

**California State Board of Pharmacy**

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

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

DATE: December 16, 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.**COMMITTEE MEMBERS** Victor Law, RPh**NOT PRESENT:****STAFF****PRESENT:** Virginia Herold, Executive Officer
Laura Hendricks, Staff Analyst
Liz McCaman, SB 493 Researcher

Call to Order

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

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

President Weisser reported that the recent enactment of AB 1535 (Bloom) has directed the board to develop a naloxone protocol through an emergency rulemaking process. For expediency, this task has been added to the agenda of this committee and will be discussed later in the meeting.

1. Discussion on Requirements of the Advanced Practice Pharmacist License

a. Presentation by National Commission for Certifying Agencies and Board of Pharmacy Specialties Certification Programs

Dr. Chad Buckendahl, chair of the National Commission for Certifying Agencies (NCCA), provided a presentation on the functions of the NCCA. A summary of the presentation is below. The entire presentation is provided following these minutes.

NCCA Mission

The NCCA helps to ensure the health, welfare, and safety of the public through the accreditation of a variety of certification programs/organizations that assess professional competency. The NCCA uses a peer review process to:

- Establish accreditation standards;
- Evaluate compliance with the standards;
- Recognize organizations/programs which demonstrate compliance; and
- Serve as a resource on quality certification.

Over 100 organizations have 300+ programs accredited covering over 15 different industries.

Application Process

- Office receives electronic notification of intent and submission
- Three application deadlines (1/31, 4/30, 8/31)
- Applications are prepared, submitted, and reviewed online
- NCCA Staff screens all applications for completeness
- Three lead reviewers are designated as primary reviewers per new application (administrative, psychometric, public member)
- Conflicts of interest are addressed prior to assignment

Overview of NCCA Standards

- NCCA accredits certification programs, not organizations, agencies, or testing services as an organization may have multiple programs all with different testing and methodology
- Programs may be sponsored by non-profit or for-profit organizations
- Accreditation is generally awarded for five years. Every program is evaluated at *least* every 5 years.
- NCCA Standards are intended to be consistent with the Standards for Educational and Psychological Testing (AERA, APA, & NCME, 2014), and others
- Purpose is to evaluate process and products, not content. NCCA are not content experts (for example they are not pharmacists). Therefore they look to see if the program has subject matter experts

involved at key points in the program to ensure the appropriate knowledge is there.

Dr. Gutierrez asked how long NCCA has been certifying pharmacy programs. Dr. Buckendahl responded that he is unsure how long NCCA has been accrediting pharmacy programs. William Ellis, from the Board of Pharmacy Specialties (BPS), noted that BPS has been certified for 7 years.

President Weisser asked if NCCA looks at how many people pass the exams and how vigorous the program is. Dr. Buckendahl responded that the NCCA relies on the profession itself to determine if the standards are rigorous enough.

Mr. Ellis noted that when a program is reviewed they have report any complaints they have received from the public and how that complaint was resolved. Having a complaint process is also a requirement for initial accreditation. President Weisser asked what type of complaint a program might receive. Mr. Ellis responded that they may receive a complaint that someone is not practicing to the minimum standards of the profession.

Ms. Veale asked how they ensure that a program is upholding the standards for competent practice. Dr. Buckendahl responded that for certification or licensure the consideration is whether a person will likely cause harm if they are granted the license or certificate. They have to ensure that the person has the *minimum* skills and knowledge to practice without doing harm.

Ms. Herold asked how a program handles a complaint that someone who is certified by the program is incompetent. Mr. Ellis explained that the complaint would be forwarded to the regulatory agency that has the authority to discipline the license. If the regulatory agency investigates and chooses to discipline the license, then the program would use that discipline to revoke their certification. Mr. Ellis noted that this complaint and resolution would be reported to the NCCA during the program review process.

President Weisser asked Mr. Ellis how BPS maintains the rigor of their program. Mr. Ellis responded that BPS uses subject matter experts who practice in the field to validate their testing. He briefly reviewed the process for picking subject matter experts.

Dr. Gutierrez asked how BPS is going to be addressing the expansion of the practice of pharmacy. Mr. Ellis explained that annually there are writing and adding new questions to the exam based on current practice standards.

