



SENATE BILL 493 IMPLEMENTATION COMMITTEE

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Report of the Senate Bill 493 Implementation Committee Meetings held November 5, 2014 and December 16, 2014

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

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

Minutes of the November 5 and December 16 meetings are provided in **Attachment 6** at the back of this report

a. FOR INFORMATION: Review of a Proposed Schedule for Action on Provisions Established by SB 493

Attachment 1

The meetings held November 5 and December 16 were the 4th and 5th major committee meetings devoted to the implementation of SB 493. A work schedule has been developed for the various projects. **Attachment 1** contains the proposed work schedule for the future six months (this schedule has been shared with the board before).

The board has determined to convene a meeting of the SB 493 Implementation Committee at least once every two months until the work projects are finished. During the most recent two committee meetings, the committee worked on development of the protocols for hormonal contraception and smoking cessation. They also worked to develop a protocol for pharmacies to provide Naloxone as authorized by AB 1535 (Bloom, Chapter 326, Statutes of 2014).

At this meeting and later in this report, these protocols will be provided to the board for review and approval. The protocols, if approved, will then be reviewed and hopefully approved by the Medical Board during their meeting on January 30.

The schedule also identifies the first phase of APP registration qualifications will be put forth for board approval at this meeting. This will also occur at this meeting later in this report.

The next meeting of this committee has not yet been set, but will likely be in late February. The committee needs to know whether it will have to rework the protocols based on comments from this board and the Medical Board, or can the committee continue to work on other components.

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

Discussion during both committee meetings involved whether written guidance to licensees should be developed in three areas. The minutes of the meetings provide details about these discussions. The highlights are summarized below.

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

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

To initiate immunizations, a pharmacist must:

- complete an immunization training program endorsed by the CDC,
- be certified in basic life support,
- comply with all state and federal recordkeeping requirements, and provide information to the patient’s primary care physician and perhaps into the CDPH’s immunization registry. (DCA Counsel Kristy Schieldge commented at the August meeting that SB 493’s language is open to interpretation and if the board wants to make reporting to CDPH a requirement, there would need to be a regulation to require this)

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

At the November meeting, the committee heard a presentation by Dr. Steve Nickell from the California Immunization Registry (CAIR), who provided information about California’s immunization registry. Currently reporting to the registry is voluntary, and

the wording of section 4052.9 is unclear about whether a pharmacist must report immunizations into the registry. (DCA Counsel Kristy Schieldge commented at the August meeting that SB 493's language is open to interpretation and if the board wants to make reporting to CDPH a requirement, there would need to be a regulation to require this.) The minutes of the November meeting provide a summary description about the CAIR program.

At the December meeting, the committee heard a presentation by Lauren Dunning, JD, MPH, from the Los Angeles County Department of Public Health. She provided additional information about the benefits of immunization registries in general. She added that some chain store pharmacies, including Rite Aid, Safeway, Walgreens and Kaiser, currently report immunizations they administer in California into the registry.

There were general supportive comments made by committee members to having pharmacists report immunizations in the state's immunization registry.

Discussion at both meetings also occurred on how the board would perform enforcement checks of pharmacists who provide immunizations under this expanded immunization authority. One process could involve an inspector asking the pharmacist to provide the board with evidence that he or she possesses the required training. Discussion has also involved questions about whether the board would accept ACIP training provided to California pharmacy school students while in pharmacy school, and if so:

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

Since the August meeting, there has been committee discussion about a draft of a qualifications letter that is being developed by the eight accredited schools of pharmacy deans to identify training provided as part of the core curriculum. The plan is to develop a standardized form to be submitted to the board showing completion of a certification program on immunization, travel meds, smoking cessation and hormonal contraception.

At both the November and December meetings, this component was discussed but not finalized, in part because the documentation letter format has not been finalized. Once the letter is ready, it will be brought to the next SB 493 committee meeting.

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

Under SB 493 pharmacists may furnish prescription medications not requiring a diagnosis that are recommended by the CDC for individuals traveling outside the U.S.

Over the course of all SB 493 Implementation Committee Meetings, the discussion has focused on the minimal wording in the statute for travel medications and the need for some interpretation or guidance to the profession. Does the legislation applied only to the administration of travel immunizations or does it go beyond that scope to include other medications a traveler may need such as antibiotics or anti-nausea medications? Since the protocol provision for immunizations was left untouched by SB 493, could a pharmacist still provide ACIP-routinely recommended travel vaccines, as long as the pharmacist does so under protocol, which still requires physician involvement?

Statistics indicate that only 5 percent of the traveling population sees a healthcare professional before traveling. President Weisser has stated that SB 493 makes the process of getting travel medications much easier in a travel clinic setting, something that has been historically difficult due to protocol requirements. However, the committee discussed concerns that a board-produced protocol could be difficult to maintain because with travel medications, things can change overnight based on outbreaks and protocols would take time to modify.

At the two committee meetings, this topic continued to be discussed at length.

There was carry-over of discussion initiated at the August meeting on this topic during the November and December meetings. For example, in August Ms. Schieldge advised there are two separate provisions in the Business and Professions Code governing pharmacist-administered immunizations: one that allows all pharmacists to administer a vaccine under a protocol and one that allows a pharmacist to initiate a vaccine pursuant to the CDC guidelines. The second type of vaccination would require additional training for the pharmacist. She also commented that the committee should define what “not requiring a diagnosis” means and identify the CDC guidance document.

The committee has learned that the CDC “Yellow-book” is the guidance document that the legislation is referring to. There is a chapter in the CDC Yellow-book on self-treatable illnesses. In some countries, medication requiring a prescription in the US is available over-the-counter at the selection of the patient.

Ms. Scheildge encouraged the committee to consider how quickly the patient’s primary care physician needs to be notified, and what information needs to be placed in the patient file after a pharmacist provides the travel medications.

Additional questions needing resolution include could a pharmacist write a prescription for travel medications and have the patient fill it at another pharmacy?

During the November and December meetings, concern was expressed about patients using this authority as a means to secure unnecessary antibiotics or Ambien (saying it is needed for jet lag). One solution the committee has considered for this is for the pharmacy to require the traveler to provide a travel itinerary or tickets to show travel is

forthcoming, or to provide limits on how much medication could be dispensed.

California schools of pharmacy do not generally instruct about travel medications as part of the core curriculum, but it is an elective component.

At the December meeting, the committee discussed the need for a possible regulation for travel medications. The committee asked that the regulation establish appropriate training requirements and proof of future travel and other record keeping.

Action taken: The committee approved a motion to direct staff to develop regulatory language for travel medications for discussion at future meetings.

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

- All pharmacists can:
Order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies. A pharmacist who orders and interprets tests pursuant to this paragraph shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescription, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or enter the appropriate information in a patient record system shared with the prescriber, when available and as permitted by the prescriber. (CA B&P Code section 4052(a)(12))
- APP licensed pharmacists can:
Order and interpret drug-therapy related tests

At prior meetings, the committee has commented that any guidelines developed should identify the professional standards pharmacists should follow when ordering and interpreting tests for monitoring the efficacy and safety of drug therapy.

Questions have been asked about whether pharmacists now will be required to order tests prior to dispensing a medication in order to fulfill their professional obligations. As SB 493 was created to give pharmacists more independence to use their educations, the need for testing should be on a case by case basis and would be a tool a pharmacist could use to improve patient care rather than a requirement.

Concern has been expressed that requiring testing could affect access to care if a patient is told he or she must be tested in order to receive the medication. Senate Bill 493 says a pharmacist *may* order tests -- this grants additional authority to use professional judgment to order tests if pharmacists are worried about the efficacy or toxicity of a drug.

Only that an APP pharmacist can choose to adjust or discontinue the drug therapy based on the test results. Whereas, a non-APP licensed pharmacist would need to consult

with the prescriber and the prescriber would then adjust or discontinue the drug therapy.

At the November and December meetings, the committee continued discussions in these areas. One option suggested during discussion was for the board to identify specific medications that would require a pharmacist to secure test results, either directly or from the patient's primary care provider. However there was concern that this was perhaps overreaching and could delay care to patients – instead, a pharmacist's professional judgment is really the determinant. The minutes of the November meeting detail the major components of the discussion, which really concluded with the ordering of tests was intended as a collaboration between primary care provider and pharmacist, and that the pharmacist would need to use professional judgment about when to order tests.

c. **FOR INFORMATION: Discussion on Requirements for the Advanced Practice Pharmacist License and Summary of a Presentation by the National Commission for Certifying Agencies and the Board of Pharmacy Specialties**

Attachment 2

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

The law (in Business and Professions Code section 4210) establishes requirements that a pharmacist must possess to become licensed as an APP. Specifically, a pharmacist must 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.

At a prior meeting, the committee discussed whether to require certification programs to apply to the board or if the board would simply list the specific entities they will recognize. Also would a pharmacist be allowed to count the hours they spent completing their

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

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

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

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

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

Board of Pharmaceutical Specialties and Commission for Certification in Geriatric Pharmacy:
At the February 2014 Licensing Committee Meeting, the board heard a lengthy presentation by the Board of Pharmacy Specialties on their certification programs.

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

The eight specialties are:

- Ambulatory care pharmacy

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

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

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

The BPS and CCGP programs are not accredited by ACPE, as ACPE does not accredit certification programs. Both certification programs are accredited by NCCA.

For this Board Meeting:

At the November SB 493 Implementation Committee, the committee noted that at the October 2014 Board Meeting, staff was directed to develop regulation language to recognize NCCA-approved providers as a qualifying route to APP licensure.

At the December SB 493 Implementation Committee, the committee heard a presentation on NCCA by chair Chad Buckendahl. Minutes of this meeting provide details about the presentation and NCCA certification process.

Overview of NCCA Standards

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

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

Attachment 2 contains information provided to the board at prior meetings and contains:

1. Information from the NCCA Handbook about the NCCA Certification Programs (pages 1-24)
2. Information from the Commission for Certification in Geriatric Pharmacy on its certification program
3. Example: Information about the Board of Pharmaceutical Specialties Ambulatory Care Pharmacist Certification Program
4. Appendix C: Credentialing Programs for Pharmacists, which displays the pharmacy programs approved by NCCA

d. FOR DISCUSSION AND POSSIBLE ACTION: Action to Add Title 16 to the California Code of Regulations as Section 1730 To Provide Acceptance of Programs Certified by the National Commission for Certifying Agencies

Based on a motion from the board at the October Board Meeting, staff submits the following text for release for public comment as a regulation, initiating the rulemaking process. This proposal will need a formal motion and second during the board meeting.

