroduced in both the House of Representatives and the Senate and will allow pharmacists to enroll in Part B and to serve underserved populations (a map is available to view underserved areas). Dr. Grey also reported on the challenges with Medicare Part D.

I. <u>Public Comment for Items Not on the Agenda, Matters for Future Meetings</u>

A member of the public shared her difficulties in getting her Vitamin B shots covered by Medicare.

A pharmacist stated that he felt that California should change its regulations for refills on controlled substances to be more in line with federal regulations.

President Weisser adjourned the meeting at 3:20 p.m.

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STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
SB 493 IMPLEMENTATION COMMITTEE MEETING
MINUTES

DATE: April 13, 2015

LOCATION: University of Southern California – *Orange County Center*
2300 Michelson Drive, Classroom B
Irvine, Ca 92612

COMMITTEE MEMBERS PRESENT:
Stanley C. Weisser, President, Committee Chair
Deborah Veale, RPh
Amy Gutierrez, PharmD.
Victor Law, RPh

COMMITTEE MEMBERS NOT PRESENT:

STAFF PRESENT:
Virginia Herold, Executive Officer
Laura Hendricks, Staff Analyst
Liz McCaman, SB 493 Researcher

Call to Order

President Weisser called the meeting to order at 10:04 a.m.

President Weisser conducted a roll call. Committee members present: Stanley Weisser, Amy Gutierrez, Victor Law and Deborah Veale.

President Weisser reported that SB 493 creates a number of new opportunities for pharmacists to provide direct care to patients. There are essentially two levels of additional services authorized – one for all pharmacists, and another to create a new licensure category of advanced practice pharmacist to provide additional duties.

President Weisser stated that the board has formed this committee to implement the multiple requirements of SB 493.

Victor Law commented and Ms. Herold noted that some minor changes needed be made to the February meeting minutes.

a. Discussion on the Requirements for Licensure as Advanced Practice Pharmacists

President Weisser reported that at the January 2015 Board Meeting, the board approved and moved to initiate a regulation rulemaking that specifies the ways and supporting documentation needed to qualify for registration as an advance practice pharmacist. Additionally, a fee of $300 was selected as the application and renewal fee for this license.

President Weisser stated that the SB 493 Implementation Committee made several modifications in the text at its February 2015 meeting.

President Weisser explained that he agendized this item so that the committee could review the requirements one more time before the April board meeting and make necessary edits.

Below is the language as discussed at the meeting (items in red were amended at the February committee meeting).

Article 3.5
Advanced Practice Pharmacist

1730 Acceptable Certification Programs

The board recognizes the pharmacy patient care certification programs that are certified by the National Commission for Certification Agencies (NCCA) for purposes of satisfying the requirements in Business and Professions Code section 4210(a)(2)(A).

1730.1 Documentation Requirements for Advanced Practice Pharmacist Licensure

(a) Documentation of possession of a certification as specified in California Business and Professions Code section 4210(a)(2)(A) shall be via:
(1) A ~~notarized~~ copy of the certification award that includes the name of the applicant pharmacist, the area of specialty and date of completion, or
(2) A letter from the certification program attesting the award of the certification that includes the name of the applicant pharmacist, the area of specialty and the date of completion.

(b) Documentation of completion of a postgraduate residency earned through an accredited postgraduate institution as specified in California Business and

Professions Code section 4210(a)(2)(B) shall be via either:

(1) A ~~notarized~~ copy of the residency certificate awarded by the postgraduate institution that includes the name of the applicant pharmacist, the area of specialty, and dates of participation and completion, or

(2) A letter of completion of a postgraduate residency signed by the dean or residency program director of the postgraduate institution and sent directly to the board from the postgraduate institution that lists the name of the applicant pharmacist, the dates of participation and completion, and areas of specialty.

