



**California State Board of Pharmacy**

1625 N. Market Blvd, Suite N219, Sacramento, CA 95834  
Phone (916) 574-7900  
Fax (916) 574-8618  
www.pharmacy.ca.gov

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

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

**DATE:** April 13, 2015

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

**COMMITTEE MEMBERS**

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

**COMMITTEE MEMBERS**

**NOT PRESENT:**

**STAFF**

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

---

**Call to Order**

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

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

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

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

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

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

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

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

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

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

Article 3.5

Advanced Practice Pharmacist

1730 Acceptable Certification Programs

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

1730.1 Documentation Requirements for Advanced Practice Pharmacist Licensure

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

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

- (1) A ~~notarized~~ copy of the residency certificate awarded by the postgraduate institution that includes the name of the applicant pharmacist, the area of specialty, and dates of participation and completion, or
  - (2) A letter of completion of a postgraduate residency signed by the dean or residency program director of the postgraduate institution and sent directly to the board from the postgraduate institution that lists the name of the applicant pharmacist, the dates of participation and completion, and areas of specialty.
- (c) Documentation of experience earned under a collaborative practice agreement or protocol for at least one year with no fewer than 1,500 hours as specified in California Business and Professions Code section 4210(a)(2)(C) shall be via:
- ~~(1) A copy of an agreement or protocol under which the applicant pharmacist has provided clinical services to patients, and~~
  - ~~(2)(1) A letter~~ An attestation or letter from the supervising practitioner, program director or health facility administrator attesting under penalty of perjury that the applicant pharmacist has completed at least one year of the experience providing clinical services to patients.

The committee discussed the requirements section-by-section.

#### **1730.1 (a)**

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

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

#### **1730.1 (b)**

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

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

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

#### **1730.1 (c)**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**Motion:** Amend 1730.1 (c) as follows:

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

M/S: Gutierrez/Law

Support: 4          Oppose: 0          Abstain: 0

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

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

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

M/S: Veale/Gutierrez

Support: 4          Oppose: 0          Abstain: 0

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

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

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

**1749. Fee Schedule.**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

Support: 4		Oppose: 0		Abstain: 0	
Name	Support	Oppose	Abstain	Not Present	
Gutierrez	x				
Law	x				
Veale	x				
Weisser	x				

**b. Update on the Status of the Drafted Protocols:**

1. *For Pharmacists Who Furnish Self-Administered Hormonal Contraceptives*

**Note:** see the committee meeting materials for a copy of the protocol and fact sheets as discussed below.

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

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

There were no comments from the public.

2. *For Pharmacists Who Furnish Nicotine Replacement Products*

**Note:** see the committee meeting materials for a copy of the protocol as discussed below.

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

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

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

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

3. *For Pharmacists Who Furnish Naloxone Under Emergency Provisions*

**Note:** see the committee meeting materials for a copy of the protocol as discussed below.

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

**c. Review and Discussion of the Naloxone Protocol**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

M/S: Veale/Gutierrez

Support: 4      Oppose: 0      Abstain: 0

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

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

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

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

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

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

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

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

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

M/S: Gutierrez/Law

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

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

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

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

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

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

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

M/S: Law Gutierrez

M/S: Gutierrez/Law

Support: 3      Oppose: 0      Abstain: 0

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

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

The committee made no changes to section (c).

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

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

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

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

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

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

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

**f. General Discussion Concerning Implementation of SB 493**

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

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

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

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

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

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



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

### **§1746.3 Protocol for Pharmacists Furnishing Naloxone Hydrochloride**

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

(a) As used in this section:

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

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

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

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

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

(3) When naloxone hydrochloride is furnished:

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

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

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

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

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

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

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

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

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

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

for the naloxone recipient, and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense. The medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours.

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

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

For the Board of Pharmacy's website:

Naloxone

Suggested Kit Labeling (by route of administration):

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

# Letter from Dr. Andrew Lowe

April 10, 2015

Stan Weisser, President  
California State Board of Pharmacy

Dear President Weisser,

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

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

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

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

Consider the following example:

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

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

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

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

Thank you for your consideration of my remarks.

Sincerely yours,

Andrew Lowe, Pharm.D.  
Redlands, CA