Article 3.5

Advanced Practice Pharmacist

1730 Acceptable Certification Programs

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

e. FOR DISCUSSION AND POSSIBLE ACTION: Action to Amend Title 16 of the California Code of Regulations Section 1749 (f) and (g)

The board will need to establish fees for the APP application and license. Below is the proposal to do this. This regulation can be combined with proposal to add section 1730 into a single rulemaking. The proposal will need a motion and second during the board meeting.

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.

f. FOR DISCUSSION AND POSSIBLE ACTION: Add Title 16 California Code of Regulations Section 1746.1 on the Protocol Requirements for Pharmacists Who Furnish Self-Administered Hormonal Contraceptives

Attachment 3

At this meeting, the board will review and comment on the developed protocol for pharmacists to provide self-administered hormonal contraception. The version approved by the board at this meeting will be provided to the Medical Board at its meeting on January 30th. If both boards approve the same text, this board may initiate a rulemaking to adopt the protocol as a regulation.

The requirements for the development of a protocol for self-administered hormonal contraception include that the protocol must be approved by the Medical Board and the Board of Pharmacy. These requirements include:

- Public collaboration with Medical Board of California, American Congress of Obstetricians and Gynecologists, the California Pharmacists Association and “other appropriate entities”
- A patient self-screening tool to identify risk factors based on the current US Medical Eligibility Criteria (USMEC) for Contraceptive Use developed by the CDC as part of the protocol
- Referral of the patient to patient’s primary care provider, or if the patient has no provider, to nearby clinics if a self-administered hormonal contraceptive is not recommended.
- Development of a fact sheet for women on indications and contraindications for use of the drug, the appropriate method for using the drug, and need for medical follow up. Again, collaboration with the CA Department of Public Health, American Congress of Obstetricians and Gynecologists and the CA Pharmacists Association in developing the fact sheet is required. Alternatively provision of an existing publication developed by nationally recognized medical organizations may fulfill this requirement.

The SB 493 Implementation Committee reviewed and discussed a draft version of this protocol at the November and December committee meetings. It was noted that over time, since the CDC guidelines are updated annually, the two boards will need to periodically, perhaps annually, update the protocol.

At the December SB 493 Implementation Committee, the committee approved the protocol and moved it to the board for review and approval. **Attachment 3** contains the protocol. Word-smithing changes are being reviewed as this packet is being finalized. If the final text is modified, it will be highlighted to you at the board meeting.

The minutes for each meeting provide an overview of the discussion that led to the final text of the protocol.

MOTION: SB 493 Implementation Committee: Approve the protocol for self-administered hormonal contraception.

In the event the Medical Board approves the same version of the protocol, the board may want to make a second motion to initiate a rulemaking to adopt the finalized text of the protocol.

g. FOR DISCUSSION AND POSSIBLE ACTION: Add Title 16 California Code of Regulations Section 1746.2 Protocol Requirements for Pharmacists Who Furnish Nicotine Replacement Products

Attachment 4

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

- Certification of the pharmacist in smoking cessation therapy by an organization recognized by the board
- Development of a protocol developed and approved by this board and the Medical Board of California following development with other “appropriate entities”
- The pharmacist maintains records of all prescription drugs and devices furnished for at least three years
- The patient’s primary care provider is notified of any drugs or devices furnished, or information is added to a shared patient record. If the patient has no primary care provider, the pharmacist provides the patient with a written record and advises the patient to consult a physician of the patient’s choice
- The pharmacist completes one hour of CE on smoking cessation therapy biennially.

The SB 493 Implementation Committee discussed a draft version of this protocol at the November and December committee meetings. The minutes detail the discussion.

At the December SB 493 Implementation Committee, the committee approved the protocol and moved it to the board for review and approval. **Attachment 4** contains the protocol. Word-smithing changes are being reviewed as this packet is being finalized. If the final text is modified, it will be highlighted to you at the board meeting.

MOTION: SB 493 Implementation Committee: Approve the protocol for nicotine replacement therapy

The board-approved version of the protocol will be provided to the Medical Board for approval at its January 30th meeting. In the event the Medical Board approves the same version of the protocol, the board may want to make a second motion to initiate a rulemaking to adopt the finalized text of the protocol.

- h. **FOR DISCUSSION AND POSSIBLE ACTION: Add Title 16 California Code of Regulations Section 1746.3 Protocol for Pharmacists Who Furnish Naloxone Pursuant to AB 1535 (Bloom, Chapter 326, Statutes of 2014)**

Attachment 5

Last year's AB 1535 authorizes the Board of Pharmacy to work with the Medical Board to develop a jointly approved protocol for pharmacists involving the distribution of naloxone. The California Pharmacists Association and California Society of Addiction Medicine are specifically mentioned to participate in this process. The board is also authorized to pursue an emergency rulemaking to secure the benefits of this law as soon as possible. (An emergency rulemaking allows the immediate implementation of the regulation if accepted by the Office of Administrative Law. Thereafter the regulation will remain in effect for 180 days. Meanwhile the adopting agency can initiate a regular rulemaking to formally adopt the regulation.)

The specific statutory authorization for this protocol is provided in section 4052.01 of the Business and Professions Code:

4052.01.

- (a) Notwithstanding any other provision of law, a pharmacist may furnish naloxone hydrochloride in accordance with standardized procedures or protocols developed and approved by both the board and the Medical Board of California, in consultation with the California Society of Addiction Medicine, the California Pharmacists Association, and other appropriate entities. In developing those standardized procedures or protocols, the board and the Medical Board of California shall include the following:
- (1) Procedures to ensure education of the person to whom the drug is furnished, including, but not limited to, opioid overdose prevention, recognition, and response, safe administration of naloxone hydrochloride, potential side effects

or adverse events, and the imperative to seek emergency medical care for the patient.

- (2) Procedures to ensure the education of the person to whom the drug is furnished regarding the availability of drug treatment programs.
 - (3) Procedures for the notification of the patient's primary care provider with patient consent of any drugs or devices furnished to the patient, or entry of appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider, and with patient consent.
- (b) A pharmacist furnishing naloxone hydrochloride pursuant to this section shall not permit the person to whom the drug is furnished to waive the consultation required by the board and the Medical Board of California.
 - (c) Prior to performing a procedure authorized under this section, a pharmacist shall complete a training program on the use of opioid antagonists that consists of at least one hour of approved continuing education on the use of naloxone hydrochloride.
 - (d) The board and the Medical Board of California are each authorized to ensure compliance with this section. Each board is specifically charged with enforcing this section with respect to its respective licensees. This section does not expand the authority of a pharmacist to prescribe any prescription medication.
 - (e) 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).

At the November and December SB 493 Implementation Committees, a draft protocol was reviewed and discussed. Minutes of these meetings provide detail about the discussions.

At the December meeting, the committee moved the protocol to the board for adoption with several modifications. A copy of the text of this protocol is provided in **Attachment 5**.

MOTION: SB 493 Implementation Committee: Incorporate the edits made during the committee meeting and bring to the board for approval.

Very recently, several edits were made during discussion with Amy Gutierrez earlier this week. These changes are currently being run past the expert reviewers who have assisted the staff in developing the drafts. Any modifications will be highlighted during the board meeting.

This protocol is also on the agenda for January 30 at the Medical Board. If both boards approve the same version of the protocol, the board may file this regulation with the Office of Administrative Law under the emergency provisions enacted as part of AB 1535. This will allow the protocol to go into effect immediately, and then the board can go through the regular rulemaking process to permanently adopt the regulation.

If this desired, the board will need to make a motion to file the regulation with OAL if the Medical Board approves the same text.

Attachment 1

Targeted Completion Dates

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Attachment 2

National Commission for Certifying Agencies

Standards for the Accreditation of Certification Programs



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Preamble

INTRODUCTION

The National Commission for Certifying Agencies (NCCA) accredits certification programs complying with its Standards. The mission of NCCA is to help ensure the health, welfare, and safety of the public through the accreditation of certification programs that assess professional competence. The NCCA uses a peer review process to establish accreditation standards, to evaluate compliance with these standards, to recognize programs which demonstrate compliance, and to serve as a resource on quality certification. The purpose of NCCA accreditation is to provide the public and other stakeholders the means by which to identify certification programs that serve their competency assurance needs. NCCA Standards address the structure and governance of the certifying agency, the characteristics of the certification program, the information required to be available to applicants, certificants, and the public, and the recertification initiatives of the certifying agency. NCCA is a separately governed accreditation arm of the Institute for Credentialing Excellence (ICE – formerly the National Organization for Competency Assurance), a membership association of certification organizations providing technical and educational information concerning certification practices.

Since the Standards were first issued in the late 1970s, NCCA has observed fundamental changes in the nature, scope, and importance of certification. First, the certification community has expanded dramatically to include a broader variety of occupational and professional credentials offered by non-profit organizations, for-profit entities, governmental agencies, and industries. Second, it is increasingly common for a certification organization to offer multiple certification programs. Third, the certification community has expanded internationally. Fourth, the certification and testing communities have introduced the computer as a means of both developing items and new assessment formats, as well as administering assessments. This change has also led to the implementation of modern testing methodologies to capitalize on the power of the computer to score and scale the assessment instruments. Fifth, an increasing number of certification programs are recognized by state and provincial regulatory authorities, a practice that expands the traditional definition of certification.

In keeping with its service to the public and to various other stakeholders of professional certification, and in order to address fundamental changes in certification, NCCA undertook the review and revision of its accreditation standards. In 1997, NCCA established two Task Forces to address the feasibility of revising the accreditation Standards to address the changes described above and to ensure the currency of the Standards for the foreseeable future. The Task Forces were eventually combined at the end of 1997 to form a Steering Committee.

In August 1998, NCCA obtained approval from the ICE Board of Directors to conduct fundraising activities in support of the continued work of the Steering Committee. As an outcome of this effort, NCCA hired an independent project manager.

During 1999 and early 2000 the Steering Committee conducted activities through the formation of four Task Forces, each focusing on a different set of accreditation standards: (1) Purpose, Governance, and Resources (2) Responsibilities to Stakeholders (3) Assessment Mechanisms, and (4) Recertification. The Task Forces represented a cross section of currently accredited groups, testing services, and other professionals with expertise in certification.

Members of the Steering Committee and the Task Forces reported to NCCA in November, 1999, and to the ICE Board and Membership in December, 1999. A complete report of the Standards Revision Project was prepared and submitted to NCCA by the Steering Committee in March, 2000. After NCCA review and revision of the Steering Committee's report a draft of these documents was made available for public comment. Following numerous revisions and review periods throughout 2001 the draft Standards were presented to the organizations accredited by the NCCA for ratification in January, 2002. The Standards were approved in February, 2002.