(c) Documentation of experience earned under a collaborative practice agreement or protocol for at least one year with no fewer than 1,500 hours as specified in California Business and Professions Code section 4210(a)(2)(C) shall be via:

~~(1) A copy of an agreement or protocol under which the applicant pharmacist has provided clinical services to patients, and~~

~~(2)~~(1)~~A letter~~ An attestation or letter from the supervising practitioner, program director or health facility administrator attesting under penalty of perjury that the applicant pharmacist has completed at least one year of the experience providing clinical services to patients.

The committee discussed the requirements section-by-section.

1730.1 (a)

The committee determined that the certificate required in section (a) should be current at the time of application.

Ms. Freedman noted that she had some non-substantive changes to the language.

1730.1 (b)

The committee discussed if the postgraduate residency program should only be accepted if it was earned within the last 10 years. Ms. Herold recommended not placing a time limit on the postgraduate residency completion.

The committee discussed if the residency programs from a foreign program should be accepted. Ms. Freedman explained that, as written, the board would have to accept residency programs earned outside of the United States.

The committee decided to require that postgraduate residency be completed in the United States.

1730.1 (c)

Dr. Gutierrez provided an example of a pharmacist who earned experience under a collaborative practice agreement 20 years ago and since that time has been working in a field unrelated to pharmacy. She expressed her concern that as written, this pharmacist,

who would have no current working experience, would still qualify to become an advanced practice pharmacist.

The committee shared this concern and discussed how many years back the experience must have been earned to be acceptable. The committee determined that the experience must have been earned within the last 10 years.

The committee also discussed if the experience must be earned in a concentrated period of time or if it could be spread out over numerous years. The committee stated that they wanted the experience to be earned in a 12-month period.

Ms. Freedman noted that she would like to format the language differently to provide clarity. She noted that her formatting changes would not change the content or policy intent of the language. The committee agreed to allow Ms. Freedman to make formatting changes and provide the updated language at the April board meeting.

Ms. Freedman recommended changing the language to read: "A writing from the supervising practitioner, program director or health facility administrator…" The committee agreed with her recommendation.

The committee discussed whether the postgraduate residency experience (b) and clinical experience (c) could be gained concurrently. The committee felt that the experience could be earned concurrently and asked Ms. Freedman to conduct a legal review to ensure that this was permissible.

Pharmacist Felix Pham submitted into the record a letter from Dr. Andrew Lowe who was unable to attend the meeting (the letter is provided following these minutes). Dr. Pham summarized two points from the letter: 1) the pharmacist should be required to complete five continuing education units per year and 2) the experience under the collaborative practice agreement should be earned after the completion of the postgraduate residency program.

Sean Agabanof asked if pharmacists are allowed to be paid while they are earning experience under the collaborative practice agreement. The committee clarified that the pharmacist could be paid while working under a collaborative practice agreement.

Jeff Goad, from Chapman University, expressed support for allowing the postgraduate residency experience (b) and clinical experience (c) to be gained concurrently.

Dr. Goad expressed concern with having an administrator or human resources director attest that the applicant pharmacist has completed at least one year of the experience providing clinical services to patients. He recommended allowing the pharmacist to self-

certify their experience. The committee expressed some concern with a pharmacist self-certifying their experience with no third-party verification.

Lisa Kroon, from the University of California, San Francisco, stated that she would support allowing the postgraduate residency experience (b) and clinical experience (c) to be gained concurrently.

Dr. Kroon expressed concern that a working pharmacist may be unable to gain 1,500 hours of experience providing clinical patient care in a one year timeframe. She stated that to become a Certified Diabetes Educator a pharmacist must complete 1,500 hours of direct patient care, however, it is spread over five years.

Robert Stein, from the KGI School of Pharmacy, stated that the experience in (b) and (c) should be gained separately.

Monica Trivedi, a community pharmacist, explained that pharmacists within the same pharmacy chain often have very different roles in providing direct patient care. She noted that even though two pharmacists in a chain store may have both worked the same number of hours, one may have had very little experience in direct patient care and would thus be unqualified to become an APP.

Sarah McBane, from the University of California, San Diego, expressed support for allowing the postgraduate residency experience (b) and clinical experience (c) to be gained concurrently.

