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

DATE: November 5, 2014

LOCATION: Department of Consumer Affair
First Floor Hearing Room
1625 North Market Blvd.
Sacramento, Ca 95834

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

COMMITTEE MEMBERS NOT PRESENT: Deborah Veale, RPh

STAFF PRESENT: Virginia Herold, Executive Officer
Laura Hendricks, Staff Analyst
Michael Santiago, DCA Staff Counsel

Call to Order

President Weisser called the meeting to order at 10:19 a.m.

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

President Weisser acknowledged current board member Allen Schaad in the audience.

1. Proposed Schedule for Action on Provisions Established by SB 493 (Hernandez, Chapter 469, Statutes of 2013)

President Weisser introduced Liz McCaman, who will we working with the committee on drafting protocols. President Weisser explained that at today's meeting the committee would be reviewing the draft protocols for hormonal contraception and nicotine replacement.

President Weisser briefly reviewed that schedule of action that was provided in the meeting materials.

There were no comments from the board of from the public.

2. Identification of Materials Where Board Guidance Is Envisioned, Discussion of the Requirements:

(a) For Pharmacists Who Initiate and Administer Immunizations Pursuant to Recommended Immunization Schedules by the Federal Advisory Committee of Immunization Practices

President Weisser explained that 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 CDPH's immunization registry.

President Weisser noted that at the August SB 493 Committee Meeting, the committee held a lengthy discussion about reporting immunization into the immunization registry.

Dr. Steve Nickell, from California Immunization Registry (CAIR) provided a presentation via phone to the committee. Highlights from his presentation are below. The entire presentation follows these minutes.

Overview

- CAIR is a consortium of 9 regional registries
- 7 use same 'CAIR' software and are operated by CDPH
- 'CAIR 7' cover 48 of 58 CA counties; 87% of population

Benefits

- FOR PATIENTS:
  - Consolidate in one record all immunizations a patient has received.

  - Provide an accurate, official copy of a child's immunization history for personal, day care, school, or camp entry requirements.
  - Help ensure that a patient's immunizations are up to date.
  - Help ensure timely immunization for children whose families move or switch healthcare providers.
  - Prevent unnecessary (duplicative) immunizations.
- FOR PROVIDERS, PLANS AND PURCHASERS:
  - Provide definitive information on immunizations due or overdue.
  - Provide current recommendations and information on new vaccines.
  - Complete required school, camp, and day care immunization records.
  - Facilitate introduction of new vaccines or changes in the vaccine schedule.
  - Help manage vaccine inventories.
  - Generate coverage reports for managed care (e.g., Healthcare Effectiveness Data and Information Set [HEDIS®]) and other organizations.

CAIR Disclosure

- Patients must be informed that their information will be shared prior to the provider sharing the information with CAIR
- Patients have right to:
  - Refuse sharing with other CAIR users
  - Correct record
  - Request list of users who have viewed their record
- CAIR Disclosure ('Immunization Registry Notice to Patients and Parents') is available in multiple languages at: http://cairweb.org/cair-forms/

CAIR Participation

Interface	*Participant Type*	*# Active*	*# Pending*
Web (manual entry)	**Clinical**	**~2,400**	
	Read-Only (schools)	**>4,000**	
Electronic	**Clinical**	**>2,000**	**~2,000**

President Weisser asked if patients can access their own information. Dr. Nickell responded that the new version that is currently under development will have a patient portal.

President Weisser asked to clarify if the current system allows schools to see student information. Dr. Nickell responded that currently there are approximately 4,000 schools and daycare facilities that have read-only rights, allowing them to check student immunizations.

Mr. Law asked if they are concerned about the capacity of the system. Dr. Nickell responded that the system has plenty of room to expand and in the future they will be looking to delete entries for people who have passed away.

Dr. Gray, from the Institute for Community Pharmacy, asked how the CAIR system ensures that the practitioner has the correct patient. Dr. Nickell answered that the system uses algorithms. He noted that there are sometimes problems with patients not having a NPI.

Dr. Gray asked when a pharmacist gives a vaccine how will it be determined what exact pharmacy location gave the immunization. Dr. Nickell answered that there are ID's given to each pharmacy, which includes the exact location (address, store number, etc).

Dr. Gray asked if information is automatically uploaded to the Federal Database. Dr. Nickell responded that it is not.

Dr. Gray asked if Veterans Affairs is inputting data. Dr. Nickell answered that currently there is nothing coming from the VA.

Dan Robinson, Dean of Western University, commented that currently reporting to the registry is voluntary. He added that if the board makes it mandatory for pharmacists to report, they would be the only health care provider required to do so. President Weisser commented that the shift to vaccines being provided by pharmacists rather than doctors would justify them reporting to the database. Ms. Herold stated she doesn't think reporting is currently a requirement.