In November of 2006, the Commission approved a revised definition of "Public Member." This was considered an editorial revision.

STRUCTURE AND DEVELOPMENT OF THE STANDARDS

The Standards focus on certification programs and are organized into five sections: (1) Purpose, Governance, and Resources, containing five Standards (2) Responsibilities to Stakeholders, containing four Standards (3) Assessment Instruments, containing nine Standards (4) Recertification, containing two Standards, and (5) Maintaining Accreditation, containing one Standard.

To earn or maintain accreditation by NCCA, the certification program must meet *all* Standards and provide evidence of compliance through the submission of required documentation.

The statements describing the Standards are numbered consecutively. Accompanying each Standard are *Essential Elements*, which are directly related to the Standard and specify what a certification program must do to fulfill requirements of the Standard.

A second subsection under each Standard is called *Commentary*. The Commentary section clarifies terms, provides examples of practice that help explain a Standard, or offers suggestions regarding evidence that must be documented to demonstrate compliance. NCCA reserves the right to revise the Essential Elements and the Commentary sections in response to changes in certification practice.

The development of the Standards was guided by the following assumptions:

1. A number of previous NCCA Standards, such as the requirement that the certifying agency be non-governmental, nonprofit, and national in scope, are restrictive. Further, by opening the accreditation process to include certification programs in for-profit organizations, NCCA more effectively achieves its public service mission.
2. The appropriate unit of accreditation is the certification program rather than the certifying organization. In fact, NCCA accreditation previously required that all certification programs offered by an agency meet all standards in order for the agency to achieve accreditation.
3. NCCA accreditation should be awarded for a period of five years for the initial program certification. If organizations or agencies apply for NCCA accreditation of additional programs following accreditation of the original program(s), any new programs will be accredited until the date the organization's initial accreditation expires. All of an organization's accredited programs will be eligible for renewal on the same the five-year renewal cycle.
4. Autonomy in the management and administration of certification protects certification programs from undue influence. Autonomy is required in order for certification programs to serve stakeholder interests, primarily those of consumers of professional services. However, since certification programs take different forms for different professions and occupations, a variety of structures may be effectively employed to prevent undue influence from competing interests.

5. The term stakeholder has been used to refer to candidates and the public, as well as to members of a profession, occupation, or regulatory body. The term denotes the primary interest of the public and other consumers of the certification program. The term also encompasses certificants and the entities offering certification, as well as educators, and employers. It is appropriate to acknowledge the legitimate influence of all stakeholder bodies.
6. The NCCA Standards pertaining to assessment instruments should be consistent with the Standards for Educational and Psychological Testing (American Educational Research Association, American Psychological Association, and National Council on Measurement in Education, 1999), as well as other standards and guidelines related to certification accreditation developed by specific professions, occupations, governmental agencies, and international organizations, or certification activity criteria more generally, such as (but not limited to) Principles of Fairness: An Examining Guide for Credentialing Boards (Council on Licensure Enforcement and Regulation and the National Organization for Competency Assurance, 1993) and the Uniform Guidelines on Employee Selection Procedures (Equal Employment Opportunity Commission, Civil Service Commission, U.S. Department of Labor, and U.S. Department of Justice, 1978).
7. Recertification is valuable for all certification programs. Demonstrating continuing competence through a variety of recertification mechanisms is in the best interests of both the public and the discipline certified.

Standards

PURPOSE, GOVERNANCE, and RESOURCES

Standard 1

The purpose of the certification program is to conduct certification activities in a manner that upholds standards for competent practice in a profession, occupation, role, or skill.

Essential Element:

- A. It is the responsibility of the certification program applying for NCCA accreditation to identify the population being certified and to provide justification for the appropriateness of its certification activities. Typically, a certification program issues a credential or title to those certified. If the applying program does not, an explanation should be provided explaining why the issuance of a credential or title is not appropriate to the profession, occupation, role, or skill.

Commentary:

- A. Suggested evidence to document that the Standard has been met may include a mission statement, bylaws, articles of incorporation, a policy and procedures document, a governing committee charter, or candidate brochures.

Standard 2

The certification program must be structured and governed in ways that are appropriate for the profession, occupation, role, or skill, and that ensure autonomy in decision making over essential certification activities.

Essential Elements:

- A. The certifying program must show that the governance structure, policies, and procedures that have been established protect against undue influence that could compromise the integrity of the certification process.
- B. The governance structure, policies, and procedures must provide for autonomy in decision making regarding important aspects of the certification program such as eligibility standards; the development, administration, and scoring of the assessment instruments; selection of personnel; and operational processes.
- C. The development, administration, and scoring of assessment instruments must promote the purpose of the certification program.
- D. To avoid conflicts of interest between certification and education functions, the certification agency must not also be responsible for accreditation of educational or training programs or courses of study leading to the certification.

Commentary:

- A. The appropriate structure and governance of a certification program will reflect the interests of the general public in the credential. In traditional forms of professional or occupational certification, public interest requires direct protection of essential certification decisions from undue influence. Such protection is especially important when a certification program is sponsored by a professional membership association or proprietary entity. In these cases it is appropriate that the certification program's structure and governance protect the integrity of essential certification decisions.

When the certification program involves a proprietary product or service, the issue of undue influence is different. In these cases it is assumed that the proprietor has a clear and reasonable self-interest in preventing external or competing influences from diminishing the quality of the certification. It is recognized that the public is often not a direct consumer of the activities of the certified population. The public interest will be adequately protected when the needs of the proprietor, employers, or purchasers who rely on the credential provide significant direction over certification policy and decision making.

- B. Pressure to adjust certification standards either to limit the number of certificants or to reduce or elevate the established standard by changing requirements could interfere with the maintenance of standards established for a given certification.
- C. Certification programs may satisfy the requirement for autonomy of the governing body or governing committee in a number of ways. Incorporation of the certifying agency as an independent unit usually ensures autonomy. The bylaws of a parent organization may be constructed so that certification program governance and decision-making are defined as the responsibility of a specific unit of the organization with complete authority over all essential certification decisions. A governing committee may be given such authority in the policies and procedures and organizational chart of a corporation.
- D. In addition to not *accrediting* programs leading to the initial certification, the certification organization must not require that candidates complete that organization's program for certification eligibility. If a certification organization *provides* an educational program (including but not limited to primary education, exam preparation courses, study guides), the organization must not state or imply that: 1) this program is the only available route to certification; or 2) that purchase or completion of this program is required for initial certification.
- E. Suggested evidence to document that the Standard has been met may include a mission statement, bylaws, articles of incorporation, business plans, a policy and procedures document, a governing committee charter, or organizational charts.

Standard 3

The certification board or governing committee of the certification program must include individuals from the certified population, as well as voting representation from at least one consumer or public member. For entities offering more than one certification program, a system must be in place through which all certified populations are represented, with voting rights, on the certification board or governing committee.

Essential Elements:

- A. A system or structure must be established for ensuring appropriate stakeholder involvement by designating certain representative positions on the governing body. To ensure a balance of

program input, the governing body may implement a rotating system of representation over a set period of time.

- B. The certification program must establish bylaws and/or policies and procedures for the selection of individuals who serve on the board or governing committee. This information must show that the selection of these individuals prevents inappropriate influence from a parent or outside body.

Commentary:

- A. It is important that stakeholders (e.g., the public and other consumers, employers, regulators, and certificants) are represented on the body(ies) that sets policies regarding the certification program, including activities related to eligibility and the development, administration, and scoring of the assessment instrument.
- B. Suggested evidence to document that the Standard has been met may include a mission statement, bylaws, articles of incorporation, business plans, a policy and procedures document, a governing committee charter, or organizational charts.
- C. The public member is considered by NCCA to be a person who represents the direct and indirect users of certificants' skills/services. Because this may be defined very broadly, a rotating system for representation of various publics may be implemented over time. The public member may be a professional, but should not have similar credentials to the certificants. The public member should not be a member of a related profession or a profession that provides services that are complementary to certificants' services. The NCCA recommends, but does not require, that the public member has been or is a potential a consumer of the certificants' skills or services. It is also recommended that public members have experience with public advocacy.

The public member should not be:

- A current or previous member of the profession encompassed by the certification programs of the certification organization.
- A member of a related profession or a profession that provides complementary services to the certificants' services.
- An employer or an employee of individuals in the profession encompassed by the certification programs of the certification organization.
- An employee of an individual certified by the certification organization or of an employer of individuals in the profession encompassed by the certification programs of the certification organization.
- An employee of any certification organization.
- Currently deriving more than 5% of their total income from the profession encompassed by the certification programs of the certification organization.

The public member should not have:

- Derived in any of the five years preceding my appointment as a public member on the governing body more than 5% of their total income from the profession encompassed by the certification programs of the certification organization.
- Worked for or provided contract services to the certification organization at any time during the five years preceding my appointment as a public member on the governing body.

Standard 4

The certification program must have sufficient financial resources to conduct effective and thorough certification and recertification activities.

Essential Element:

- A. Financial reports of the certification program must demonstrate adequate resources available to support ongoing certification and recertification processes.

Commentary:

- A. The certification program should be able to document that monies used for the certification program are readily available.
- B. Suggested evidence to document that the Standard has been met includes financial statements for the certification program.

Standard 5

The certification program must have sufficient staff, consultants, and other human resources to conduct effective certification and recertification activities.

Essential Elements:

- A. Key staff and non-staff consultants and professionals must possess adequate knowledge and skill to conduct certification program activities.
- B. The certification program must have adequate resources to conduct the activities (e.g., processing of applications, administering the assessment instrument, storage of records) of the certification program.

Commentary:

- A. Documentation of resource availability and activity occurrence does not mean that every certification program must have its own office or building; in some cases, all activities could be adequately handled with services from a testing company, consultants, or management service.
- B. Suggested evidence to document that the Standard has been met may include resumes or curriculum vitae of key staff, non-staff consultants, and professionals, and associated organizational charts describing the inter-relationships among the individuals providing services to the certification program.

RESPONSIBILITIES to STAKEHOLDERS

Standard 6

A certification program must establish, publish, apply, and periodically review key certification policies and procedures concerning existing and prospective certificants such as those for determining eligibility criteria; applying for certification; administering assessment instruments; establishing performance domains, appeals, confidentiality, certification statistics, and discipline; and complying with applicable laws.