President Weisser reported that at the October 2014 Board Meeting, the board approved a motion that directs staff to develop regulation language to recognize NCCA approved providers as a qualifying route to APP licensure.

Ms. Herold commented that she asked NCCA and BPS to attend this committee meeting to ensure that the committee was comfortable with NCCA standards.

Ms. Herold noted that she would recommend that the regulation language be drafted to ensure that the board only accepts certification programs that are pharmacy related. The committee agreed.

Ms. Veale asked if there were other programs beside NCCA. Ms. Herold responded that the language would also include the Commission for Certification in Geriatric Pharmacy.

Dan Robinson, Dean of Western University, asked by doctors and dentists do not use NCCA for accreditation. Dr. Buckendahl explained that there is no business reason for these entities to be accredited by NCCA.

Dr. Steve Gray asked if there are other programs similar to NCCA. Dr. Buckendahl responded that similar programs would be American National Standards Institute, Buros Center for Testing and Cito (in Europe).

b. Presentation from Department of Public Health on Immunization Registry Usage

At prior committee meetings, the committee has discussed various aspects of immunizations, including required reporting into the immunization registry. To provide more information Lauren Dunning from the Los Angeles County Department of Public Health provided a presentation. A summary of the presentation is below; the entire presentation can be viewed immediately following these minutes.

Approaches to Increasing Immunization Registry Usage

Rational

- Community Preventive Services Task Force recommends immunization registries “on the basis of strong evidence of effectiveness in increasing vaccination rates.”
 - Create or support effective interventions
 - Determine client vaccination status
 - Guide public health responses to outbreaks
 - Inform assessments of vaccination coverage
 - Facilitate vaccine management and accountability

Examples of Other Jurisdictions

- Minnesota: “Mark of Excellence” voluntary recognition program
- New Jersey: Requirement to enter information into the registry for children under 7
- Arizona: Requirement that all immunizations given to children must be recorded in the registry, but pharmacies must also enter information for adults

- Summary: In 2013, 31 jurisdictions currently mandate at least one type of provider report immunizations (up from 12 in 2000).

Policy Options

- Incentives and voluntary initiatives
- Requirements to enter immunizations into the registry
 - Which providers?
 - VFC, public health providers, private providers, pharmacists, all
 - Which age groups?
 - Young children, children and adolescents, all age groups
 - Which vaccines?
 - Influenza, all

Dr. Dunning reported that many chain pharmacies have begun submitting information to the database.

President Weisser asked if the upcoming software update will allow all of the systems to communicate with each other. Dr. Dunning confirmed that this was the goal and it will be fully implemented at the end of 2016.

Dr. Gutierrez asked what chain pharmacies are already submitting information. Dr. Dunning responded that Rite Aid, Safeway, Walgreens and Kaiser.

Dr. Gutierrez asked how an independent pharmacy could become registered in the system. Dr. Dunning responded that she did not have personal experience in this area, but she understands that the pharmacy would receive training on the use of the system.

Dr. Gutierrez asked if the system tracks adverse events. Dr. Dunning was unaware if the system was capable of this function.

The committee recessed for a break at 11:50 a.m. and resumed at 12:00 p.m.

c. Other Certification Programs (e.g., Commission for Certification in Geriatric Pharmacy)

There were no comments from the committee or from the public.

d. Report of Other Programs Envisioned or Under Development

There were no comments from the committee or from the public.

e. Documentation of Experience Earned Working Under Protocols or During a Pharmacy Residency

Ms. Herold reported that she is currently collecting information on approved residencies and protocols to meet the requirements of paragraphs (B) and (C). These are documentation issues principally to show possession of the experience or training specified in the law.

Ms. Herold requested the schools of pharmacy to submit documentation to her so that it could be reviewed by the committee. Dr. Gray commented that the committee should require proof that the residency program is approved by ACPE and proof of completion of the clinical, residency program.

Dr. Gray provided information on how protocols are handled in the medical community. Ms. Herold noted that in California there has to be a patient specific protocol. Ms. Herold asked for input from pharmacists who are working under protocols, so that the committee can determine what kind of documentation should be required.