Dr. McBane stated that the committee should look to the Certified Diabetes Educator program which allows a pharmacist to self-attest to their experience and allows them to earn it over a period of four years.

The committee asked Dr. McBane if the intent of the legislation was to allow the postgraduate residency experience (b) and clinical experience (c) to be gained concurrently. Dr. McBane responded that the original language only required pharmacists to fulfill *one* of the three requirements; so allowing (b) and (c) to be earned concurrently would not be contradictory to the intent of the legislation.

Melissa McNair, a community pharmacist, stated that the board should allow the 1,500 hours to be earned over a period of at least two years.

After hearing the public comments the committee decided to amend section (c) as follows:

1. Require the 1,500 hours of experience as specified in California Business and Professions Code section 4210(a)(2)(C) to be earned in a period of four years.

2. Allow the pharmacist to self-attest to their experience, with verification from a supervising practitioner, program director or health facility administrator.
3. Experience earned under a collaborative practice agreement or protocol must be earned within 10 years of the time application for APP licensure.

Motion: Amend 1730.1 (c) as follows:

1. Require the 1,500 hours of experience as specified in California Business and Professions Code section 4210(a)(2)(C) to be earned in a period of four years.
2. Allow the pharmacist to self-attest to their experience, with verification from a supervising practitioner, program director or health facility administrator.
3. Experience earned under a collaborative practice agreement or protocol must be earned within 10 years of the time application for APP licensure.

M/S: Gutierrez/Law

Support: 4 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Gutierrez	x			
Law	x			
Veale	x			
Weisser	x			

Ms. Veale noted that the committee needed to vote on the change to 1730.1 (a) and (b) as discussed earlier.

Motion: Amend 1730.1 (a) to require current certification at the time of application for APP licensure. Amend 1730.1(b) to require that postgraduate residency be completed in the United States.

M/S: Veale/Gutierrez

Support: 4 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Gutierrez	x			
Law	x			
Veale	x			
Weisser	x			

The committee recessed for a break at 11:55 a.m. and resumed at 12:03 p.m.

Ms. Freedman stated that she would like to amend the language in 1749 (below) to make it clear that the $300 fee is the application fee. She recommended the board issue the license at no additional fee. Ms. Freedman also recommended amending the language to clarify that the $300 renewal fee is in addition to the pharmacists' renewal license fee.

1749. Fee Schedule.

The fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with sections 163.5, 4110, 4127.5, 4196, and 4400 of the Business and Professions Code are hereby fixed as follows:

(a) The fee for the issuance of a pharmacy license is four hundred dollars ($400). The fee for the annual renewal of pharmacy license is two hundred fifty dollars ($250). The penalty for failure to renew is one hundred and twenty five dollars ($125).

(b) The fee for the issuance of a temporary license is two hundred fifty dollars ($250).

(c) The fee for the issuance of a pharmacy technician license shall be one hundred five dollars ($105). The fee for the biennial renewal of a pharmacy technician license shall be one hundred thirty dollars ($130). The penalty for failure to renew a pharmacy technician license is sixty-five dollars ($65).

(d) The fee for application and examination as a pharmacist is one hundred eighty-five dollars ($185). (e) The fee for regrading an examination is eighty-five dollars ($85).

(f)**(1)** The fee for the issuance of an original pharmacist license is one hundred fifty dollars ($150).

(2) The fee for application and issuance of an advanced practice pharmacist license is three hundred dollars ($300).

(g)**(1)** The fee for the biennial renewal of a pharmacist's license is one hundred fifty dollars ($150). The penalty fee for failure to renew is seventy-five dollars ($75).

(2) The fee for the biennial renewal of an advanced practice pharmacist license is three hundred dollars ($300). The penalty fee for failure to renew is one hundred fifty dollars ($150).

(h) The fee for the issuance or renewal of a wholesaler's license is six hundred dollars ($600). The penalty for failure to renew is one hundred fifty dollars ($150).

(i) The fee for the issuance or renewal of a hypodermic license is one hundred twenty five dollars ($125). The penalty for failure to renew is sixty-two dollars and fifty cents ($62.50).