Essential Elements:

- A. Published documents that clearly define the certification responsibilities of the organization must include the following:

- The purpose of the certification program
 - Eligibility criteria and application policies and procedures
 - Materials outlining all examination processes and procedures
 - A detailed listing and/or outline of the performance domains, tasks, and associated knowledge and/or skills
 - A summary of certification activities (number of candidates examined, pass/fail statistics, and number of individuals currently certified) for each program
 - Discipline, nondiscrimination, and confidentiality policies and procedures
 - Appeals policies and procedures
- B. Confidentiality policies must (a) ensure that candidate application status and examination results are held confidential, and (b) delineate the circumstances under which this information may be disclosed or made public.
- C. Policies and procedures must be published and must include guidelines by which candidates may question eligibility determination, assessment instrument results, and certification status.
- D. Disciplinary policies must include procedures to address complaints that may concern conduct that is harmful to the public or inappropriate to the discipline (e.g., incompetence, unethical behavior, or physical/mental impairment affecting performance). These policies must ensure appropriate treatment of sensitive information and fair decision making.

Commentary:

- A. Publications concerning eligibility criteria, applications, assessment instruments, appeals, discipline, confidentiality, etc., are required to inform candidates and other stakeholders about program policies.
- B. Applicable laws and regulations include nondiscrimination, disabilities, and other issues which may affect fairness to candidates or protection for consumers.
- C. Procedures for requesting accommodations for disabled candidates should be stated clearly and published in an appropriate agency document. The process should include mechanisms that will ensure that proper evidence is submitted to the agency to assist the agency in making a determination regarding the requested accommodation.
- D. Any accommodation provided should be reasonable and not compromise the validity and reliability of the assessment instruments.
- E. Suggested evidence to document that the Standard has been met may include a policy and procedures manual, a candidate handbook, and any written documents or forms regarding procedures for obtaining approval for an accommodation.

Standard 7

The certification program must publish a description of the assessment instruments used to make certification decisions as well as the research methods used to ensure that the assessment instruments are valid.

Essential Element:

- A. Procedures related to assessment instruments must address development and validation, eligibility requirements, and administration (e.g., availability and location, fees, reporting of results).

Commentary:

- A. Suggested evidence to document that the Standard has been met may include a candidate handbook, brochures about the certification program, and other public documents.

Standard 8

The certification program must award certification only after the knowledge and/or skill of individual applicants has been evaluated and determined to be acceptable.

Essential Elements:

- A. If any current certificants (at the time the application for accreditation is made) were granted certification without having to meet the examination requirements established for certification, a rationale must be provided to explain how the competence of those individuals was evaluated and found to be sufficient. The period during which such test exemptions were granted must have been terminated before the certification program is eligible for accreditation.
- B. Once a program is accredited, "grandfathering," or any other procedure for granting a credential in the absence of evaluating the knowledge and/or skill of an individual, is not acceptable.

Commentary:

- A. Grandfathering is generally seen as a conflict with stakeholder interests. It is used from time to time in licensure as a means of protecting the rights of individuals who entered a profession prior to its regulation and should not be excluded from the right to practice. Professional certification does not normally carry such potential to restrict the right to practice.
- B. Suggested evidence to document that the Standard has been met may include a policy and procedures document, a candidate handbook, brochures about the certification program, and other public documents.

Standard 9

The certification program must maintain a list of and provide verification of certified individuals.

Essential Element:

- A. The certification program must maintain a list of current and previous certificants.

Commentary:

- A. The certification program should provide and verify that a certificant possesses currently valid certification upon request from any member of the public. Policies governing verification should allow disclosure of whether or not the certificant is currently in good standing, without communicating other information which may violate the confidentiality rights of certificants or applicants.
- B. The certification program may discard information about previous certificants after a reasonable time period when such information is no longer valuable to the certification program's stakeholders.
- C. Suggested evidence to document that the Standard has been met may include a policy and procedures document, a candidate handbook, brochures about the certification program, directories in which certificant names are published, and other public documents.

ASSESSMENT INSTRUMENTS

Standard 10

The certification program must analyze, define, and publish performance domains and tasks related to the purpose of the credential, and the knowledge and/or skill associated with the performance domains and tasks, and use them to develop specifications for the assessment instruments.

Essential Elements:

- A. A job/practice analysis must be conducted leading to clearly delineated performance domains and tasks, associated knowledge and/or skills, and sets of content/item specifications to be used as the basis for developing each type of assessment instrument (e.g., multiple-choice, essay, oral examination).
- B. A report must be published that links the job/practice analysis to specifications for the assessment instruments.

Commentary:

- A. No single method exists to define performance domains, tasks, and associated knowledge and/or skills. Appropriate strategies include (a) committees of representative experts to define performance domains and tasks and associated knowledge and/or skills, including a review of related practice- or job-based information, or a review of the information from a previous study (b) rating scales (e.g., frequency and importance) to identify and select critical performance domains, tasks, and associated knowledge and/or skills (c) collection of job/practice information using logs, observations of practice, and/or interviews, or (d) review of proposed performance domains, tasks, associated knowledge and/or skills, and rating scales by an independent panel of experts.
- B. Validation of performance domains, tasks, and associated knowledge and/or skills is typically accomplished by conducting a survey of current certificants and/or individuals providing services or performing a job consistent with the purpose of the credential. It is important to sample widely within the profession, occupation, or role, or among those who use or support a product, to ensure representation in terms of major practice areas, job titles, work settings, geography, ethnic diversity, gender, and work experience. Stakeholders such as educators, supervisors, and employers may be included, as appropriate. An adequate sample size should be used to ensure that the estimated level of measurement error is defensible.
- C. Analysis of ratings information collected in the survey should determine how and to what degree the performance domains, tasks, and associated knowledge and/or skills relate to the purpose of the credential. Linkages to the content of the assessment instruments should be based on the use of ratings data. Empirical algorithms or other psychometric methods used to analyze or combine ratings from different scales should be specified. Analyses of demographic information collected from survey participants should also be examined to evaluate representativeness of the findings.
- D. A table of specifications should be prepared for each assessment instrument specifying the weighting of performance domains, tasks, and associated knowledge and/or skills to be included. The weighting system should be based primarily on data collected from survey participants, with informed review and interpretation provided by a panel of subject-matter experts. Decision rules used to eliminate performance domains, tasks, and associated knowledge and/or skills from the specification table should be explained. The specifications may also include instructions to the item writers to be used in developing assessment instruments.

- E. Because rapid changes may occur in knowledge and/or skills and in technology, it is important that certification programs periodically review performance domains, tasks, and associated knowledge and/or skills in the specifications to ensure that they are current. Since it is impossible to specify with precision how often the review should be conducted, each certification agency should develop its own timeframe and rationale. For existing certification programs, any changes between new specifications and previous specifications should be noted and explained.
- F. Suggested evidence to document that the Standard has been met requires a complete report summarizing the results of the job/practice analysis, which may include:
- A description of the background and experience of subject-matter experts and professionals who participated in various phases of the job/practice analysis
 - Identification of the psychometric consultants or organization used to conduct the job/practice analysis or important phases of it
 - A description of methods used to delineate performance domains, tasks, and associated knowledge and/or skills
 - A copy of the job analysis survey, including all instructions, rating scales, open-ended questions, and background demographic information collected from participants
 - A description of the survey's sampling plan and its rationale
 - Documentation of survey results, including return rate, analysis of ratings data, algorithms or other psychometric methods used to analyze or combine ratings data, and a rationale supporting representativeness of survey findings
 - A table of specifications for each assessment instrument specifying weighting of the performance domains, tasks, and associated knowledge and/or skill, along with any decision rules used to eliminate any of these elements from the table of specifications
 - Date of the study and description of a plan to update periodically the job/practice analysis
- G. The formal report of the job/practice analysis study to be provided to demonstrate compliance with this standard may be considered by the organization to be a confidential document, and therefore, the organization may decide to not make it widely available. However, in these cases, the organization must publish and make available a summary of the study or statement(s) describing the exam specifications development process for dissemination to prospective candidates and other interested members of the public.

Standard 11

The certification program must employ assessment instruments that are derived from the job/practice analysis and that are consistent with generally accepted psychometric principles.

Essential Elements:

- A. Assessment instruments, including assessment items, exhibits, instructions to examinees, scoring procedures, and training procedures for administration of assessments, must be products of an appropriately designed and documented development process.
- B. The content sampling plan for test items or other assessment components must correspond to content as delineated and specified in the job/practice analysis.
- C. An ongoing process must exist to ensure that linkage between the assessment instruments and the job/practice analysis is maintained, as assessment components are revised and replaced over time.

This linkage between assessment content and job/practice analysis must be documented and available for review by stakeholders.

- D. Certification programs must follow a valid development process that is appropriate for assessment instruments.
- E. A systematic plan must be created and implemented to minimize the impact of content error and bias on the assessment development process. Assessment content must be reviewed by qualified subject matter experts.

Commentary:

- A. Documentation for assessments should include a detailed description of the delivery format for each portion of the assessment and the type of response required of candidates. Developers should take reasonable steps to ensure that modes of presentation and response are justified by job relatedness. If the form of the assessment instrument is to be delivered on computer, the documentation of item selection rules or display features should be described. Certification programs should document how background and experience factors of the candidate population were considered in selecting item types or other assessment formats.
- B. Qualifications of subject matter experts, assessment development professionals, content reviewers, and others involved in assessment development should be appropriate to the content area tested and assessment procedures used and documented.
- C. Training provided to item writers, item reviewers, and others who produce assessment content should be structured, delivered, and documented in a professional and consistent manner.
- D. The development and assembly process for assessment instruments should be documented.
- E. The development process should include pilot testing of new items with a representative sample of the target population, with revision based on statistical analysis of results, where appropriate.
- F. Certification programs should document procedures used to examine the performance of items or other assessment components and describe the criteria used to identify components for revision or removal from the assessment.
- G. The size of the item pool must be sufficient to sample specifications for the assessment and to provide adequate item exposure control to safeguard the security and integrity of the item bank and test forms, particularly in relation to computer-based administration.
- H. Provision should be made for monitoring continued validity of each assessment item and assessment form during the period in which they are active.
- I. Suggested evidence to document that the Standard has been met may include: specifications for the assessment instruments; training materials, agendas, and reports on item development; procedures for the development of assessment instruments; and technical reports.

Standard 12

The certification program must set the cut score consistent with the purpose of the credential and the established standard of competence for the profession, occupation, role, or skill.

Essential Elements:

- A. Cut scores must be set using information concerning the relationship between assessment performance and relevant criteria based on the standard of competence.

- B. A report must be published documenting the methods and procedures used to establish the standard of competence and set the cut score, along with the results of these procedures.