President Weisser reported that at the August meeting, there was considerable discussion about whether students who may have received this training in pharmacy school could use their training without retaking it somewhere else. The question arose as to how they could document they completed this training several years before.

Lisa Kroon, from the University of California, San Francisco, reported that several schools have created an affidavit. Dr. Kroon explained that the affidavit outlines the curriculum that was received by the student either in the core curriculum or in an elective. She explained that the student would keep this and provide it to the board with their application. She noted that the student signs under penalty of perjury that they did receive all of the education listed on the affidavit. The school will also fill out a portion of the affidavit confirming the students' enrollment and graduation date.

Ms. Herold commented that the board would like to see what dates the schools started teaching immunizations as part of their core curriculum. Dr. Kroon responded that this information could be researched and provided to the committee.

Ms. McCaman commented that the committee should also determine if the schools teach hormonal contraception to the US MEC standards.

Dr. Gutierrez asked if the school, rather than the student, could attest to the student receiving the education. Dr. Kroon responded that there was concern about the amount of paperwork the school would have to complete. Dan Robinson, Dean of Western University added that it may be difficult for the school to attest to the specific education received as much of it is received through experience.

Dr. Gray, commented that during the SB 493 hearings the Medical Board and AMA stated that they expected the Pharmacy Board to replicate the Medical Board's process for verifying education. The Medical Board does not require upfront documentation; rather the licensee must provide proof upon the request of the medical board.

The committee asked if the schools could provide information on when each component became part of the core curriculum at the December committee meeting.

(b) For Prescription Medications Not Requiring a Diagnosis that Are Recommended by the CDC for Travel Outside the US

President Weisser explained that at this meeting, the committee will continue its discussions about the parameters for travel medications. Below are excerpts from the August 6 meeting minutes (**Attachment 2).**

President Weisser reported that at the August committee meeting Dr. Goad indicated that the CDC Yellow-book is the guidance document that the legislation is referring to. He reported that there is a chapter in the CDC Yellow-book on self-treatable illnesses.

President Weisser stated that at the August committee meeting the board's counsel, Kristy Scheildge, commented that the committee should define what "not requiring a diagnosis" means and identify the CDC guidance document.

At the last meeting President Weisser commented that self-treatable illnesses are very broad. President Weisser asked if the board can refer to the CDC Yellow-book. Ms. Scheildge responded that the committee would need to review it in order to determine if it is appropriate and clear enough for licensees.

President Weisser reported that at the August meeting Dr. Steve Gray noted that the goal of SB 493 was to help alleviate the work of doctors and nurses. During the negotiations with the medical professionals, they asked that pharmacists follow the same guidelines that they do, which would be the CDC Yellow-book. Dr. Gray noted that in many other countries these travel medications are available over the counter.

President Weisser reported that at the August meeting Ms. Scheildge encouraged the committee to consider how quickly the primary care physicians need to be notified, and what information needs to be placed in the patient file after a pharmacist provides the travel medications.

President Weisser stated that a draft document on travel medications prepared by a team of individuals from CSHP and CPhA was provided in the meeting materials. President Weisser asked if anyone in the audience could comment on the document in Dr. Goad's absence.

Dr. Robinson clarified that travel medications do not apply to previously diagnosed disease; they are only for anticipated diseases that may occur during travel.

Dr. Gutierrez asked how long the "certificate of travel health" referenced in the document was valid for. Dr. Robinson responded that if pharmacists are going to provide travel medications they should follow the outline of the "travel health" education. The certificate is referenced in the document only to show that this training would be the gold standard of education for pharmacists wanting to provide travel meds.

President Weisser asked how a pharmacist would respond if someone came into a pharmacy saying they have jet-lag and asked for Ambien. Dr. Robinson responded that he would need to ask someone who works in travel medicine.

Dr. Gutierrez expressed her concern with patients trying to receive unnecessary antibiotics. Dr. Robinson responded that the pharmacist should be talking to the patient about their travel to determine what medications they actually require.

Dr. Gray commented that doctors are required to perform a good faith examination prior to prescribing travel meds. However, the exam does not need to be a physical examination. The Medical Board has specific requirements for when the exam must be physical.

Dr. Gray recommended that the committee have travel clinics come to a future meeting to discuss their process.

Dr. Gray suggested that the board create requirements for which records a pharmacist must have to show how they determined that the patient needed that travel medicine. Dr. Gray added that a pharmacist would need a personal DEA number to provide a controlled substance.

Sara McBane provided her personal experience regarding travel medicine when she traveled abroad.

Mr. Law commented that the burden should be on the traveler to prove that they will be traveling to an area that justifies the need for travel meds.

Brian Warren, from the California Pharmacists Association, suggested that the committee look at existing safeguards for travel clinics and doctors.

Andrew Lowe, a pharmacist, commented that he is concerned with documentation of travel and proof should be provided for the protection of the patient and pharmacists. Mr. Lowe added that he is also concerned with patients seeking controlled substances; he suggested that the committee create a quantity limit for the dispensing of controlled substances.

