



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

SENATE BILL 493 IMPLEMENTATION COMMITTEE

Stan Weisser, RPh, Board President and Committee Chair

Amy Gutierrez, Pharm D

Debbie Veale, RPh

Victor Law, RPh

Report of the Senate Bill 493 Implementation Committee Meeting held August 6, 2014

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

The board has formed this committee to implement the multiple requirements of SB 493. This committee, called simply the Senate Bill 493 Implementation Committee, will work on components to implement the multiple provisions of this bill. The meetings where these deliberations will occur are public, and will be listed on the board's website. We invite interested individuals to attend.

a. FOR INFORMATION: Review of a Proposed Project Plan for Implementation of SB 493

Attachment 1

The meeting held August 6 was the board's third major committee meeting devoted to the implementation of SB 493. Since this meeting, board staff has met with the California HealthCare Foundation to secure their support for a staff person to work with the board's staff and committee in developing work products for review and discussion. The board also has determined to convene a meeting of the SB 493 Implementation Committee at least once every two months until the work projects are finished.

The next two meeting of the committee are scheduled for:

- November 5 – Sacramento
- December 16 – Los Angeles

Attachment 1 contains the proposed work schedule for the future eight months.

At the next two meetings, the committee will convene work sessions to develop the protocols for hormonal contraception and smoking cessation. It is hoped to have both protocols sent to the Board of Pharmacy and to the Medical Board for approval at the end of January 2015.

The schedule also identifies the first phase of APP registration qualifications will be put forth for board approval by the January Board of Pharmacy Meeting. Thereafter, the board will need to promulgate regulations to put these requirements into effect. The board is currently recruiting for a regulations analyst to provide the staff work for this phase of implementation.

b. FOR DISCUSSION: Identification of Materials Where Board Guidance Is Envisioned, Discussion of the Requirements

During the August meeting, the committee discussed possible board written guidance to licensees in three areas. The minutes of the meeting provide details about these discussions. The highlights are summarized below.

1. For pharmacists who initiate and administer immunizations pursuant to recommended immunization schedules by the federal Advisory Committee of Immunization Practices

- Senate Bill 493 allows a pharmacist to independently initiate and administer vaccines listed on routine immunization schedules of the CDC for persons three years of age or older (CA Business and Professions Code section 4052.8)

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.
- A pharmacist may initiate and administer epinephrine or diphenhydramine by injection (section 4052.8)

Future enforcement checks of practitioners who provide immunizations under this provision will the board with evidence the pharmacists possess the required training and are submitting information to the immunization registry and the patient’s primary care physician.

One of the issues discussed during the meeting was whether the board would accept ACIP training provided to California pharmacy school students, and if so:

- What documentation would be available and acceptable to provide to the board’s inspectors?
- How far back did California students receive this training?
- How long should the board accept this training earned in pharmacy school?
- Did all CA pharmacy schools provide this training?

At the August 6 meeting, Dean Dan Robinson of Western University advised that at a future meeting of the eight accredited schools of pharmacy deans in September, there will be discussion of what certification programs are currently available in each curriculum. Dr. Robinson noted that all the programs are APHA approved and students get a certificate upon completion. Dr. Robinson stated that a goal of the September meeting will be to develop a standardized form to be submitted to the board showing completion of a certification program on immunization, travel meds, smoking cessation and hormonal contraception. This item will be discussed again at the November 6 meeting.

Ms. Veale commented that a new requirement in SB 493 is the reporting of immunizations to the California Department of Public Health (CDPH). Ralphs currently reports immunizations provided by their pharmacists to the patient's provider, but not to CDPH. DCA Counsel Kristy Schiedge commented that SB 493's language is open to interpretation and if the board wants to make reporting to CDPH a requirement, there would need to be a regulation to require this. Physicians are not required to report immunization information to CDPH. Should pharmacists be held to a higher reporting standard? Dr. Jeff Goad, from Chapman University, reported that in other states providers are required to report to The Department of Public Health; however, in California they are not required to report to CDPH. Much of the pushback on reporting requirements comes from the medical community. Dr. Goad commented that Kaiser and many chain pharmacies do report to CDPH.

This issue will be discussed during the November meeting. It is hoped to have someone from CDPH's Immunization Registry present.

2. For Prescription Medications not Requiring a Diagnosis that Are Recommended by the CDC for Travel Outside the US

During the August 6 meeting, President Weisser explained that under SB 493 pharmacists may furnish prescription medications not requiring a diagnosis recommended by the CDC for individuals traveling outside the U.S.

The category of travel medications is very broad. Does the legislation applied only to the administration of travel immunizations or does it go beyond that scope to include other medications a traveler may need such as antibiotics or anti-nausea medications? Since the protocol provision for immunizations was left untouched by SB 493, could a pharmacist still provide ACIP-routinely recommended travel vaccines, as long as the pharmacist does so under protocol, which still requires physician involvement? President Weisser asked that the board's attorneys review this issue.

Statistics are that only 5 percent of the traveling population sees a healthcare professional before traveling. President Weisser explained that SB 493 makes the process of getting travel medications much easier in a travel clinic setting, something that has been historically difficult due to protocol requirements. However, the committee discussed concerns that a board-produced protocol could be difficult to maintain because with travel medications, things can

change overnight based on outbreaks and protocols would take time to modify.

The committee discussed this topic at length, some of which is provided below. Much more discussion is needed by the committee on this topic.

Ms. Schieldge advised there are two separate provisions in the Business and Professions Code governing pharmacist-administered immunizations: one that allows all pharmacists to administer a vaccine under a protocol and one that allows a pharmacist to initiate a vaccine pursuant to the CDC guidelines. The second type of vaccination would require additional training for the pharmacist.

Ms. Scheildge commented that the committee should define what “not requiring a diagnosis” means and identify the CDC guidance document. She added that she does not believe that that board needs to create a protocol for travel medications.

Dr. Gutierrez expressed concern that the lack of protocol will create a loophole in the law. Ms. Scheildge commented that by clarifying the CDC guidance document and “not requiring a diagnosis” no loophole would be created.

Dr. Goad advised 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. Dr. Goad added that CHPA and CSHP worked together to create a document that outlines travel meds. President Weisser commented that the term self-treatable illnesses is very broad.

President Weisser asked if the board can just 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.

Dr. Steve Gray commented 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 as 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.

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.

Ms. Veale asked if a pharmacist can write a prescription for travel medications and have the patient fill it at another pharmacy. Ms. Scheildge responded that she does not see anything in the law that specifies where the patient needs to have their medication filled and does not feel that the committee needs to address this issue.

Stan Goldenberg commented that the payer might have an issue with who wrote the

prescription and where it was filled.

Dr. Gutierrez asked that at the next meeting the committee look closely at the travel medications document that Dr. Goad discussed.

The committee commented that they did not want to overregulate travel medication.

3. For Ordering and Interpreting Tests to Monitor and Manage Drug Therapies

- 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

President Weisser reminded the committee that at the prior meeting the committee had commented that any guidelines developed should identify the professional standards pharmacists should follow when ordering and interpreting tests for monitoring the efficacy and safety of drug therapy. A summary of the discussion at the August meeting is provided below.