Commentary:

- A. No single method exists to set cut scores. Appropriate strategies include the use of judges or panelists who focus their attention on assessment content by rating each item or task, or who consider the candidates or their completed assessments.
- B. The raters in a cut score study must understand the purpose of the assessment, the standard of competence, and how to apply the cut score process that is to be used. Raters should have a sound basis for making required judgments. If data are available, estimates of the effects of setting the cut score at various points should be provided.
- C. The cut score study should be documented in sufficient detail to allow for replication, including full descriptions of the procedures followed, results, and how they should be interpreted.
- D. Suggested evidence to document that the standard has been met includes a report of the cut score study that addresses the following:
- Overview of the cut score process
 - Qualifications of those designing and implementing the process
 - Number of panelists, manner of selecting the panelists, and their qualifications
 - Material used
 - Data collection procedures
 - Descriptions or conceptualizations developed by the panelists
 - Data collection activities
 - Meeting agendas
 - Any adjustments made to the cut score by a governing body or policy group
- E. This formal cut score report may be considered confidential by the organization; however NCCA accreditation review requires that a formal report of the cut score be submitted with the application. In these cases, the organization must make available a summary of the study or statement regarding the study to prospective candidates and other interested stakeholders. The summary can be in journal articles, candidate bulletin, or other information accessible to candidates and stakeholders.

Standard 13

The certification program must document the psychometric procedures used to score, interpret, and report assessment results.

Essential Elements:

- A. The certification program must describe procedures for scoring, interpreting, and reporting assessment results.
- B. For responses scored by judgment, developers must document training materials and standards for training judges to an acceptable level of valid and reliable performance. Any prerequisite background or experience for selection of judges must also be specified.

- C. Candidates must be provided meaningful information on their performance on assessment instruments. Such information must enable failing candidates to benefit from the information and, if psychometrically defensible, understand their strengths and weaknesses as measured by the assessment instruments.
- D. Reports of aggregate assessment data in summarized form must be made available to stakeholders without violating confidentiality obligations.

Commentary:

- A. Certification programs are responsible for establishing quality control procedures that regularly monitor the precision of calculations used to compute assessment scores and their conversion to standardized, equated, or scaled scores, if performed.
- B. The certification program should publish an explanation of the appropriate uses and misuses of reported score information.
- C. Suggested evidence to document that the Standard has been met may include descriptions of scoring procedures, training documents, quality control procedures, and sample score reports for passing and failing candidates.
- D. Evidence in support of essential element D should include documentation of aggregate assessment data to the various stakeholder groups on interest. For example, details of the aggregate assessment data might be appropriate reported to representatives of the program sponsor (e.g. a board or committee) and documented in the NCCA Accreditation application. In addition, however, some aggregate data must be available to the public and the certificant population, at a minimum addressing the number of candidates and the number of individuals attaining the certification credential during a specified period of time.

Standard 14

The certification program must ensure that reported scores are sufficiently reliable for the intended purposes of the assessment instruments.

Essential Element:

- A. Certification programs must provide information to indicate whether scores (including any subscores) are sufficiently reliable for their intended uses, including estimates of errors of measurement for the reported scores. Information must be provided about reliability or consistency of pass/fail decisions. When appropriate, information should be provided about the standard error of measurement or similar coefficients around the cut score.

Commentary:

- A. The level of reliability required for an assessment instrument depends on the type of assessment device and the purpose for which scores will be used.
- B. Different types of assessment instruments require different methods of estimating reliability. Reliability should be estimated using methods that are appropriate for characteristics of the assessment instruments and the intended uses of the scores.
- C. Suggested evidence to document that the Standard has been met may include:
 - Methods used to assess reliability of scores (including subscores), and the rationale for using them
 - Characteristics of the population involved (e.g., demographic information, employment status)

- A reliability coefficient, an overall standard error of measurement, an index of classification consistency, an information function, or other methods for estimating the consistency of scores
- Standard errors of measurement or other measures of score consistency around the cut score
- Information about the speededness of performance on the assessment instruments
- Any procedures used for judgmental or automated scoring
- The level of agreement among judges

Standard 15

The certification program must demonstrate that different forms of an assessment instrument assess equivalent content and that candidates are not disadvantaged for taking a form of an assessment instrument that varies in difficulty from another form.

Essential Elements:

- A. Equating or other procedures used to ensure equivalence and fairness must be documented, including a rationale for the procedure used.
- B. When assessment instruments are translated or adapted across cultures, certification programs must describe the methods used in determining the adequacy of the translation or adaptation and demonstrate that information attained from adapted and source versions of the assessment instruments produce comparable test scores and inferences.

Commentary:

- A. Different ways exist to link assessment scores, ranging in rigor from strict equating models to judgmental methods.
- B. When certification programs use more than one mode of administration (e.g., paper/pencil and computer-based testing), it is important to document equivalence of score information and any score adjustment method used to achieve equivalence.
- C. A rationale should be provided for the reporting scales selected and methods used to determine score scales.
- D. The scales on which scores are reported should not encourage finer distinctions among candidates than can be supported by the precision of the assessment instruments. The scale values should be chosen in a manner that avoids confusion with other scales that are widely used by the same population of candidates.
- E. Raw scores should not be reported except under one or more of the following circumstances:
 - Only one form of the assessment instrument is to be offered
 - Scores on one form will not be compared with scores on another form
 - Raw or percentage scores on all forms are comparable, or
 - Raw or percentage scores are reported in a context that supports intended interpretations.
- F. When scaling scores, the stability of the score scale should be checked periodically. When indicated, steps should be taken to minimize score misinterpretations. If a change to the assessment instrument or to the composition of the candidate population alters the meaning of

scores, it may be appropriate to rescale the scores to minimize confusion between the old and new scores, or in the absence of rescaling, to ensure that the differences between the old and new scores are clearly communicated to candidates and to other stakeholders.

G. Certification programs should, whenever possible, conduct pilot studies prior to implementation of the adapted version of the assessment instruments. Field study research should be part of a program of ongoing maintenance and improvement. Tryout and field studies should be part of a larger research program to ensure comparability and quality of cross-cultural information on the assessment instruments.

H. Suggested evidence to document that the Standard has been met may include:

- A description of the methods used to determine that different forms of an assessment instrument measure equivalent content and ensure that candidates are not disadvantaged for taking a form of the assessment instrument that varies in difficulty from another form
- An equating and scaling report

Standard 16

The certification program must develop and adhere to appropriate, standardized, and secure procedures for the development and administration of the assessment instruments. The fact that such procedures are in force should be published.

Essential Element:

A. Assessment instruments must be administered securely, using standardized procedures that have been specified by the certification program sponsor.

Commentary:

A. Non-standardized administration procedures may adversely influence scores as well as the inferences drawn from these scores. When administration procedures deviate from the expected, such irregularities must be thoroughly documented.

B. Chief examiners and proctors should be thoroughly trained in proper administration of the assessment instruments in an effort to minimize the influence of test administration on scores. Similarly, all candidates should have equal access to preparatory materials and instructions available from the sponsor.

C. Certification programs are responsible for protecting the integrity of assessment information. This responsibility requires a security program that restricts access to assessment information to authorized personnel.

D. Administration sites should offer similar conditions, such as adequate lighting, comfortable seating, and an environment free from noise and other distraction.

E. Suggested evidence to document that the Standard has been met may include:

- Candidate handbook or similar document
- Chief examiner and/or proctor manual
- Quality control policy and procedures documents
- Security procedures manual

Standard 17

The certification program must establish and document policies and procedures for retaining all information and data required to provide evidence of validity and reliability of the assessment instruments.

Essential Element:

- A. Policies and procedures must ensure that items and forms of the assessment instruments are stored in a medium and method that emphasizes security, while being accessible to authorized personnel. Such policies must not only describe procedures for a secure system but also address actions required of personnel.

Commentary:

- A. Policies should establish a time period for retention of physical or electronic copies of forms of the assessment instruments and of reports and analyses related to the development process. The documents may be used in matters relating to challenges concerning scores, validity, or other essential issues. Documentation of the secure retention of assessment instruments and development information (e.g. cut score studies, technical reports) must be provided as part of the NCCA Application Accreditation. Note here how this information is securely maintained.
- B. Suggested evidence to document that the Standard has been met should include policy and procedures documents.

Standard 18

The certification program must establish and apply policies and procedures for secure retention of assessment results and scores of all candidates.

Essential Element:

- A. Organizational policy must determine the length of time that assessment results will be retained.

Commentary:

- A. Organizational policy concerning the length of time that assessment results will be retained and score reports provided should be stated clearly in information provided to candidates.
- B. Certification program policy should prevent assessment results and other personal information from the candidate's file being provided to a third party without the candidate's documented permission. The policy should be stated in information provided to candidates.
- C. Suggested evidence to document that the Standard has been met should include policy and procedures documents.

RECERTIFICATION

Standard 19

The certification program must require periodic recertification and establish, publish, apply, and periodically review policies and procedures for recertification.

Essential Elements:

- A. The published policy must contain a statement of the basis and purpose for recertification and all recertification requirements.
- B. The rationale for the recertification time interval must be included in the policy.
- C. Recertification policies and procedures in handbooks, guides, and/or electronic media must be published and made available to certificants and the public.

Commentary:

- A.. The goals of recertification can differ for different organizations. Examples might include: to assess core knowledge and skills; to assess knowledge and skills in specific areas of practice; to encourage continued professional development; to ensure maintenance of competence; to promote lifelong learning; etc. An organization's recertification policy should clearly state the purpose of recertification.
- B. An explanation of consequences for the certificant when recertification requirements are not met should be provided.
- C. In the case of a certification program involving a proprietary product or service, the proprietor may describe recertification on the basis of a systemic process of upgrading the product of service in connection with steps taken to withdraw technical support provided by the proprietor for the previous version of the product.
- D. Suggested evidence to document the Standard has been met should include renewal policy and procedure documents and a candidate handbook.

Standard 20

The certification program must demonstrate that its recertification requirements measure or enhance the continued competence of certificants.

Essential Element:

- A. If the purpose of recertification is to *measure* continued competence of certificants, then the certification program must substantiate the validity and reliability of the assessment instruments used to measure continued competence.
- B. If the purpose is to *enhance* continued competence of certificants, then the certification program must demonstrate how the policy contributes to professional development of the individual certificant.

Commentary:

- A. If an assessment method is used (e.g. self-assessment, third-party assessment, peer review, up to date version of the initial certification exam, portfolio), then the application and documentation must include an explanation of the validity and reliability of the assessment or process.
- B. If the enhancement method is used (e.g. continuing education, mentoring, clinical skills or practice improvement modules, institutional or web-based learning), then the application and

documentation must include the applicant's rationale for how the method(s) supports the professional development and enhances the competence of the certificant (e.g. how an enhancement method is related to an individual certificant's needs assessment; how the applicant evaluates the quality and relevance of the competency enhancement methods; whether the enhancement method includes a mechanism, such as a post-test, to assess whether certificant knowledge and/or practical skills have been enhanced.)