Ms. McCaman commented that documentation could be as simple as the traveler showing an electronic confirmation for their flight, hotel, etc.

(c) For Ordering and Interpreting Tests to Monitor and Manage Drug Therapies

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 enter 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 the August committee meeting, Dr. Gutierrez asked how the board might handle cases of patients who have an adverse medical event which could have been prevented if the pharmacist would have ordered a test.

At the August committee meeting Ms. Herold commented that there are really two issues the committee should discuss:

1. Can the board discipline a pharmacist for not ordering a test; and
2. What is the pharmacist's civil liability in regards to testing?

President Weisser reported that at the August committee meeting, Dr. Gray commented that during creation of the legislation, doctors stated that they wanted pharmacists to have the ability to order tests in order to make recommendations on the patient's care based on actual data.

President Weisser reported that at the August committee meeting Lisa Kroon, from the University of California, San Francisco, commented at this time the language in SB 493 states that pharmacists *may* order tests to improve patient safety and access to care. However, she noted that in the future she could see the standard of care evolving to a point where a pharmacist *must* order a test prior to dispensing a certain medication.

Dr. Gutierrez expressed her concern that ordering tests may cause delays in patients receiving their medication, especially in an independent pharmacy.

Ms. Herold asked the committee to determine if they wanted to draft a regulation on ordering tests or create a guidance document.

Mr. Law commented that ordering tests should not be mandatory, but should be an option for pharmacists who feel it is in the patients' best interest.

Dr. Kroon commented that SB 493 *allows* a pharmacist to order tests, it does not require it. She added that until Healthcare Information Exchange (HIE) sharing is available in all pharmacies, ordering tests should not be required.

President Weisser commented that the committee should consider if there are any liability concerns for an independent pharmacist who decided not to order a test.

Dr. Gutierrez commented that the board should encourage the use of testing where appropriate, but not require it. She added that a pharmacist would need to use their professional judgment to determine if it is worth it to delay a patient's medication in order to conduct testing.

Ms. Herold stated that the committee could draft a policy statement for pharmacists. She noted that it would need to be drafted carefully so that it does not become a de facto regulation.

Mr. Law stated that he sees this applying more towards hospital pharmacies. President Weisser commented that he anticipates that it will expand to community pharmacies. Dr. Kroon agreed that the goal is for community pharmacies to have access to testing.

Dr. Gray and Dr. Robinson stated that the word *may* was used very deliberately when SB 493 was drafted.

Dr. Robinson commented that at previous meetings the committee had been provided a document with guidelines for ordering tests. Ms. Herold commented that this document had been provided in previous meeting materials.

Dr. Gray commented that coordination between a pharmacist and the physician will be very important as pharmacists begin ordering tests. Dr. Robinson agreed that the intent was for doctors and pharmacists to work in collaboration when ordering tests.

Dr. Robinson noted that prior to ordering tests, a pharmacist will need to find a way for the test to be paid for.

Dr. Gutierrez stated that she is not concerned with pharmacists who are working as part of a health system; rather, her concern is for independent pharmacies which may have to significantly delay treatment to order a test.

Keith Yokishoka, pharmacist, commented that the intent for allowing pharmacists to order tests was to increase patient access and decrease the burden on physicians.

The committee recessed for a break at 12:11 p.m. and resumed at 1:04 p.m.

3. Review and Discussion on a Draft Protocol for Pharmacists who Furnish Self-Administered Hormonal Contraceptives

President Weisser explained that the California HealthCare Foundation provided support to the board to develop various components that the board needs to meet the requirements of SB 493. This support was in the way of a researcher to develop draft components for board review. One such component is the development of a protocol for self-administered hormonal contraception.

President Weisser reported that SB 493 requires the development of a protocol for self-administered hormonal contraception. The protocol must be developed and approved by both this board and the Medical Board, in consultation with the American Congress of Obstetricians and Gynecologists, the CA Pharmacists Association and other appropriate entities. It requires a self-screening tool for use by patients based on the current United States Medical Eligibility Criteria (USMEC). The pharmacist must also provide to the patient a fact sheet approved by the same group identified above and the California Department of Public Health.

Below is the draft protocol that was provided in the meeting materials. The self-screening tool and "birth control options" chart are provided following these minutes.

Self-Administered Hormonal Contraception

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

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

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

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

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

- Oral;
- Transdermal patch;
- Vaginal ring.

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

- Ask the patient to use and complete the self-screening tool;
- Review the self-screening answers and clarify responses if needed;
- Measure and record the patient's seated blood pressure.
- When a self-administered hormonal contraceptive is furnished:

o The patient shall be provided with appropriate counseling and information on the product furnished, including dosing, potential side effects, safety concerns, and the FDA required patient product information leaflet.

o The patient shall be advised of the importance of receiving recommended preventative health screenings.

o The patient shall be informed that most contraceptive methods do not protect against sexually transmitted infections (STIs). Consistent and correct use of the latex condom reduces the risk of STIs and HIV.

