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

SENATE BILL 493 IMPLEMENTATION COMMITTEE

For the Meeting of April 13, 2015

Stan Weisser, RPh, Board President and Committee Chair
Amy Gutierrez, Pharm D
Debbie Veale, RPh
Victor Law, RPh

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. 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.

A copy of the minutes from the February 2015 SB 493 Implementation Committee meeting is provided in **Attachment 8**, and may be of value for the discussions planned for this meeting.

a. <u>Update: Requirements for Licensure as Advanced Practice Pharmacists</u>

Attachment 1

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.

The SB 493 Implementation Committee made several modifications in the text at its February 2015 meeting. This modified text will be brought to the board in April for a vote before it is released for the 45 day comment period. The revised text is provided in **Attachment 1**. An excerpt of the minutes from the February committee meeting where this item was discussed is also provided in **Attachment 1.**

At the last meeting of the committee, the committee removed the requirement for

notarized documentation and streamlined several records requirements.

Proposed action for the committee meeting: finalize language and move to the board for initiation of a rulemaking to formally adopt the regulation.

b. <u>Update on the Status of the Drafted Protocols:</u>

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

Attachment 2

At the March Board Meeting, the board approved the proposed protocol for hormonal contraception, and moved the regulation to initiate the 45 day public comment period required for regulations. Staff have prepared the necessary documents to release the language to initiate a rulemaking and these are undergoing review by the department and the legal office, prerequisites before filing the documents with the Office of Administrative Law.

Attachment 2 contains the approved protocol. Meanwhile Liz McCaman has finalized 10 patient fact sheets to educate the public about each form of hormonal contraception. These fact sheets are included in **Attachment 2**.

Proposed Action for the committee meeting: review of fact sheets against the protocol for applicability and educational value to patients.

2. Protocol for Pharmacists Who Furnish Nicotine Replacement Products

Attachment 3

At the January Board of Pharmacy Meeting, the board approved the proposed protocol for nicotine replacement products. The board also moved to initiate the rulemaking process if the Medical Board of California approved the protocol during its meeting on January 30.

The Medical Board approved the protocol. The approved protocol is provided in **Attachment 3.** Staff is preparing the required documents to initiate the rulemaking process, which will undergo legal review before the filing with the Office of Administrative Law.

Proposed Action for the committee meeting: none

3. Protocol for Pharmacists Who Furnish Naloxone

Attachment 4

At the January Board Meeting, the board approved the proposed protocol for pharmacists to provide naloxone to the public. The Medical Board of California approved the protocol

during its meeting on January 30.

The naloxone protocol was authorized by AB 1535 (Bloom, Chapter 346, Statutes of 2014). This bill contained a provision that specifies:

> The board may adopt emergency regulations to establish the standardized procedures or protocols. The adoption of regulations pursuant to this subdivision shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The emergency regulations authorized by this subdivision are exempt from review by the Office of Administrative Law. The emergency regulations authorized by this subdivision shall be submitted to the Office of Administrative Law for filing with the Secretary of State and shall remain in effect until the earlier of 180 days following their effective date or the effective date of regulations adopted pursuant to subdivision (a).

The board has filed the protocol as an emergency regulation with the Office of Administrative Law, and we believe it will become effective on April 10. The approved protocol is provided in **Attachment 4.**

c. <u>Review and Discussion About the Naloxone Protocol</u>

Attachment 5

Proposed action for this committee meeting:

1. The committee will be asked to review a draft protocol that has been modified by board attorney Laura Freedman. This draft is not currently available but will be distributed before the meeting.
2. The committee needs to recommend approval of the final version of what will become the permanent protocol at the meeting. The protocol will then be provided to the Medical Board for their review and approval at their May Board Meeting.
3. The board has also prepared sample prescription container labels, but development of the labels resulted in the identification of some shortcomings in the protocol's labeling specifications. Moreover, the protocol is silent on how the prescription container will be labeled (e.g., name of patient? Name of the purchaser of naloxone? A name at all?). A component to require labeling in the name of the purchaser of the naloxone would be one resolution, and if acceptable should be considered for addition into the protocol. Additionally, when the labels are developed, the protocol's specification of "use as directed" is not likely to aid patients confronting the emergency and terror of an OD situation when someone is attempting to use naloxone.
   Executive Officer Herold is working on the text of the labels with several board inspectors and Dr. Gutierrez.

Attachment 5 contains examples of labels.

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

Attachment 6

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.

During this meeting, the committee needs to address certain issues that have been discussed at the last few meetings.

Mandatory Reporting to an Immunization Registry

At prior committee meetings, the committee has discussed various aspects of immunizations, including required reporting into an immunization registry.
The committee needs to identify whether it will make reporting of vaccinations into the CDPH Immunization Registry mandatory, and whether patients can opt out. If so, there are some issues to resolve, including:

- How long from the time of immunization must the pharmacy/pharmacist input the information into the registry?
- Will patients be provided with written information document the immunization(s) they receive?
- How long does the pharmacist have to provide immunization information to the primary care provider? In what form?
- What documentation must the pharmacist maintain?

Required Training for Those Providing Immunizations

The law (section 4052.8(b)(1) of the B&P Code) requires that a pharmacist complete an immunization training program endorsed by the CDC (this would seem to be the APhA Pharmacy-Based Immunization Delivery Program), that at a minimum includes hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines, and shall maintain that training.

Does the committee wish to be more specific in what it will require under this category (i.e., APhA's Pharmacy-Based Immunization Delivery Program)?

What does "shall maintain that training" mean – a certain number of CE hours? Or does the

pharmacist need to be recertified periodically, perhaps every three years? Every five years? Every 10 years?

Additional discussion items:

1. What information shall be placed in patient records regarding vaccinations?
2. What are the "required records" the statute refers to in 4052.8(b)(3)

   > "Comply with all state and federal recordkeeping and reporting requirements, including providing documentation to the patient's primary care provider and entering information in the appropriate immunization registry designated by the immunization branch of the State Department of Public Health."
3. Is there a difference between "initiate" and "administer" as used in section 4052.8(a)

   > "In addition to the authority provided in paragraph 11 of subdivision (a) of section 4052, a pharmacist may independently initiate and administer vaccines listed on the routine immunization schedules recommended from the Federal Advisory Committee on Immunization Practices …"

Attachment 6 contains a draft regulation establishing many of these elements discussed at prior meetings. The committee needs to determine if it wishes to move forward with this proposal.

Also included is a description of the US vaccine injury reporting requirements. Finally included is a chart describing when compensation will be provided for vaccine-related injuries.

e. <u>Discussion and Development of Proposed Requirements for Pharmacists to Provide Prescription Medications Not Requiring a Diagnosis that Are Recommended by the CDC for Travel Outside the US</u>

Attachment 7

At this meeting, the committee will continue its discussion about the parameters for travel medications. The committee has indicated it may wish to establish regulations for some of the travel medication components. **Attachment 7** contains a draft regulation establishing requirements the committee has discussed in the past.

At this meeting: The committee should plan on reviewing these requirements for relevancy and completeness.

f. General Discussion Concerning Implementation of SB 493

Attachment 8

This item is to allow for general discussion about all things SB 493. A copy of the minutes from the February 2015 meeting is provided in **Attachment 8**, and may be of value for this discussion.

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

**(Note: the committee may not discuss or take action on any matter raised during the public comment section that is not included on this agenda, except to decide to place the matter on the agenda of a future meeting. Government Code Sections 11125 and 11125.7(a))*

Attachment 1

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.

Article 6. Fees

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.

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SB 493 IMPLEMENTATION COMMITTEE MEETING
FEBRUARY 25, 2015 -MINUTES EXCERPT

c. Update on the Status of 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. Board staff will very soon be noticing this language to initiate the rulemaking process.

As a review:
California Business and Professions Code section 4210 provides that applicants:

Satisfy any two of the following criteria:
(A) Earn certification in a relevant area of practice, including, but not limited to, ambulatory care, critical care, geriatric pharmacy, nuclear pharmacy, nutrition support pharmacy, oncology pharmacy, pediatric pharmacy, pharmacotherapy, or psychiatric pharmacy, from an organization recognized by the Accreditation Council for Pharmacy Education or another entity recognized by the board.
(B) Complete a postgraduate residency through an accredited postgraduate institution where at least 50 percent of the experience includes the provision of direct patient care services with interdisciplinary teams.
(C) Have provided clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system.

President Weisser noted that since the language has not yet been released, the committee may wish to discuss questions on the language. He added that any modification would need to be returned to the board for its review at the March 9 meeting.

Below is the draft language.

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) A letter from the supervising practitioner attesting under penalty of perjury that the applicant pharmacist has completed at least one year of the experience providing clinical services to patients.

Ms. Herold explained that she placed this item on the agenda because she wanted the committee to clarify how they would like to handle clinical experience that was gained many years ago. Documenting the experience may be difficult for some of the more experienced pharmacists.

Dr. Gutierrez asked what the definition of clinical would be in the language. Ms. Herold responded that California Business and Professions Code section 4210 defines clinical as: Providing clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system.

Dr. Besinque commented that many pharmacists work under institutional protocols, which would make it difficult to get the signature of a supervising physician, especially if they no longer work at the institution. Dr. Besinque recommended allowing the pharmacist to attest to their own experience and provide the board with the information on the setting in which they gained the experience rather than requiring a letter from the supervising practitioner.

Dr. Besinque commented that she also did not see the value of collecting the protocols as the board staff would be unable to validate them.

Jon Roth agreed with Dr. Besinque's recommendation to allow the pharmacist to attest to their own experience. If the attestation is subsequently found to be false, enforcement action would then follow.

Pharmacist Sara McBane stated that she agreed with the self-attestation approach and noted that North Carolina uses this method.

Ms. Veale expressed concern with not collecting documentation from someone else besides the applicant themself. Ms. Herold added that self-attestation would essentially be allowing people to submit resumes to the board as proof of experience.

Mr. Law noted that an institution should have someone who could at least verify that a pharmacist worked at the institutions for a certain time period.

Jon Roth suggested that the board handle the APP experience in the same way it currently handles continuing education requirements. The board could simply do spot checks on the documentation of experience.

Ms. Herold explained that when the board issues a license they are doing so in the interest of protecting the public and essentially stating that the licensee meets the minimum standards to practice. The applicants need to prove that they possess the experience set out in the law.

Dr. Besinque stated that the requirement to have the documents notarized is onerous and unnecessary. She again expressed her opinion that getting a letter from a supervising practitioner will be very difficult for many pharmacists.

Ms. Veale asked if the supervising practitioner had to be a physician. Ms. Herold clarified that it did not have to be physician, it could be a pharmacist.

Ms. Veale asked if the committee could strike (c)(1) and only require the letter attesting to one year of clinical experience. The committee agreed to eliminate (c)(1).

The committee modified the language to read "~~A letter~~ An attestation from the supervising practitioner or director…"

Dr. Gutierrez asked if the residency program director could sign the letter of completion of a postgraduate residency (required in (b)(2)) and have it also count towards the one year of clinical experience required in (c)(2). Ms. Veale commented that the committee previously

discussed this and wanted them to be two separate requirements. Ms. Herold noted that there is nothing in the statute that separates them, so the board would have to build it in.

Dr. Grey recommended removing the "supervisor" requirement as some pharmacists may not have a direct supervisor. Ms. Herold recommended that the committee keep the supervisor requirement.

Rebecca Cupp, from Ralph's pharmacy, asked if a program director leaves a program if the new director could attest to experience gained prior to them taking over the program. Ms. Herold confirmed that the current director could attest.

Sara McBane recommended removing the notarization requirement. The committee agreed to remove the notary requirement.

Dr. Besinque and Sara McBane asked for clarification on the application and renewal fees. Ms. Herold explained that it would be $300 for the initial application and $300 for each renewal. She noted that $300 covers the cost to run the program.

Dr. Gutierrez expressed concern with the competency of someone whose experience was earned 20 years ago. Ms. Herold responded that the committee could add in a certain time frame in which the experience must have been earned. Ms. Veale agreed with Dr. Gutierrez's concern.

Jon Roth recommended adding "health facility administrator" to the list of those who could sign a letter of attestation.

Motion: Approve the draft 1730 language with the modifications made by the committee (below).

Article 3.5
Advanced Practice Pharmacist

1730 Acceptable Certification Programs

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

1730.1 Documentation Requirements for Advanced Practice Pharmacist Licensure

(a) Documentation of possession of a certification as specified in California Business and Professions Code section 4210(a)(2)(A) shall be via:
(1) A ~~notarized~~ copy of the certification award that includes the name of the applicant pharmacist, the area of specialty and date of completion, or

(2) A letter from the certification program attesting the award of the certification that includes the name of the applicant pharmacist, the area of specialty and the date of completion.

(b) Documentation of completion of a postgraduate residency earned through an accredited postgraduate institution as specified in California Business and Professions Code section 4210(a)(2)(B) shall be via either:

(1) A ~~notarized~~ copy of the residency certificate awarded by the postgraduate institution that includes the name of the applicant pharmacist, the area of specialty, and dates of participation and completion, or

(2) A letter of completion of a postgraduate residency signed by the dean or residency program director of the postgraduate institution and sent directly to the board from the postgraduate institution that lists the name of the applicant pharmacist, the dates of participation and completion, and areas of specialty.

(c) Documentation of experience earned under a collaborative practice agreement or protocol for at least one year with no fewer than 1,500 hours as specified in California Business and Professions Code section 4210(a)(2)(C) shall be via:

~~(1) A copy of an agreement or protocol under which the applicant pharmacist has provided clinical services to patients, and~~

~~(2)~~(1)~~A letter~~ An attestation from the supervising practitioner or program director or health facility administrator attesting under penalty of perjury that the applicant pharmacist has completed at least one year of the experience providing clinical services to patients.

M/S: Veale/Law

Support: 3 Oppose: 0 Abstain: 1

Ms. Veale asked if the committee wanted to address the issue of earning their postgraduate experience (b) and clinical experience (c) concurrently. The committee decided not to amend the language as they felt that the experience could be gained concurrently.

Lisa Croon explained that due to a lag in licensure time many residents will have earned 1,500 hours of experience, but would have only have been licensed for 10 months. The committee noted that the language does not state that they have been licensed for one year, only that they are earning experience under a collaborative practice agreement for one year.

Dr. Gutierrez again expressed her concern with licensing APP's who gained their experience 20 or more years ago.

The committee recessed for a lunch break at 1:23 pm. and resumed at 2:00 p.m.

Attachment 2

Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraception

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

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

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

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

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

- Oral;
- Transdermal;
- Vaginal;
- Depot Injection.

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

- Ask the patient to use and complete the self-screening tool;
- Review the self-screening answers and clarify responses if needed;
- Measure and record the patient's seated blood pressure if combined hormonal contraceptives are requested or recommended.
- Before furnishing self-administered hormonal contraception, the pharmacist shall ensure that the patient is appropriately trained in administration of the requested or recommended contraceptive medication.
- When a self-administered hormonal contraceptive is furnished, the patient shall be provided with appropriate counseling and information on the product furnished, including:
    - Dosage;
    - Effectiveness;
    - Potential side effects;
    - Safety;
    - The importance of receiving recommended preventative health screenings;
    - That self-administered hormonal contraception does not protect against sexually transmitted infections (STIs).

(5) Self-Screening Tool: The pharmacist shall provide the patient with a self-screening tool containing the list of questions specified in this protocol. The patient shall complete the self-screening tool, and the pharmacist shall use the answers to screen for all Category 3 and 4 conditions and characteristics for self-administered hormonal contraception from the current United States Medical Eligibility Criteria for Contraceptive Use (USMEC) developed by the federal Centers for Disease Control and Prevention (CDC). The patient shall complete the self-screening tool annually, or whenever the patient indicates a major health change.

A copy of the most recently completed self-screening tool shall be securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense.