- C. Suggested evidence to document that the Standard has been met should include certification renewal policy and procedure documents and a candidate handbook.

MAINTAINING ACCREDITATION

Standard 21

The certification program must demonstrate continued compliance to maintain accreditation.

Essential Elements:

- A. The certification program must annually complete and submit information requested on the current status of the certification agency and its programs.
- B. The certification program must report any change in purpose, structure, or activities of the certification program.
- C. The certification program must report any substantive change in examination administration procedures.
- D. The certification program must report any major change in examination techniques or in the scope or objectives of the examination.
- E. The certification program must submit any information NCCA may require to investigate allegations of lack of compliance with NCCA Standards.

Glossary

Accommodation—

A reasonable modification in an assessment instrument or its administration made to compensate for the effects of a qualified disability without altering the purpose of the assessment instrument.

Accountability—

Responsibility of a certification board, governing committee, or other sponsor of a certification program to its stakeholders to demonstrate the efficacy and fairness of certification policies, procedures, and assessment instruments.

Accreditation—

1. **General use:** Approval of an educational program according to defined standards.
2. **As related to NCCA:** Status awarded to a certification program that has demonstrated compliance with the *Standards for the Accreditation of Certification Programs* set forth by the National Commission for Certifying Agencies.

Administrative Independence—

An organizational structure for the governance of a certification program that ensures control over all essential certification and recertification decisions without being subject to approval by or undue influence from any other body. See Autonomy.

Applicant—

An individual who declares interest in earning a credential offered by a certification program, usually through a request for information and the submission of materials. See Candidate.

Assessment Instruments—

Any one of several standardized methods for determining if candidates possess the necessary knowledge and/or skill related to the purpose of the certification.

Autonomy—

Control over all essential certification and recertification decisions without being subject to approval by or undue influence from any other body. Autonomy in the management and administration of certification enhances the ability of certification programs to serve stakeholder interests, primarily those of consumers of professional services. See Administrative Independence.

Bias—

IN THE CONTEXT OF SCORING: a systematic error in a score on an assessment instrument.

IN THE CONTEXT OF EXAMINATION FAIRNESS: may refer to the inappropriateness of content in the assessment instrument, either in terms of its irrelevance, overemphasis, or exclusion.

IN THE CONTEXT OF ELIGIBILITY AND RECERTIFICATION REQUIREMENTS: may refer to the inappropriateness or irrelevance of requirements for certification or recertification if they are not reasonable prerequisites for competence in a profession, occupation, role, or skill. See Fairness.

Candidate—

An individual who has met the eligibility qualifications for, but has not yet earned, a credential awarded through a certification program. See Applicant.

Certificant—

An individual who has earned a credential awarded through a certification program.

Certification—

A process, often voluntary, by which individuals who have demonstrated the level of knowledge and skill required in the profession, occupation, role, or skill are identified to the public and other stakeholders.

Certification Agency—

The organizational or administrative unit that offers and/or operates a certification program.

Certification Board—

A group of individuals appointed or elected to govern one or more certification programs as well as the certification agency, and responsible for all certification decision making, including governance.

Certification Committee—

A group of individuals appointed or elected to recommend and implement policy related to certification program operation. (See governing committee)

Certification Program—

The standards, policies, procedures, assessment instruments, and related products and activities through which individuals are publicly identified as qualified in a profession, occupation, role, or skill.

Commentary—

Comments, remarks, and observations that clarify terms, provide examples of practice that help explain a standard, or offer suggestions regarding evidence that must be documented to demonstrate compliance.

Content Domains—

The set of organized categories characterizing subject matter under which knowledge and skills may be represented in specifications for assessment instruments.

Consumer—

See also "Public Member"

Continuing Competence—

The ability to provide service at specified levels of knowledge and skill, not only at the time of initial certification but throughout an individual's professional career. See Recertification and Continuing Education.

Continuing Education—

Activities, often short courses, that certified professionals engage in to receive credit for the purpose of maintaining continuing competence and renewing certification. See Recertification and Continuing Competence.

Cut Score—

A specific score on an assessment instrument or instruments at or above which passing decisions are made and below which failing decisions are made.

Discipline—

A formal, published process for the enforcement of standards governing the professional behavior (i.e., ethics) of certificants.

Eligibility Requirements—

Published criteria, often benchmarks for education, training, and experience, with which applicants must demonstrate compliance in order to qualify for certification.

Equating—

A statistical process used to convert scores on two or more alternate forms of an assessment instrument to a common score for purposes of comparability and equivalence.

Essential Element—

A statement that is directly related to a Standard and specifies what a certification program must do to fulfill the requirement of the Standard.

Fairness—

The principle that all applicants and candidates will be treated in an equitable manner throughout the entire certification process. See Bias.

Grandfathering—

The process by which individuals are granted certification without being required to meet a formal examination requirement. This process is frequently invoked when a certification program is initiated, as a way of recognizing the experience and expertise of long-term experts, and/or to allow grandfathered individuals to develop the initial form(s) of the certification examination. Individuals initially certified through grandfathering may, in the future, be required to pass a form of the certification examination they did not participate in developing in order to maintain certification.

Governing Committee—

A group of individuals appointed or elected to formulate and implement policy related to certification program operation. The NCCA uses this term to denote those committees that are given complete authority over all essential certification decisions.

Incorporation Status—

Legal recognition granted by states to organizations; determines IRS classification as for-profit or nonprofit.

Item—

A general term referring to problems and/or questions that appear in assessment instruments and to which candidates must respond.

Item Bank—

The system by which test items are maintained, stored, and classified to facilitate item review, item development, and examination assembly.

Item Type or Format—

The structure of a problem or question in an assessment instrument (i.e., multiple choice, open-ended).

Job/Practice Analysis/Role Delineation Study—

Any of several methods used singly or in combination to identify the performance domains and associated tasks, knowledge, and/or skills relating to the purpose of the credential and providing the basis for validation.

Parent Organization—

The legal entity under which a certification program is established when the certification program is governed as part of a larger organization.

Performance Domains—

The set of organized categories characterizing a role or job under which tasks and associated knowledge and/or skills may be represented in the job/practice analysis.

Public Member—

A representative of the consumers of services provided by a defined certificant population, serving as a voting member on the governing body of a certification program, with all rights and privileges, including holding office and serving on committees. The public member should bring a perspective to the decision and policy making of the organization that is different from that of the certificants, and helps to balance the organization's role in protecting the public while advancing the interests of the profession.

(remove "consumer" from the glossary, as it has no definition)

Publish—

Make available in hardcopy, electronic, or web-based formats and easily accessible and available on request. The degree of accessibility may be a function of the level of confidentiality of the information.

Recertification—

Requirements and procedures established as part of a certification program that certificants must meet in order to ensure continuing competence and renew their certification. See Continuing Competence and Continuing Education.

Reliability—

The degree to which the scores on an assessment instrument are free of measurement error.

Role—

A more specific or narrower set of knowledge and skills than may be encompassed by the term *profession* or *occupation*, and may also be the focus of certification for a particular product or service to the public.

Self-Assessment—

A process by which an assessment instrument is self-administered for the specific purpose of providing performance feedback rather than a pass/fail decision.

Stakeholders—

The various groups with an interest in the quality, governance, and operation of a certification program, such as the public, certificants, candidates, employers, customers, clients, and third party payers.

Standard—

An accreditation requirement that must be met by a certification program submitting an application to the National Commission for Certifying Agencies.

Standardization—

IN THE CONTEXT OF ASSESSMENT INSTRUMENTS: ensuring that the process is conducted according to a specified plan in order to provide the same conditions for all candidates.

IN THE CONTEXT OF SCORING: ensuring that candidate responses are judged using predefined criteria in order to provide a consistent basis for evaluating all candidates.

Technical Report—

A summary of psychometric procedures and their results as implemented in the assessment instruments used in a certification program, often addressing such issues as content validity, item writing, test assembly, reliability analysis, cut score development, scoring, and equating.

Undue influence—

Control of decision making over essential certification policy and procedures by stakeholders or other groups outside the autonomous governance structure of a certification program.

Validity—

The degree to which accumulated evidence supports specific interpretations of all components of a certification program (e.g., education, experience, and assessment instruments).

**Information from the Commission for
Certification in Geriatric Pharmacy on its
certification program**



May 27, 2014

Virginia Herold, MS, Chief Executive Officer
California State Board of Pharmacy
1625 N Market Blvd, N219
Sacramento, CA 95834

Dear Ms. Herold:

The Commission for Certification in Geriatric Pharmacy was created by the American Society of Consultant Pharmacists in 1997 as an independent 501(c)(6) non-profit organization with its own Board of Commissioners. CCGP was charged with improving the care of older adults by recognizing and credentialing pharmacists with knowledge and expertise in geriatric pharmacy practice. Geriatric pharmacy is one of the areas of certification identified as part of eligibility criteria for individuals who seek recognition as an "advanced practice pharmacist" in legislation signed by California Governor Jerry Brown in 2013.

CCGP now has 2,460 Certified Geriatric Pharmacists in the United States, Canada, Australia, and a number of other countries. The CGP credential is recognized by the government of Australia as one of two pathways to qualify pharmacists for payment for Home Medication Reviews and Residential Medication Reviews. About 78% of Certified Geriatric Pharmacists are located in the United States, and 9% of those are in California.

CCGP is accredited by the National Commission for Certifying Agencies. Enclosed is a Fact Sheet that provides additional information about the rigorous process used by CCGP and our test partner, Applied Measurement Professionals, to develop a psychometrically sound and legally defensible certification examination in geriatric pharmacy.

CCGP encourages the California State Board of Pharmacy to consider recognizing CCGP and Certified Geriatric Pharmacists as the Board develops and approves regulations to implement Senate Bill 493.

Please let us know if you have any questions or would like any additional information. Thank you for your consideration.

Respectfully,

Thomas R. Clark, RPh, MHS, CGP
Executive Director

cc: CCGP Board of Commissioners

Commission for Certification in Geriatric Pharmacy
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Alexandria, VA 22314
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info@ccgp.org



Commission for Certification in Geriatric Pharmacy Fact Sheet

Vision and Mission

The **Vision** of CCGP is to ensure that all seniors receive high-quality pharmaceutical care from Certified Geriatric Pharmacists; and, that CCGP certified pharmacists are recognized as the preferred providers of pharmaceutical care to seniors.

