California State Board of Pharmacy
1625 N. Market Blvd, N219, Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov

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.