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

(6) Fact Sheet: The pharmacist shall provide the patient with the FDA-required patient product information leaflet included in all self-administered hormonal contraception products, as required by the Business and Professions Code Section 4052.3(c). The pharmacist shall answer any questions the patient may have regarding self-administered hormonal contraception.

Pharmacists should provide the patient with a copy of a current consumer-friendly comprehensive birth control guide such as that created by the FDA, and a copy of an administration-specific factsheet; examples of appropriate guides and factsheets are available on the Board of Pharmacy's website.

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

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

(9) Referrals and Supplies: If self-administered hormonal contraception services are not immediately available or the pharmacist declines to furnish pursuant to a conscience clause, the pharmacist shall refer the patient to another appropriate health care provider.

The pharmacist also shall comply with all state mandatory reporting laws, including sexual abuse laws.

(10) Product Selection: The pharmacist, in consultation with the patient, may select any hormonal contraceptive listed in the current version of the USMEC for individuals identified as Category 1 or 2, based on the information reported in the self-screening tool and the blood pressure (if recorded by the pharmacist). The USMEC shall be kept current and maintained in the pharmacy or health care facility, and shall be available on the Board of Pharmacy's website.

Generic equivalent products may be furnished.

(11) Documentation: Each self-administered hormonal contraceptive furnished by a pharmacist pursuant to this protocol shall be documented in a patient medication record and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense. A patient 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.

(12) Training: Prior to furnishing self-administered hormonal contraception, pharmacists who participate in this protocol must have completed a minimum of one hour of a board-approved continuing education program specific to self-administered hormonal contraception, application of the USMEC, and other CDC guidance on contraception. An equivalent curriculum-based training program completed on or after the year 2014 in an accredited California school of pharmacy is also sufficient training to participate in this protocol.

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

(14) Self-Screening Tool Questions

HORMONAL CONTRACEPTION SELF-SCREENING TOOL QUESTIONS

1	What was the first date of your last menstrual period?	/ /	
2	Have you ever taken birth control pills, or used a birth control patch, ring, or shot/injection? (If no, go to question 3)	Yes ☐	No ☐
	Did you ever experience a bad reaction to using hormonal birth control?	Yes ☐	No ☐
	Are you currently using birth control pills, or a birth control patch, ring, or shot/injection?	Yes ☐	No ☐
3	Have you ever been told by a medical professional not to take hormones?	Yes ☐	No ☐
4	Do you smoke cigarettes?	Yes ☐	No ☐
5	Do you think you might be pregnant now?	Yes ☐	No ☐
6	Have you given birth within the past 6 weeks?	Yes ☐	No ☐
7	Are you currently breastfeeding an infant who is less than 1 month of age?	Yes ☐	No ☐
8	Do you have diabetes?	Yes ☐	No ☐
9	Do you get migraine headaches, or headaches so bad that you feel sick to your stomach, you lose the ability to see, it makes it hard to be in light, or it involves numbness?	Yes ☐	No ☐
10	Do you have high blood pressure, hypertension, or high cholesterol?	Yes ☐	No ☐
11	Have you ever had a heart attack or stroke, or been told you had any heart disease?	Yes ☐	No ☐
12	Have you ever had a blood clot in your leg or in your lung?	Yes ☐	No ☐
13	Have you ever been told by a medical professional that you are at a high risk of developing a blood clot in your leg or in your lung?	Yes ☐	No ☐
14	Have you had bariatric surgery or stomach reduction surgery?	Yes ☐	No ☐
15	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	Yes ☐	No ☐
16	Do you have or have you ever had breast cancer?	Yes ☐	No ☐
17	Do you have or have you ever had hepatitis, liver disease, liver cancer, or gall bladder disease, or do you have jaundice (yellow skin or eyes)?	Yes ☐	No ☐
18	Do you have lupus, rheumatoid arthritis, or any blood disorders?	Yes ☐	No ☐
19	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?	Yes ☐	No ☐
	If yes, list them here:		
20	Do you have any other medical problems or take regular medication?	Yes ☐	No ☐
	If yes, list them here:		

Note: Authority cited: Section 4052.3, Business and Professions Code. Reference: Section 4052(a)(10), Business and Professions Code.

Protocol Sources

Centers for Disease Control and Prevention, "United States Medical Eligibility Criteria for Contraceptive Use," (2010) *available at* http://www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm.

This resources serves as the basis for which self-administered hormonal contraception medications from which a pharmacist may select.

Centers for Disease Control and Prevention, "U.S. Selected Practice Recommendations for Contraceptive Use, 2013," *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6205a1.htm.

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S. Shotorbani, et al., "Agreement Between Women's and Providers' Assessment of Hormonal Contraceptive Risk Factors," 73 CONTRACEPTION 501, 501-506 (2006).

This article provided a Medical History Questionnaire that was used in the development of the protocol's self-assessment tool. The article's research found 96% agreement between women's self-administered risk factor questionnaire and their providers' evaluation of their medical eligibility for hormonal contraceptive use.

CPhA/CSHP, "Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraceptives."

This draft protocol was consulted in development of the Board's recommended protocol.

Food and Drug Administration Office of Women's Health, "HPV, HIV, Birth Control" (last updated June 24, 2014), *available at* http://www.fda.gov/ForConsumers/ByAudience/ForWomen/WomensHealthTopics/ucm117971.htm

This site contains a consumer-friendly birth control guide recommended for patient education.

Office on Women's Health, U.S. Department of Health and Human Services, "Birth Control Methods" (last updated Nov. 21, 2011), *available at* http://www.womenshealth.gov/publications/our-publications/fact-sheet/birth-control-methods.pdf.

This fact sheet was consulted in development of the Board's recommended fact sheet.

Division of Reproductive Health, Centers for Disease Control and Prevention, "Contraception" (last updated Oct. 14, 2014), http://www.cdc.gov/reproductivehealth/unintendedpregnancy/contraception.htm.

This website, especially the chart, is recommended as a resource for pharmacists choosing to provide additional user-friendly information on various birth control methods.

The American College of Obstetricians and Gynecologists, "Birth Control – Especially for Teens," FAQ112 (Dec. 2013), *available at* http://www.acog.org/Patients/FAQs/Birth-Control-Especially-for-Teens.

This fact sheet was consulted in development of the Board's recommended fact sheet.

J. McIntosh et al., "Changing Oral Contraceptives from Prescription to Over-the-Counter Status: An Opinion Statement of the Women's Health Practice and Research Network of the American College of Clinical Pharmacy," Pharmacotherapy Vol. 31, Number 4, 424-437 (2011).

This opinion paper discusses pharmacist training on page 432. Both pharmacists and pharmacy students generally expressed interest in more education specifically on appropriate product selection.

Fatim Lakha, et al., "The Acceptability of Self-Administration of Subcutaneous Depo-Provera," 72 CONTRACEPTION 14-18 (2005).

This research finds that subcutaneous self-injectable hormonal contraception is beneficial for many women with appropriate training and reminder system.

Nicole J. Monastersky Maderas & Sharon Cohen Landau, "Pharmacy and Clinic Partnerships To Expand Access to Injectable Contraception," 47 J. AM. PHARM. ASSOC. 527-531 (2007).

This research finds that pharmacy reinjection of contraception is a viable option for many women, and is most successful when combined with primary care provider support and integration.

Sujatha Prabhakaran & Ashley Sweet, "Self-Administration of Subcutaneous Depot Medroxyprogesterone Acetate for Contraception: Feasibility and Acceptability," 85 CONTRACEPTION 453-457 (2012).

This research article finds that self-administration injections were easy and convenient for women with training from two Planned Parenthood health centers.

Sharon T. Cameron, et al., "Pilot Study of Home Self-Administration of Subcutaneous Depo-Medroxyprogesterone Acetate for Contraception," 85 CONTRACEPTION 458-464 (2012).

This research concludes that self-administration is feasible and has similar continuation and satisfaction rates to clinician-administration injections.

Rebekah L. Williams, et al., "Self-Administration of Subcutaneous Depot Medroxyprogesterone Acetate by Adolescent Women," 88 CONTRACEPTION 401-407 (2013).

This research concludes that many adolescents are interested in and capable of self-administration with brief education and minimal assistance.

S. Vinker, et al., "The Effect of Drug Information Leaflets on Patient Behavior," ISR. MED. ASSOC. J. 9(5) 383-4386 (May 2007).

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21 C.F.R §§ 201 "Labeling," *available at*
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=201.
These FDA regulations require manufacturers to include comprehensive patient leaflets in both prescription-only and OTC products.

21 C.F.R. § 310.501 "Patient Package Inserts for Oral Contraceptives," (Apr. 1, 2014), *available at*
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=310.501.
These FDA regulations are specific to leaflet requirements for oral contraceptives.

FACT SHEET : PROGESTIN-ONLY/ MINI-PILL

Remember, the mini-pill **does not protect you from Sexually Transmitted Infections or HIV.** Always use condoms to protect yourself!

HOW DOES THE MINI-PILL WORK?

- The mini-pill contains a hormone like the ones your body makes. It works by making the mucus in your cervix too thick for sperm to pass through. If sperm cannot reach the egg, you cannot get pregnant.
- No method of birth control is 100% effective. Progestin-only birth control pills are 91-99% effective.

HOW DO I START THE MINI-PILL?

- There are 2 ways to start the pill:
  - **Quick Start:** Take your first pill as soon as you get the pack.
  - **Next period:** Take your first pill soon after your next period begins.
- If you take your first pill *up to 5 days after the start of your period*, you are protected against pregnancy **right away**.
- If you take your first pill *more than 5 days after the start of your period*, you should **use condoms as back-up for the first 7 days**.

HOW DO I USE THE MINI-PILL?

- **Once you start using the pill**, take 1 pill each day. Take your pill at the same time each day.
- After you finish a pack of pills, you should start a new pack the next day. You should have NO day without a pill.

WHAT IF I MISS MINI-PILLS?

- **I forgot ONE pill:** Take your pill as soon as you can. If you take your pill more than 3 hours late, **use condoms for the next 7 days.**
- **I forgot TWO pills or more:** Take your pill as soon as you can. Take your next pill at the usual time. **Use condoms for the next 7 days. Use emergency contraception (EC) if you have unprotected sex.**

WHAT IF I STOPPED TAKING THE MINI-PILL AND HAD UNPROTECTED SEX?

- Take Emergency Contraception (EC) **right away**. EC can prevent pregnancy up to 5 days after sex, and it works better the sooner you take it.

HOW DOES THE MINI-PILL HELP ME?

- The mini-pill is safe & effective birth control. The mini-pill is safe for you to use while breastfeeding.
- The mini-pill has **no effect** on your ability to get pregnant in the future, after you stop taking it.

HOW WILL I FEEL ON THE MINI-PILL?

- You will feel about the same. Most women notice changes in their periods. You may have spotting or no period at all. This is normal. You may have nausea, spotting, weight change, and/or breast pain. These problems often go away after 2-3 months.

DOES THE MINI-PILL HAVE RISKS?

- The mini-pill is very safe.

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HOJA INFORMATIVA: MINI PÍLDORA/ LA PÍLDORA SOLO DE PROGESTINA

Recuerde, la mini píldora **no la protege contra las infecciones de transmisión sexual o el VIH.** Siempre use condones para protegerse!

¿CÓMO FUNCIONA LA MINI PÍLDORA?

- La mini píldora contiene una hormona como las que produce su cuerpo. Funciona haciendo que el moco de su cuello uterino sea demasiado espeso para que los espermatozoides lo puedan atravesar. Si los espermatozoides no pueden llegar al óvulo, usted no puede quedar embarazada.
- Ningún método anticonceptivo es 100% efectivo. Las píldoras anticonceptivas de progestina son 91-99% efectivas.

¿COMO EMPIEZO A USAR LA MINI PÍLDORA?

- Hay 2 maneras de empezar las píldoras:
  - **Inicio Inmediato:** Tome la primera píldora tan pronto que obtenga el paquete.
  - **Siguiente menstruación:** Tome la primera píldora poco después de que empieze su próximo período.
- Si toma la primera píldora hasta 5 días después del inicio de su período, su protección contra el embarazo es **inmediato**.
- Si toma la primera pildora más de 5 días después del inicio de su período, **debe usar condones como método de respaldo durante los primeros 7 días**.

¿CÓMO DEBO USAR LA MINI PÍLDORA?

- **Una vez que comience a usar la píldora**, tome 1 píldora todos los días. Tómela a la misma hora cada día.
- **Use condones durante los primeros 7 días** de su *primer* paquete de píldoras anticonceptivas.
- Cuando termine un paquete de píldoras, debería comenzar un nuevo paquete al día siguiente. Usted NO debería pasar NI UN día sin una píldora.

¿QUÉ PASA SI SE ME OLVIDAN ALGUNAS PÍLDORAS?

- **Se me olvidó UNA píldora:** Tómela tan pronto como pueda. Si toma la píldora más de 3 horas de retraso, use condones durante los próximos 7 días.
- **Se me olvidaron DOS o más píldoras:** Tome su píldora tan pronto como sea posible. Tome su siguiente píldora a la hora habitual. **Use condones durante los próximos 7 días. Use anticoncepción de emergencia (AE) si tiene relaciones sexuales sin protección.**

¿QUÉ PASA SI DEJÉ DE TOMAR LAS PÍLDORAS Y TUVE RELACIONES SEXUALES SIN PROTECCIÓN?

- Tome anticonceptivos de emergencia (AE) **inmediatamente**. Los AE puede prevenir el embarazo hasta 5 días después de una relación sexual, y funciona mejor cuanto más pronto la tome.

¿CÓMO ME AYUDA LA MINI PÍLDORA?

- La mini píldora es un anticonceptivo seguro y efectivo. La mini píldora es segura y usted la puede usar mientras esté amamantando porque no afecta la producción de leche. Después de que deje de tomar la mini píldora, **no tiene ningún efecto** sobre su capacidad de quedar embarazada en el futuro.

¿CÓMO ME SENTIRÉ CUANDO ESTÉ TOMANDO LA MINI PÍLDORA?

- Usted sentirá más o menos igual. La mayoría de las mujeres notan cambios en sus menstruaciones. Usted puede tener algún manchado, o no tener menstruaciones del todo. Esto es normal. En los primeros meses usted puede tener náusea, manchado, cambios de peso y/o dolor en los pechos. Estos problemas con frecuencia desaparecen a los 2-3 meses.

¿LA MINI PÍLDORA TIENE RIESGOS?

- La mini píldora es muy segura.

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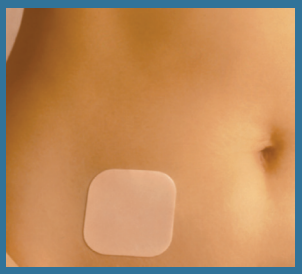
HOJA INFORMATIVA : SOBRE EL PARCHE

Recuerde, el parche **no la protege contra las Infecciones de Transmisión Sexual o el VIH.** Siempre use condones para protegerse!



¿CÓMO FUNCIONA EL PARCHE?

- El parche contiene hormonas como las que produce su propio cuerpo. Estas hormonas impiden que sus ovarios liberen óvulos. Sin un óvulo usted no puede quedar embarazada.
- No existe un método anticonceptivo que sea 100% efectivo. El parche es 91-99% efectivo.

¿COMO EMPIEZO A USAR EL PARCHE?

- Hay 2 maneras de empezar a usar el parche:
  - **Inicio Inmediato:** Coloquese el primer parche tan pronto que lo obtenga.
  - **Siguiente menstruación:** Coloquese el primer parche poco después de que empieze su próximo período.
- Si se coloca el primer parche hasta 5 días después del inicio de su período, su protección contra el embarazo es **inmediato**.
- Si se coloca el primer parche *más de 5 días después del inicio de su período,* **debe usar condones como método de respaldo durante los primeros 7 días.**

¿CÓMO DEBO USAR EL PARCHE?