Dr. Gutierrez asked if pharmacists will now be required to order tests prior to dispensing a medication in order to fulfill their corresponding responsibly. Ms. Scheildge responded that a pharmacist should use professional judgment and noted that SB 493 was created to give pharmacists more independence to use their educations. Ms. Scheildge also commented that the need for testing should be on a case by case basis and would be a tool a pharmacist could use to improve patient care rather than a requirement.

Dr. Gutierrez expressed concern that requiring testing could affect access to care if a patient is told he or she must be tested in order to receive the medication. Ms. Scheildge responded that 493 says that a pharmacist *may* order tests. She interprets this as granting additional authority to use professional judgment to order tests if pharmacists are worried about the efficacy or toxicity of a drug.

Ms. Scheildge stated that only that an APP pharmacist can choose to adjust or discontinue the drug therapy based on the test results. Whereas, a regular pharmacist would need to consult with the prescriber and the prescriber would then adjust or discontinue the drug therapy.

Dr. Gutierrez explained that her concern is how the board will handle cases of patients who

have an adverse medical event that could have been prevented if the pharmacist would have ordered a test. She commented that she would like to hear from pharmacists, especially independent pharmacies, on how this would affect their practice. 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.

Dr. Gray, representing Kaiser commented that the intent was to give pharmacists a tool. He also commented that during the 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.

Lisa Kroon from the University of California, San Francisco, commented that 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 commented that the board needs to educate pharmacists on their expanded role in the healthcare team. She encouraged the board to use the *Script* to disseminate the information.

Concern was also express that insurance companies will likely stop a pharmacist from ordering a test if that patient has recently had the same test. This would address the concern raised about pharmacists ordering unnecessary tests.

c. FOR DISCUSSION: Summary of the Discussion on the Requirements for Pharmacists who Furnish Self-Administered Hormonal Contraceptives and the Development of Draft Protocols

During the August committee meeting, the committee continued discussions about the requirements for the development of a protocol for self-administered hormonal contraception that must be approved by the Medical Board and the Board of Pharmacy. President Weisser noted that at least two public meetings will be scheduled to include the required groups and any other interested parties to develop the protocols, the self-assessment questionnaire and the fact sheet. These meetings will occur at the November 5 and December 16 meetings.

Dr. Hill Besinque suggested that the board protocols should not be too prescriptive and should reference the CDC guidelines. Dr. Gutierrez asked if the board could reference the CDC guidelines in their regulation. Ms. Scheildge suggested that the board follow the same procedure as was used in the creation of the emergency contraception protocol with the Medical Board. President Weisser agreed that the joint effort with the Medical Board was successful.

Dr. Gutierrez asked if the protocol would need to reference a list of medications or could just

address the procedure. Ms. Scheildge responded that she did not see that the language required a list of medications to be included.

Ms. Veale and President Weisser asked if the board would have to update the regulation each time the CDC updated their guidelines. Ms. Scheildge responded that it would need to be updated each time a revision was made to the guidelines.

Dr. Hill Besinque reported that the CDC guidelines are updated annually. She also noted that the guidelines are not really a protocol. Instead, they are more of a safety guideline, so the board would need to create a protocol to supplement the CDC guidelines.

Dr. Hill Besinque stated that there is no universally accepted self-screening document and she also reported that there is an FDA requirement to hand out a fact sheet each time hormonal contraception is dispensed. She encouraged the board not to create an additional fact sheet.

President Weisser asked if the board could word the regulation in a way that would make all future updates of the CDC guidelines acceptable in order to avoid having to update the regulation each time. Ms. Scheildge responded that the Office of Administrative Law requires the title, date and edition of any document referenced in the regulation. This would require the regulation to be updated any time the CDC guidelines are updated.

Brian Warren commented that the statute does not say that the protocol needs to be adopted in regulation; it only says it needs to be developed by the Medical Board and Board of Pharmacy. Ms. Herold responded that it needs to be in regulation to use for enforcement purposes. Ms. Scheildge added that the Administrative Procedure Act requires this to be done via regulation.

Dr. Gray commented that the committee shouldn't hesitate to reference a document. He added that the board can use judgment to determine if the change in the document is significant enough to update the regulation.

Ms. Veale asked if the board could create a high-level draft prior to the meeting with the Medical Board and use it to start the process. Ms. Herold responded that she would recommend going into the meeting with a draft to modify.

The board will have a discussion draft available at the November 5 meeting for the committee to review, modify and approve.

Alejandro Huerta, from the California Family Health Council, commented that the goal should be to champion and promote sexual health and improve access to all. He suggested that the committee get the public involved in the development of the protocol. Ms. Herold responded that the committee meetings and workgroup meetings would be open to the public and noticed on the website.

d. FOR DISCUSSION: Summary of the Discussion on the Requirements for Pharmacists Who Furnish Nicotine

Senate Bill 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 following development with other “appropriate entities”
- The pharmacist maintains 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.

President Weisser noted during the committee meeting that as with the hormonal contraception protocol, board staff proposes that a series of at least two public meetings be scheduled and should include the required groups.

Ms. Veale asked if the board could allow recent graduation from pharmacy school to qualify the pharmacist to begin furnishing nicotine replacement products, rather than making them take a certification program. Ms. Herold responded that this could be clarified in the protocol if the board agrees that recent graduation is an appropriate qualification method.

Does the board wish to acknowledge and accept training during a pharmacist’s school of pharmacy training as qualifying training for providing this service?

President Weisser asked if the board could require that *all* pharmacists take one hour of CE for each renewal period. Ms. Veale expressed that she would not like to require all pharmacists to take an hour of smoking cessation CE.

Ms. Scheildge commented that the board needs to determine what organizations they would like to recognize as certification programs for smoking cessation. Dr. Gutierrez asked if there is a list of certification programs available. Ms. Herold commented that she is not aware of any other than the CDC.

Dr. Gray asked if the board must adopt criteria that an organization must meet in order to be certified by the board. Ms. Scheildge responded that the committee could choose to create an application process or could just list the organizations in the regulation.

Robin Corelli, from the University of California, San Francisco commented that the Rx for Change tobacco cessation curriculum has been the training that is the standard of care in California since 2000. Ms. Scheildge asked if upon completion of the program pharmacists are given a certificate of completion. Dr. Corelli responded that they do not currently, but they would be willing to provide one in order to comply with SB 493.

President Weisser asked if the curriculum is used in schools outside of California. Dr. Corelli responded that the curriculum was distributed nationwide in 2005. However, she could not speak as to what schools outside of California are currently using.

Ms. Veale asked if the RX for Change program was available to current licensees, as well as students. It was confirmed that while Rx for Change was initially designed for training students, it is also used for training licensed health professionals.

Mr. Law asked if the program UCSF uses was required for a school to receive ACPE accreditation. Dr. Corelli explained that is not a requirement for ACPE accreditation.