(j) The fee for the issuance of a license as a designated representative pursuant to Section 4053 of the Business and Professions Code shall be two hundred fifty dollars ($250). If the applicant is not issued a license as a designated representative, the board shall refund one hundred ten dollars ($110) of the fee. The fee for the annual renewal of a license as a designated representative shall be one hundred fifty dollars ($150). The penalty for failure to renew is seventy-five dollars ($75).

(k) The fee for the issuance or renewal of a license as a nonresident wholesaler is six hundred dollars ($600). The penalty for failure to renew is one hundred fifty dollars ($150).

(l) The fee for an intern pharmacist license is seventy-five dollars ($75). The fee for transfer of intern hours or verification of licensure to another state is twenty dollars ($20).

(m) The fee for the reissuance of any permit, license, or certificate, or renewal thereof, which must be reissued because of change in the information, other than name change, is one hundred dollars ($100).

(n) The fee for evaluation of continuing education courses for accreditation is forty dollars ($40) for each hour of accreditation requested.

(o) The fee for the issuance of a clinic license is four hundred dollars ($400). The fee for the annual renewal of a clinic license is two hundred fifty dollars ($250). The penalty for failure to renew is one hundred and twenty five dollars ($125).

(p) The fee for the issuance of a nongovernmental license, or renewal of a license, to compound sterile drug products is six hundred dollars ($600). The penalty for failure to renew is one hundred fifty dollars ($150).

(q) The fee for the issuance of a license as a designated representative for a veterinary food-animal drug retailer shall be two hundred fifty dollars ($250). If the applicant is not issued a license as a designated representative, the board shall refund one hundred fifty dollars ($150) of the fee. The fee for the annual renewal of a license as a designated representative shall be one hundred ten dollars ($110). The penalty for failure to renew is fifty-five dollars ($55).

(r) The fee for a veterinary food-animal drug retailer license is four hundred dollars ($400). The annual renewal fee for a veterinary food-animal drug retailer is two hundred and fifty dollars ($250). The fee for the issuance of a temporary license is two hundred and fifty dollars ($250)

(s) The fee for the issuance of a retired pharmacist license shall be thirty dollars ($30).

Authority cited: Sections 163.5 and 4005, Business and Professions Code. Reference: Sections 163.5,
4005, 4110, 4112(h), 4120, 4127.5, 4196, 4200,**4210** 4400, 4401 and 4403, Business and Professions
Code.

Motion: Amend 1749 subdivision (f)(2) to make the application fee $300 and issue the initial license at no additional cost. Amend the language to clarify that the $300 renewal fee is in addition to the pharmacist license renewal.

Support: 4 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Gutierrez	x			
Law	x			
Veale	x			
Weisser	x			

b. Update on the Status of the Drafted Protocols:

1. *For Pharmacists Who Furnish Self-Administered Hormonal Contraceptives*
   Note: see the committee meeting materials for a copy of the protocol and fact sheets as discussed below.

   The committee reviewed the fact sheets provided in the meeting materials against the protocol for applicability and educational value to patients. The committee stated that they approved of the fact sheets as provided.

   Ms. McCaman reported that the fact sheets would be translated into five languages and provided on the board's website.

   There were no comments from the public.

2. *For Pharmacists Who Furnish Nicotine Replacement Products*
   Note: see the committee meeting materials for a copy of the protocol as discussed below.

Ms. Freedman stated that she was concerned that, as provided, the protocol does not clearly state what the licensee is required to do in a practice environment.

Ms. Freedman stated that the law requires the pharmacist to be certified in smoking cessation therapy, while section (b)(8) of the protocol states that the pharmacist must complete two hours of an approved continuing education program. Ms. Freedman explained that this creates a disconnect between the statute and the protocol. To solve the disconnect, Ms. Freedman recommended amending the language to read: "To be certified in smoking cessation therapy a pharmacist must have completed two hours of an approved continuing education program."

A member of the public explained that many pharmacy associations provide approved continuing education programs.