- El parche es como una calcomanía que usted usa sobre su piel durante una semana. Usted puede usar el parche en cualquier lugar de su piel excepto en sus pechos, sus genitales, las palmas de sus manos y las plantas de sus pies.
- Escoja un lugar de su cuerpo donde usted pueda ver el parche si se cae. Coloque el parche en un área limpia y seca y asegúrese que los bordes queden bien pegados.
- Debe usar un parche nuevo cada semana durante tres semanas y no usarlo durante la cuarta semana.
- **Use condones los primeros 7 días** de su primer parche.
- Espere ver su menstruación durante la semana libre de parche. (Usted podría tener una menstruación más ligera o no tenerla del todo.)
- Comience una nueva caja de parches al final de la 4ta semana.

¿QUÉ PASA SI EL PARCHE SE CAE?

- Si el parche se cae, póngalo de vuelta inmediatamente. Si el parche no se pega, use un parche nuevo.
- Si el parche se mantiene despegado por más de un día, use un parche nuevo y condones por los siguientes 7 días.
- Colóquese su siguiente parche a la semana de haberse puesto este parche.

¿QUÉ PASA SI ME OLVIDO DE CAMBIAR EL PARCHE PASADOS LOS 7 DÍAS?

- El parche tiene hormonas suficientes para 9 días o menos, solo póngase un parche nuevo.
- Si se deja el parche puesto por más de 9 días, póngase un nuevo parche y use condones durante los siguientes 7 días.

¿QUÉ PASA SI DEJÉ DE USAR EL PARCHE Y TUVE RELACIONES SEXUALES SIN PROTECCIÓN?

- Tome anticonceptivos de emergencia (AE) inmediatamente. Los AE puede prevenir el embarazo hasta 5 días después de la relación sexual, y funcionan mejor cuanto más pronto los tome.

¿CÓMO ME AYUDA/ME BENEFICIA EL PARCHE?

- El parche es anticoncepción segura y efectiva. Sus menstruaciones pueden ser más regulares, más ligeras y más cortas. Su piel se puede aclarar del acné. El parche disminuye su riesgo de desarrollar cáncer del útero y de los ovarios. El parche **no tiene nignún efecto** sobre su capacidad de quedar embarazada en el futuro, después de que deje de usarlo.

¿CÓMO ME SENTIRÉ CUANDO USE EL PARCHE?

- Usted se sentirá más o menos igual que siempre. Durante los primeros 2-3 meses podría tener náusea, sangrado entre menstruaciones, cambios de peso y/o dolor en sus pechos. Estos problemas con frecuencia en 2-3 meses.

¿EL PARCHE TIENE RIESGOS?

- El parche es muy seguro. Los problemas serios son raros. Si usted tiene alguno de los síntomas enumerados abajo, llame a su proveedor de atención a la salud:
  - -Dolor, hinchazón y enrojecimiento en la pierna
  - -Debilidad o adormecimiento en un lado de su cuerpo
  - -Dolor de cabeza severo
  - -Problemas de la visión
  - -Dolor de pecho
- Su proveedor de atención a la salud puede ayudarla a determinar si estos síntomas son señales de un problema serio.

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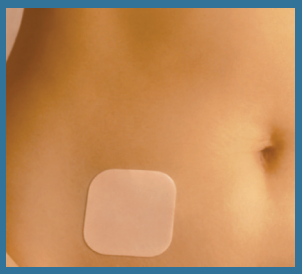
FACT SHEET : THE PATCH

Remember, the patch **does not protect you from Sexually Transmitted Infections or HIV.** Always use condoms to protect yourself!



HOW DOES THE PATCH WORK?

- The patch contains hormones like the ones your body makes. These hormones stop your ovaries from releasing eggs. Without an egg, you can't get pregnant.
- No method of birth control is 100% effective. The patch is 91-99% effective.

HOW DO I START THE PATCH?

- There are 2 ways to start the patch:
  - **Quick Start:** Put on your first patch as soon as you get the pack.
  - **Next period:** Put on your first patch soon after your next period begins.
- If you put on your first patch *up to 5 days after the start of your period*, you are protected against pregnancy **right away**.
- If you put on your first patch *more than 5 days after the start of your period*, you should **use condoms as back-up for the first 7 days**.

HOW DO I USE THE PATCH?

- The patch is like a sticker you wear on your skin for a week. You can wear the patch anywhere on your skin except your breasts, your genitals, palms of your hands or soles of your feet.
- Choose a spot on your body where you can see the patch if it falls off. Place the patch on a clean, dry area and make sure the edges stick well.
- You will use a new patch every week for 3 weeks and no patch for the 4th week.
- Expect your period during the patch-free week. (You may have a light period or no period at all.)
- Start a new box of patches at the end of the 4th week.

WHAT IF THE PATCH COMES OFF?

- If the patch comes off, put it back on right away. If it does not stick, use a new patch.
- If the patch falls off for more than a day, put on a new patch and **use condoms for the next 7 days**.
- Put on your next patch a week from the date of this new patch.

WHAT IF I FORGET TO CHANGE THE PATCH AFTER 7 DAYS?

- The patch has enough hormones for 9 days. If you leave the patch on for 9 days or less, just put on a new patch.
- If you leave the patch on for more than 9 days, put on a new patch and **use condoms for the next 7 days**.

WHAT IF I STOPPED USING THE PATCH AND HAD UNPROTECTED SEX?

- Take Emergency Contraception (EC) **right away**. EC can prevent pregnancy up to 5 days after sex, and it works better the sooner you take it.

HOW DOES THE PATCH HELP ME?

- The patch is safe and effective birth control. Your periods may be more regular, lighter, and shorter. You may have clearer skin.
- The patch lowers your risk of getting cancer of the uterus and ovaries.
- The patch has **no effect** on your ability to get pregnant in the future, after you stop using it.

HOW WILL I FEEL ON THE PATCH?

- You will feel about the same. During the first 2-3 months you may have nausea, bleeding between periods, weight change, and/or breast pain. These problems often go away after 2-3 months.

DOES THE PATCH HAVE RISKS?

- The patch is very safe. Serious problems are rare. If you have any of the symptoms below, call your health provider:
  - Leg pain, swelling, and redness
  - Weakness or numbness on 1 side of your body
  - Bad headache
  - Vision problems
  - Chest pain
- Your health provider can help you find out if these symptoms are signs of a serious problem.

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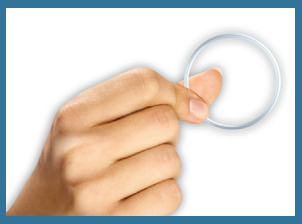
FACT SHEET : THE RING

Remember, the ring **does not protect you from Sexually Transmitted Infections or HIV.** Always use condoms to protect yourself!



HOW DOES THE RING WORK?

- The ring contains hormones like the ones your body makes. These hormones stop your ovaries from releasing eggs. Without an egg, you cannot get pregnant.
- No method of birth control is 100% effective. The ring is 91-99% effective.

HOW DO I START THE RING?

- There are 2 ways to start the ring:
  - **Quick Start:** put in your first ring as soon as you get the pack.
  - **Next period:** put in your first ring soon after your next period begins.
- If you put your first ring in *up to 5 days after the start of your period*, you are protected against pregnancy **right away**.
- If you put your first ring in *more than 5 days after the start of your period*, you should **use condoms as back-up for the first 7 days**.

HOW DO I USE THE RING?

- The ring is a small, bendable, plastic circle that you insert into your vagina.
- You leave the ring in your vagina for 3 weeks, and remove it for the 4th week.
- Remove the ring by hooking a finger under the rim and pulling it out.
- Most women get their period during the ring-free week.
- Insert a new ring at the end of the 4th week.
- You can store the ring at room temperature up to four months. In the refrigerator, the ring lasts much longer.

DO I HAVE TO GET A PERIOD?

- Because the ring has enough hormones to last 35 days, you can leave it in for more than 3 weeks. You can change the ring on the same day of each month (for instance, March 1st, April 1st, May 1st, etc.). If you remove the old ring and insert the new ring on the same day, you may not get a period. This is ok.

WHAT IF THE RING COMES OUT?

- The ring may slip out during sex or when you use the bathroom. The ring can stay out of your body for up to 3 hours and still prevent pregnancy. If the ring is out of your body for more than 3 hours, you should put it back into your vagina and **use condoms for the next 7 days**.

WHAT IF I STOPPED USING THE RING AND HAD UNPROTECTED SEX?

- Take Emergency Contraception (EC) **right away**. EC can prevent pregnancy up to 5 days after sex, and it works better the sooner you take it.

HOW DOES THE RING HELP ME?

- The ring is safe and effective birth control. Your periods may be more regular, lighter, and shorter. You may have clearer skin. The ring lowers your risk of getting cancer of the uterus and ovaries. The ring has **no effect** on your ability to get pregnant in the future, after you stop using it.

HOW WILL I FEEL ON THE RING?

- You will feel about the same. In the first few months you may have nausea, bleeding between periods, weight change, and/or breast pain. These problems often go away after 2-3 months.

DOES THE RING HAVE RISKS?

- The ring is very safe. Serious problems are rare. If you have any of the symptoms below, call your health provider:
  - Leg pain, swelling, and redness
  - Weakness or numbness on 1 side of your body
  - Bad headache
  - Vision problems
  - Chest pain
- Your health provider can help you find out if these symptoms are signs of a serious problem.

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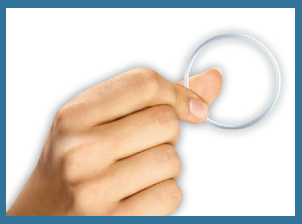
HOJA INFORMATIVA : SOBRE EL ANILLO

Recuerde, el anillo **no la protege contra las infecciones de transmisión sexual o el VIH.** Siempre use condones para protegerse!



¿CÓMO FUNCIONA EL ANILLO?

- El anillo contiene hormonas como las que su cuerpo produce. Estas hormonas impiden que sus ovarios liberen óvulos. Sin un óvulo, usted no puede quedar embarazada.
- Ningún método anticonceptivo es 100% efectivo. El anillo es 91-99% efectivo.

¿COMO EMPIEZO A USAR EL ANILLO?

- Hay 2 maneras de empezar a usar el anillo:
  - **Inicio Inmediato:** Inserte el primer anillo tan pronto que lo obtenga.
  - **Siguiente menstruación:** Inserte el primer anillo después de que empieze su próximo período.
- Si inserta el primer anillo hasta *5 días después del inicio de su período*, su protección contra el embarazo es **inmediato**.
- Si inserta el primer anillo *más de 5 días después del inicio de su período*, **debe usar condones como método de respaldo durante los primeros 7 días.**

¿CÓMO DEBO USAR EL ANILLO?

- El anillo es un círculo plástico, pequeño y flexible que usted introduce en su vagina.
- Usted deja el anillo en su vagina por 3 semanas, y lo retira para la cuarta semana.
- **Use condones por 7 días** al insertar su *primer* anillo.
- Remueva el anillo enganchándolo con el dedo y jalándolo.
- La mayoría de mujeres presentan su menstruación durante la semana libre de anillo.
- Introduzca un nuevo anillo al final de la cuarta semana.
- Usted puede almacenar el anillo a temperatura ambiente por hasta cuatro meses. En el refrigerador, el anillo dura mucho más.

¿TENGO QUE TENER UNA MENSTRUACIÓN?

- Debido a que el anillo tiene suficientes hormonas para 35 días, usted puede dejarlo puesto por más de 3 semanas. Usted puede cambiar el anillo el mismo día de cada mes (por ejemplo, 1ro de marzo, 1ro de abril, 1ro de mayo, etc.). Si usted retira el anillo Viejo y coloca uno nuevo el mismo día, es probable que no tenga una menstruación. Esto está bien.

¿QUÉ PASA SI EL ANILLO SE CAE?

- El anillo se puede deslizar durante la relación sexual o cuando usted use el baño. El anillo puede permanecer fuera de su cuerpo por hasta 3 horas y aun prevenir el embarazo. Si el anillo permanece fuera de su cuerpo por más de 3 horas, usted debe ponerlo de vuelta en su vagina y **usar condones durante los siguientes 7 días**.

¿QUÉ PASA SI DEJÉ DE USAR EL ANILLO Y TUVE RELACIONES SEXUALES SIN PROTECCIÓN?

- Tome anticonceptivos de emergencia (AE) **inmediatamente**. Los AE pueden prevenir el embarazo hasta 5 días después de una relación sexual, y funciona mejor cuanto más pronto los tome.

¿CÓMO ME AYUDA/ME BENEFICIA EL ANILLO?

- El anillo es anticoncepción segura y efectiva. Sus menstruaciones podrían ser más regulares, ligeras y cortas. Su piel se podría aclarar del acné. El anillo disminuye su riesgo de desarrollar cáncer uterino y de los ovarios. El anillo no tiene **ningún efecto** sobre su capacidad de quedar embarazada en el futuro, después que usted lo deje de usar.

¿CÓMO ME SENTIRÉ CON EL ANILLO?

- Usted se sentirá más o menos igual. En los primeros meses usted podría tener náusea, sangrado entre menstruaciones, cambios de peso y/o dolor en los pechos. Estos problemas generalmente desaparecen a los 2-3 meses.

¿EXISTEN RIESGOS?

- El anillo es muy seguro. Los problemas serios son raros. Si usted tiene alguno de los síntomas enumerados abajo, llame a su proveedor de atención a la salud:
  - -Dolor, hinchazón y enrojecimiento de las piernas
  - -Debilidad o adormecimiento en un lado de su cuerpo
  - -Dolor de cabeza severo
  - -Problemas de la visión
  - -Dolor de pecho
- Su proveedor de atención a la salud puede ayudarle a determinar si estos síntomas son señales de un problema serio.

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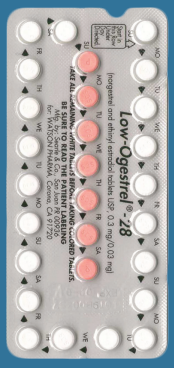
FACT SHEET : THE PILL

Remember, the pill **does not protect you from Sexually Transmitted Infections or HIV.** Always use condoms to protect yourself!



HOW DO BIRTH CONTROL PILLS WORK?

- Birth control pills contain hormones like the ones your body makes. These hormones stop your ovaries from releasing eggs. Without an egg, you cannot get pregnant.
- No method of birth control is 100% effective. Birth control pills are 91-99% effective.

HOW DO I START THE PILL?

- There are 2 ways to start the pill:
  - **Quick Start:** Take your first pill as soon as you get the pack.
  - **Next period:** Take your first pill soon after your next period begins.
- If you take your first pill *up to 5 days after the start of your period*, you are protected against pregnancy **right away**.
- If you take your first pill *more than 5 days after the start of your period*, you should **use condoms as back-up for the first 7 days.**

HOW DO I USE THE PILL?

- **Once you start using the pill**, take 1 pill each day. Take your pill at the same time each day.
- After you finish a pack of pills, you should start a new pack the next day. You should have NO day without a pill.

WHAT IF I MISS PILLS?

- **I forgot ONE pill:** Take your pill as soon as you can.
- **I forgot TWO pills or more:** Take your pill as soon as you can. Take your next pill at the usual time. **Use condoms for 7 days. Use emergency contraception (EC) if you have unprotected sex.**

WHAT IF I STOPPED TAKING THE PILL AND HAD UNPROTECTED SEX?

- Take Emergency Contraception (EC) **right away**. EC can prevent pregnancy up to 5 days after sex, and it works better the sooner you take it.

HOW DOES THE PILL HELP ME?

- The pill is safe and effective birth control.
- Your periods may be more regular, lighter, and shorter. You may have clearer skin.
- The pill lowers your risk of getting cancer of the uterus and ovaries.
- The pill has **no effect** on your ability to get pregnant in the future, after you stop taking it.

HOW WILL I FEEL ON THE PILL?

- You will feel about the same. In the first 2-3 months you may have nausea, bleeding between periods, weight change, and/or breast pain. These problems often go away after 2-3 months.