Jon Roth commented that professional associations would be willing to work with the schools of pharmacy to expand the certification programs available for licensed pharmacists. He noted that there are numerous programs available for the one hour of ongoing CE.

Mr. Roth asked if the board could state in the regulation that the board would recognize any certification program that was approved by the ACPE, rather than listing an actual organization name. Ms. Scheildge was unsure if this would be appropriate; however, it was something that could be researched and discussed.

e. FOR INFORMATION: Summary of the Discussion on Application Requirements of the Advanced Practice Pharmacist License

President Weisser explained that the advanced practice pharmacist category of pharmacist licensure will allow such licensed pharmacists to perform physical assessments; order and interpret medication-related tests; refer patients to other providers; initiate, adjust, and discontinue medications under physician protocol or as part of an integrated system such as an ACO; and participate in the evaluation and management of health conditions in collaboration with other providers.

The requirements a pharmacist must meet to become licensed as an APP requires satisfaction of 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.

Mr. Law noted that an APP pharmacist must have an active pharmacist license that is in good standing. He asked for clarification of the term “good standing.” Ms. Herold responded a pharmacist who is on probation would not be in good standing. She noted that a citation and fine and letter of admonishment are not considered discipline. Ms. Scheildge stated that the board could clarify “good standing” on the application so that those seeking to become an APP would understand the requirement.

Ms. Scheildge encouraged the committee to determine if they would like to require certification programs to apply to the board or if the board would simply list the entities they will recognize.

Ms. Veale asked if a pharmacist would be allowed to count the hours they spent completing their postgraduate residency as required in item (B) to complete the one year of clinical services under a collaborative practice agreement as required in item (C). Or if they would be required to complete the year of clinical services *after* they complete their residency. President Weisser and Dr. Gutierrez commented that they would prefer that they complete each of the three criteria separately. Ms. Scheildge said that the committee could interpret it either way.

Alex Charge, a PIC for a small hospital system, asked for a definition of a collaborative practice agreement. He noted that his colleagues in the hospital setting feel that most inpatient pharmacists have been working under protocols and will therefore fulfill item (C). The committee agreed that most inpatient pharmacists have been working under practice agreements and would fulfill item (C).

Brain Warren stated that originally the bill only required fulfillment of one of three criteria. As part of the negotiation with the Senate Business and Profession Committee, it was changed to require fulfillment of two criteria. Dr. Gray commented that during the negotiations, the Medical Board and American Medical Association also wanted the completion of two criteria in order to ensure that the pharmacist gained the necessary amount of independent practice experience.

Lisa Kroon, from the University of California, San Francisco, commented that not all inpatient pharmacists work in a collaborative practice agreement. Dr. Kroon briefly explained the residency program at UCSF.

The committee expressed a desire to ensure that any direct patient care experience has occurred recently relative to the application date to ensure that the pharmacist is truly ready to practice as an APP.

A student at Western University commented that the current language does not restrict an applicant from counting hours completed during residency as part of the year of experience required in item (C).

Dr. Gutierrez commented that she sees the requirements in item (C) as a way to qualify pharmacists who have already been operating under collaborative practice agreements.

Sarah McBane commented that there is an expectation of ownership and responsibility for residents, even though they operate under a preceptor. She also directed the committee's attention to a recent legal precedent that has been set from a case in Utah, where a pharmacist was held responsible for a recommendation they made for an over-the-counter drug.

The committee discussed if ASHP-accredited residency programs would fulfill the requirement in item (B) or if the board would need to analyze each applicant's residency work to ensure that at least 50 percent of the experience included direct patient care services with interdisciplinary teams. Ms. Scheildge discouraged the board from this approach and recommended that the burden be on the school to certify that the residency meets the criteria. It was also noted that there are residency programs that are not accredited and the board would need to decide if they would accept those programs. Mr. Roth agreed with Mr. Scheildge's recommendation and pointed out that the statute requires that the residency be completed in an accredited institution.

Rebecca Cupp commented that there is not a specific percentage requirement for residency programs to become accredited. However, the main emphasis of the program must be clinical services in order to become accredited by ASHP.

Annetta Racelian, a residency program director, commented that most of the ambulatory care, residency care programs focus heavily on patient care.

Ms. Herold asked if an independent pharmacy could create a residency program and become accredited by ASHP or if they must be affiliated with a school of pharmacy. Members of the public explained that while most residency programs are affiliated with a school of pharmacy, it is not required.

Ms. Veale asked that staff compile a list of accredited programs for the committee to review.

Board of Pharmaceutical Specialties and Commission for Certification in Geriatric Pharmacy:

At the February 2014 Licensing Committee Meeting, the board heard a lengthy presentation by the Board of Pharmacy Specialties on their certification programs.

The Board of Pharmacy Specialties (BPS) has developed certification programs for eight pharmacy practice areas. The BPS literature states that certification of pharmacists promotes the recognition and value of specialized training, knowledge and skills in pharmacy.

The eight specialties are:

- Ambulatory care pharmacy
- Critical care pharmacy
- Nuclear pharmacy
- Nutrition support pharmacy
- Pediatric pharmacy
- Pharmacotherapy
- Psychiatric pharmacy
- Oncology pharmacy

The requirements for BPS certification are high and recertification is required every seven years.

At the June SB 493 Implementation Committee meeting, the board heard a presentation from the Commission for Certification in Geriatric Pharmacy (CCGP) on their certification program.

The BPS and CCGP programs are not accredited by ACPE, as ACPE does not accredit certification programs. Both certification programs are accredited by NCCA. Ms. Veale noted that the *continuing education* that BPS offers is accredited by ACPE.

President Weisser asked if a legislation change would be required to accept NCCA accreditation. Ms. Scheildge responded that it would not require a legislative change; the board would simply need to recognize them.

Mr. Roth reported that CPHA created a document that outlined elements they felt that a certification program must contain in order to be recognized by the board. Developing criteria would allow the board to accept applications from certification programs that wish to be recognized by the board.

The committee asked that at the next meeting they receive information on existing accreditation programs in order to determine if they should list specific ones, such as NCCA or create an application process for certification programs based on criteria developed by the board.

Dan Robinson, dean of Western University, expressed his concern that the existing accredited certification programs are not geared toward community pharmacists and generalists. Dr. Robinson reported that there is a certification program offered by the Canadian Pharmacists Association that applies specifically to community pharmacists. President Weisser expressed his concern that the program is not accredited. Ms. Veale asked if the program could apply to become accredited by NCCA. Dr. Robinson stated that the program may already be accredited by ACPE, he will verify and report to back to the committee.

Megan Coder asked if an APP who was certified in one of the eight specialties offered by BPS could choose to practice in a different area; i.e., if a pharmacist originally was certified in

oncology through BPS and in the future chose to work in pediatric pharmacy as an APP. It was clarified that once a pharmacist becomes licensed as an APP he or she could choose to practice in any area, as long as CE was completed in the area which they are *currently* practicing.

Dr. Kroon briefly described the certification program offered by the Canadian Pharmacists Association and encouraged the board to consider the program.