Dr. Gutierrez noted that most pharmacists who work under protocols work in health systems. Dr. Gray agreed, but noted that there has been expansion into other areas.

Dr. Gutierrez recommended that the committee consider having the pharmacist attest to their experience and under what protocols they are working on a form to be collected by the board. Ms. Herold commented that she wants to make sure the information they gather is meaningful.

Jeff Goad, of Chapman University, commented that protocols vary widely but there are some elements that are present in all protocols that would be useful to the board. Ms. Herold asked if Dr. Goad could provide her with information on protocols.

Dr. Gray commented that the committee may want to look at how Colorado handles their protocols.

Dr. Gutierrez commented that APHA has information on how states are handling collaborative practice agreements.

Andrew Lowe, pharmacist, commented that in health systems there is an approval process for collaborative practice agreements. He added that no two institutions will have identical protocols.

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

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

Immunizations may be provided by pharmacists who possess the required training to provide immunizations. Specifically: to initiate immunizations, a pharmacist must:

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

President Weisser explained that future enforcement checks of practitioners who provide immunizations under this provision will require that the board be provided with evidence that the pharmacists possess the required training.

President Weisser reported that at the August meeting, there was considerable discussion about whether students who may have received this training in pharmacy school could use their training without retaking it somewhere else. At this meeting, the committee asked representatives of several schools of pharmacy to provide the next iteration of a form and possible mechanism by which schools and pharmacists can track if they possess the required training.

Dr. Dan Robinson, dean of Western University, reported that a survey is being developed to be distributed to all California schools that will collect the information the committee has requested.

Dr. Goad commented that an article in an upcoming issue of the *California Pharmacist* will have statistics on training on immunizations and travel medications. Dr. Goad reported that some schools of pharmacy choose not to use the ASHP immunization training in their curriculum and they offer it in different semesters.

Ms. Veale asked how many programs use training programs other than the ASHP training. Dr. Goad responded that the ASHP training is predominantly used.

Dr. Gutierrez asked if the committee could get statistics from the schools on what training program they use and what semester they teach it. Dr. Robinson stated that it would be possible to gather the information from the schools.

President Weisser asked if pharmacists would be required to display proof of their immunization training. Ms. Herold responded that she expects that a pharmacist would be required to produce the proof during an inspection.

Ms. Veale asked how many organizations use training programs other than the ASHP training. Dr. Goad responded that the ASHP training is predominantly used.

Dr. Gray commented that a different level of training is required to administer an immunization vs. initiating an immunization. Dr. Gutierrez noted that the training
The committee recessed for a break at 12:49 p.m. and resumed at 1:27 p.m.

b. 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, and initiate or modify therapy
This item is on the agenda so the committee and audience may discuss it.

President Weisser explained 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 in order 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 the last 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.

Dr. Gutierrez commented that the committee wants to balance the need for testing and delaying patient care.

Ms. Veale commented that a pharmacist now has the ability to order a test, but at this time the board will not be requiring testing.

President Weisser asked if the committee would like to consider *requiring* tests for certain medications. Ms. Veale commented that having to order tests for every prescription that is received would cause a significant delay in pharmacies. Dr. Gutierrez

commented that it should be in the pharmacists' professional judgment to decide when a test is needed.

Dr. Steve Gray commented that the language was changed from blood tests to lab tests so that pharmacists could order things like bone scans and chest X-rays. He encouraged the committee to allow the standard of care for testing to evolve naturally overtime.

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

President Weisser stated that at this meeting, the committee will continue its discussions about the parameters for travel medications.

Provided in the meeting materials (attachment 5) was a document created by the California Pharmacists Association and the California Society of Health-System Pharmacists which outlines the current standards for travel medicine. Dr. Goad briefly reviewed this document.

Ms. Veale asked if other states allow pharmacists to practice travel medicine. Dr. Goad commented that to his knowledge California has the most liberal requirements.

President Weisser explained that the committee is concerned that pharmacists may take advantage of travel meds in order to make a profit; especially in regards to the prescribing antibiotics and controlled substances. Dr. Goad responded that the pharmacist needs to use their professional judgment to prescribe travel meds appropriately.

President Weisser asked Dr. Goad if a patient should be required to provide proof of travel. Dr. Goad responded that there is a "travel history form" required for all patients who are seeking travel meds.