DOES THE PILL HAVE RISKS?

- The pill is very safe. Serious problems are rare. If you have any of the symptoms below, call your health provider.
- Leg pain, swelling, and redness
- Weakness or numbness on 1 side of your body
- Bad headache
- Vision problems
- Chest pain
- Your health provider can help you find out if these symptoms are signs of a serious problem.

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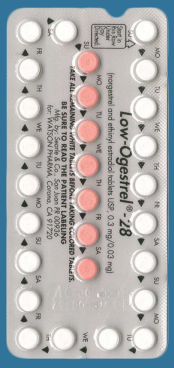
HOJA INFORMATIVA : SOBRE LA PÍLDORA

Recuerde, la píldora **no la protege contra las Infecciones de Transmisión Sexual o el VIH.** Siempre use condones para protegerse!



¿CÓMO FUNCIONAN LAS PÍLDORAS ANTICONCEPTIVAS?

- Las píldoras anticonceptivas contienen hormonas como las que produce su cuerpo. Estas hormonas impiden que sus ovarios liberen óvulos. Sin óvulos usted no puede quedar embarazada.
- Ningún método es 100% efectivo. Las píldoras anticonceptivas son 91-99% efectivas.

¿COMO EMPIEZO A USAR LA PÍLDORA?

- Hay 2 maneras de empezar las píldoras:
  - **Inicio Inmediato:** Tome la primera píldora tan pronto que obtenga el paquete.
  - **Siguiente menstruación:** Tome la primera píldora poco después de que empieze su próximo período.
- Si toma la primera píldora hasta *5 días después del inicio de su período,* su protección contra el embarazo es **inmediato**.
- Si toma la primera pildora *más de 5 días después del inicio de su período,* **debe usar condones como método de respaldo durante los primeros 7 días.**

¿CÓMO DEBO USAR LAS PÍLDORAS ANTICONCEPTIVAS?

- **Una vez que comience a usar la píldora**, tome 1 píldora todos los días. Tómela a la misma hora cada día.
- Después que termine un paquete de píldoras anticonceptivas, necesita comenzar otro paquete al día siguiente. No debería tener NI UN solo día sin píldoras.

¿QUÉ PASA SI ME OLVIDAN LAS PÍLDORAS?

- **Se me olvidó UNA píldora:** Tómela tan pronto como pueda.
- **Se me olvidaron DOS o más píldoras:** Tome su píldora tan pronto como sea posible. Tome su siguiente píldora a la hora habitual. **Use condones durante 7 días. Use anticoncepción de emergencia (AE) si tiene relaciones sexuales sin protección.**

¿QUÉ PASA SI DEJÉ DE TOMAR LAS PÍLDORAS Y TUVE RELACIONES SEXUALES SIN PROTECCIÓN?

- Tome anticonceptivos de emergencia (AE) **inmediatamente.** Los AE puede prevenir el embarazo hasta 5 días después de una relación sexual, y funciona mejor cuanto más pronto la tome.

¿CÓMO ME AYUDA LA PÍLDORA?

- La píldora es anticoncepción segura y efectiva.
- Sus menstruaciones pueden ser más regulares, más ligeras y más cortas.
- Su piel se podría aclarar del acné. La píldora disminuye su riesgo de desarrollar cáncer del útero y de los ovarios.
- La píldora no tiene ningún efecto sobre su capacidad de quedar embarazada en el futuro, después que deje de tomarla.

¿CÓMO ME SENTIRÉ CUANDO TOME LA PÍLDORA?

- Se sentirá más o menos igual. En los primeros 2-3 meses podría tener nausea, sangrado entre menstruaciones, cambios de peso y/o dolor en los pechos. Estos problemas generalmente desaparecen a los 2-3 meses.

¿LA PÍLDORA TIENE RIESGOS?

- La píldora es muy segura. Los problemas serios son raros. Si tiene cualquiera de los síntomas enumerados abajo, llame a su proveedor o escríbanos por medio de *mychart*:
  - -Dolor, hinchazón o enrojecimiento de las piernas
  - -Debilidad o adormecimiento en 1 lado de tu cuerpo
  - -Dolor de cabeza severo
  - -Problemas de la visión
  - -Dolor de pecho
- Nosotros podemos ayudarle a averiguar si estos síntomas son señales de un problema serio.

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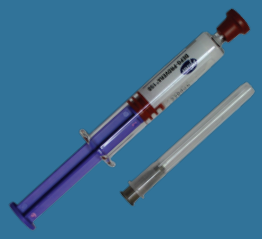
FACT SHEET : THE SHOT/DEPO-PROVERA

Remember, Depo **does not protect you from Sexually Transmitted Infections or HIV.** Always use condoms to protect yourself!



HOW DOES DEPO WORK?

- Depo contains a hormone like the ones your body makes. This hormone stops your ovaries from releasing eggs. Without an egg, you cannot get pregnant.
- No method of birth control is 100% effective. Depo is 94-99% effective.

HOW DO I USE DEPO?

- You get a Depo injection in the arm or in the buttocks.
- **Use condoms as back-up the first 7 days** after your first shot of Depo.
- You should get a shot every 3 months (every 12 weeks).

WHAT IF I AM LATE FOR THE NEXT SHOT?

- Depo works best if you get a new shot every 12 weeks.
- If your shot is more than 4 weeks late, you should get a pregnancy test before the next shot. You should **use condoms for the next 7 days**.

WHAT IF I AM LATE GETTING A SHOT AND HAD UNPROTECTED SEX?

- If your last shot was more than 16 weeks ago, take Emergency Contraception (EC) **right after** unprotected sex. EC can prevent pregnancy up to 5 days after sex, and it works better the sooner you take it.

HOW DOES DEPO HELP ME?

- Depo is safe & effective. It keeps you from getting pregnant for 3 months.
- The shot lowers your risk of cancer of the uterus.
- It is safe to breastfeed while on Depo.

HOW WILL I FEEL ON DEPO?

- You will most likely have spotting between periods. You may have weight gain, bloating, headaches and/or mood changes. Talk to your health care provider about treating any side effects.
- After the first 2-3 shots, you may have *no period at all*. This is normal.
- Your bones may become slightly weaker while you take Depo. Bone strength returns to normal once you stop getting the shot.
- After you stop Depo, it takes a few months for your fertility to return to normal. This means that it may take a while for you to get pregnant (even if you're trying) – but if you don't want to get pregnant, you need to use a new form of birth control after you stop Depo.

DOES DEPO HAVE RISKS?

- The shot is very safe. Severe problems are rare. If you have any of the symptoms below, call your doctor:
  - Severe headaches
  - Very heavy bleeding
- Your health care provider can help you find out if these symptoms are signs of a severe problem.

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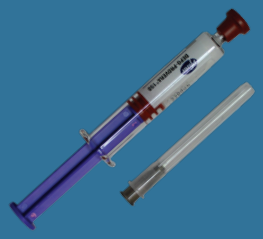
HOJA INFORMATIVA : LA INYECCIÓN/DEPO-PROVERA

Recuerde, la Depo **no la protege contra las Infecciones de Transmisión Sexual o el VIH.** ¡Siempre use condones para protegerse!



¿CÓMO FUNCIONA LA DEPO?

- La Depo contiene una hormona como las que produce su cuerpo. Esta hormona impide que sus ovarios liberen óvulos. Sin un óvulo, usted no puede quedar embarazada.
- Ningún método anticonceptivo es 100% efectivo. La Depo es 94-99% efectiva.

¿CÓMO DEBO USAR LA DEPO?

- Usted recibe una inyección de Depo en el brazo o en la cadera.
- **Use condones como método de resplando por los primeros 7 días** después que reciba su *primera* inyección de Depo.
- Usted debería recibir una inyección cada 3 meses (cada 12 semanas).

¿QUÉ PASA SI ME RETRASO PARA LA SIGUIENTE INYECCIÓN?

- La Depo funciona mejor si usted recibe una nueva inyección cada 12 semanas.
- Si su inyección está retrasada más de 4 semanas, usted debería hacerse una prueba de embarazo antes de su próxima inyección. Usted debería **usar condones durante los siguientes 7 días.**

¿QUÉ PASA SI ME RETRASO PARA LA SIGUIENTE INYECCIÓN Y TUVE RELACIONES SEXUALES SIN PROTECCIÓN?

- Si su última inyección fue hace más de 16 semanas, tome anticonceptivos de emergencia (AE) **inmediatamente** después de la relación sexual sin protección. Los AE pueden prevenir el embarazo hasta 5 días después de la relación sexual, y funcionan mejor cuanto más pronto los tome.

¿CÓMO ME AYUDA LA DEPO?

- La Depo es segura y eficaz. Le ayuda a prevenir el embarazo por 3 meses.
- La inyección disminuye su riesgo de cáncer uterino.
- Amamantar es seguro mientras esté usando la Depo.

¿CÓMO ME SENTIRÉ AL USAR LA DEPO?

- Es muy probable que tenga algo de manchado entre sus menstruaciones. Usted podría aumentar de peso, tener hinchazón, dolores de cabeza y/o cambios en su estado de ánimo. Hable con su proveedor de salud sobre el tratamiento de cualquier efecto secundario.
- Después de las primeras 2-3 inyecciones, usted podría *no tener menstruaciones del todo*. Esto es normal.
- Sus huesos podrían debilitarse un poco mientras esté usando la Depo. La fuerza ósea regresa a lo normal una vez que usted deje de recibir las inyecciones.
- Después de que deje de usar la Depo, toma algunos meses para que su fecundidad regrese a lo normal. Esto significa que puede tomar algo de tiempo para que usted quede embarazada (aun si está tratando) –pero si no desea quedar embarazada, usted debe usar una nueva forma de anticoncepción después que deje de usar la Depo.

¿LA DEPO TIENE RIESGOS?

- La inyección es muy segura. Los problemas severos son raros. Si usted tiene cualquiera de los síntomas mencionados abajo, llame a su doctor:
  - -Dolores de cabeza severos
  - -Sangrado muy abundante
- Su proveedor de salud puede ayudarle a saber si estos síntomas son señales de un problema severo.

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Attachment 3

Protocol for Pharmacists Furnishing Nicotine Replacement Products

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

(b) Protocol for Pharmacists Furnishing Nicotine Replacement Products

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

(2) Purpose: To provide timely access to nicotine replacement products and to ensure that the patient receives information to appropriately initiate smoking cessation medication therapy.

(3) Explanation of Products Covered: Prescription nicotine replacement products approved by the federal Food and Drug Administration and provided by a pharmacist for smoking cessation are covered under this protocol. Pharmacists may continue to provide over-the-counter smoking cessation products without use of this protocol.

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

- Review the patient's current tobacco use and past quit attempts.
- Ask the patient the following screening questions:
    - Are you pregnant or plan to become pregnant? (If yes, do not furnish and refer to an appropriate health care provider)
    - Have you had a heart attack within the last 2 weeks? (If yes, furnish with caution and refer to an appropriate health care provider)
    - Do you have any history of heart palpitations, irregular heartbeats, or have you been diagnosed with a serious arrhythmia? (If yes, furnish with caution and refer to an appropriate health care provider)
    - Do you currently experience frequent chest pain or have you been diagnosed with unstable angina? (If yes, furnish with caution and refer to an appropriate health care provider)
    - Do you have any history of allergic rhinitis (e.g., nasal allergies)? (If yes, avoid nasal spray)

    - Have you been diagnosed with temporal mandibular joint (TMJ) dysfunction? (If yes, avoid nicotine gum)

These screening questions shall be made available in alternate languages for patients whose primary language is not English.

- When a nicotine replacement product is furnished:
    - The pharmacist shall review the instructions for use with every patient using a nicotine replacement product.
    - Pharmacists should recommend the patient seek additional assistance for behavior change, including but not limited to the California Smokers' Helpline (1-800-NO-BUTTS), web-based programs (e.g., http://smokefree.gov), apps, and local cessation programs.
- The pharmacist shall answer any questions the patient may have regarding smoking cessation therapy and/or nicotine replacement products.

(5) Product Selection: The pharmacist, in consultation with the patient, may select any nicotine replacement product (alone or in combination) from the list of therapies specified in this protocol in the Table "Nicotine Replacement Therapy Medications for Smoking Cessation." This list shall be kept current and maintained in the pharmacy or health care facility, and shall be available on the Board of Pharmacy's website.

Generic equivalent products may be furnished.

(6) Notifications: The pharmacist shall notify the patient's primary care provider of any prescription drug(s) and/or device(s) furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the prescription drug(s) and/or device(s) furnished and advise the patient to consult an appropriate health care provider of the patient's choice.

(7) Documentation: Each nicotine replacement product provided for smoking cessation and furnished by a pharmacist pursuant to this protocol shall be documented in a patient medication record and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense. A patient 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.

(8) Training: Prior to furnishing prescription nicotine replacement products, pharmacists who participate in this protocol must have completed a minimum of two hours of an approved continuing education program specific to smoking cessation therapy and nicotine replacement therapy, or an equivalent curriculum-based training program completed within the last two years in an accredited California school of pharmacy.

Additionally, pharmacists who participate in this protocol must complete ongoing continuing education focused on smoking cessation therapy from an approved provider once every two years.

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

10) Nicotine Replacement Therapy Medications for Smoking Cessation
Insert chart

Note: Authority cited: Section 4052.9, Business and Professions Code. Reference: Section 4052(a)(10), Business and Professions Code.

Protocol Sources

Centers for Disease Control and Prevention, "Quitting Smoking," *available at* http://www.cdc.gov/tobacco/data_statistics/fact_sheets/cessation/quitting/index.htm.
This resource describes the methods of quitting smoking and their effectiveness.

CPhA/CSHP, "Pharmacists Protocol for Dispensing Nicotine Replacement Products."
This draft protocol was consulted in development of the Board's recommended protocol.

Frank Vitale, "Brief Intervention Protocol for Assisting Patients with Tobacco Cessation," 64 AM. J. HEALTH-SYST PHARM. 2583 (2007).
This commentary provides important resources and specific dialogue for a pharmacists' procedure for assisting patients with tobacco cessation.

Nicole Van Hoey, "Opportunities for Smoking Cessation Services in Emerging Models of Care," America's Pharmacist (Oct. 2014).
This Continuing Education provided helpful referral resources, especially smartphone resources.

University of California, San Francisco, "Smoking Cessation Leadership Center," http://smokingcessationleadership.ucsf.edu/.
This site offers evidence-based resources for providers as well as continuing education opportunities in smoking cessation for CME and CEU credit.

University of California, San Francisco, "Rx for Change," http://rxforchange.ucsf.edu/.
This site offers evidence-based resources for providers and non-providers.

Accreditation Council for Pharmacy Education, "Basic Tobacco Intervention Workshop," P.L.A.N. Search Detail, *available at* https://www.acpe-accredit.org/pwtool/plan/DetailResultsPLAN.aspx?progtype=1&id=267501&cosp=289079&fromdate=10/27/2014.
This website shows ACPE-approved education involving smoking cessation.

Agency for Healthcare Research and Quality, "Treating Tobacco Use and Dependence: 2008—Clinical Practice Guideline," *available at* http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/tobacco/clinicians/index.html.
This site provides tobacco reference materials and guides for health care providers.