Dr. Hill Besinque asked to clarify that certification is an entry threshold not a renewal threshold; therefore after someone becomes licensed as an APP he or she could let the BPS certification expire and still be licensed as an APP. Ms. Herold and Ms. Scheildge confirmed that pharmacists could let their BPS certification expire as long as they met the CE requirements of SB 493.

Dr. Gray expressed his opinion that the board would need to recognize specific certification programs not NCCA. Ms. Scheildge disagreed with Dr. Gray's interpretation of the language.

At this Board Meeting, the board should discuss their preferred approach: recognize the certification agency or the specific program, or perhaps both routes.

f. FOR POSSIBLE ACTION: Development of Elements for Advanced Practice Pharmacist Licensure

Attachment 2

Initiation of Rulemaking to Identify Certificate Programs of the Board of Pharmacy Specialties

The SB 493 Implementation Committee and discussions held during 2014 board meetings have generally supported acceptance of BPS certification as one qualifying route for APP licensure. However, the board has never specifically requested staff to start drafting requirements for such a rulemaking. This item has been added to the agenda in the event the board wishes to move an initial acceptance process by which pharmacists could qualify for APP licensure to include BPS certification. Other routes can be added through subsequent rulemakings.

Other routes for APP Licensure:

Additionally, two specific routes of qualification for APP licensure authorized in SB 493 allow:

- completion of a postgraduate residency through an accredited postgraduate institution where at least 50 percent of the experience includes provision of direct patient care services with interdisciplinary teams, or
- At least one year of providing clinical services to patients under collaborative practice agreements or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system.

Staff are ready to refine the forms to collect documentation for such experience. At this meeting, the board will have an opportunity to discuss possible approaches for collecting this information. **Attachment 2** contains a draft application form for APP licensure. This is provided as an example of an application form to collect this information: the board will not want to include this form within the specific regulation requirements.

Alternatively, staff can be directed to bring specific language to the January Board Meeting to initiate a rulemaking for APP licensure.

Meeting minutes from the August 6, 2014 meeting are provided in **Attachment 3**.

Attachment 1

SB 493 Work Product Timeline

Targeted Completion Dates

1. Protocol for Nicotine Replacement Products (California Business & Professions Code 4052 and 4052.9)

- November 5: First draft to committee for review and discussion
- December 16: Finalized draft to committee for approval
- January 28: Draft to Board of Pharmacy for review and action
- January 29 or 30: Same Draft to Medical Board for review and action
- February Committee Meeting: If needed: Incorporate changes from review by the two boards, refine and bring back to Board of Pharmacy and Medical Board at their next quarterly meetings
- Completion: Once text approved by both boards (January or April 2015), initiation of a formal rulemaking will be undertaken by the Board of Pharmacy staff within 45 days.

2. Protocol for Self-Administered Hormonal Contraception (California Business & Professions Code 4052 and 4052.3)

- November 5: First draft to committee for review and discussion
- December 16: Finalized draft to committee for approval
- January 28: Draft to Board of Pharmacy for review and action
- January 29 or 30: Same Draft to Medical Board for review and action
- February Committee Meeting: If needed: Incorporate changes from review by the two boards, refine and bring back to Board of Pharmacy and Medical Board at their next quarterly meetings
- Completion: Once text approved by both boards (January or April 2015), initiation of a formal rulemaking to be initiated by the Board of Pharmacy staff within 45 days.

3. Parameters for Licensure of Advanced Practice Pharmacists (California Business & Professions Code 4016.5 and 4210)

- November 5: First draft to committee for review and discussion
- December 16: Finalized draft to committee for approval
- January 28: Draft to Board of Pharmacy for review and action
Note: a fee audit is underway at the board, which is scheduled for review and approval at the January 2015 Board Meeting. The board will be unable to establish a fee for the advanced practice pharmacist classification until the audit is reviewed and approved by the board.
- February Committee Meeting: If needed: Incorporate changes from review by the board.
- April 21 Board Meeting: to board for review and action

- Completion: Once text and final fee are approved by the Board of Pharmacy (January or April 2015), initiation of a formal rulemaking is to be initiated by board staff within 45 days.

4. Immunizations (California Business & Professions Code 4052.8):

- Fact Sheet: Requirements for pharmacists who administer vaccinations pursuant to ACIP guidelines
- Documentation Certificate: educational completion of ACIP guidelines while in pharmacy school, means for other pharmacists to document possession of required training
 - December 16: Discussion seeking approach of committee on this topic
 - February Committee Meeting: Draft of work products available for committee review
 - April Committee Meeting: Revised draft of work products available for committee review
 - April 21 Board Meeting: Final guidance to board for approval
 - Completion: to board staff for formatting and design. Publication in board newsletter and as online guidance.

5. Travel Medications (California Business & Professions Code 4052(a)(10)(A)(3)

- Fact Sheet: Requirements for pharmacists who provide travel medications
- Documentation Certificate: or process to attest educational completion of training while in pharmacy school
- Possible regulation text: for reporting requirements to patient profiles and primary care providers
 - February Committee Meeting: Discussion by members and public – direction to staff for specific work products
 - April Committee Meeting: Draft of work products available for committee review
 - April 21 Board Meeting: Documents to board for approval
 - June Committee Meeting: finalization of committee work products if board has not already finalized them
 - July 28 Board meeting: Documents to board for approval
 - Completion: Board staff will format and design completed guidance. Publication will occur in the newsletter and as online guidance.

6. Guidelines for ordering tests, required record keeping, notices to primary care providers, consideration of additional processes to qualify for advance practice pharmacists

- February Committee Meeting: Discussion by members and public -- direction to staff for specific work products
- April Committee Meeting: Draft of work products available for committee review
- April 21 Board Meeting: Documents to board for approval

- June Committee Meeting: finalization of committee work products if board has not already finalized them
- July 28 Board meeting: Documents to board for approval. Those products not completed will be worked and finalized by staff
- Completion: Board staff will format and design completed guidance. Publication will occur in the newsletter and as online guidance.

Attachment 2



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

APPLICATION FOR ADVANCED PRACTICE PHARMACIST

Print or type

Name:	Last	First	Middle	Former	CA Pharmacist License No:
**Address of record:	Number	Street		City	State Zip Code
Residence Address: <small>(if different from above)</small>	Number	Street		City	State Zip Code
Home telephone number: ()	Work telephone number: ()			Fax Number: ()	
Email address:	Date of Birth:			Social Security Number: ***	
Qualification Methods: (Check all that apply)					
<input type="checkbox"/> Certification in a relevant area of practice as specified in B&PC 4210 (a)(2)(A) <u>What type of documentation?</u>					
<input type="checkbox"/> Completion of postgraduate residency program – <u>What type of documentation?</u>					
<input type="checkbox"/> Worked under a collaborative practice agreement or protocol for one year <u>What type of documentation?</u>					
Type of Services to be provided: (check all that apply)					
<input type="checkbox"/> Order and Interpret tests for medication management and monitoring					
<input type="checkbox"/> Initiate or Adjust controlled substances therapy –Enter DEA licensure number _____					
Location(s) where services will be provided: (attach additional sheets, if needed)					
Name	Street Address			City	State Zip
Name	Street Address			City	State Zip
Name	Street Address			City	State Zip

Please read carefully and sign below.