President Weisser asked what kind of documentation would be required for people who have problems after they return from a trip. Dr. Goad responded that when a patient comes in after travel with an illness (fever, diarrhea, etc.) the pharmacist must *refer* them to a doctor for care.

Dr. Gutierrez asked if a pharmacist should prescribe an antibiotic to someone who will be traveling and gets chronic upper respiratory tract infections. Dr. Goad responded that it is *very rare* for antibiotics to be prescribed prior to travel as the average person will not be able to self-diagnose an upper respiratory tract infection.

Ms. Veale commented that the language in SB 493 does not specifically address what type of training would be required for pharmacists who wish to practice travel meds, this is something that could be addressed in the regulation.

Ms. Veale and President Weisser stated that they feel the next step would be to draft regulation language. Dr. Gutierrez commented that she wants to be sure that the language addresses appropriate training. Ms. Veale added that the language should include requirements for proof of travel and other record keeping.

Dr. Christine Wiggin from the Los Angeles County Department of Public Health commented that she was glad to hear that antibiotics were not regularly prescribed for travelers who believe they will have an upper respiratory tract infection.

Dr. Wiggin asked how controlled substances would be handled. Dr. Gray responded that in order for a pharmacist to initiate a prescription for a controlled substance they must have an Individual DEA Registration Number.

Brian Warren from the California Pharmacists Association commented that the committee should consider if additional training is needed for a pharmacist to practice travel meds or if they already possess the knowledge necessary. Dr. Goad commented that most schools of pharmacy do not teach much on travel meds; it is usually offered as an elective.

Stan Goldenberg recommended when drafting the regulation the committee remember how quickly travel meds change, sometime on a daily basis.

President Weisser asked if all pharmacists can practice travel meds (not just APP). Ms. Herold confirmed that any pharmacist could choose to practice travel meds, therefore training will be essential. Dr. Gutierrez agreed that current, ongoing training is necessary.

Motion: Direct staff to draft regulatory language for travel medicine requirements.

M/S: Veale/Gutierrez

Support: 3 Oppose: 0 Abstain: 0

3. Discussion on the Draft Protocol Requirements for Pharmacists Who Furnish Self-Administered Hormonal Contraceptives

President Weisser reported that SB 493 requires the development of a protocol for self-administered hormonal contraception. The protocol must be developed and approved by both this board and the Medical Board, in consultation with the American Congress of

Obstetricians and Gynecologists, the CA Pharmacists Association and other appropriate entities.

President Weisser noted that the California HealthCare Foundation has provided support to the board to develop various components that board needs to meet the requirements of SB 493. This support was in way of a researcher, Liz McCaman, who has worked to develop draft components for board review.

Ms. McCaman reviewed the draft protocol that was provided in the meeting materials. She noted a few minor typographical errors that will be corrected.

Dr. Gutierrez asked how many languages the information will be provide in. Ms. Herold responded that it will be provided in at least the top five languages in California.

Ms. Herold noted that the list of references will not be part of the final protocol.

Kathy Hill-Besinque recommended changing section 9 to read, "...the pharmacist shall refer the patient another ~~self-administered hormonal contraception~~ provider." The committee agreed to this change.

Holly Strom, pharmacist, asked if the language should be changed to require that the materials to be provided in alternative languages. Ms. Herold agreed that the language should be updated as the board now provides items in the top five languages.

Motion: Approve the draft language with the edits discussed during the committee meeting and bring it to the January 2015 board meeting for approval.

M/S: Gutierrez/Veale

Support: 3 Oppose: 0 Abstain: 0

4. Discussion on the Draft Protocol Requirements for Pharmacists Who Furnish Nicotine Replacement Products

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

- Certification of the pharmacist in smoking cessation therapy by an organization recognized by the board
- Development of a protocol developed and approved by this board and the Medical Board of California with other "appropriate entities"
- The pharmacist maintain records of all prescription drugs and devices furnished for at least three years

- The patient's primary care provider is notified of any drugs or devices furnished, or information is added to a shared patient record. If the patient has no primary care provider, the pharmacist provides the patient with a written record and advises the patient to consult a physician of the patient's choice
- The pharmacist completes one hour of CE on smoking cessation therapy biennially.