Nicotine Replacement Therapy Medications for Smoking Cessation

	Nicotine Replacement Therapy (NRT) Formulations Used as Monotherapy					Combination NRT
	Gum	**Lozenge**	**Patch**	**Nasal Spray**	**Inhaler**	
Product	**Nicorette[1], Generic** OTC 2 mg, 4 mg original, cinnamon, fruit, mint	**Nicorette Lozenge,[1]** **Nicorette Mini Lozenge,[1]** **Generic** OTC 2 mg, 4 mg cherry, mint	**NicoDerm CQ[1], Generic** OTC (NicoDerm CQ, generic) Rx (generic) 7 mg, 14 mg, 21 mg (24-hour release)	**Nicotrol NS[2]** Rx Metered spray 0.5 mg nicotine in 50 mcL aqueous nicotine solution	**Nicotrol Inhaler[2]** Rx 10 mg cartridge delivers 4 mg inhaled nicotine vapor	**Combinations with demonstrated efficacy** Nicotine patch + nicotine gum Nicotine patch + nicotine lozenge Nicotine patch + nicotine nasal spray Nicotine patch + nicotine oral inhaler
Precautions	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Temporomandibular joint disease ▪ Pregnancy[3] and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Pregnancy[3] and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Pregnancy[3] (Rx formulations, category D) and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Underlying chronic nasal disorders (rhinitis, nasal polyps, sinusitis) ▪ Severe reactive airway disease ▪ Pregnancy[3] (category D) and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Bronchospastic disease ▪ Pregnancy[3] (category D) and breastfeeding ▪ Adolescents (<18 years)	▪ See precautions for individual agents
Dosing	*1st cigarette ≤30 minutes after waking:* 4 mg *1st cigarette >30 minutes after waking:* 2 mg Weeks 1–6: 1 piece q 1–2 hours Weeks 7–9: 1 piece q 2–4 hours Weeks 10–12: 1 piece q 4–8 hours ▪ Maximum, 24 pieces/day ▪ Chew each piece slowly ▪ Park between cheek and gum when peppery or tingling sensation appears (~15–30 chews) ▪ Resume chewing when tingle fades ▪ Repeat chew/park steps until most of the nicotine is gone (tingle does not return; generally 30 min) ▪ Park in different areas of mouth ▪ No food or beverages 15 minutes before or during use ▪ Duration: up to 12 weeks	*1st cigarette ≤30 minutes after waking:* 4 mg *1st cigarette >30 minutes after waking:* 2 mg Weeks 1–6: 1 lozenge q 1–2 hours Weeks 7–9: 1 lozenge q 2–4 hours Weeks 10–12: 1 lozenge q 4–8 hours ▪ Maximum, 20 lozenges/day ▪ Allow to dissolve slowly (20–30 minutes for standard; 10 minutes for mini) ▪ Nicotine release may cause a warm, tingling sensation ▪ Do not chew or swallow ▪ Occasionally rotate to different areas of the mouth ▪ No food or beverages 15 minutes before or during use ▪ Duration: up to 12 weeks	*>10 cigarettes/day:* 21 mg/day x 4–6 weeks 14 mg/day x 2 weeks 7 mg/day x 2 weeks *≤10 cigarettes/day:* 14 mg/day x 6 weeks 7 mg/day x 2 weeks ▪ May wear patch for 16 hours if patient experiences sleep disturbances (remove at bedtime) ▪ Duration: 8–10 weeks	1–2 doses/hour (8–40 doses/day) One dose = 2 sprays (one in **each** nostril); each spray delivers 0.5 mg of nicotine to the nasal mucosa ▪ Maximum – 5 doses/hour or – 40 doses/day ▪ For best results, initially use at least 8 doses/day ▪ Do not sniff, swallow, or inhale through the nose as the spray is being administered ▪ Duration: 3–6 months	6–16 cartridges/day Individualize dosing; initially use 1 cartridge q 1–2 hours ▪ Best effects with continuous puffing for 20 minutes ▪ Initially use at least 6 cartridges/day ▪ Nicotine in cartridge is depleted after 20 minutes of active puffing ▪ Inhale into back of throat or puff in short breaths ▪ Do NOT inhale into the lungs (like a cigarette) but "puff" as if lighting a pipe ▪ Open cartridge retains potency for 24 hours ▪ No food or beverages 15 minutes before or during use ▪ Duration: 3–6 months	*Reserve for patients smoking ≥10 cigarettes/day:* **Long-acting NRT**: to prevent onset of severe withdrawal symptoms ▪ **Nicotine patch** 21 mg/day x 4-6 weeks 14 mg/day x 2 weeks 7 mg/day x 2 weeks **PLUS** **Short-acting NRT**: used as needed to control breakthrough withdrawal symptoms and situational urges for tobacco ▪ **Nicotine gum (2 mg)** 1 piece q 1–2 hours as needed *OR* ▪ **Nicotine lozenge (2 mg)** 1 lozenge q 1–2 hours as needed *OR* ▪ **Nicotine nasal spray** 1 spray in each nostril q 1–2 hours as needed *OR* ▪ **Nicotine inhaler** 1 cartridge q 1–2 hours as needed

	Nicotine Replacement Therapy (NRT) Formulations Used as Monotherapy					Combination NRT
	Gum	Lozenge	Patch	Nasal Spray	Inhaler	
Adverse Effects	▪ Mouth/jaw soreness ▪ Hiccups ▪ Dyspepsia ▪ Hypersalivation ▪ Effects associated with incorrect chewing technique: – Lightheadedness – Nausea/vomiting – Throat and mouth irritation	▪ Nausea ▪ Hiccups ▪ Cough ▪ Heartburn ▪ Headache ▪ Flatulence ▪ Insomnia	▪ Local skin reactions (erythema, pruritus, burning) ▪ Headache ▪ Sleep disturbances (insomnia, abnormal/vivid dreams); associated with nocturnal nicotine absorption	▪ Nasal and/or throat irritation (hot, peppery, or burning sensation) ▪ Rhinitis ▪ Tearing ▪ Sneezing ▪ Cough ▪ Headache	▪ Mouth and/or throat irritation ▪ Cough ▪ Headache ▪ Rhinitis ▪ Dyspepsia ▪ Hiccups	▪ See adverse effects listed for individual agents
Advantages	▪ Might serve as an oral substitute for tobacco ▪ Might delay weight gain ▪ Can be titrated to manage withdrawal symptoms ▪ Can be used in combination with other agents to manage situational urges	▪ Might serve as an oral substitute for tobacco ▪ Might delay weight gain ▪ Can be titrated to manage withdrawal symptoms ▪ Can be used in combination with other agents to manage situational urges	▪ Once daily dosing associated with fewer adherence problems ▪ Of all NRT products, its use is least obvious to others Can be used in combination with other agents; delivers consistent nicotine levels over 24 hours	▪ Can be titrated to rapidly manage withdrawal symptoms ▪ Can be used in combination with other agents to manage situational urges	▪ Might serve as an oral substitute for tobacco ▪ Can be titrated to manage withdrawal symptoms ▪ Mimics hand-to-mouth ritual of smoking ▪ Can be used in combination with other agents to manage situational urges	▪ Provides consistent nicotine levels over 24 hours and patients can titrate therapy to manage withdrawal symptoms and situational urges for tobacco ▪ Research studies suggest combination therapy provides a small, but meaningful increase in success rates compared to single agent NRT ▪ Attractive option for patients who have previously failed treatment with monotherapy ▪ See advantages listed for individual agents
Disadvantages	▪ Need for frequent dosing can compromise adherence ▪ Might be problematic for patients with significant dental work ▪ Proper chewing technique is necessary for effectiveness and to minimize adverse effects ▪ Gum chewing might not be acceptable or desirable for some patients	▪ Need for frequent dosing can compromise adherence ▪ Gastrointestinal side effects (nausea, hiccups, heartburn) might be bothersome	▪ When used as monotherapy, cannot be titrated to acutely manage withdrawal symptoms ▪ Not recommended for use by patients with dermatologic conditions (e.g., psoriasis, eczema, atopic dermatitis)	▪ Need for frequent dosing can compromise adherence ▪ Nasal administration might not be acceptable or desirable for some patients; nasal irritation often problematic ▪ Not recommended for use by patients with chronic nasal disorders or severe reactive airway disease	▪ Need for frequent dosing can compromise adherence ▪ Cartridges might be less effective in cold environments (≤60°F)	▪ Combination therapy is more costly than monotherapy ▪ See disadvantages listed for individual agents

[1] Marketed by GlaxoSmithKline.
[2] Marketed by Pfizer.
[3] The U.S. Clinical Practice Guideline states that pregnant smokers should be encouraged to quit without medication based on insufficient evidence of effectiveness and theoretical concerns with safety. Pregnant smokers should be offered behavioral counseling interventions that exceed minimal advice to quit.

Abbreviations: NRT, nicotine replacement therapy; OTC, over-the-counter (non-prescription product); Rx, prescription product.

For complete prescribing information, please refer to the manufacturers' package inserts.

Attachment 4

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

§1746.3 Protocol for Pharmacists Furnishing Naloxone Hydrochloride

(a) A pharmacist furnishing naloxone hydrochloride pursuant to Section 4052.01 of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Naloxone Hydrochloride

(1) Authority: Section 4052.01(a) of the California Business and Professions Code authorizes a pharmacist to furnish naloxone hydrochloride in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol in this section satisfies that requirement.

(2) Purpose: To provide access to naloxone hydrochloride via standardized procedures so that pharmacists may educate about and furnish naloxone hydrochloride to decrease harm from opioid[1] overdose.

(3) Procedure: When someone requests naloxone hydrochloride, or when a pharmacist in his or her professional judgment decides to advise of the availability and appropriateness of naloxone hydrochloride, the pharmacist shall complete the following steps:

(A) Screen for the following conditions:[2]
  (i.) Whether the potential recipient[3] currently uses or has a history of using illicit or prescription opioids (If yes, skip question ii and continue with Procedure);
  (ii.) Whether the potential recipient is in contact with anyone who uses or has a history of using illicit or prescription opioids (If yes, continue with Procedure);
  (iii.) Whether the person to whom the naloxone hydrochloride would be administered has a known hypersensitivity to naloxone? (If yes, do not furnish).

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

(C) 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.

---

[1] For purposes of this protocol, "opioid" is used generally to cover both naturally derived opiates and synthetic and semi-synthetic opioids.

[2] These screening questions shall be made available in alternate languages for patients whose primary language is not English.

[3] For purposes of this protocol, "recipient" means the person to whom naloxone hydrochloride is furnished.

(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: Naloxone hydrochloride may be supplied as an intramuscular injection, intranasal spray, and auto-injector. Other FDA approved products may be used. Those administering naloxone should choose the route of administration based on the formulation available, how well they can administer it, the setting, and local context.

(5) Suggested Kit Labeling:

Intramuscular	Intranasal	Auto-Injector
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. Syringe 3ml 25G X 1" # 2 SIG: Use as directed for naloxone administration. Kit should contain 2 vials and 2 syringes.	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. Mucosal Atomization Device (MAD) # 2 SIG: Use as directed for naloxone administration. Kit should contain 2 prefilled needleless syringes and 2 atomizers.	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. Kit is commercially available as a twin pack with directions for administration included.

Optional items for the kits include alcohol pads, rescue breathing masks, and rubber gloves.

Kit labels shall include an expiration date for the naloxone hydrochloride furnished. An example of appropriate labeling is available on the Board of Pharmacy 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.

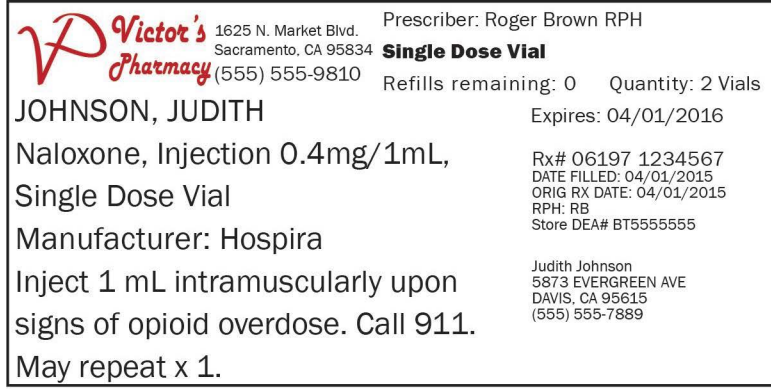
(9) Training: Prior to furnishing naloxone hydrochloride, pharmacists who participate in this protocol must have successfully completed a minimum of one hour of an approved continuing education program specific to the use of naloxone hydrochloride, or an equivalent curriculum-based training program completed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

(10) 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.

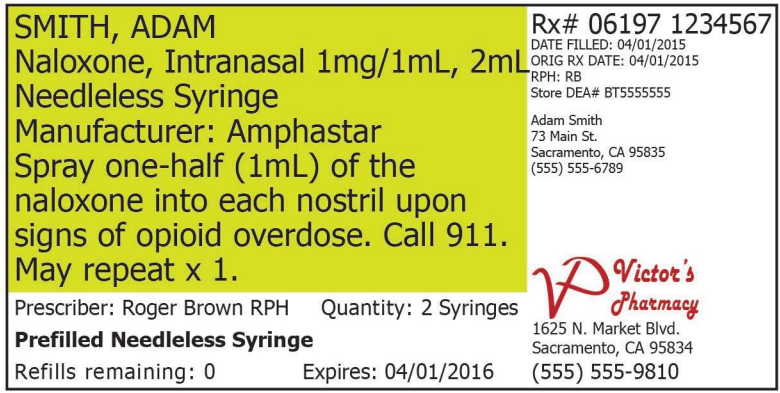
Authority and Reference: Section 4052.01, Business and Professions Code.

Attachment 5

Franklin Gothic



Tahoma



Arial

Franklin Gothic

Victor's Pharmacy
1625 N. Market Blvd.
Sacramento, CA 95834
(555) 555-9810

Prescriber: Roger Brown RPH
Syringe
Refills remaining: 0
Quantity: 2 Syringes Expires: 04/01/2016

JOHNSON, JUDITH
Syringe, 3mL, 25G X 1”
Manufacturer: BD
Use as directed for naloxone administration.

Rx# 06198 1234567
DATE FILLED: 04/01/2015
ORIG RX DATE: 04/01/2015
RPH: RB
Store DEA# BT5555555

Judith Johnson
5873 EVERGREEN AVE
DAVIS, CA 95615
(555) 555-7889

Tahoma

SMITH, ADAM
Mucosal Atomization Device (MAD)
Manufacturer: LMA
Use as directed for naloxone administration.

Rx# 06198 1234567
DATE FILLED: 04/01/2015
ORIG RX DATE: 04/01/2015
RPH: RB
Store DEA# BT5555555

Adam Smith
73 Main St.
Sacramento, CA 95835
(555) 555-6789

Prescriber: Roger Brown RPH Quantity: 2 MAD
Mucosal Atomization Device
Refills remaining: 0 Expires: 04/01/2016

Victor's Pharmacy
1625 N. Market Blvd.
Sacramento, CA 95834
(555) 555-9810

Attachment 6

Title 16. Board of Pharmacy. Adopt §1746.X, which is new regulation text, as follows:

§1746.X Pharmacists Initiating and Administering Vaccines

(a) A pharmacist initiating and/or administering vaccines pursuant to Section 4052.8 of the Business and Professions Code shall follow the requirements specified in subdivisions (b) through (f) of this section.

(b) Training: A pharmacist who initiates and/or administers any vaccine shall keep documentation of:

(1) Current completion of an approved immunization training program;

(2) Current basic life support certification.

This documentation shall be kept on site and available for inspection.

(c) Continuing Education: Pharmacists must complete one hour of ongoing continuing education focused on immunizations and vaccines from an approved provider once every two years.

(d) Notifications: The pharmacist shall notify the patient's primary care provider of any vaccines administered to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a vaccine administration record and advise the patient to consult an appropriate health care provider of the patient's choice.

(e) Immunization Registry: A pharmacist shall fully report the information described in Section 120440(c) of the Health and Safety Code into one or more state and/or local immunization information systems within 15 days of the administration of any vaccine. The pharmacist shall inform the patient or the patient's guardian of immunization recordsharing preferences, detailed in Section 120440(e) of the Health and Safety Code.

(f) Documentation: For each vaccine administered by a pharmacist, a patient medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 42, section 300aa-25 of the United States Code, and 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.

Authority and Reference: Sections 4052(a)(11), 4052.8, Business and Professions Code.

Vaccine injury table.