In order to achieve our Vision, CCGP commits to the following **Mission**:

- Protect and serve the public interest through the credentialing of qualified practitioners of geriatric pharmaceutical care.
- Develop and administer clinically relevant, legally-defensible, and psychometrically-sound certification programs and processes.
- Promote the value of CCGP credentials to the public, practitioners, employers, and payers.
- Advance the profession by establishing rigorous standards of care based on the most appropriate medications, therapies, and technologies, to ensure optimum outcomes.
- Ensure that CCGP products, services, organizational structure, and customer relations are viewed as the benchmark standard for credentialing organizations.

Through a long-term commitment to its Mission, CCGP will become a well-recognized organization known as the leader in providing quality credentials in pharmaceutical care.

Governance

The Commission for Certification in Geriatric Pharmacy was created in 1997 by the American Society of Consultant Pharmacists. CCGP is a separate 501(c)(6) non-profit organization with its own Board of Commissioners. A member of the ASCP Board of Directors serves as a non-voting member of the CCGP Board of Commissioners. CCGP has a full-time Executive Director.

NCCA Accreditation

CCGP has been fully accredited by the National Commission for Certifying Agencies since 2012. NCCA is the nationally recognized accrediting body for certifying agencies in the United States. NCCA accredits certification programs in a wide range of professions and occupations, from nurses to crane operators. Accreditation by NCCA means that CCGP follows nationally recognized standards for accreditation, and is accountable to an external third party for quality assurance purposes.

About the CGP Examination

The Certified Geriatric Pharmacist examination is based upon a role delineation study (RDS) for geriatric pharmacy practice, conducted by CCGP in conjunction with test partner Applied Measurement Professionals (AMP). This RDS was conducted by an expert panel of geriatric pharmacists in a variety of practice settings, with input from psychometricians from AMP. A survey of over 2,000 geriatric pharmacists was conducted as part of the RDS.

The content map resulting from the RDS serves as the basis for examination items that sample the knowledge, skills, and abilities related to geriatric pharmacy practice. Each item on the CGP examination is linked to an element on the content map. The examination is prepared by a committee of Certified Geriatric Pharmacists, with input from AMP psychometricians.

The computer-based examination consists of 150 multiple-choice items. It is administered over a three-hour time period at a network of test centers in the United States, Canada, and other countries throughout the world.

Exam Test Windows

The CGP examination is offered by appointment at test centers during four test windows throughout the year: January/February; April/May; July/August; and October/November. The deadline for registration is the fifteenth of the month prior to the beginning of each test window.

Eligibility Criteria

Graduation from a school or college of pharmacy that qualifies one to practice pharmacy in the U.S. or other jurisdiction is a requirement for eligibility to take the CGP examination, along with two years of experience as a pharmacist. A current, active license to practice pharmacy in the U.S. or another jurisdiction is needed to apply to take the examination. A passing score on the CGP examination is required for certification as a Certified Geriatric Pharmacist.

Recertification

The length of certification is five years. Renewal of certification may occur by retaking the examination or through the Professional Development Pathway (PDP). Renewal by PDP requires completion of 75 credit hours of designated geriatric continuing education over the five-year certification cycle, with at least part of that CE completed part way through the cycle. A current active license to practice pharmacy is also required for recertification.

The CCGP Professional Development Committee oversees criteria and continuing education used for CGP recertification, with final approval from the CCGP Board of Commissioners.

Commission for Certification in Geriatric Pharmacy
1321 Duke Street, Suite 400
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www.ccgp.org



Commission for Certification in Geriatric Pharmacy Policy on Spacing of Professional Development Credits

Policy

For Certified Geriatric Pharmacists who recertify on or after January 1, 2019, the following provision applies to those who recertify through the Professional Development Program:

At least 15 hours of Professional Development credits must be completed no later than three years prior to the expiration date of the credential; AND

At least 30 hours of Professional Development credits must be completed no later than two years prior to the expiration date of the credential.

Rationale for change

This change will strengthen credibility of the recertification option through the Professional Development Pathway. It will help reassure stakeholders that CGPs who recertify in this way are maintaining ongoing competence.

Maintenance of competence should be an ongoing activity. It is not desirable that a Certified Geriatric Pharmacist should go for a period of four years or longer without completing any appropriate continuing education for maintenance of competence. When the Professional Development Program is to be used for recertification, the designated CE and self-assessment components included in the learning programs should be periodically completed as part of an ongoing process for maintenance of competence.

By requiring completion of some of the continuing education midway through the cycle, the Certified Geriatric Pharmacist is required to begin focusing on learning and self-assessment well before the expiration of the credential. Although the explicit requirement is not overly rigorous, the CGP will be encouraged to complete some of the CE requirements each year in order to stay on track with the Professional Development Pathway.

Developed by the Professional Development Committee

Approved by the Board of Commissioners

January 28, 2014

*Commission for Certification in Geriatric Pharmacy
1321 Duke Street
Alexandria, VA 22314*



Commission for Certification
In Geriatric Pharmacy

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[Home](#)

About the Certified Geriatric Pharmacist Examination

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Benefits of Board Certification

Board certification is a way to demonstrate knowledge and expertise in geriatric pharmacy practice. It shows that the certified pharmacist has special expertise that is beyond that of a licensed pharmacist. The certification credential may be useful in qualifying for a promotion with a current employer or in obtaining a job with a new employer.

Some employers will pay for the costs of taking the certification examination. In some cases, additional compensation (such as a step grade increase in pay or a bonus) may be provided by the employer. In the long-term care setting, geriatric expertise is especially valued. At least one long-term care facility chain requires their pharmacists to have or obtain the CGP credential as a condition for employment.

As the clinical role of pharmacists continues to expand, with the growth of Medication Therapy Management and other services, employers and payers are increasingly seeking pharmacists who have demonstrated clinical competence beyond the basic requirement of a pharmacist license.

With the aging of the population, expertise in geriatrics will be valued even more in coming years. Certification in geriatric pharmacy practice is a good investment for the future.

Eligibility

To be eligible for the certification examination in Geriatric Pharmacy Practice, an applicant must currently be a licensed pharmacist and must have a minimum of two years of experience as a licensed pharmacist. Applications must be accompanied by a photocopy of current pharmacist registration certificate/license and a check, money order, or credit card payment.

Dates, Deadlines, and Fees

The Certified Geriatric Pharmacist examination is a computer-based examination offered at test centers around the United States and in a number of other countries. The examination is offered in four test windows throughout the year, as shown in the table below.

Testing Window	Deadline to Register
January/February	December 15
April/May	March 15
July/August	June 15
October/November	September 15

The application fee for the examination is \$600. Candidates who successfully complete the requirements for certification are responsible to pay a certification maintenance fee. A single payment of \$250 may be paid to cover

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the full five-year period of certification. Alternatively, the fee may be paid in four annual installments of \$75 each, beginning the year after certification. This fee is used to provide services to Certified Geriatric Pharmacists, such as The Credential, a quarterly electronic newsletter, and a listing of Certified Geriatric Pharmacists on the CCGP Web site.

Brief Video - Taking the CCGP Examination

CCGP's test partner, Applied Measurement Professionals, has prepared a video (approximately 5 minutes) that provides an overview of the process of taking a computer-based examination. Note that this video is general in nature and may not specifically reflect CCGP policies and procedures. In addition, the focus of the video is on the experience of candidates in the United States, rather than international candidates. However, candidates may find the video to be helpful in understanding and preparing for the experience of taking a computer-based examination. [The video may be viewed here.](#)

Scoring Process

Score reports are mailed to candidates following the examination. Applicants often have questions about how scores are calculated for the CCGP examination. Scoring for certification examinations is different from scoring for examinations people are used to taking in school. Instead of a fixed passing score, such as 70%, the passing score on a certification examination is determined with statistical adjustment based on the difficulty level of each form of the examination. This ensures fairness to candidates so that a candidate who takes a more difficult version of the examination is not disadvantaged.

A more [detailed explanation of scoring](#) is available.

Related Links

- [Register for the Examination](#)
- [Preparing for the Examination](#)
- [Content Outline for the Examination](#)
- [Download a Candidate Handbook](#)
- [Purchase a Self-Assessment Examination](#)
- [Locate a Test Center](#)
- [Test Your Geriatric IQ](#)
- [Frequently Asked Questions](#)

Promoting Excellence in Geriatric Health Care through Education and Certification

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Detailed Content Outline

I. GENERAL PRINCIPLES OF AGING (38 items, 25%)

A. Biology of Aging (8 items)

1. Recognize the spectrum of aging from healthy aging to frailty.
2. Recognize the physiological heterogeneity of the older adult population.
3. Apply the knowledge of physiologic changes associated with aging to the clinical use of medications.

B. Socioeconomics of Aging (30 items)

1. Social Issues

- a. Evaluate the interrelationship between social issues and aging on healthcare decisions (e.g., family, cultural, community, housing, access to care, policy issues).
- b. Recognize signs of substance and medication misuse/abuse in older adults.
- c. Identify and manage the social issues of medication use for individual patient's therapy.

2. Ethics

- a. Recognize ethical issues that arise during therapy with individuals who have diminished decision making capacity
- b. Facilitate the resolution of ethical dilemmas in the provision of optimal patient-centered care.
- c. Recognize the role of advanced directives and living wills, power of attorney, and other substitute decision-makers documents in medication use decisions.

3. Elder Abuse

- a. Recognize elder abuse/neglect (e.g., physical, psychological, and financial).
- b. Identify resources to assist in prevention, reporting, and treatment of elder abuse/neglect.

4. Economic Issues

- a. Recognize issues related to payer coverage and benefits.
- b. Assist patient with payment issues for medications, medication therapy management services, and medical equipment.
- c. Assess financial/reimbursement issues (e.g., formularies, insurance coverage) when making therapeutic recommendations.

5. Cultural Competencies

- a. Understand cultural competencies (e.g., ethnic/ racial, religion, spiritual, age related, language) relevant to the older adult population.
- b. Describe differences in healthcare beliefs that may exist between older adults and pharmacists.