I understand that falsification of the information on this form may constitute grounds for denial or revocation of the license. I hereby certify under penalty of perjury under the laws of the State of California to the truth and accuracy of all statements, answers and representations made in this application, including all supplementary statements. I also certify that I personally completed this application and have read and understand the instructions attached to this application.

Signature of applicant (in full—no initials)

Date signed

DO NOT WRITE BELOW THIS LINE

Certification No. _____ Application fee no. _____

Date Issued _____ Amount _____

Date Cashiered _____

Attachment 3



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 IMPLIMENTATION COMMITTEE MEETING
MINUTES**

DATE: August 6, 2014

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
Kristy Schieldge, DCA Staff Counsel
Laura Hendricks, Staff Analyst

Call to Order

President Weisser called the meeting to order at 9:06 a.m.

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

President Weisser acknowledged current board member Lavanza Butler and former board president Stan Goldberg in the audience.

President Weisser stated that as the committee continues its activities to implement SB 493, questions have been raised about how to implement certain provisions. At the June 4, 2014, meeting of the committee, a number of questions and areas for further review were identified. President Weisser noted these questions were placed in the meeting materials and will be discussed at this meeting.

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

Senate Bill 493 allows pharmacists to practice at the full scope of their knowledge and experience and increases their involvement in direct patient care. The following three items are areas where pharmacists, who possess the minimum requirements for providing the services, may do so without specific board licensure.

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

President Weisser outlined the immunization requirements as follows.

- Senate Bill 493 allows a pharmacist to independently initiate and administer vaccines listed on routine immunization schedules of the CDC for persons three years of age or older (CA Business and Professions Code section 4052.8)

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.
- A pharmacist may initiate and administer epinephrine or diphenhydramine by injection (section 4052.8)
 - Pharmacists who do such immunizations need to be trained to perform these functions.
 - The law recognizes the following process: complete an immunization training program endorsed by the CDC or the Accreditation Council for Pharmacy Education (ACPE) 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.
 - California’s law requires training in basic life support. This is a recommended supplement of both the ACPE and CPhA programs, but it is not part of the immunization training.

- Enforcement checks of practitioners in the future who provide immunizations under this provision will need to be able to provide the board with evidence they possess the required training and are submitting information to the immunization registry and the patient's primary care physician.

President Weisser asked if the public had any comments on immunizations.

Dan Robinson, dean of Western University, reported that on September 17, 2014 there will be a meeting with deans of the eight California accredited schools of pharmacy to determine what certification programs are currently available in each curriculum. Dr. Robinson noted that the programs are APHA approved and students will get a certificate upon completion. Dr. Robinson stated that a goal of the meeting will be to develop a standardized form to be submitted to the board showing completion of a certification program on immunization, travel meds, smoking cessation and hormonal contraception.

Ms. Herold noted she will be at the meeting to provide and can provide feedback to the deans and report back to the committee.

President Weisser asked how far back the board should accept certification from a graduate of a school of pharmacy. Ms. Veale expressed that perhaps the schools should need to decide how far back they would feel comfortable certifying that a graduate received education in these areas. Dr. Robinson responded that this is something that would be discussed at the September 17 meeting. The committee requested the results of this meeting be discussed at their next meeting.

Mr. Law asked if there is a reporting procedure for certification programs completed during school. Dr. Robinson responded that this item would be discussed at the September 17 meeting. Ms. Herold noted that the board does not want the paperwork coming into the board with the initial application, but it must be made available to the board upon request.

Steve Gray, individual, commented that at the NABP meeting there was a lot of discussion on SB 493. Many board members from other states who were present at the NABP meeting warned that the board should not be in the business of collecting and approving protocols. Dr. Gray added that in one state the protocol must be approved by both the medical board and pharmacy board and it created significant delays.

Dr. Gutierrez asked if locations that currently provide immunizations already meet the standards outlined in SB 493. This was confirmed by Rebecca Cupp, from Ralphs. Ms. Herold noted that many locations that just provide flu shots are currently working under protocols, she would expect these protocols to slowly go away as pharmacists gain the training to administer immunizations independently.

Ms. Veale commented that a new requirement in SB 493 is the reporting of immunizations to

the California Department of Public Health (CDPH). Ms. Herold confirmed. Rebecca Cupp, from Ralphs, commented that currently their pharmacists provide the immunization information to the doctor, but not to CDPH. She added that there are different opinions on this requirement due to HIPPA violations. Ms. Schieldge commented that the language is open to interpretation and if the board wants to make reporting to CDPH a requirement, they would need to do so via a regulation.

The committee asked if a physician is required to report immunization information to CDPH. They noted that if physicians are not required, then it does not seem that pharmacists should be held to a higher reporting standard.

Jeff Goad, from Chapman University, reported that in other states providers are required to report to The Department of Public Health; however, in California they are not required to report to CDPH. Dr. Goad stated that much of the pushback on reporting requirements comes from the medical community. Dr. Goad commented Kaiser and many chain pharmacies do report to CDPH.

Ms. Veale asked if there are any HIPPA concerns in reporting to CDPH. Dr. Goad responded that other states have not raised any HIPPA concerns. Ms. Cupp noted that if reporting is mandated, then there is no HIPPA problem.

Dr. Gutierrez and Ms. Veale asked if there are IT concerns for pharmacies trying to report to the CDPH database. Dr. Goad responded that in his experience it is an easy process. However he recommended that the board remember that independent pharmacies may have different IT constraints than large chains or health systems.

Ms. Veale commented that if the board decided to require reporting to CDPH then it should only be required for California patients. The committee agreed.

Mr. Law asked if patients have access to the information so that they can review their immunization records. Dr. Goad responded that currently the system is difficult to use; however, the new version is supposed to be easier for patients and providers to access the immunization information.

Ms. Veale made the following motion: Require immunization information be reported to CDPH for California patients at least quarterly.

Dr. Gutierrez asked if there are any independent pharmacies in attendance who could speak to any IT difficulties. Mr. Law commented that he does not see independent pharmacies having too much difficulty in obtaining any necessary software, especially since providing immunizations will increase their revenue.

Dan Robinson asked if in mass immunization programs the reporting requirements would be the same. He said reporting requirements could prevent pharmacists from participating in

these community programs. Dr. Goad stated that there are many things to consider for mass immunization events, such as who donated the vaccines.

Ms. Herold commented that perhaps the committee should invite a CDPH representative to their next meeting so that these types of questions could be discussed. Ms. Veale agreed that hearing from CDPH and independent pharmacies would be very helpful. Ms. Veale tabled her previous motion.

Brian Warren, from the California Pharmacists Association, commented that reporting requirements are different in each county and not all county databases communicate with each other.

President Weisser commented that it seems there should be some mechanism to allow patients, pharmacist and doctors to view immunization records.