- When considering a specific clinical situation, pharmacists are encouraged to consult the Centers for Disease Control and Prevention's *U.S. Selected Practice Recommendations for Contraceptive Use, 2013*, available at *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6205a1.htm (or the most updated version or supplement); this document offers guidance on how to use contraceptive methods most effectively, and addresses common but sometimes complicated issues in contraceptive management.

(5) Self-Screening Tool: The pharmacist shall provide the patient with a self-screening tool for use of self-administered hormonal contraceptives. The patient shall complete the self-screening tool, and the pharmacist shall use the answers to identify patient risk factors. The patient shall complete the tool annually, or whenever the patient indicates a major health change.

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

(6) Fact Sheet: The pharmacist shall provide the patient with a copy of the current self-administered hormonal contraception fact sheet approved by the Board of Pharmacy as required by the Business and Professions code Section 4052.3(c). The pharmacist shall review any questions the patient may have regarding self-administered hormonal contraception.

This fact sheet should be made available in alternate languages for patients whose primary language is not English.

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

(8) Notifications: The pharmacist shall notify the patient's primary care provider of any drug(s) or device(s) furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, the pharmacist shall provide the patient with a written record of the drug(s) or device(s) furnished and advise the patient to consult a physician of the patient's choice.

(9) Referrals and Supplies: If self-administered hormonal contraception services are not immediately available at the pharmacy or the pharmacist declines to furnish pursuant to conscience clause, the pharmacist shall refer the patient to another self-administered hormonal contraception provider. The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.

(10) Product Selection: The pharmacist may select any hormonal contraceptive listed in the current version of the United States Medical Eligibility Criteria (USMEC) for Contraceptive Use as Category 1 or 2, based on the information reported in the self-screening tool and the blood pressure as recorded by the pharmacist. The USMEC shall be kept current and

maintained in the pharmacy. Furthermore, generic equivalent products may be furnished.

(11) Documentation: Each self-administered hormonal contraceptive furnished by a pharmacist pursuant to this protocol shall be documented in a patient medication record as required by law. A patient medication record shall be maintained in an automated data processing or manual record mode such that the following information is readily retrievable during the pharmacy's normal operating hours:
(A) The patient's full name and address, telephone number, date of birth or age, and gender;
(B) For each self-administered hormonal contraceptive dispensed by the pharmacist:
(i) The name, strength, dosage form, route of administration, quantity, and directions for use;
(ii) The furnishing pharmacist's name and where appropriate, license number, DEA registration number, or other unique identifier;
(iii) The date on which the self-administered hormonal prescription was dispensed or refilled;
(iv) The prescription number for each self-administered hormonal contraception prescription;
(v) Any additional information required by title 16, sections 1717 and 1701.1 of the California Code of Regulations.
(C) Any of the following which may relate to the contraceptive therapy: patient allergies, idiosyncrasies, current medications and relevant prior medications including nonprescription medications and relevant devices, or medical conditions which are communicated by the patient or the patient's agent.
(D) Any other information that the pharmacist, in his or her professional judgment, deems appropriate.

The patient medication record and a copy of the completed self-screening tool shall be securely stored within the originating pharmacy for at least one year from the date when the last self-administered hormonal contraception product was furnished.

(12) Training: Prior to furnishing self-administered hormonal contraception, pharmacists who participate in this protocol must have completed a minimum of one hour of a ACPE- or ASHP-approved continuing education program specific to self-administered hormonal contraception and application of the USMEC, or an equivalent curriculum-based training program completed on or after 2010 in a California School of Pharmacy.

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

Ms. McCaman briefly reviewed the draft protocol. She then asked for input from experts in the profession, particularly regarding the weight of a patient.

President Weisser asked if an exam was needed for the vaginal ring. Ms. McCaman responded that no exam was needed.

President Weisser asked if the FDA requires a fact sheet. Ms. McCaman responded that the FDA requires a fact sheet be provided for each prescription, but it is specific to the specific medication being dispensed. She felt it was necessary to provide information on all types of contraception.

President Weisser asked why she used one hour for the training time. Ms. McCaman responded that there was no specific requirement for training time, so she used one hour. She asked that those with knowledge on appropriate training provide her with feedback.

Ms. Herold commented that if a pharmacist had a problem with providing hormonal contraception they would not take the one-hour training in order to provide this service, thus the conscience clause could be removed.

Dr. Gutierrez asked if the fact sheet would be translated. Ms. Herold commented that the board strives to translate all documents provided to the public in at least 5 languages.

Mr. Law asked if there is a continuing education requirement. Ms. McCaman responded that she did not include any because she did not see a continuing education requirement in the SB 493 language. She added that if the board felt it was necessary it could be added.