President Weisser asked if the board could leave the protocol unchanged so that it would not have to be re-approved by the Medical Board. Ms. Freedman responded that by leaving the language unchanged the board would risk the protocol not being approved by the Office of Administrative Law (OAL). The committee decided to leave the protocol unchanged and provide information to OAL if they have questions during the rulemaking process.

3. *For Pharmacists Who Furnish Naloxone Under Emergency Provisions*
   Note: see the committee meeting materials for a copy of the protocol as discussed below.

   President Weisser reported that the board has filed the protocol as an emergency regulation with the Office of Administrative Law, and it became effective on April 10.

c. Review and Discussion of the Naloxone Protocol

Ms. McCaman stated that during the regular rulemaking process the board should clarify that training programs must provide training on *all* routes of administration. The committee clarified that this change would not affect the emergency rulemaking that has already been filed. Ms. Freedman explained the regular rulemaking process.

The committee stated that there are some companies that are providing training programs that only promote their product. The committee stated that this type of training would not be sufficient as it does not cover all routes of administration. It was noted that CPhA is providing both web and in-person training that covers all routes of administration.

Ms. Herold explained that board staff used common labeling software to create sample labels for naloxone products, and it became clear that the standard directions for use did not translate well onto the labels.

Ms. Freedman stated that she reformatted the protocol without changing the policy. The reformatted protocol was provided to the committee members and is provided immediately following these minutes.

Ms. Herold stated that the committee needs to decide whose name should be on the label, the patient or the recipient.

The committee discussed the requirement for pharmacists to provide translated fact sheets and screening questionnaires. The committee was concerned that a pharmacist may not dispense the naloxone if they did not have a translated fact sheet available or screening questionnaire available. The committee asked Ms. Freedman to draft the language to say that the pharmacist shall provide the translated information that is provided on the board's website.

Ms. Freedman recommended amending subsection (4) of the emergency regulation so that the protocol would require the pharmacist to provide advice to the patient on how to choose the formulation which is appropriate for them. As the protocol would have to be re-approved by the Medical Board as part of the regular rulemaking process, the committee decided that it would be best to amend subsection (4).

The committee elected to remove references to kits as the product may not always be dispensed as part of a kit.

The committee discussed how best to label the product so that someone could purchase naloxone to use on someone else in an emergency situation. Ms. Herold provided the example of a teacher or law enforcement officer purchasing naloxone so that they would have it ready if an emergency situation arose.

It was suggested to label the product for Jane or John Doe. President Weisser noted that labeling the product for Jane or John Doe would only work if the person was paying cash and not looking to be reimbursed by insurance.

Robert Stein, from KGI School of Pharmacy, stated that he would be concerned with creating an electronic medical record for someone who is not the patient.

Rebecca Cupp, from Ralph's Pharmacy, clarified that if the pharmacist created a patient profile for John Doe there would be hundreds of patients under that fictitious profile. The committee agreed that this would be acceptable.

Dr. Cupp asked how a pharmacy would handle a recall of naloxone as the fictitious patient profile would not have patient contact information. Ms. Herold stated that the board would

not expect the pharmacy to contact recipients that received the naloxone under the fictitious name John Doe.

Lisa Kroon noted that there was no time requirement for the naloxone training (example taking the training within the last two years). The committee discussed if they wanted to require the training to be completed recently. The committee decided not to place a time limit on the training as they felt it would create a barrier for a pharmacist who wanted to provide naloxone to a patient in need.

Motion: Direct board staff to use the newly revised protocol (as provided at the meeting), amend it based on the committee discussion and bring it to the April board meeting for approval.

M/S: Veale/Gutierrez

Support: 4 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Gutierrez	x			
Law	x			
Veale	x			
Weisser	x			

The committee recessed for lunch at 1:20 p.m. and resumed at 1:52 p.m.

d. Discussion and Development of Proposed Requirements for Pharmacists Who Initiate and Administer Immunizations Pursuant to Recommended Immunization Schedules by the Federal Advisory Committee of Immunization Practices

President Weisser explained that under Business and Professions Code section 4052.8, immunizations may be provided by pharmacists who possess the required training to provide immunizations. Specifically, to initiate immunizations, a pharmacist must:

- complete an immunization training program endorsed by the CDC,
- be certified in basic life support,
- comply with all state and federal recordkeeping requirements,
- provide information to the patient's primary care physician and into the appropriate immunization registry designated by the immunization branch of the CDPH.