Dr. Gray, representing Kaiser, commented that Kaiser uses a system called "KITS" so that doctors and patients within the system can view immunization records. Dr. Gray also reminded the committee that there are different reporting requirements for different types of vaccines.

Mr. Law commented that reporting to CDPH is good for the profession. It will allow the tracking of how many pharmacists have provided vaccines to see how SB 493 has improved patient health.

President Weisser asked Jon Roth, of CPHA, to provide an overview of their immunization training program. Mr. Roth reported that the program they use is actually the APHA program. Mr. Roth confirmed that the program provides 20 continuing education units.

Ms. Schiedge asked Mr. Roth if the training program was recognized by ACPE or the CDC. Mr. Roth confirmed that it is approved by ACPE. Ms. Herold noted that the CDC website links to the APHA training program.

Dr. Gutierrez asked if currently a pharmacist who has completed the APHA training and has had training in basic life support can conduct immunizations without a protocol. Ms. Herold responded that if they meet the training requirements then they can conduct immunizations. Ms. Schiedge noted that the board would want to make certain there are records showing that they have met the all the education requirements. Dr. Gutierrez commented that the board needs to clarify what is considered accurate record keeping as far as education requirements and records of the actual administration of the immunization.

Dr. Gray commented that SB 493 does not give a pharmacist the right to purchase immunizations. The pharmacist would need to give the owner of the vaccine a record of the immunization that were administered or discarded.

Ms. Herold noted the board doesn't want to discourage mass immunization programs, but

needs to make sure there are accurate records kept.

Dr. Goad commented that there is a form called the Vaccine Administration Record that collects information that is required to be reported to the federal government. He noted that there is no federal mandate to report the information, just that the information be collected when the immunization is administered.

Dr. Goad reported that there is a statewide immunization registry called CAIR (California Immunization Registry).

Stan Goldenberg, former board president, commented that it may be very difficult to have every entity that provides immunizations report them to CDPH, due to the sheer volume of immunizations provided and the different settings they are provided in.

b. For Prescription Medications not Requiring a Diagnosis that Are Recommended by the CDC for Travel Outside the US

President Weisser explained that pharmacists may furnish prescription medications not requiring a diagnosis recommended by the CDC for individuals traveling outside the U.S.

At the June 2014 committee meeting, it was noted that the category of travel medications is very broad. President Weisser commented that at the meeting a member of the audience asked if the legislation applied only to the administration of travel immunizations or does it go beyond that scope to include other medications a traveler may need such as antibiotics or anti-nausea medications.

Additionally, President Weisser stated that since the protocol provision for immunizations was left untouched by SB 493, a pharmacist could still provide ACIP routinely recommended travel vaccines, as long as they do so under protocol, which still requires physician involvement. He noted that the board is having its attorneys review this issue.

At the June 2014 committee meeting, it was reported that approximately 5 percent of the traveling population sees a healthcare professional before traveling. President Weisser explained that SB 493 makes the process of getting travel medications much easier in a travel clinic setting, something that has been historically difficult due to protocol requirements. However, the committee is concerned that a board-produced protocol could be difficult to maintain because with travel medications, things can change overnight based on outbreaks and protocols would take time to modify.

Ms. Veale asked if there is anything in the legislation that defines the difference between an immunization and a travel vaccine. Ms. Schieldge responded that there are two separate sections of the business and professions code, one that allows all pharmacists to administer a vaccine under a protocol and one that allows a pharmacist to initiate a vaccine pursuant to the CDC guidelines. The second type of vaccine would require additional training for the

pharmacist.

Ms. Scheildge commented that the committee should define what “not requiring a diagnosis” means and identify the CDC guidance document. She added that she does not believe that that board needs to create a protocol for travel medications. Ms. Veale agreed.

Dr. Gutierrez expressed concern that the lack of protocol will create a loophole in the law. Ms. Scheildge commented that by clarifying the CDC guidance document and “not requiring a diagnosis” no loophole would be created.

Dr. Goad clarified that the CDC Yellow-book is the guidance document that the legislation is refereeing to. He reported that there is a chapter in the CDC Yellow-book on self-treatable illnesses. Dr. Goad added that CHPA and CSHP worked together to create a document that outlines travel meds. President Weisser commented that self-treatable illnesses are very broad.

President Weisser asked of the board can just 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 asked Dr. Goad if the documents created are clearer than the Yellow-book. Dr. Goad responded that the document they created is clearer than the CDC Yellow-book.

Dr. Steve Gray commented 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 as 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.

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.

Ms. Veale asked if a pharmacist can write a prescription for travel medications and have the patient fill it at another pharmacy. Ms. Scheildge responded that she does not see anything in the law that specifies where the patient needs to have their medication filled and does not feel that the committee needs to address this issue.

Stan Goldenberg commented that the payer might have an issue with who wrote the prescription and where it was filled.

Dr. Gutierrez asked that at the next meeting the committee look closely at the travel medications document that Dr. Goad discussed.

The committee commented that they did not want to overregulate travel medication.

c. For Ordering and Interpreting Tests to Monitor and Manage Drug Therapies

- 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

President Weisser reported that at the June meeting CSHP distributed guidelines that one of their committees had developed for ordering and interpreting tests after the passage of SB 493. President Weisser stated that the committee had commented that any guidelines developed should identify the professional standards pharmacists should follow when ordering and interpreting tests for monitoring the efficacy and safety of drug therapy.

Dr. Gutierrez asked if pharmacists will now be required to order tests prior to dispensing a medication in order to fulfill their corresponding responsibly. Ms. Scheildge responded that a pharmacist should use professional judgment and noted that SB 493 was created to give pharmacists more independence to use their education. Ms. Scheildge also commented that the need for testing should be on a case by case basis and would be a tool a pharmacist could use to improve patient care rather than a requirement.

Dr. Gutierrez expressed concern that requiring testing could affect access to care if a patient is told he or she must be tested in order to receive the medication. Ms. Scheildge responded that 493 says that a pharmacist *may* order tests. She interprets this as granting additional authority to use professional judgment to order tests if pharmacists are worried about the efficacy or toxicity of a drug.

President Weisser reported that at the June meeting, Mr. Roth stated that the language in SB 493 sets two different requirements for regular pharmacists and APP pharmacists. Ms. Herold commented that she is unclear of the difference between the two requirements. Ms. Scheildge responded that the difference is only that an APP pharmacist can choose to adjust or discontinue the drug therapy based on the test results. Whereas, a regular pharmacist would need to consult with the doctor and the doctor would then adjust or discontinue the drug therapy. Ms. Herold commented that the committee may want to establish a time period in which the APP pharmacist must notify the doctor of the change in drug therapy.

Dr. Gutierrez explained that her concern is how the board will handle cases of patients who have an adverse medical event that could have been prevented if the pharmacist would have ordered a test. She commented that she would like to hear from pharmacists, especially

independent pharmacies, on how this would affect their practice. Ms. Herold commented that there are really two issues the board 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.