In accordance with section 312(b) of the National Childhood Vaccine Injury Act of 1986, title III of Pub. L. 99-660, 100 Stat. 3779 (42 U.S.C. 300aa-1 note) and section 2114(c) of the Public Health Service Act (42 U.S.C. 300aa-14(c)), the following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program:

VACCINE INJURY TABLE

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
I. Vaccines containing tetanus toxoid (e.g., DTaP, DTP, DT, Td, or TT)	A. Anaphylaxis or anaphylactic shock	4 hours.
	B. Brachial Neuritis	2-28 days.
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable.
II. Vaccines containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (e.g., DTP, DTaP, P, DTP-Hib)	A. Anaphylaxis or anaphylactic shock	4 hours.
	B. Encephalopathy (or encephalitis)	72 hours.
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable.
III. Measles, mumps, and rubella vaccine or any of its components (e.g., MMR, MR, M, R)	A. Anaphylaxis or anaphylactic shock	4 hours.
	B. Encephalopathy (or encephalitis)	5-15 days (not less than 5 days and not more than 15 days).
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above	Not applicable.

	which illness, disability, injury, or condition arose within the time period prescribed	
IV. Vaccines containing rubella virus (e.g., MMR, MR, R)	A. Chronic arthritis	7-42 days.
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable.
V. Vaccines containing measles virus (e.g., MMR, MR, M)	A. Thrombocytopenic purpura	7-30 days.
	B. Vaccine-Strain Measles Viral Infection in an immunodeficient recipient	6 months.
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable.
VI. Vaccines containing polio live virus (OPV)	A. Paralytic Polio	
	—in a non-immunodeficient recipient	30 days.
	—in an immunodeficient recipient	6 months.
	—in a vaccine associated community case	Not applicable.
	B. Vaccine-Strain Polio Viral Infection	
	—in a non-immunodeficient recipient	30 days.
	—in an immunodeficient recipient	6 months.
	—in a vaccine associated community case	Not applicable.
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable.
VII. Vaccines containing polio inactivated virus (e.g., IPV)	A. Anaphylaxis or anaphylactic shock	4 hours
	B. Any acute complication or sequela (including death of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period	Not applicable.

	prescribed.	
VIII. Hepatitis B. vaccines	A. Anaphylaxis or anaphylactic shock	4 hours.
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable.
IX. Hemophilus influenzae type b polysaccharide conjugate vaccines	No Condition Specified	Not applicable.
X. Varicella vaccine	No Condition Specified	Not applicable.
XI. Rotavirus vaccine	No Condition Specified	Not applicable.
XII. Pneumococcal conjugate vaccines	No Condition Specified	Not applicable.
XIII. Hepatitis A vaccines	No Condition Specified	Not applicable.
XIV. Trivalent influenza vaccines	No Condition Specified	Not applicable.
XV. Meningococcal vaccines	No Condition Specified	Not applicable.
XVI. Human papillomavirus (HPV) vaccines	No Condition Specified	Not applicable.
XVII. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by the Secretary of a notice of coverage *	No Condition Specified	Not applicable.

*Now includes all vaccines against seasonal influenza (except trivalent influenza vaccines, which are already covered), effective November 12, 2013.

§300aa–25. Recording and reporting of information

(a) General rule

Each health care provider who administers a vaccine set forth in the Vaccine Injury Table to any person shall record, or ensure that there is recorded, in such person's permanent medical record (or in a permanent office log or file to which a legal representative shall have access upon request) with respect to each such vaccine—

(1) the date of administration of the vaccine,

(2) the vaccine manufacturer and lot number of the vaccine,

(3) the name and address and, if appropriate, the title of the health care provider administering the vaccine, and

(4) any other identifying information on the vaccine required pursuant to regulations promulgated by the Secretary.

(b) Reporting

(1) Each health care provider and vaccine manufacturer shall report to the Secretary—

(A) the occurrence of any event set forth in the Vaccine Injury Table, including the events set forth in section 300aa–14(b) of this title which occur within 7 days of the administration of any vaccine set forth in the Table or within such longer period as is specified in the Table or section,

(B) the occurrence of any contraindicating reaction to a vaccine which is specified in the manufacturer's package insert, and

(C) such other matters as the Secretary may by regulation require.

Reports of the matters referred to in subparagraphs (A) and (B) shall be made beginning 90 days after December 22, 1987. The Secretary shall publish in the Federal Register as soon as practicable after such date a notice of the reporting requirement.

(2) A report under paragraph (1) respecting a vaccine shall include the time periods after the administration of such vaccine within which vaccine-related illnesses, disabilities, injuries, or conditions, the symptoms and manifestations of such illnesses, disabilities, injuries, or conditions, or deaths occur, and the manufacturer and lot number of the vaccine.

(3) The Secretary shall issue the regulations referred to in paragraph (1)(C) within 180 days of December 22, 1987.

(c) Release of information

(1) Information which is in the possession of the Federal Government and State and local governments under this section and which may identify an individual shall not be made available under section 552 of title 5, or otherwise, to any person except—

(A) the person who received the vaccine, or

(B) the legal representative of such person.

(2) For purposes of paragraph (1), the term “information which may identify an individual” shall be limited to the name, street address, and telephone number of the person who received the vaccine and of that person's legal representative and the medical records of such person relating to the administration of the vaccine, and shall not include the locality and State of vaccine administration, the name of the health care provider who administered the vaccine, the date of the vaccination, or information concerning any reported illness, disability, injury, or condition resulting from the administration of the vaccine, any symptom or manifestation of such illness, disability, injury, or

condition, or death resulting from the administration of the vaccine.

(3) Except as provided in paragraph (1), all information reported under this section shall be available to the public.

(July 1, 1944, ch. 373, title XXI, §2125, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3774; amended Pub. L. 100–203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221.)

Codification

In subsec. (b)(1), (3), "December 22, 1987" was substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

Amendments

1987—Subsec. (b)(1), (3). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this part".

Effective Date

Subpart effective Dec. 22, 1987, see section 323 of Pub. L. 99–660, set out as a note under section 300aa–1 of this title.

Attachment 7

Title 16. Board of Pharmacy. Adopt §1746.X, which is new regulation text, as follows:

§1746.X Pharmacists Furnishing Travel Medications

(a) For purposes of section 4052(a)(10)(A)(3), "not requiring a diagnosis" means either
(1) a self-diagnosable and self-treatable condition under the federal Centers for Disease Control and Prevention's (CDC) Health Information for International Travel (commonly called the Yellow Book); or
(2) a prophylactic.

(b) A pharmacist furnishing prescription medications not requiring a diagnosis that are recommended by the CDC for individuals traveling outside the 50 states and the District of Columbia pursuant to Section 4052(a)(10) of the Business and Professions Code shall follow the requirements specified in subdivisions (c) through (f) of this section.

(c) Training: A pharmacist who initiates and/or administers any vaccine shall keep documentation of:
(1) Current completion of an approved immunization training program, which must consist of at least 30 hours and cover the International Society of Travel Medicine's body of knowledge;
(2) Completion of the CDC Yellow Fever Vaccine Course;
(3) Current basic life support certification.
This documentation shall be kept on site and available for inspection.

(d) Continuing Education: Pharmacists must complete two hours of ongoing continuing education focused on travel medicine, separate from continuing education in immunizations and vaccines, from an approved provider once every two years.

(e) Prior to furnishing travel medication, a pharmacist shall perform a good faith examination, though not necessary a physical examination, of the patient, including evaluation of a patient travel history form using a destination-specific travel database. The travel history form must include all the information necessary for a risk assessment during pre-travel consultation, as identified in the CDC Yellow Book. An example of an appropriate and comprehensive travel history form is available on the Board of Pharmacy's website.

(f) Notifications: The pharmacist shall notify the patient's primary care provider of any drugs and/or devices furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with written record of the drugs and/or devices furnished and advise the patient to consult a physician of the patient's choice.

(g) Documentation: For each travel medication furnished by a pharmacist, a patient medication record shall be maintained and securely stored in an automated data processing or manual record mode such that the required information under title 42, section 300aa-25 of the United States Code, and 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.

A pharmacist shall provide the patient with a progress note, which fully documents the clinical assessment and travel plan. An example of an appropriate and comprehensive progress note is available on the Board of Pharmacy's website.

Authority and Reference: Sections 4052(a)(10)(A)(3), 4052(a)(10)(B), Business and Professions Code.

Date:_____

Travel History Form

Name:_____ DOB:_____ Sex (circle): M F

Telephone: Home: _____ Work: _____ Mobile:_____

Home Address:_____

City:_____ State:_____ ZIP:_____ Email: _____

Who is your primary care physician?_____ Telephone: _____

Primary Insurance: _____ Insurance ID: _____

Does your insurance cover: Health care overseas? ❑ Yes ❑ No ❑ Not sure Medical evacuation? ❑ Yes ❑ No ❑ Not sure

Travel Plans

(list additional information on back of form if needed)

Purpose of Trip (check all that apply): ❑ Vacation ❑ Business ❑ Study ❑ Other: _____

Planned activities: _____

Will you be:	Yes	No	
	❑	❑	Visiting ONLY urban areas? If no, explain:_____
	❑	❑	Visiting friends and/or family?
	❑	❑	Ascending to high altitudes (8,000 feet or higher)?
	❑	❑	Working with potential exposure to bodily fluids (e.g., medical or dental work)?
	❑	❑	Working with exposure to animals?
	❑	❑	Potentially having new sexual partners?

Countries and Cities in order of visit	Arrival Date	Departure Date

Accommodations: (Check all that apply.)

_____Resorts or large hotels ____Small hotels ____Cruise Ship ____Private Home ____Camp ____Dormitory

____Youth Hostel _____Other (list)_____

Have you traveled outside the United States before? ❑ Yes ❑ No

If yes, when and where? _____

Health History

Medical Conditions (such as heart disease, stroke, cancer, arthritis, diabetes, hypertension, psychiatric illnesses, etc) _____

_____

Surgical History:

Allergies (include medications, foods (incl. eggs), environmental allergens such as ragweed):_____

_____

Intolerances or other reactions (include side effects from previous medications, such as nausea, constipation, sleepiness, dizziness, stomach upset, etc.):_____

_____

Date:_____

Vaccination History

Were you born in the United States? ❑ Yes ❑No If no, where? _____

Have you received the following immunizations?

Hepatitis A	❑ Yes	When? _____	❑ No	❑ Not sure
Hepatitis B	❑ Yes	When? _____	❑ No	❑ Not sure
Meningococcal Meningitis	❑ Yes	When? _____	❑ No	❑ Not sure
Measles/Mumps/Rubella	❑ Yes	When? _____	❑ No	❑ Not sure
Polio	❑ Yes	When? _____	❑ No	❑ Not sure
Tetanus	❑ Yes	When? _____	❑ No	❑ Not sure
Typhoid	❑ Yes	When? _____	❑ No	❑ Not sure
Yellow Fever	❑ Yes	When? _____	❑ No	❑ Not sure
Japanese Encephalitis	❑ Yes	When? _____	❑ No	❑ Not sure
Influenza	❑ Yes	When? _____	❑ No	❑ Not sure

Other: _____

Have you ever had an adverse reaction to an immunization? ❑ Yes Explain: _____ ❑ No

Medications

Are you currently using corticosteroids, receiving cancer treatment, or other immunosuppressive therapy? ❑ Yes ❑ No

Prescription medications: List all current prescription medications and condition treated. (include birth control pills):

Prescription Medication	Reason for Use/Medical Condition

Nonprescription products: List all over-the-counter, herbal, homeopathic products, vitamins, supplements etc.)

Nonprescription medications	Reason for Use/Medical Condition

Women Only

Are you pregnant now, or do you suspect that you might be pregnant? ❑ Yes ❑ No
Do you have plans to become pregnant in the next 3 months ❑ Yes ❑ No
Date of your last menstrual period: _____

Questions/Concerns:

List any additional questions or concerns you have about your travel: _____
_____
_____

PROGRESS NOTE ***INTERNATIONAL TRAVEL HEALTH CLINIC***

PT NAME (*last, first*):				**DOB:**		**MRN:**
BP:	**P:**	**WT:**	**HT:**	**TEMP:**	**SEX:**	**ALLERGIES:**

SUBJECTIVE/OBJECTIVE:

Destination:

_____ Departure Date (from U.S.) _____ Return Date_____

Details of Itinerary:_____

_____

_____

Past Medical History: _____

Medications:_____

Immunization hx (date completed): Hep A_____ Hep B_____ Td/Tdap _____ Polio_____ Other: _____

ASSESSMENT: *Per patient's itinerary, at risk for…*

PLAN:

✓	Vaccine	Recommended by: (Date)	Administered on: (Date)	Administration Details (Vaccine Name; Manufacturer; Lot number; Expiration Date; VIS; Dose; Route; Location)	Administered by:
	Hepatitis A # 1 , 2				
	Hepatitis B # 1, 2, 3				
	Hepatitis A + B combo # 1, 2, 3				
	Influenza (Inactivated)				
	Influenza (Live Intranasal)				
	Japanese Encephalitis				
	Meningococcal				
	Pneumococcal				
	Polio (IPV)				
	Rabies				
	TD or Tdap (circle one)				
	Typhoid Injection / PO				
	Yellow Fever				
	Int'l Certificate of Immunization				

✓		Date
	General Advice (Including: Accident and Risk Awareness)	
	Food/Water Precautions	
	Traveller's Diarrhea (written information provided), Loperamide & BSS use	
	Vector Borne Disease Precautions	
	HIV / Hepatitis B / Hepatitis C Precautions: □ Sexual Activity □ Risk Avoidance □ Contraceptive Foam & Condoms from USA	
	Malaria Prophylaxis (written information provided), DEET & permethrin use	
	Rabies: Animal Bites and Scratches	

✓	Medications	QTY
	Ciprofloxacin 500 mg Sig: Take 1 tablet BID x 3 days for traveler's diarrhea Take 2 tabs one time for traveler's diarrhea. May repeat dose.	
	Levofloxacin 500 mg Sig: Take 1 tablet QD x 3 days for traveler's diarrhea	
	Azithromycin 500 mg Sig: □ Take 1 tab QD x 3 days for traveler's diarrhea □ Take 2 tabs one time for traveler's diarrhea **Alternate dosing: Azithromycin** _____	
	Chloroquine phosphate 500 mg (eq 300mg base) Sig: Take 1 table weekly starting 1 week before entering malarious area, continue weekly during the stay and continue for 4 weeks after leaving area. Take with food.	
	Mefloquine 250 mg Sig: take one tablet weekly starting 1 week before entering malarious area, continue weekly during the stay and continue for 4 weeks after leaving area.	
	Doxycycline 100 mg Sig: Take 1 tab QD starting 1 day before entering malarious area, during stay, and for 4 weeks after leaving area.	
	Malarone (atovaquone-proguanil) 250 mg / 100 mg Sig: Take 1 tab QD 1 day before arrival in malarious area, take 1 tab QD while there, then take 1 tablet daily for 7 days after leaving area. Take with food.	
	Malarone (atovaquone-proguanil) 250 mg / 100 mg ~ SELF TREATMENT~ Sig: Take 4 tab daily as a single dose for 3 days for treatment of malaria.	**12**
	Acetazolamide 125 mg BID Sig: Take 1 tablet BID the day before ascent, then take 1 tablet BID during ascent, and then 1 tablet BID for 2 days while at altitude	
	Transderm Scop (Scopolamine) 0.5 mg/24hr. patch Sig: Apply 1 disc (0.5 mg delivered over 3 days) to skin behind the ear 4 hours before antiemetic effect is needed. The disc may be left in place for three days.	
	Typhoid Vaccine Live Oral Ty21a Sig: Take 1 capsule PO once daily for 4 alternate days (days 1, 3, 5 and 7), taken 1 hour before meals with cold or lukewarm water.	**4**

Additional Notes: _____

_____

_____

_____

Pharmacist Name and Signature:_____ Date: _____

Attachment 8

California State Board of Pharmacy
1625 N. Market Blvd, N219, Sacramento, CA 95834
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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: February 25, 2015

LOCATION: County of Los Angeles - Department of Health Services
313 N. Figueroa Street
1st Floor Auditorium
Los Angeles, CA 90012

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

COMMITTEE MEMBERS NOT PRESENT:

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

Call to Order

Dr. Gutierrez called the meeting to order at 10:15 a.m. in President Weisser's absence.