The committee discussed if they wanted to require pharmacists to report to the state and/or local immunization information system. Dr. Gutierrez stated that reporting the information is important to public health.

Ms. Veale asked if the patient can opt out of having their vaccination information placed in the state database. Ms. McCaman explained that for public health reasons the information is required to be reported to the database; however the patient can choose not to allow their information to be shared with other entities (such as schools).

The public asked if physicians are required to enter immunization information into the database. Ms. Herold responded that currently doctors are not required to report, pharmacists will be setting the standard.

Motion: Accept section (e) as provided in the meeting materials.

M/S: Gutierrez/Law

Support: 4 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Gutierrez	x			
Law	x			
Veale	x			
Weisser	x			

Ms. Veale left the room at 2:05 p.m.

President Weisser asked if patients receive information when they receive the vaccine. Pharmacists in the audience explained that in chain pharmacies, patients receive information on what vaccine they received and the information is recorded in the patient profile. The committee elected to require the pharmacist to provide written documentation to the patient at the time the vaccine is administered.

The committee discussed how long the pharmacy should be required to keep the immunization records. Dr. Goad explained that federal law requires the information to be maintained for the life of the patient and recommended that pharmacist follow this standard. President Weisser expressed his concern that requiring a pharmacy to archive the records indefinitely would discourage independent pharmacies from providing vaccines. The committee decided to leave section (f) unchanged pharmacists as must comply with the federal requirements referenced in the section.

The committee decided to require the pharmacist to report the immunization information to the physician within 15 days of administration.

Motion: Require the pharmacist to report the immunization information to the physician within 15 days of administration. Require the pharmacist to provide the patient with

written documentation of the type of immunization, date of administration, who administered the immunization and where it was administered.

M/S: Law Gutierrez

M/S: Gutierrez/Law

Support: 3 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Gutierrez	x			
Law	x			
Veale				x
Weisser	x			

The committee discussed the training requirements for immunization training as listed in section (b). The committee elected to remove "current" from section (b)(1) as they did not feel that a pharmacist needed to complete intensive immunization training every three years. The committee also decided to remove "current" from section (b)(2) as it was unnecessary.

The committee made no changes to section (c).

Ms. Herold recommended removing the references to 1717 and 1707.1 in section (f). The committee agreed.

Dr. Goad stated that he felt the requirement in section (e) to report to the registry within 15-days is too short of a timeframe for independent pharmacies. The committee decided to change section (e) to require reporting to the registry at least every three months.

e. Discussion and Development of Proposed Requirements for Pharmacists For Prescription Medications not Requiring a Diagnosis that Are Recommended by the CDC for Travel Outside the US

Ms. McCaman noted that she would update the language so that it followed the same format as the immunization language (i.e. remove references to 1717 and 1707.1).

Ms. Veale returned at 2:31 p.m.

The committee discussed the training requirements for pharmacists who will administer the yellow fever vaccine. The committee determined that it was appropriate for pharmacists practicing travel medicine to take the yellow fever training, even if they will not be administering the vaccine themselves.

Ms. McCaman concluded that she would make minor editing corrections and provide the language to the board at the April meeting.

f. General Discussion Concerning Implementation of SB 493

Dr. Gutierrez asked what the timing would be for implementation of the APP licensure program. Ms. Herold responded that the protocols and the APP requirements are to be moved to regulation hearing no later than the July board meeting. The committee decided to schedule a board meeting on June 3-4, 2015 to address any changes the full board makes at the April board meeting.