Ms. McCaman reviewed the draft protocol that was provided in the meeting materials.

Ms. Herold asked that the schools provide information on when the schools of pharmacy began teaching nicotine replacement products so that it can be accurately reflected in the language.

Dr. Hill-Besinque recommended changing the language to require the completion of training within the last two years. This would eliminate the need for schools to provide information on the year they began teaching nicotine replacement. The committee agreed to the change.

Motion: Approve the draft language with the edits discussed during the committee meeting and bring it to the January 2015 board meeting for approval.

M/S: Gutierrez/Veale

Support: 3 Oppose: 0 Abstain: 0

5. Discussion on the Draft Protocol Requirements of Pharmacists Who Furnish Naloxone Pursuant to AB 1535 (Bloom, Chapter 326, Statutes of 2014)

This year AB 1535 authorizes the Board of Pharmacy to work with the Medical Board to develop a jointly approved protocol for pharmacists. The California Pharmacists Association and California Society of Addiction Medicine are specifically mentioned to participate in this process. The board is also authorized to pursue an emergency rulemaking to secure the benefits of this law as soon as possible.

Ms. McCaman reviewed the draft protocol that was provided in the meeting materials.

Ms. Herold noted that the protocol requires that the patient receive consultation, they cannot waive it.

The committee discussed the need to review the language and use the phrase patient or agent when appropriate. Ms. McCaman agreed that the language needs to be carefully reviewed in order to ensure that it accurately reflects that a pharmacist can dispense Naloxone to either the patient or an agent of the patient.

Dr. Gutierrez asked if there is any quantity limits for Naloxone products. Ms. Herold suggested changing the language in section three to say "...provide naloxone hydrochloride in reasonable quantities..." Dr. Hill-Besinque recommended not placing a limit on the quantities. Megan Ralston from the Drug Policy Alliance (co-sponsor of the bill) asked the committee to not put limits on the quantities.

Dr. Hill-Besinque commented that if an agent of the patient picks up the product for someone else they do not have the right to consent to notify the patient's doctor. The committee agreed and Ms. McCaman stated that she would review the language to ensure that the issue of patient vs. an agent of the patient is resolved.

Jon Roth, from CPHA, agreed that clarity was needed for the requirements for patients vs. an agent of the patient.

Brian Warren recommended avoiding the use of the term "agent" and recommended using the phrase "patient or person to whom the naloxone is being furnished." Ms. Herold asked how the prescription would be labeled. Ms. McCaman responded that the label would reflect the person picking up the prescription.

Brian Warren recommended not listing each type of formulation, rather stating "all FDA approved formulations." However he noted that the intranasal spray is not currently FDA approved.

Holly Strom, pharmacist, asked if a patient refuses consultation the pharmacist has to refuse to dispense. Ms. Herold confirmed that the consultation is required prior to dispensing.

Dr. Gray recommended using the term "recipient" in place of patient.

Dr. Gray noted that as naloxone is already being used nation-wide the board should not require training to be completed in a California school of pharmacy. The committee agreed.

A member of the public asked how a pharmacist should ensure that the patient is properly and appropriately trained. The committee responded that it would be done through the consultation process. Ms. McCaman commented that she would update the language to clarify this point.

Dr. Gutierrez commented that the fact sheet needs to make it clear that the product should not be used after the expiration date.

Ms. Herold asked to clarify if the type of administration should be removed in item six. The committee decided that the language should include the administration type.

Motion: Approve the draft language with the edits discussed during the committee meeting and bring it to the January 2015 board meeting for approval.

M/S: Gutierrez/ Veale

Support: 3 Oppose: 0 Abstain: 0

6. General Discussion Concerning Implementation of SB 493

Dr. Gutierrez asked if there were any future meeting planned. Ms. Herold responded that there are no meeting dates planned, but it is possible that there will be a meeting at the end of February.

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

Dr. Gray, individual, reported that the Centers for Medicare issued a final rule that starting December 1, 2015, a Part D prescription will not be valid unless it is issued by an enrolled Part B prescriber.

President Weisser adjourned the meeting at 3:21 p.m.