Dr. Gutierrez conducted a roll call. Committee members present: Stanley Weisser (arrived at 10:16 a.m.), Amy Gutierrez, Victor Law and Deborah Veale.

a. Discussion and Identification of Materials Where Board Guidance Is Envisioned, Discussion of the Requirements: For Prescription Medications Not Requiring a Diagnosis that Are Recommended by the CDC for Travel Outside the US

Dr. Jeff Goad, from Chapman University, provided a presentation on how a pharmacist would effectively practice travel medicine. The presentation can be found immediately following these minutes. Below is a summary of the presentation.

Dr. Goad explained that the CDC travel guide is published in hard copy annually, and is continually updated electronically.

Dr. Goad noted that "not requiring a diagnosis" can be broken into two categories:

1) **Self-treatable conditions**
    - Traveler's diarrhea
    - Altitude sickness
    - Jet lag
    - Motion sickness
    - URI
    - UTI
    - Bacterial skin infections
    - Vaginal yeast infections
    - HIV PEP
    - Malaria SBET
2) **To prevent illness**
    - IGIM (Hep A protection)
    - Influenza prophylaxis
    - Leptospirosis
    - Malaria
    - Travelers' diarrhea

Dr. Goad explained that pharmacists must ensure that they are providing a comprehensive or are part of a comprehensive Travel Health Service. They must also ensure that they have received the proper training and are current on emerging issues for people traveling abroad.

Dr. Goad provided an example of a "travel history form" that must be used for each patient and shared with a primary health care provider.

Dr. Goad reviewed different software (both through the CDC and commercially) that is available to pharmacists that allow them to research current travel guidelines based on the area of travel.

Dr. Goad noted that 95% of the public does not see a health care provider before they travel. Dr. Steve Gray noted that most seniors do not see a health care provider before they travel and they often have existing conditions that could affect their health while traveling.

Dr. Goad warned the committee not to make the same mistake as Public Health and only allow pharmacists to administer vaccines and ignore other travel medicines.

Dr. Gutierrez asked what the cost is for commercial travel medicine software. Dr. Goad responded that it ranges from $300 to $800 per year. The committee also discussed the CDC software, which is free, but is not as user friendly as other commercial software. Dr. Gray noted that some health systems have their own software.

Dr. Gutierrez asked if the CDC software or commercial software is more up-to-date. Dr. Goad explained that the commercial software allow doctors to provide current information on outbreaks. The CDC will also receive this information; however, they must vet it before they put it online, so it will be slightly delayed.

Liz McCaman asked if a pharmacist should require the traveler to provide proof of travel (flight itinerary). Ms. Veale asked if Dr. Goad had ever had someone make up a trip to obtain medication. Dr. Goad responded that in his many years of experience in travel medicine he has never had this problem.

At the request of the committee, Dr. Goad explained the process for obtaining a yellow fever stamp. He explained that in California only a physician can apply for a stamp with the California Department of Public Health; however, they can delegate it to other health care providers.

Liz McCaman asked if a pharmacist, who has been delegated a yellow fever stamp, would have to take the CDC yellow fever training. Dr. Goad responded that anyone who has the stamp or has been delegated must take the training.

Dr. Gray asked if a traveler should go to a travel clinic if they are visiting a United States territory (Guam, Puerto Rico, etc.). Ms. Herold responded that from a legal perspective they are treated as part of the United States. Dr. Goad noted that while they are part of the United States they often do not have the same standards for water and food sanitation.

Dr. Gutierrez asked if the law currently allows a pharmacist to *furnish* or *prescribe* travel medicine. It was confirmed that a pharmacist could furnish travel medicine.

Dr. Goad explained that the travel history form could be modified by a clinic to fit their needs. Liz McCaman noted that the CDC has guidelines for what information should be gathered from the traveler.

Mr. Law asked if members of a group of travelers would each have to be counseled individually. Dr. Goad explained that some of the information could be given to an entire group, but each traveler would have to meet with the pharmacist to discuss their individual medical history.

The committee discussed proofing of travel (itinerary). It was determined that the travel history form would adequately gather enough information that a copy of an itinerary would be unnecessary.

President Weisser asked if there was a possibility for the Department of Public Health to allow pharmacists to obtain their own yellow fever stamp. Michael Santiago responded that there is a federal regulation (42 CFR 71.3) that delegates that authority to issue stamps to the Department of Public Health. The federal regulation specifically states that the stamps can only be issued to physicians or health facilities. Dr. Gutierrez asked if other states interpret the federal regulations the same way that California does. Dr. Goad explained that a protocol with a doctor is required for yellow fever, so either way a pharmacist would need to be involved.

The committee discussed the required travel medicine training and continuing education. Liz McCaman provided the following draft language.

> Prior to furnishing prescription travel medication not requiring a diagnosis, pharmacists must complete the American Pharmacy Association's pharmacy-based travel health services training or an equivalent training program of at least 30 hours, which covers the International Society of Travel Medicine's body of knowledge.

Ms. Herold noted that in the regulation the board would have to be specific on the definition of "equivalent."

Dr. Goad noted that the ISTM is a good place to start for anyone who wants to develop a training program.

Lisa Croon, from the California State University, San Francisco outlined how the schools of pharmacy teach travel medicine. Mr. Law asked if the students are given a certificate when they complete the training. Dr. Croon confirmed that they do receive a certificate.

The committee asked Ms. McCaman to draft regulation language for travel medicine training based on the committee's discussion.

Ms. Veale asked Ms. McCaman to be sure that any pharmacist who will be providing travel medicine has completed immunization training.

The committee moved the discussion from training to the requirements for the practice of travel medicine. Ms. McCaman provided the following draft language:

> Prior to furnishing prescription travel medication not requiring a diagnosis, a pharmacist shall preform a good faith evaluation, though not necessarily a physical examination, of the patient including the

evaluation of the travel history form. The travel history form must include all of the information necessary for a risk assessment during pre-travel consultation as identified in the CDC yellow book. An example of an appropriate, comprehensive travel history form is available on the Board of Pharmacy's website.

Ms. Veale asked to modify the draft language to say the good faith evaluation must be documented and be based on the travel history form. Ms. McCaman noted that the statute requires the pharmacist to report to the primary care provider.

The committee then discussed continuing education requirements for travel medicine.

Dr. Goad reported that there are many places to receive continuing education.

The committee determined that as part of the 30 hours of required continuing education, a pharmacist practicing travel medicine must take two hours of travel medicine and one hour of immunization continuing education. Jon Roth, of the California Pharmacist's Association, supported this recommendation.

Ms. Herold asked if the committee wanted to require the use of certain travel software. Dr. Goad did not recommend specific software, only that their information be based on the CDC yellow book. Ms. Herold stated that the language must mention the CDC and the yellow book, but should allow for the use of other software based on the CDC. Ms. McCaman noted that she would draft the language to reflect this.

Dr. Steve Gray and Dr. Besinque warned the committee not to be too prescriptive in the requirements for SB 493. President Weisser responded that as this is a new area of practice the board needs to provide adequate guidance. Ms. Veale stated that as there is not a standard of practice for pharmacists in this area, they are being more prescriptive so pharmacists understand the expectations. Dr. Gutierrez agreed with Ms. Veale and President Weisser.

Ms. Herold and Mr. Santiago noted that the Office of Administrative Law is requiring regulation language to be very specific before they approve it.

Ms. Herold asked how long a pharmacist has to notify the primary healthcare provider. Ms. McCaman noted that the other protocols do not have a specific time period. The committee decided not to include a certain time frame but to leave it to the pharmacist's professional judgment.

The committee recessed for a break at 11:52 a.m. and resumed at 11:58 a.m.

b. <u>Protocol For Pharmacists Who Furnish Self-Administered Hormonal Contraceptives</u>

President Weisser reported that at the January Board Meeting, the board approved the proposed protocol for hormonal contraception. The board also moved to regulation hearing the approved protocol if the Medical Board of California approved the protocol during its meeting on January 30.

The Medical Board approved the protocol with a small change. The approved protocol, with the Medical Board suggested change, immediately follows these minutes.

President Weisser stated that, the American Congress of Obstetricians and Gynecologists (ACOG), who under SB 493 the board is required to consult in developing the protocol, appeared at the Medical Board meeting to request changes in the protocol. The Medical Board did not incorporate ACOG's recommendations into the protocol when it modified and approved the protocol.

President Weisser noted that if additional changes are made to the protocol, the Board of Pharmacy and the Medical Board will both need to approve the modifications.

Liz McCaman commented that one of ACOG's concerns was the inclusion of depo-injections in the protocol. Ms. McCaman explained that the board decided to include it based on information from the CDC, USMEC and multiple studies showing its safety and effectiveness.

Ms. Veale asked if depo-injections were included in the protocol approved by the Medical Board. Ms. McCaman confirmed that the Medical Board approved the protocol with depo-injections included.

Mr. Law commented that he was pleased that the Medical Board approved the protocol with only a minimal change.

Ms. Veale asked why the committee was reviewing the protocol again if the Medical Board had already approved it. Ms. Herold responded that ACOG wanted the opportunity to address their concerns with the protocol as approved. President Weisser again stated that if any modifications were made at today's committee meeting the protocol would have to be approved again by the full board and the Medical Board.

Dr. Laura Sirott, practicing obstetrician and Vice Chairman for California, ACOG, commented that per their national policy ACOG is in support of over-the-counter access of oral contraceptives. Dr. Sirott noted that they define oral contraceptives as the pill, patch or ring and exclude the depo-injection.

Dr. Sirott stated that ACOG understands the desire to increase accessibility to the depo-injection; however, they are concerned with patients self-administering an intramuscular

injection as they are deep and painful. Dr. Sirott encouraged the committee to limit the protocol to subcutaneous injections with adequate training provided to the patient.

Dr. Sirott asked the committee to consider changing the language to say “offer to measure blood pressure.” ACOG is of the opinion that most patients will know their blood pressure or could measure it themselves using the blood pressure stations available in most pharmacies. Dr. Sirott explained that ACOG is concerned that having the pharmacist take the patient’s blood pressure could be a barrier to access.

Dr. Gutierrez asked if in a doctor’s office contraceptives would be prescribed without taking the patient’s blood pressure. Dr. Sirott responded that she would not prescribe contraceptives without first taking blood pressure as it is the standard of care.

Dr. Sirott asked the committee to consider changing the term “primary care provider” to “primary health care provider” because the federal definition of primary care provider does not include OBGYNs. Liz McCaman responded that the governing statute uses the term “primary care provider,” so the committee could not change the term.

Dr. Sirott expressed ACOG’s opinion that the self-screening tool is overly complicated and could be simplified.

Dr. Kathy Hill-Besinque stated that pharmacists already dispense intramuscular injections to patients and the self-administered depo injections are already used worldwide. She added that the protocol specifically states that the patient must be trained by the pharmacist.

Dr. Hill-Besinque commented that most pharmacists would not feel comfortable dispensing hormonal contraceptives without first taking the patient’s blood pressure. Dr. Hill-Besinque stated that a pharmacist should be following the same standard of care as a doctor or other health care professional.

Dr. Hill-Besinque noted that the language allows the questionnaire to be modified as long as it contains the same content.

Mr. Law asked how students are being trained for injections. Dr. Hill-Besinque responded that they receive extensive injection training and would be qualified to train the patient.

A member of the public commented that limiting the protocol to subcutaneous injections would limit patient access.

Dr. Sirott comments that ACOG’s primary goal is to increase access to contraception.

Ms. McCaman stated that the author of one of the studies used as a reference for the creation of the protocol indicated that verifying normal blood pressure is essential to good,

clinical decision making. Dr. Gutierrez added that the board would be holding the pharmacist responsible for their clinical decisions.

The committee did not take any action to modify the protocol based on ACOG's concerns. President Weisser thanked Dr. Sirott for attending the meeting and providing comments.

Ms. Herold noted that ACOG would have another opportunity to voice their concerns during regulation process during the 45-day comment period.

c. <u>Update on the Status of Requirements for Licensure as Advanced Practice Pharmacists</u>

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

As a review:
California Business and Professions Code section 4210 provides that applicants:

Satisfy any two of the following criteria:

(A) Earn certification in a relevant area of practice, including, but not limited to, ambulatory care, critical care, geriatric pharmacy, nuclear pharmacy, nutrition support pharmacy, oncology pharmacy, pediatric pharmacy, pharmacotherapy, or psychiatric pharmacy, from an organization recognized by the Accreditation Council for Pharmacy Education or another entity recognized by the board.

(B) Complete a postgraduate residency through an accredited postgraduate institution where at least 50 percent of the experience includes the provision of direct patient care services with interdisciplinary teams.

(C) Have provided clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system.

President Weisser noted that since the language has not yet been released, the committee may wish to discuss questions on the language. He added that any modification would need to be returned to the board for its review at the March 9 meeting.

Below is the draft language.

<u>Article 3.5</u>
<u>Advanced Practice Pharmacist</u>

<u>1730 Acceptable Certification Programs</u>

<u>The board recognizes the pharmacy patient care certification programs that are certified by the</u>

National Commission for Certification Agencies (NCCA) for purposes of satisfying the requirements in Business and Professions Code section 4210(a)(2)(A).

1730.1 Documentation Requirements for Advanced Practice Pharmacist Licensure

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

(b) Documentation of completion of a postgraduate residency earned through an accredited postgraduate institution as specified in California Business and Professions Code section 4210(a)(2)(B) shall be via either:
  (1) A notarized copy of the residency certificate awarded by the postgraduate institution that includes the name of the applicant pharmacist, the area of specialty, and dates of participation and completion, or
  (2) A letter of completion of a postgraduate residency signed by the dean or residency program director of the postgraduate institution and sent directly to the board from the postgraduate institution that lists the name of the applicant pharmacist, the dates of participation and completion, and areas of specialty.

(c) Documentation of experience earned under a collaborative practice agreement or protocol for at least one year with no fewer than 1,500 hours as specified in California Business and Professions Code section 4210(a)(2)(C) shall be via:
  (1) A copy of an agreement or protocol under which the applicant pharmacist has provided clinical services to patients, and
  (2) A letter from the supervising practitioner attesting under penalty of perjury that the applicant pharmacist has completed at least one year of the experience providing clinical services to patients.

Ms. Herold explained that she placed this item on the agenda because she wanted the committee to clarify how they would like to handle clinical experience that was gained many years ago. Documenting the experience may be difficult for some of the more experienced pharmacists.

Dr. Gutierrez asked what the definition of clinical would be in the language. Ms. Herold responded that California Business and Professions Code section 4210 defines clinical as: Providing clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system.

Dr. Besinque commented that many pharmacists work under institutional protocols, which would make it difficult to get the signature of a supervising physician, especially if they no longer work at the institution. Dr. Besinque recommended allowing the pharmacist to

attest to their own experience and provide the board with the information on the setting in which they gained the experience rather than requiring a letter from the supervising practitioner.

Dr. Besinque commented that she also did not see the value of collecting the protocols as the board staff would be unable to validate them.

Jon Roth agreed with Dr. Besinque's recommendation to allow the pharmacist to attest to their own experience. If the attestation is subsequently found to be false, enforcement action would then follow.

Pharmacist Sara McBane stated that she agreed with the self-attestation approach and noted that North Carolina uses this method.

Ms. Veale expressed concern with not collecting documentation from someone else besides the applicant themself. Ms. Herold added that self-attestation would essentially be allowing people to submit resumes to the board as proof of experience.