Dr. Kathy Hill-Besinque recommended that the board should make the FDA fact sheet the minimum requirement. She said if a pharmacist wants to provide additional information they can give the patient the fact sheet developed by the board. Ms. McCaman responded that her interpretation of SB 493 was that the board must create their own fact sheet. Dr. Hill-Besinque stated that she felt the FDA fact sheets would be sufficient and as information is constantly changing it would be difficult for the board to keep their fact sheet up-to-date.

Dr. Hill-Besinque commented that some of the language regarding record keeping is duplicative of existing California law. President Weisser agreed.

Dr. Hill-Besinque commented that medroxyprogesterone acetate by injection (Depo-Provera) is not required to be administered by a healthcare provider. Thus, it should be included as a self-administered option. Ms. McCaman commented that originally it did include the injection;

however, after her research she determined that an injection is not self-administered. She noted that she is not opposed to including it if she can

President Weisser asked if diaphragms are still used. Dr. Hill-Besinque commented that they are still used; however, they require fitting by a doctor.

Sally Raffi, from the University of California, San Diego, commented that she was encouraged that the board was open to including depo-injections as they are the most effective form of self-administered birth control.

Ms. Raffi recommended that the board remove “patch” and “ring” so that as products change the board will not have to update the language.

Dr. Hill-Besinque recommended reorganizing the self-screening tool so that the questions do not begin with “scary” questions that may discourage the use of contraception. She recommended removing the question about being older than 35 and the question about the patient being in a wheelchair.

Ms. Raffi recommended the removal of the question regarding the patient’s weight. A patient’s weight will not affect their eligibility to receive contraception or its safety. She noted that it may affect the medications efficacy, but that is not the purpose of the self-screening tool. Dr. Hill-Besinque commented that studies have shown that weight is not a factor in the efficacy for hormonal contraception. Ms. McCaman asked if they recommended removal of all questions about weight. Dr. Hill-Besinque and Ms. Raffi confirmed that weight should not be included on the self-screening tool.

Dr. Hill-Besinque and Ms. Raffi discussed the need for the pharmacist to take every patient’s blood pressure versus for only those who are taking medication that would affect their blood pressure.

President Weisser asked how a pharmacist deals with a young patient seeking birth control. Dr. Hill-Besinque commented that there is no minimum age for a patient seeking birth control. Hormonal contraception is only recommended for those who have started menstruating, so the pharmacist would need to discuss that with them.

Brianna Pitman, from Planned Parenthood, commented that she appreciated the inclusion of the conscience clause so that patients are not denied care. Ms. Pitman added that depo-injections were not discussed during the creation of SB 493; however, their inclusion should be researched and discussed. Ms. Pitman concluded that she would like to see a list created of clinics that a pharmacist could refer a patient to if they needed additional care of if the pharmacist conscientiously objected to dispensing birth control.

Shannon Smith-Crowley, American Congress of OBGYNs, commented that her main concern is preventing barriers to patients care. She added that she does not feel that a pharmacist needs to take a patient's blood pressure. It should be offered to the patient, but it should not prevent them from receiving care if they decline.

Ms. Herold commented that the fact sheet created by the board was meant to give women information on birth control options that they may not be aware of.

Dr. Hill-Besinque commented that hormonal contraception can be harmful for patients with high blood pressure, so taking blood pressure is necessary.

Dr. Hill-Besinque commented that she would eliminate question regarding regular menstrual cycles, she recommended instead asking when the last menstrual cycle occurred.

Ms. Raffi recommended removing the question about how many cigarettes a person smokes.

Ms. Raffi recommended removing the pregnancy test suggestion. Ms. McCaman responded that she would review this item.

Ms. Raffi commented that the language should be changed from "ACPE- or ASHP-approved continuing education program" to "board approved continuing education program."

Robert Stein, pharmacist, recommended that the board keep the conscience clause for clarity.

Brian Warren, representing the California Pharmacists Association, recommended changing the language to read "The pharmacist shall notify the patient's primary care provider, with patient consent…" Ms. McCaman responded that SB 493 states that the provider must be notified; however, she would like input from the board's legal counsel. Dr. Hill-Besinque commented that it is important for the board to protect a women's right to privacy in this area.

Mr. Warren stated that SB 493 allows the board to create a fact sheet or use a nationally recognized fact sheet. Ms. Herold commented that the FDA fact sheet comes in the medication packaging and is specific to the particular medication.

Mr. Warren asked if pharmacies could put the questions in their own formatting. Ms. Herold responded that she would ask legal counsel.

Ms. Raffi commented that SB 493 gives specific elements that must be included in the fact sheet, and some of the elements are missing from the current draft. Ms. McCaman agreed and noted she would be modifying it based on feedback received.