Dr. Gray, representing Kaiser commented that the intent was to give pharmacists a tool. He also commented that during the 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.

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 commented that the board needs to educate pharmacists on their expanded role in the healthcare team. She encouraged the board to use the *Script* to disseminate the information.

A fourth year pharmacy student at Western University commented that insurance companies will likely stop a pharmacist from ordering a test if they see that that patient has recently had the same test, which will address the concern raised about pharmacists ordering unnecessary tests.

The committee recessed for a break at 10:50 a.m. and resumed at 11 a.m.

2. Discussion on the Requirements for Pharmacists Who Furnish Self-Administered Hormonal Contraceptives and the Development of Draft Protocols

President Weisser reported that during the June 2014 meeting, the committee discussed the requirements for the development of a protocol for self-administered hormonal contraception that must be approved by the Medical Board and the Board of Pharmacy. President Weisser noted that board staff proposes that a series of at least two public meetings be scheduled to include the required groups and any other interested parties to develop the protocols, the self-assessment questionnaire and the fact sheet.

Dr. Gutierrez noted at the June meeting, Dr. Hill-Besinque suggested that the board protocols should not be too prescriptive and should reference the CDC guidelines. Dr. Gutierrez asked if the board could reference the CDC guidelines in their regulation. Ms. Scheildge suggested that the board follow the same procedure as was used in the creation of the emergency contraception protocol with the Medical Board. President Weisser agreed that the joint effort with the Medical Board was successful.

Dr. Gutierrez asked if the protocol would need to reference a list of medications or could just

address the procedure. Ms. Scheildge responded that she did not see that the language required a list of medications to be included.

Ms. Veale and President Weisser asked if the board would have to update the regulation each time the CDC updated their guidelines. Ms. Scheildge responded that it would need to be updated each time a revision was made to the guidelines.

Kathy Hill-Besinque reported that the CDC guidelines are updated annually. She also noted that the guidelines are not really a protocol. Instead, they are more of a safety guideline, so the board would need to create a protocol to supplement the CDC guidelines.

Dr. Hill- Besinque stated that there is no universally accepted self-screening document and she also reported that there is an FDA requirement to hand out a fact sheet each time hormonal contraception is dispensed. She encouraged the board not to create an additional fact sheet.

President Weisser asked if the board could word the regulation in a way that would make all future updates of the CDC guidelines acceptable in order to avoid having to update the regulation each time. Ms. Scheildge responded that the Office of Administrative Law requires the title, date and edition of any document referenced in the regulation. This would require the regulation to be updated any time the CDC guidelines are updated.

Brian Warren commented that the statute does not say that the protocol needs to be adopted in regulation; it only says it needs to be developed by the Medical Board and Board of Pharmacy. Ms. Herold responded that it needs to be in regulation to use for enforcement purposes. Ms. Scheildge added that the Administrative Procedure Act requires this to be done via regulation.

Dr. Gray commented that the committee shouldn't hesitate to reference a document. He added that the board can use judgment to determine if the change in the document is significant enough to update the regulation.

Ms. Veale asked if the board could create a high-level draft prior to the meeting with the Medical Board and use it to start the process with them. Ms. Herold responded that she would recommend going into the meeting with a draft to modify. She added that it will be the staff's duty to create a draft for the board to review, modify and approve.

The committee discussed the scheduling of the workgroup meetings to develop the protocol. It was decided that the committee should create a high-level draft before the workgroup has their first meeting.

Alejandro Huerta, from the California Family Health Council, commented that the goal should be to champion and promote sexual health and improve access to all. He suggested that the committee get the public involved in the development of the protocol. Ms. Herold responded that the committee meetings and workgroup meetings would be open to the public and noticed

on the website.

3. Discussion on the Requirements for Pharmacists Who Furnish Nicotine Replacement Products and Development of Draft Protocols

President Weisser explained that Senate Bill 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.

President Weisser noted that as with the hormonal contraception protocol, board staff proposes that a series of at least two public meetings be scheduled and should include the required groups.

Ms. Veale asked if the board could allow recent graduation from pharmacy school to qualify the pharmacist to begin furnishing nicotine replacement products, rather than making them take a certification program. Ms. Herold responded that this could be clarified in the protocol if the board agrees that recent graduation is an appropriate qualification method.

President Weisser asked if the board could require that *all* pharmacists take one hour of CE for each renewal period. Ms. Veale expressed that she would not like to require all pharmacists to take an hour of smoking cessation CE.

Ms. Scheildge commented that the board needs to determine what organizations they would like to recognize as certification programs for smoking cessation. Dr. Gutierrez asked if there is a list of certification programs available. Ms. Herold commented that she is not aware of any other than the CDC.

Dr. Gray asked if the board must adopt criteria that an organization must meet in order to be certified by the board. Ms. Scheildge responded that the committee could choose to create an application process or could just list the organizations in the regulation.

Robin Corelli, from the University of California, San Francisco commented that the Rx for

Change tobacco cessation curriculum has been the training that is the standard of care in California since 2000. Ms. Scheildge asked if upon completion of the program pharmacists are given a certificate of completion. Dr. Corelli responded that they do not currently, but they would be willing to in order to comply with 493.

President Weisser asked if the curriculum is used in schools outside of California. Dr. Corelli responded that the curriculum was distributed nationwide in 2005. However, she could not speak as to what schools outside of California are currently using.

Ms. Veale asked if the RX for Change program was available to current licensees, as well as students. It was confirmed that while Rx for Change was initially designed for training students, it is also used for training licensed health professionals.

Mr. Law asked if their program was required for a school to receive ACPE accreditation. Dr. Corelli explained that is not a requirement for ACPE accreditation.

Jon Roth commented that professional associations would be willing to work with the schools of pharmacy to expand the certification programs available for licensed pharmacists. He noted that there are numerous programs available for the one hour of ongoing CE.

Mr. Roth asked if the board could state in the regulation that the board would recognize any certification program that was approved by the ACPE, rather than listing an actual organization name. Ms. Scheildge was unsure if this would be appropriate; however, it was something that could be researched and discussed.

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

4. Discussion on Application Requirements of the Advanced Practice Pharmacist License

President Weisser explained that the advanced practice pharmacist category of pharmacist licensure will allow such licensed pharmacists to perform physical assessments; order and interpret medication-related tests; refer patients to other providers; initiate, adjust, and discontinue medications under physician protocol or as part of an integrated system such as an ACO; and participate in the evaluation and management of health conditions in collaboration with other providers.

President Weisser also outlined the requirements a pharmacist must meet to become licensed as follows:

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.

Mr. Law noted that an APP pharmacist must have an active pharmacist license that is in good standing. He asked for clarification of the term “good standing.” Ms. Herold responded a pharmacist who is on probation would not be in good standing. She noted that a citation and fine and letter of admonishment are not considered discipline. Ms. Scheildge stated that the board could clarify “good standing” on the application so that those seeking to become an APP would understand the requirement.

Ms. Scheildge encouraged the committee to determine if they would like to require certification programs to apply to the board or if the board would simply list the entities they will recognize.