Felix Pham expressed his concern with the number of residency programs available and asked if the board could create a grant program to help create residency programs. Ms. Herold responded that the board did not have the funding. Rebecca Cupp reported that APHA and other organizations are looking for ways to increase the availably of community residency programs.

g. Public Comment for Items Not on the Agenda, Matters for Future Meetings

A member of the public asked the committee to consider liability concerns for pharmacists who administer naloxone to a patient in a pharmacy in an emergency situation. Ms. McCaman noted that other states have had major issues with people bringing patients to pharmacies instead of emergency rooms for overdose situations. Ms. Freedman stated that liability is not in the purview of the committee's work. Ms. Herold stated that this may be an issue that will need to be addressed at some point in the future.

President Weisser adjourned the meeting 3:03 p.m.

Naloxone Protocol as Amended by Laura Freedman Provided to the Committee on April 13, 2015

Title 16. Board of Pharmacy. Adopt §1746.3, which is new regulation text, as follows:

§1746.3 Protocol for Pharmacists Furnishing Naloxone Hydrochloride

A pharmacist furnishing naloxone hydrochloride pursuant to Section 4052.01 of the Business and Professions Code shall satisfy the requirements of this section.

(a) As used in this section:
(1) "Kit" means _____ and may include optional items, including alcohol pads, rescue breathing masks, and rubber gloves.
(2) "Opioid" means naturally derived opiates as well as synthetic and semi-synthetic opioids.
(3) "Recipient" means the person to whom naloxone hydrochloride is furnished.

(b) Training. Prior to furnishing naloxone hydrochloride, pharmacists who use this protocol must have successfully completed a minimum of one hour of an approved continuing education program specific to the use of naloxone hydrochloride, or an equivalent curriculum-based training program completed in a board recognized school of pharmacy.

(c) Protocol for Pharmacists Furnishing Naloxone Hydrochloride. Before providing naloxone hydrochloride, the pharmacist shall:

(1) Screen the potential recipient by asking the following questions:
(i) Whether the potential recipient currently uses or has a history of using illicit or prescription opioids? (If the recipient answers yes, the pharmacist may skip screening question ii.);
(ii) Whether the potential recipient is in contact with anyone who uses or has a history of using illicit or prescription opioids. If the recipient answers yes, the pharmacist may continue.
(iii) Whether the person to whom the naloxone hydrochloride would be administered has a known hypersensitivity to
Naloxone. If the recipient answers yes, the pharmacist may not provide the Naloxone. If the recipient responds no, the pharmacist may continue.
The screening questions shall be made available in alternate languages for recipients and patients whose primary language is not English.

(2) Provide the recipient training in opioid overdose prevention, recognition, response, and administration of the antidote naloxone.

(3) When naloxone hydrochloride is furnished:

(i) The pharmacist shall provide the recipient with appropriate counseling and information on the product furnished, including dosing, effectiveness, adverse effects, storage conditions, shelf-life, and safety. The recipient is not permitted to waive the required consultation.

(ii) The pharmacist shall provide the recipient with any informational resources on hand and/or referrals to appropriate resources if the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time.

(iii) The pharmacist shall answer any questions the recipient may have regarding naloxone hydrochloride.

(4) Product Selection: A pharmacist shall advise the recipient to how to choose the kit and route of administration based on the formulation available, how well it can likely be administered, the setting, and local context. The pharmacists may supply naloxone hydrochloride as an intramuscular injection, intranasal spray, auto-injector, or other FDA approved products.

(5) Kit Labeling: A pharmacist shall label the kit consistent with law and regulations. Labels shall include an expiration date for the naloxone hydrochloride furnished. An example of appropriate labeling is available on the Board of Pharmacy's website.

(6) Fact Sheet: The pharmacist shall provide the recipient a copy of the current naloxone fact sheet approved by the Board of Pharmacy. This fact sheet shall be made available in alternate languages for patients whose primary language is not English.

(7) Notifications: If the recipient of the naloxone hydrochloride is also the person to whom the naloxone hydrochloride would be administered, then the naloxone recipient is considered a patient for purposes of this protocol and notification may be required under this section.