4. Review and Discussion on a Draft Protocol for Pharmacists Who Furnish Nicotine Replacement Products and Development of Draft Protocols

President Weisser explained that SB 493 provides that a pharmacist may furnish nicotine replacement products approved by the FDA for use by prescription in accordance with standardized protocols. Implementation of this provision requires:

- Certification of the pharmacist in smoking cessation therapy by an organization recognized by the board
- Development of a protocol developed and approved by this board and the Medical Board of California with other "appropriate entities"
- The pharmacist maintain records of all prescription drugs and devices furnished for at least three years
- The patient's primary care provider is notified of any drugs or devices furnished, or information is added to a shared patient record. If the patient has no primary care provider, the pharmacist provides the patient with a written record and advises the patient to consult a physician of the patient's choice
- The pharmacist completes one hour of CE on smoking cessation therapy biennially

A draft protocol for nicotine replacement products is provided below.

Nicotine Replacement

(a) A pharmacist furnishing nicotine replacement products pursuant to Section 4052.9 of the Business and Professions code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Nicotine Replacement Products

(1) Authority: Section 4052.9(a) of the California Business and Professions code authorizes a pharmacist to furnish nicotine replacement products approved by the federal Food and Drug Administration for use by prescription only in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol in this section satisfies that requirement.

(2) Purpose: To provide timely access to nicotine replacement products and to ensure that the patient receives adequate information to successfully comply with smoking cessation therapy.

(3) Explanation of Covered Products: Prescription-only nicotine replacement products with the following routes of administration are covered by this protocol:

- Nicotine patch;

- Inhaler;
- Nasal spray.

The smoking cessation medications Bupropion SR (also marketed as Zyban) and Varenicline (also marketed as Chantix) are not covered by this protocol; these medications are not considered Nicotine Replacement Therapy, and therefore not authorized by Section 4052.9 of the California Business and Professions code.

(4) Procedure: When a patient requests nicotine replacement or smoking cessation products, or when a pharmacist in his or her professional judgment decides to initiate smoking cessation counseling, the pharmacist shall complete the following steps:

- Ask the patient to explain his or her current illness and then clearly connect the illness with smoking. It is important to be specific because general statements like "smoking will kill you" may come across as nagging;
- Review the patients' past quit attempts and examine three key questions:

o What type of behavior-change techniques did the patient use in the past?
o How did the patient use the smoking-cessation medication(s) of choice?
o If the patient did not make any behavior changes or use medication(s), why not?
o Did the patient experience any adverse effects during past quit attempts?

- Ask the patient the following screening questions:

o Are you pregnant or plan to be pregnant? (If yes, do not furnish and refer to obstetrician)
o Have you had a recent heart attack or any heart procedures within the last 2 weeks?
o Do you have any history of arrhythmias?
o Do you have any chest pain?
o Have you been diagnosed with temporomandibular joint (TMJ) disorder, or do you wear dentures? (If yes, avoid gum)
o Do you have any history of allergic rhinitis (e.g. nasal allergies)? (If yes, avoid nasal spray)
o Do you have any history of asthma or COPD? (If yes, avoid inhaler and nasal spray).

Screening questions should be asked again annually, or whenever the patient indicates a major health change.

- When a nicotine replacement product is furnished:

- The pharmacist shall review the instructions for use with every patient using a nicotine replacement product.
- The patient shall be informed of the importance of coping with quitting; referring the patient to a behavior-change program will significantly increase his or her likelihood of success.
- The patient shall be provided with appropriate information on the national telephone quit line, 1-800-QUIT-NOW and/or the California telephone quit line, 1-800-NO-BUTTS.
- Pharmacists are encouraged to recommend the patient seek additional assistance, including but not limited to a formal cessation plan available for free through the quit lines. Pharmacists are also encouraged to research and refer patients to smartphone apps such as QuitSTART, QuitPal, and QuitGuide.
- The pharmacist shall review any questions the patient may have regarding smoking cessation therapy and/or nicotine replacement products.
- When considering a specific clinical situation, pharmacists are encouraged to consult the tools, resources, and publications from the University of California, San Francisco available at http://rxforchange.ucsf.edu/registration.php and http://smokingcessationleadership.ucsf.edu/.

(5) Product Selection: Based on the information gathered from the patient during the Procedure outlined above, the pharmacist may select any nicotine replacement products from the list of therapies specified in the Table "Pharmacologic Product Guide: FDA-Approved Medications for Smoking Cessation." This list shall be kept current and maintained in the pharmacy. Furthermore, generic equivalent products may be furnished.

(6) Follow-Up Care: The pharmacist shall refer the patient to an appropriate health care provider for follow-up care in the following situations:

- Women who are pregnant or are planning to become pregnant.
- Patients with significant cardiac concerns, for example:
  - Myocardial infarction within the previous 2 weeks;
  - Serious underlying arrhythmias;
  - Serious or worsening angina pectoris.
- Patients with uncontrolled mental health conditions.