Ms. Veale asked if a pharmacist would be allowed to count the hours they spent completing their postgraduate residency as required in item (B) to complete the one year of clinical services under a collaborative practice agreement as required in item (C). Or if they would be required to complete the year of clinical services *after* they complete their residency. President Weisser and Dr. Gutierrez commented that they would prefer that they complete each of the three criteria separately. Ms. Scheildge said that the committee could interpret it either way.

Alex Charge, a PIC for a small hospital system, asked for a definition of a collaborative practice agreement. He noted that his colleagues in the hospital setting feel that most inpatient pharmacists have been working under protocols and will therefore fulfill item (C). The committee agreed that most inpatient pharmacists have been working under practice agreements and would fulfill item (C).

Brain Warren stated that originally the bill only required fulfillment of one of three criteria. As part of the negotiation with the Senate Business and Profession Committee, it was changed to require fulfillment of two criteria. Dr. Gray commented that during the negotiations, the Medical Board and American Medical Association also wanted the completion of two criteria in order to ensure that the pharmacist gained the necessary amount of independent practice experience.

Lisa Kroon, from the University of California, San Francisco, commented that not all inpatient pharmacists work in a collaborative practice agreement. Dr. Kroon briefly explained the residency program at UCSF.

The committee expressed their desire to ensure that any direct patient care experience has occurred recently relative to the application date to ensure that the pharmacist is truly ready to

practice as an APP.

A student at Western University commented that the current language does not restrict an applicant from counting hours completed during residency as part of the year of experience required in item (C).

Dr. Gutierrez commented that she sees the requirements in item (C) as a way to grandfather in people who have already been operating under a collaborative practice agreement.

Sarah McBane commented that there is an expectation of ownership and responsibility for residents, even though they operate under a preceptor. She also directed the committee's attention to a recent legal precedent that has been set from a case in Utah, where a pharmacist was held responsible for a recommendation they made for an over-the-counter drug.

The committee discussed if ASHP-accredited residency programs would fulfill the requirement in item (B) or if the board would need to analyze each applicant's residency work to ensure that at least 50 percent of the experience included direct patient care services with interdisciplinary teams. Ms. Scheildge discouraged the board from this approach and recommended that the burden be on the school to certify that the residency meets the criteria. It was also noted that there are residency programs that are not accredited and the board would need to decide if they would like to accept those programs. Mr. Roth agreed with Mr. Scheildge's recommendation and pointed out that the statute requires that the residency be completed in an accredited institution.

Rebecca Cupp commented that there is not a specific percentage requirement for residency programs to become accredited. However, the main emphasis of the program must be clinical services in order to become accredited by ASHP.

Annetta Racelian, a residency program director, commented that most of the ambulatory care, residency care programs focus heavily on patient care.

Ms. Herold asked if an independent pharmacy could create a residency program and become accredited by ASHP or if they must be affiliated with a school of pharmacy. Members of the public explained that while most residency programs are affiliated with a school of pharmacy it is not required.

Ms. Veale asked that staff compile a list of accreditation programs for the committee to review.

a. Board of Pharmacy Specialties Certification Programs and Commission for Certification in Geriatric Pharmacy

Ms. Veale reported that at the February 2014 Licensing Committee Meeting, the board heard a lengthy presentation by the Board of Pharmacy Specialties on their certification programs.

The Board of Pharmacy Specialties (BPS) has developed certification programs for eight pharmacy practice areas. The BPS literature states that certification of pharmacists promotes the recognition and value of specialized training, knowledge and skills in pharmacy. The eight specialties are:

- Ambulatory care pharmacy
- Critical care pharmacy
- Nuclear pharmacy
- Nutrition support pharmacy
- Pediatric pharmacy
- Pharmacotherapy
- Psychiatric pharmacy
- Oncology pharmacy

Ms. Veale noted that the Licensing Committee felt that the requirements for BPS certification are high and recertification is required every seven years.

Ms. Veale reported that at the June SB 493 Implementation Committee meeting the board heard a presentation from the Commission for Certification in Geriatric Pharmacy (CCGP) on their certification program.

Ms. Veale reported that the BPS and CCGP programs are not accredited by ACPE, as ACPE does not accredit certification programs. Both certification programs are accredited by NCCA. Ms. Veale noted that the *continuing education* that BPS offers is accredited by ACPE.

President Weisser asked if a legislation change would be required to accept NCCA accreditation. Ms. Scheildge responded that it would not require a legislative change; the board would simply need to recognize them.

A member of the public offered to provide the committee with a list of agencies that provide certification.

Mr. Roth reported that CPHA created a document that outlined elements they felt that a certification program must contain in order to be recognized by the board. Developing criteria would allow the board to accept applications from certification programs that wish to be recognized by the board.

The committee asked that at the next meeting they receive information on existing accreditation programs in order to determine if they should list specific ones, such as NCCA or create an application process for certification programs based on criteria developed by the board.

Dan Robinson, dean of Western University, expressed his concern that the existing accredited certification programs are not geared toward community pharmacists and generalists. Dr. Robinson reported that there is a certification program offered by the Canadian Pharmacists Association that applies specifically to community pharmacists. President Weisser expressed his concern that the program is not accredited. Ms. Veale asked if the program could apply to become accredited by NCCA. Dr. Robinson stated that the program may already be accredited by ACPE, he will verify and report to back to the committee.

Megan Coder asked if an APP who was certified in one of the eight specialties offered by BPS could choose to practice in a different area, i.e., if a pharmacist originally was certified in oncology through BPS and in the future chose to work in pediatric pharmacy as an APP. It was clarified that once a pharmacist become licensed as an APP they could choose to practice in any area, as long as their CE was in the area which they are *currently* practicing.

Dr. Kroon briefly described the certification program offered by the Canadian Pharmacists Association and encouraged the board to consider the program.

Dr. Hill-Besinque asked to clarify that certification is an entry threshold not a renewal threshold; therefore after someone becomes licensed as an APP he or she could let the BPS certification expire and still be licensed as an APP. Ms. Herold and Ms. Scheildge confirmed that pharmacists could let their BPS certification expire as long as they met the CE requirements.

Dr. Gray expressed his opinion that the board would need to recognize specific certification programs not NCCA. Ms. Scheildge disagreed with Dr. Gray's interpretation of the language.

5. Development of Elements for Other Certification (or Certificate?) Programs

President Weisser reported that at the June 2014 meeting the committee identified that it may be best for the board to create objective criteria that programs must meet to be considered for board approval as an avenue to APP licensure.

At the June 2014 meeting Dr. Kroon described the Canadian Pharmacists Association's program. Dr. Kroon again provided the committee with a brief overview of the program and expressed that the program very suitable for community pharmacists. Mr. Roth added that the Canadian model is in discussion with APHA to bring the program to the United States.

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

President Weisser asked if there were any public comments for items not on the agenda. Mr. Roth asked if the board could put out a schedule for the oral contraception and smoking

cessation workgroups so that interested parties could make arrangements.

Adjournment

3:10 p.m.