If the patient gives verbal or written consent, then the pharmacist shall notify the patient's primary care provider of any drug(s) and/or device(s) furnished, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the patient and that primary care provider.

If the patient does not have a primary care provider, or chooses not to give notification consent, then the pharmacist shall provide a written record of the drug(s) and/or device(s) furnished and advise the patient to consult an appropriate health care provider of the patient's choice.

(8) Documentation: Each naloxone hydrochloride product furnished by a pharmacist pursuant to this protocol shall be documented in a medication record

for the naloxone recipient, and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense. The 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.

(9) Privacy: All pharmacists furnishing naloxone hydrochloride in a pharmacy or health care facility shall operate under the pharmacy or facility's policies and procedures to ensure that recipient confidentiality and privacy are maintained.

Authority and Reference: Section 4052.01, Business and Professions Code.

For the Board of Pharmacy's website:

Naloxone
Suggested Kit Labeling (by route of administration):

Intramuscular	Intranasal	Auto-Injector
Naloxone 0.4mg/1ml single dose vial, # 2 vials SIG: Inject 1 ml intramuscularly upon signs of opioid overdose. Call 911. May repeat x 1. Syringe 3ml 25G X 1" # 2 SIG: Use as directed for naloxone administration. Kit should contain 2 vials and 2 syringes.	Naloxone needleless prefilled syringe (1mg/1ml concentration) 2ml, # 2 syringes SIG: Spray one-half (1ml) of the naloxone into each nostril upon signs of opioid overdose. Call 911. May repeat x 1. Mucosal Atomization Device (MAD) # 2 SIG: Use as directed for naloxone administration. Kit should contain 2 prefilled needleless syringes and 2 atomizers.	Naloxone 0.4 mg/0.4 ml #1 twin pack SIG: Use one auto-injector upon signs of opioid overdose. Call 911. May repeat x 1. Kit is commercially available as a twin pack with directions for administration included.

Letter from Dr. Andrew Lowe

April 10, 2015

Stan Weisser, President
California State Board of Pharmacy

Dear President Weisser,

I am writing to you today in hopes that you will pass my remarks on to the Committee on the Implementation of SB493, as I will be unable to attend the meeting on April 13.

The passage of SB493 has presented our profession with unique opportunities to enhance the care of patients, and the provider status will allow us to seek reimbursement for our services. The Advanced Practice Pharmacist (APP) license, in my opinion, recognizes the additional training and practice experience that many pharmacists have achieved in the past several years. In discussing the proposed requirements for APP licensure, I understand that the applicants must meet two out of the following three requirements:

- Completion of an ASHP-accredited residency program
- Certification by the Board of Pharmaceutical Specialties (BPS)
- Practice under collaborative practice protocol for a minimum of one year

The reason I am writing to you is to express concern regarding the documentation needed to fulfill the third requirement (collaborative practice protocol). While first two requirements involve some form of objective demonstration of competency, the third one leaves much room for interpretation.

Consider the following example:
A pharmacist who has not completed a residency, but has passed a BPS examination, works in a medical office building. He/she has a verbal agreement with a couple of physicians in the building to manage warfarin anticoagulation. There is no assurance that the pharmacist is doing this in a competent manner, and in fact turns out that he/she lacks formal training in anticoagulation management. By the proposed rules, this pharmacist would be cleared to obtain an APP license. I am concerned that there would be no way of ensuring competency, and thus protecting the public against an inadvertent error caused by a training gap.

I would like to propose the following steps toward fulfilling this requirement:

- Provision of a collaborative protocol previously approved according to section 4052, and signed by the collaborating physician, that the applicant has practiced under for a minimum of one year, which should not include the year(s) spent in residency training
- Require a minimum of five (5) accredited continuing education hours on topics directly related to the pharmacist's area of practice. This will help ensure continuing competency.

I am very excited about these changes in our practice, and would like to, just as I am sure you do, make sure that it is a safe practice.

Thank you for your consideration of my remarks.

Sincerely yours,

Andrew Lowe, Pharm.D.
Redlands, CA