(7) Notifications: The pharmacist shall notify the patient's primary care provider of any drug(s) or device(s) furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the

patient does not have a primary care provider, the pharmacist shall provide the patient with a written record of the drug(s) or device(s) furnished and advise the patient to consult a physician of the patient's choice.

(8) Referrals and Supplies: If smoking cessation services and/or nicotine replacement products are not immediately available, the pharmacist shall refer the patient to another nicotine replacement product provider and the National and/or California Smokers' Helpline.

(9) Documentation: Each smoking cessation drug or device furnished by a pharmacist pursuant to this protocol shall be documented in a patient medication record and securely stored within the originating pharmacy for a period of at least three years from the date when the last smoking cessation product was furnished; a patient medication record shall serve the purpose of notifying other health care providers and monitoring the patient. A patient medication record shall be maintained in an automated data processing or manual record mode such that the following information is readily retrievable during the pharmacy's normal operating hours:
(A) The patient's full name and address, telephone number, date of birth or age, and gender;
(B) For each nicotine replacement product dispensed by the pharmacist:
(i) The name, strength, dosage form, route of administration, quantity, and directions for use;
(ii) The furnishing pharmacist's name and where appropriate, license number, DEA registration number, or other unique identifier;
(iii) The date on which the nicotine replacement product was dispensed or refilled;
(iv) The prescription number for each nicotine replacement medication prescription;
(v) Any additional information required by title 16, sections 1717 and 1707.1 of the California Code of Regulations.
(C) Any of the following which may relate to the smoking cessation therapy: patient allergies, idiosyncrasies, current medications and relevant prior medications including nonprescription medications and relevant devices, or medical conditions which are communicated by the patient or the patient's agent.
(D) Any other information that the pharmacist, in his or her professional judgment, deems appropriate.

(10) Training: Prior to furnishing nicotine replacement products, pharmacists who participate in this protocol must be certified in

> smoking cessation therapy by an organization recognized by the Board of Pharmacy. The Board of Pharmacy recognizes ACPE-approved CE programs of at least four hours, and recognizes the graduates of California Schools of Pharmacy.
>
> Additionally, pharmacists who participate in this protocol must complete ongoing continuing education focused on smoking cessation therapy once every two years from a CME- or ACPE-approved provider.
>
> (11) Patient Privacy: All pharmacists furnishing nicotine replacement products in a pharmacy shall operate under the pharmacy's policies and procedures to ensure that patient confidentiality and privacy are maintained.

Sarah McBane, pharmacist, recommended removing the three forms listed (patch, inhaler and spray).

Ms. McBane recommended removing the four questions about prior attempts to quit and changing it to say: Review the patient's current tobacco use and discuss their prior quit attempts.

Ms. McBane asked why the draft language states that a four-hour course is required. Ms. McCaman responded that she did research and found an ACPE program that was four hours and she found that students received six hours of education. She noted that she was willing to discuss modifying this requirement based on feedback. Dr. Kroon commented that a two hour training course would be sufficient for practicing pharmacists (students receive more training).

Dr. Kroon and Ms. McBane recommended removing: "Ask the patient to explain his or her current illness and then clearly connect the illness with smoking. It is important to be specific because general statements like "smoking will kill you" may come across as nagging."

Dr. Kroon recommended removing: "Screening questions should be asked again annually…"

Dr. Kroon recommended not including specific smartphone applications.

Ms. McBane recommended removing the entire paragraph that begins with "The smoking cessation medications Bupropion SR…"

Michael Santiago, legal counsel asked if all nicotine replacement gums are prescription only. Ms. McBane explained that some gums are over-the-counter but can also be written in a prescription so the patient's insurance will cover it. Mr. Santiago indicated that SB 493 only covers those available via prescription. The committee discussed the logistics of payment for

over-the-counter medications that are written via prescription and agreed that this needs to be looked at further.

Dr. Gray commented that the intent of SB 493 was to allow pharmacists to furnish nicotine smoking cessation products. He added that the inclusion of over-the-counter options is important because patients need to be informed on all of their options.

Dr. Gray asked if there is a problem with a pharmacist providing smoking cessation products to someone under 18 years old. The committee agreed that this should be addressed so that teenagers can get help quitting. Ms. McCaman noted that she purposely didn't include an age in the draft.

Jennifer Samosa, from the California Medical Board, commented that the Medical Board is looking forward to working with the Board of Pharmacy on these protocols. Dr. Gutierrez asked if the Medical Board has been working on the draft protocols with board staff. Ms. Herold responded that the executive officer has seen them. Ms. Samosa added that after the drafts are edited based on today's feedback they would be provided to the Medical Board's legal counsel and a few Medical Board members to review.

The committee recessed for a break at 2:35 p.m. and resumed at 2:40 p.m.