Mr. Law noted that an institution should have someone who could at least verify that a pharmacist worked at the institutions for a certain time period.

Jon Roth suggested that the board handle the APP experience in the same way it currently handles continuing education requirements. The board could simply do spot checks on the documentation of experience.

Ms. Herold explained that when the board issues a license they are doing so in the interest of protecting the public and essentially stating that the licensee meets the minimum standards to practice. The applicants need to prove that they possess the experience set out in the law.

Dr. Besinque stated that the requirement to have the documents notarized is onerous and unnecessary. She again expressed her opinion that getting a letter from a supervising practitioner will be very difficult for many pharmacists.

Ms. Veale asked if the supervising practitioner had to be a physician. Ms. Herold clarified that it did not have to be physician, it could be a pharmacist.

Ms. Veale asked if the committee could strike (c)(1) and only require the letter attesting to one year of clinical experience. The committee agreed to eliminate (c)(1).

The committee modified the language to read "~~A letter~~ An attestation from the supervising practitioner or director…"

Dr. Gutierrez asked if the residency program director could sign the letter of completion of a postgraduate residency (required in (b)(2)) and have it also count towards the one year of clinical experience required in (c)(2). Ms. Veale commented that the committee previously discussed this and wanted them to be two separate requirements. Ms. Herold noted that there is nothing in the statute that separates them, so the board would have to build it in.

Dr. Grey recommended removing the "supervisor" requirement as some pharmacists may not have a direct supervisor. Ms. Herold recommended that the committee keep the supervisor requirement.

Rebecca Cupp, from Ralph's pharmacy, asked if a program director leaves a program if the new director could attest to experience gained prior to them taking over the program. Ms. Herold confirmed that the current director could attest.

Sara McBane recommended removing the notarization requirement. The committee agreed to remove the notary requirement.

Dr. Besinque and Sara McBane asked for clarification on the application and renewal fees. Ms. Herold explained that it would be $300 for the initial application and $300 for each renewal. She noted that $300 covers the cost to run the program.

Dr. Gutierrez expressed concern with the competency of someone whose experience was earned 20 years ago. Ms. Herold responded that the committee could add in a certain time frame in which the experience must have been earned. Ms. Veale agreed with Dr. Gutierrez's concern.

Jon Roth recommended adding "health facility administrator" to the list of those who could sign a letter of attestation.

Motion: Approve the draft 1730 language with the modifications made by the committee (below).

Article 3.5
Advanced Practice Pharmacist

1730 Acceptable Certification Programs

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

1730.1 Documentation Requirements for Advanced Practice Pharmacist Licensure

(a) Documentation of possession of a certification as specified in California Business and

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

(1) A ~~notarized~~ copy of the certification award that includes the name of the applicant pharmacist, the area of specialty and date of completion, or

(2) A letter from the certification program attesting the award of the certification that includes the name of the applicant pharmacist, the area of specialty and the date of completion.

(b) Documentation of completion of a postgraduate residency earned through an accredited postgraduate institution as specified in California Business and Professions Code section 4210(a)(2)(B) shall be via either:

(1) A ~~notarized~~ copy of the residency certificate awarded by the postgraduate institution that includes the name of the applicant pharmacist, the area of specialty, and dates of participation and completion, or

(2) A letter of completion of a postgraduate residency signed by the dean or residency program director of the postgraduate institution and sent directly to the board from the postgraduate institution that lists the name of the applicant pharmacist, the dates of participation and completion, and areas of specialty.

(c) Documentation of experience earned under a collaborative practice agreement or protocol for at least one year with no fewer than 1,500 hours as specified in California Business and Professions Code section 4210(a)(2)(C) shall be via:

~~(1) A copy of an agreement or protocol under which the applicant pharmacist has provided clinical services to patients, and~~

~~(2)~~(1)~~A letter~~ An attestation from the supervising practitioner or program director or health facility administrator attesting under penalty of perjury that the applicant pharmacist has completed at least one year of the experience providing clinical services to patients.

M/S: Veale/Law

Support: 3 Oppose: 0 Abstain: 1

Ms. Veale asked if the committee wanted to address the issue of earning their postgraduate experience (b) and clinical experience (c) concurrently. The committee decided not to amend the language as they felt that the experience could be gained concurrently.

Lisa Croon explained that due to a lag in licensure time many residents will have earned 1,500 hours of experience, but would have only have been licensed for 10 months. The committee noted that the language does not state that they have been licensed for one year, only that they are earning experience under a collaborative practice agreement for one year.

Dr. Gutierrez again expressed her concern with licensing APP's who gained their experience 20 or more years ago.

The committee recessed for a lunch break at 1:23 pm. and resumed at 2:00 p.m.

d. Protocol for Pharmacists Who Furnish Nicotine Replacement Products

President Weisser reported that at the January Board of Pharmacy Meeting, the board approved the proposed protocol for nicotine replacement products. The board also moved to initiate the rulemaking process if the Medical Board of California approved the protocol during its meeting on January 30.

President Weisser stated that the Medical Board did approve the protocol, a copy of which was provided in the meeting materials. President Weisser noted that the protocol will be noticed for public comment as a regulation in the near future.

e. Protocol for Pharmacists Who Furnish Naloxone

President Weisser reported that at the January Board Meeting, the board approved the proposed protocol for pharmacists to provide naloxone, a copy of which was provided in the meeting materials. The Medical Board of California approved the protocol during its meeting on January 30.

President Weisser explained that the naloxone protocol was authorized by AB 1535 (Bloom, Chapter 346, Statutes of 2014). This bill contained a provision that specifies:

> The board may adopt emergency regulations to establish the standardized procedures or protocols. The adoption of regulations pursuant to this subdivision shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The emergency regulations authorized by this subdivision are exempt from review by the Office of Administrative Law. The emergency regulations authorized by this subdivision shall be submitted to the Office of Administrative Law for filing with the Secretary of State and shall remain in effect until the earlier of 180 days following their effective date or the effective date of regulations adopted pursuant to subdivision (a).

Ms. Herold stated that the board is ready to file the protocol as an emergency regulation following this meeting.

f. Review and Discussion About the Factsheet on Naloxone

President Weisser explained that staff has reviewed various factsheets for patients describing the use of naloxone. Recently, staff has identified a factsheet that provides information of value to consumers. At least those who have reviewed the factsheet support use of this specific document. President Weisser stated that the factsheet was developed by Phillip O. Coffin, MD, MIA, Director of Substance Use Research, San Francisco Department of Public Health and was provided in the meeting materials.

Ms. Herold noted that Dr. Coffin has granted the board permission to use this factsheet so that it may be placed on the board's website for use by pharmacies.

Mr. Roth, from CPHA, commented that the third mechanism for administration on the fact sheet (auto-injector) does not stand out as much as the other two options. Ms. McCaman noted that this fact sheet is only given out after the patient has chosen the form of administration they will be using.

Amy Swartz, from Kaleo Pharm the manufacturer of the auto-injector, provided the committee with sample auto-injectors. She noted that it is the only administration designed for take-home use; the other options are really designed for use by health care providers.

g. <u>Review and Discussion About the Factsheet on Self-Administered Hormonal Contraception</u>

Ms. McCaman briefly reviewed the examples of factsheets on various forms of hormonal contraception that were provided in the meeting materials.

President Weisser noted that some of the numbers provided for the effectiveness of birth control do not add up. Dr. Besinque explained that with contraception everything is described in two ways: "perfect use" and "typical use" and there will always be a discrepancy between the two numbers.

President Weisser noted that there was a grammatical error on the fact sheet. Ms. McCaman noted that she would work with the author of the fact sheet to correct any such errors.

Ms. McCaman stated that the author plans to translate the fact sheets into two or three new languages per year. Ms. Herold added that the board will assist with translations.

h. <u>Review and Discussion About a Factsheet on Nicotine Replacement Products</u>

President Weisser explained that most of the patient care elements enacted by SB 493 require the development of a fact sheet. However, the provision of nicotine replacement products does not require such a document.

President Weisser noted that this agenda item was added simply to affirm that the committee does not wish to develop such a factsheet. The committee agreed that no factsheet would be developed.

i. <u>For Pharmacists Who Initiate and Administer Immunizations Pursuant to Recommended Immunization Schedules by the Federal Advisory Committee of Immunization Practices</u>

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

- complete an immunization training program endorsed by the CDC,
- be certified in basic life support,
- comply with all state and federal recordkeeping requirements,

– provide information to the patient's primary care physician and into the appropriate immunization registry designated by the immunization branch of the CDPH.

President Weisser stated that during this meeting, the committee needs to address certain issues, and determine if it wishes to create requirements for these components. If so, regulations will need to be drafted if the board desires the provisions to be enforceable.

The first item the committee discussed was the mandatory reporting to an immunization registry.

President Weisser reported that at prior committee meetings, the committee discussed various aspects of immunizations, including required reporting into an immunization registry. President Weisser stated that the committee needs to identify whether it will make reporting of vaccinations into the CDPH Immunization Registry mandatory, and whether patients can opt out. If so, there are some issues to resolve, including:

- How long from the time of immunization must the pharmacy/pharmacist input the information into the registry?
- Will patients be provided with written information document the immunization(s) they receive?
- How long does the pharmacist have to provide immunization information to the primary care provider? In what form?
- What documentation must the pharmacist maintain?

Dr. Gutierrez stated that she supports the mandatory reporting to the immunization registry.

Lauren Dunning, from the Los Angeles Department of Public Health, explained how a pharmacist would enter and search information into the California Immunization Registry (CAIR).

Ms. Veale asked if there is more than one databank in California. Dr. Dunning explained that while some counties have their own system, the information is shared with CAIR.

Mr. Law asked how a pharmacist could differentiate between someone with the same name and date of birth. Dr. Dunning responded that there are other data elements, such as mother's maiden name that can be used to differentiate.

Mr. Law asked if patients have access to CAIR. Ms. Dunning responded that patients do not have access to CAIR, but the information could be shared with them to use on the "yellow cards." Dr. Dunning noted that the new version being developed will allow patients to access information.

Dr. Gutierrez stated that the more people who use the system the better the information will be.

Rebecca Cupp, from Ralphs,' asked the committee to make reporting mandatory. The attorney's for Ralph's allow reporting to databases in states where it is mandatory. However in states where reporting isn't they view it as a HIPPA violation and do not allow pharmacist to report.

A pharmacist commented that a pharmacist should have the option to report to CAIR rather than making it mandatory.

Dr. Grey recommended checking with counsel to ensure that mandatory reporting would not violate any privacy laws.

Ms. McCaman read the Business and Professions Code section that states that in order to initiate and administer an immunization a pharmacist is required to enter the information into the appropriate immunization registry designated by the state department of public health. The committee concluded that this gives the board the authority to require entry to the immunization databank.

The committee discussed the time frame in which the pharmacist must report to the databank. Ms. McCaman reported that the shortest reporting timeframe in other states was 15 days. The committee decided to require reporting at least every 15 days.

The committee discussed if a pharmacist must report to the primary healthcare provider. Ms. Veale indicated that chain stores do report. Ms. McCaman noted that the statute requires reporting. The committee elected to use the same 15 day time frame as the immunization databank reporting.

President Weisser asked how pharmacies record the patient's immunization. Ms. Veale indicated that in most pharmacies the information becomes part of the patient profile. The committee concluded that this was adequate record keeping.

President Weisser explained that the law (section 4052.8(b)(1) of the B&P Code) requires that a pharmacist complete an immunization training program endorsed by the CDC (this would seem to be the APhA Pharmacy-Based Immunization Delivery Program), that at a minimum includes hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines, and shall maintain that training.

President Weisser asked if the committee wished to be more specific in what it will require under this category (i.e., APHA's Pharmacy-Based Immunization Delivery Program).

Ms. Veale indicated that she would prefer not to list a specific program. Dr. Gutierrez noted that the committee should also consider out of state pharmacists. The committee determined not to make any changes to this section.

President Weisser reminded the committee that earlier in the meeting they had already decided to require one hour of immunization continuing education for each renewal cycle.

President Weisser asked what information was kept in the patient profile. Ms. Veale answered that the record would contain the NDC of the immunization, how much the patient was charged and date of administration. A pharmacist added that the pharmacist would also record the administration site (which arm) and lot number, although this information is kept separately from the patient profile.

Dr. Grey recommended the committee specifically state in the language how long the records must be kept because some of the information will not be kept in the patient profile and not all patients would have a patient profile. Dr. Gutierrez recommended looking at current pharmacy practice regarding immunization reporting so that the committee does not reinvent the wheel.

Ms. McCaman provided the following draft language:

> Each vaccine initiated and or administered by a pharmacist shall be documented in a patient medication record and shall be stored in the originating pharmacy or health care facility for a period of at least three years from the date of administration. A patient medication record shall be maintained in an automated data processing or manual record mode such that the required information under Title 16 section 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the pharmacy or facility's regular operating hours.

Dr. Grey noted that the National Vaccine Injury Compensation Program already requires certain records to be kept per federal law. He encouraged the committee to look at these requirements to ensure that they are not creating duplicate requirements.

President Weisser asked if the committee wanted to bring this language before the board or back to the committee. The committee decided to bring it to the next board meeting on March 9, 2015.

j. <u>For Ordering and Interpreting Tests to Monitor and Manage Drug Therapies</u>

President Weisser explained that:

- All pharmacists can:
  Order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies. A pharmacist who orders and interprets tests

pursuant to this paragraph shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescription, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by the prescriber. (CA B&P Code section 4052(a)(12)

- APP licensed pharmacists can:
  Order and interpret drug-therapy related tests, and initiate or modify therapy

President Weisser reported that at prior meetings, comments made on this topic included that during creation of the legislation, doctors stated that they wanted pharmacists to have the ability to order tests to make recommendations on the patient's care based on actual data.

President Weisser stated that the language in SB 493 states that pharmacists may order tests to improve patient safety and access to care. However, at a prior committee meeting it was noted that in the future, the standard of care could evolve to a point where a pharmacist must order a test prior to dispensing a certain medication.

CPhA drafted a guidance document for pharmacists ordering and managing tests. This document has been provided in the meeting materials.

Dr. Gutierrez asked why there is a differentiation between regular pharmacists and APP pharmacists. Ms. Herold explained that APP pharmacists have an additional level of autonomy. Jon Roth added that for regular pharmacists the tests are limited to efficacy and toxicity, an APP pharmacist would be eligible to initiate a larger range of tests.

Dr. Gutierrez stated that she did not think the language indicated different types of testing; rather an APP pharmacist could use the results to modify or initiate therapy. Dr. Grey commented that the language was intended to give all pharmacists specific authority to order tests. Dr. Grey added that currently, all pharmacists practicing in a hospital or under a collaborative practice agreement could modify or initiate therapy based on the test results.

For clarity Dr. Gutierrez recommended changing the language to state:

- APP licensed pharmacists can:
  In addition to the above, initiate or modify therapy.

k. <u>General Discussion Concerning Implementation of SB 493</u>

President Weisser asked if there were any general comments from the public or the committee on the Implementation of SB 493.

Dr. Kroon noted that the committee has voted to accept certification programs accredited

by the NCCA. Ms. Herold responded that if there are other programs that should be considered then they should be submitted to the committee for review at a future meeting.

Dr. Grey commented that many other states are looking to implement similar programs and are looking to California for leadership.

Dr. Gutierrez asked if there was any news on whether a pharmacist will be able to submit claims for Medicare reimbursement. Dr. Grey responded that HR 4190 has been reintroduced in both the House of Representatives and the Senate and will allow pharmacists to enroll in Part B and to serve underserved populations (a map is available to view underserved areas). Dr. Grey also reported on the challenges with Medicare Part D.

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

A member of the public shared her difficulties in getting her Vitamin B shots covered by Medicare.

A pharmacist stated that he felt that California should change its regulations for refills on controlled substances to be more in line with federal regulations.

President Weisser adjourned the meeting at 3:20 p.m.