5. <u>Discussion on Application Requirements of the Advanced Practice Pharmacist License</u>

President Weisser explained that the requirements a pharmacist must meet to become licensed as an advanced practice pharmacist are:

> 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 reported that at prior meetings, this committee has heard presentations from the Board of Pharmacy Specialties, and Commission for Certification in Geriatric Pharmacy as possible routes to criteria A.

President Weisser reported that at the October 2014 Board Meeting, the board approved a motion that directs staff to: Develop regulation language to recognize NCCA approved providers as a qualifying route to APP licensure, and to finalize the draft application form to collect information from applicants for APP licensure.

President Weisser noted that page 17 of Attachment 7 in the meeting materials is a list of pharmacist programs certified by the NCCA. The committee asked staff to identify what NCCA programs are applicable to SB 493.

Mr. Jon Roth, CEO of the California Pharmacist's Association, commented that at the last committee meeting members discussed approving accrediting agencies rather than reviewing and approving each individual program. He again expressed his support of this approach.

Dr. Gutierrez expressed that some of the programs accredited by NCCA do not seem to apply to an advanced practice pharmacist.

Dr. Hill-Besinque commented that if the board chooses to approve accreditation bodies, it does not mean that every course offered by the accreditation body would be acceptable for APP licensure. It would still need to be relevant to patient care.

Dr. Robinson commented that he also supports the board approving accreditation bodies rather than individual programs.

Ms. McBane suggested removing scope of practice section of the draft application. She also asked the committee to consider if the social security number was really needed on the application as the board would already have it on file. Dr. Gray agreed with Ms. McBane.

Ms. McBane also recommended that the application be updated to say "primary location," rather than having applicants list all of the possible places they may be working.

Dr. Gray recommended that the application include the NPI number if applicable.

Mr. Roth commented that in many of the documents in the meeting materials the term "APP license" is used. He stated that he doesn't believe that the board is creating a new license, rather they are granting a credential to an already existing license. Dr. Gray commented that perhaps the board could call it a registration. Ms. Herold responded that from the board's perspective it is a license. Mr. Santiago agreed that in department vernacular this is a license, not a credential or registration.

6. Discussion on the Development of Pharmacy Protocols for Naloxone, as Provided by AB 1535 (Bloom, Chapter 326, Statutes of 2014)

This year, AB 1535 authorizes the Board of Pharmacy to work with the Medical Board to develop a jointly approved protocol on naloxone for pharmacists. A draft protocol will be brought to the December Board meeting for the committee's review.

Section 4052.01 is added to the Business and Professions Code, to read:

4052.01.

(a) Notwithstanding any other provision of law, a pharmacist may furnish naloxone hydrochloride in accordance with standardized procedures or protocols developed and approved by both the board and the Medical Board of California, in consultation with the California Society of Addiction Medicine, the California Pharmacists Association, and other appropriate entities. In developing those standardized procedures or protocols, the board and the Medical Board of California shall include the following:

(1) Procedures to ensure education of the person to whom the drug is furnished, including, but not limited to, opioid overdose prevention, recognition, and response, safe administration of naloxone hydrochloride, potential side effects or adverse events, and the imperative to seek emergency medical care for the patient.

(2) Procedures to ensure the education of the person to whom the drug is furnished regarding the availability of drug treatment programs.

(3) Procedures for the notification of the patient's primary care provider with patient consent of any drugs or devices furnished to the patient, or entry of appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider, and with patient consent.

(b) A pharmacist furnishing naloxone hydrochloride pursuant to this section shall not permit the person to whom the drug is furnished to waive the consultation required by the board and the Medical Board of California.

(c) Prior to performing a procedure authorized under this section, a pharmacist shall complete a training program on the use of opioid antagonists that consists of at least one hour of approved continuing education on the use of naloxone hydrochloride.

(d) The board and the Medical Board of California are each authorized to ensure compliance with this section. Each board is specifically charged with enforcing this section with
respect to its respective licensees. This section does not expand the authority of a pharmacist to prescribe any prescription medication.

(e) 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).

Dr. Gutierrez commented that she is pleased to see the board taking steps to help deal with the adverse effects of opioids. She asked if other states already have programs in place. Ms. Herold responded that California is very behind in this area.

Brian Warren commented that there was emergency language included because there is an urgent public health risk. Mr. Warren noted that New Mexico, Rhode Island, and Washington have programs in place.

Ms. Herold commented that, unfortunately, this is a very necessary service that needs to be provided.

Dr. Gray commented that some of the latest naloxone products actually talk to the patient. He added that a future product will even email the doctor when the product is used.

Keith Yokishoka commented that www.prescribetoprevent.org has a naloxone protocol that is used in Rhode Island.

Mike McQuitty, from Department of Healthcare Services, asked when the draft protocol would be reviewed by the committee. Ms. Herold responded that the language his department provided has been used as a source document and the draft would be reviewed at the December committee meeting.

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

There were no comments from the committee or the public.

President Weisser adjourned the meeting at 3:13 p.m.