Effective Date: 01/01/2014

- c. Evaluate potential barriers to and opportunities for cultural competency in older adult care pharmacy practice.
 - d. Apply cultural competency concepts and guidelines to healthcare decisions.
6. Caregiver support
- a. Assess caregiver knowledge and expectations regarding advanced age and disease on health risks, needs, and treatment of health conditions.
 - b. Assist caregivers to identify, access, and use specialized products, professional services, and support groups that can assist with caregiving responsibilities and reduce caregiver burden.
 - c. Discuss resources for older adults and caregivers that help them meet personal goals, maximize function, maintain independence, and live in their preferred and/or least restrictive environment.
 - d. Evaluate the appropriateness of care plans and services based on older adults' and caregivers' changes in age, health status, and function; assist caregivers in altering plans and actions as needed.
7. Communication
- a. Develop verbal and nonverbal communication strategies to overcome potential sensory, language, and cognitive limitations in older adults.
 - b. Interview and counsel older adults with varying degrees of cognitive and communication abilities.
 - c. Provide drug information (verbal and written) to older adults, their caregivers and the interprofessional care team.
 - d. Evaluate adherence and provide strategies for improvement to older adults, their caregivers and the interprofessional care team.
 - e. Collaborate with older adults, their caregivers, and the healthcare team during care planning and implementation.
8. Continuum of Care
- a. Define the continuum of care available to geriatric patients, such as community resources, home care, assisted living facilities, nursing facilities, sub-acute care facilities, hospice care, and hospitals.
 - b. Participate in interprofessional decisions regarding levels of care for individual patients.
 - c. Recognize the need for continuity of treatment and communication across the spectrum of services and during transitions between care settings.
9. End of life care
- a. Recognize philosophies and processes of hospice and palliative care.
 - b. Discuss end of life issues as they relate to medication appropriateness.
 - c. Recognize the altered benefit-risk ratio of medications at the end of life.
 - d. Facilitate shared decision making when evaluating changes in the drug regimen considering patients' values, goals and preferences.



II. GENERAL PRINCIPLES OF CARING FOR OLDER ADULTS (90 items, 60%)

A. Pathophysiology (8 items)

1. Recognize the clinical presentation of diseases common in older adults.
2. Describe the normal progression of common diseases in older adults.
3. Identify atypical presentations of disease that may occur in older adults.
4. Recognize medication-induced diseases and conditions.
5. Differentiate among normal progression, atypical presentation, and medication-induced disease.

B. Geriatric Assessment (13 items)

1. Identify the components of an interprofessional, comprehensive geriatric assessment and the roles individual disciplines play in conducting and interpreting a comprehensive geriatric assessment.
2. Assess the patient's complete medication list, including prescription and over-the-counter medications, and complementary and alternative therapies.
3. Assess the impact of social behaviors, including use of tobacco, caffeine, alcohol, and illicit drugs.
4. Evaluate findings of a comprehensive history and physical exam.
5. Identify potentially inappropriate medications (PIM) for older adults.
6. Identify medications that contribute to geriatric syndromes or conditions (e.g., falls, cognitive impairment).
7. Assess cognition using a valid and reliable tool/instrument.
8. Assess mood using a valid and reliable tool/instrument.
9. Assess behavioral symptoms using a valid and reliable tool/instrument.
10. Assess physical function using a valid and reliable tool/instrument.
11. Assess nutrition using a valid and reliable tool/instrument.
12. Assess pain using a valid and reliable tool/instrument.
13. Recommend laboratory tests for the older adult.
14. Interpret laboratory results for the older adult.
15. Evaluate the pharmacotherapy regimen considering pharmacokinetic and pharmacodynamic changes associated with aging.
16. Develop a list of medication-related problems.
17. Functional Status
 - a. Evaluate the impact of potential functional barriers (e.g., transportation, housing, economics, social support structure) on medication therapies.
 - b. Identify potential medication-related causes of declining physical and cognitive function
 - c. Evaluate impact of alterations in cognition, instrumental activities of daily living (IADLs), and activities of daily living (ADLs) on medication therapy.
 - d. Evaluate self-care capacity, including medication self-administration.



18. Prioritizing Care Needs
 - a. Identify clinical situations where life expectancy, functional status, patient preference or goals of care should override standard recommendations for screening/ treatment.
 - b. Prioritize care needs considering severity of illness, patient preference, quality of life, and time to benefit.
 - c. Recognize need for referral of patients to other healthcare professionals.
19. Transitions of Care
 - a. Identify potential hazards of hospitalization for older adults, including immobility, delirium, medication side effects, malnutrition, pressure ulcers, procedures, and hospital acquired infections.
 - b. Facilitate medication reconciliation during transitions of care.
 - c. Resolve medication discrepancies during transitions of care.

C. Wellness and Health Promotion (8 items)

1. Promote evidence-based approaches for screening, immunizations, health promotion, and disease prevention for older adults.
2. Advocate interventions and behaviors that promote physical and mental health, nutrition, function, safety, social interactions, independence, and quality of life to older adults and their caregivers.
3. Assess specific risks to older adult safety, including falls, abuse, physical/chemical restraints, and other environmental hazards.

D. Treatment (42 items)

1. Define therapeutic goals incorporating patient-specific principles (e.g., age, functionality, patient preference, quality of life).
2. Develop an individualized treatment plan, in collaboration with other caregivers, based on older adult's preferences and goals, and their physical, psychological, social, and spiritual needs.
3. Evaluate clinical situations where standard treatment recommendations, based on best evidence, should be modified with regard to older adults' values, preferences, and treatment/care goals, life expectancy, co-morbid conditions, and/or functional status.
4. Determine therapeutic options based on cost and the risk/benefit to the patient (e.g., no treatment, non-pharmacologic interventions, non-prescription medications, complementary and alternative medicine, prescription medications).
5. Recommend age/patient specific regimen including medication, dose, dosage form, dosing interval, and route of administration.
6. Resolve medication-related problems:
 - a. Untreated or under-treated conditions
 - b. Improper drug selection
 - c. Subtherapeutic or supratherapeutic dosage
 - d. Adherence to medication therapies
 - e. Adverse drug events



- f. Drug interactions
 - g. Drug use without indication
 - h. Treatment failures
7. Develop deprescribing strategies to reduce, replace, or withdraw inappropriate medications.

E. Monitoring (14 items)

- 1. Develop a patient-specific plan for monitoring safety, effectiveness, and quality of life.
- 2. Implement a patient-specific monitoring plan including assignment of responsibility.
- 3. Recommend revisions to therapeutic plans based upon changes in patient status.

F. Education (3 items)

- 1. Develop educational material appropriate for the specific patient/caregiver.
- 2. Educate patient/caregiver regarding expected benefits and potential problems (e.g., side effects of medication, drug interactions) with drug therapy.
- 3. Educate on therapy options (e.g., generics, alternative therapies, non-drug therapies, formulary options).
- 4. Evaluate patient/caregiver understanding of medication use and its role in the overall treatment plan.
- 5. Educate the patient/caregiver in identifying and using adherence strategies and devices.

G. Documentation (2 items)

- 1. Document care plan recommendations using standard techniques and formats (e.g., SOAP notes).
- 2. Document rationale, interventions, and outcomes from medication therapies.
- 3. Provide reports to prescribers or other health professionals with findings and recommendations from medication review.

III. POPULATION SPECIFIC ACTIVITIES (22 items, 15%)

A. Biomedical Information (5 items)

- 1. Assess biomedical information considering study design and methodology, statistical analysis, and significance of reported data and conclusions.
- 2. Evaluate the relevance and limitations of biomedical information for the care of older adults.
- 3. Apply the findings of research to the care of older adults.
- 4. Evaluate the relevancy of clinical practice guidelines and standards of care for older adults.

B. Research (4 items)

- 1. Collect data to investigate medication use in older adults.
- 2. Evaluate data to investigate medication use in older adults.
- 3. Apply outcomes of investigations to optimize care of older adults.
- 4. Disseminate results of research to target audience.



C. Educational Programs (4 items)

1. Identify educational needs for target audiences.
2. Develop educational programs for health care professionals, patients/caregivers, and the public.
3. Implement educational programs for target audiences.
4. Evaluate the outcomes of an educational intervention.

D. Economics and Access (4 items)

1. Assess formulary management protocols for the care of older adults.
2. Develop formulary management protocols for the care of older adults.
3. Conduct a cost-benefit analysis of medication therapy for older adults.
4. Evaluate pharmacoeconomic data for the care of older adults.

E. Patient Safety (5 items)

1. Develop systems for medication reconciliation during transitions of care.
2. Apply systems for medication reconciliation during transitions of care.
3. Develop systems to identify risk factors for Adverse Drug Event (ADE) or medication incidents/ errors.
4. Apply systems to identify risk factors for Adverse Drug Event (ADE) or medication incidents/ errors.
5. Develop systems for prevention of ADE or medication incidents/ errors.
6. Apply systems for prevention of ADE or medication incidents/ errors.
7. Develop protocols for managing high risk medication.
8. Apply protocols for managing high risk medication.
9. Recognize iatrogenic conditions (e.g., healthcare associated infections, falls, pressure ulcers, medication-induced conditions).
10. Develop strategies to prevent or resolve iatrogenic conditions.



Commission for Certification in Geriatric Pharmacy Disease State List

High Priority Conditions

1. Cardiovascular Disorders
 - Cardiac Arrhythmias
 - Coronary Artery Disease
 - Heart Failure
 - Hyperlipidemia
 - Hypertension/ Hypotension
 - Myocardial Infarction
 - Peripheral Vascular Disease
2. Endocrine/Exocrine Disorders
 - Diabetes Mellitus
 - Disorders of the Adrenal Gland
 - Hormone Replacement Therapy
 - Paget's Disease
 - SIADH
 - Thyroid Disorders
3. Hematologic Disorders
 - Anemias
 - Disorders of Hemostasis
 - Thrombocytopenia
 - Thromboembolic disorders
4. Neurological Disorders
 - Acute and Chronic Pain Syndromes
 - Cerebrovascular Disease (e.g. Stroke, Transient Ischemic Attacks)
 - Delirium
 - Dementias
 - Headache
 - Movement Disorders (e.g. Parkinson's Disease, Essential Tremor)
 - Multiple Sclerosis
 - Neuropathies
 - Seizure Disorders
5. Psychiatric Disorders
 - Anxiety Disorders
 - Behavioral Disturbances
 - Depression and Other Mood Disorders
 - Schizophrenia and Other Psychotic Disorders
 - Sleep Disturbances
 - Substance Abuse

Medium Priority Conditions

6. Gastrointestinal Disorders
 - Cholelithiasis
 - Diarrhea and Constipation
 - Gastro-Esophageal Reflux Disease
 - Hepatitis, Cirrhosis
 - Inflammatory Bowel Disease
 - Irritable Bowel Syndrome
 - Nausea and vomiting
 - Pancreatitis
 - Peptic Ulcer Disease
7. Genitourinary/Renal Disorders
 - Acute and Chronic Kidney Disease
 - Benign Prostatic Hyperplasia
 - Sexual Dysfunction
 - Urinary Incontinence/Retention
8. Geriatric Syndromes
 - Dizziness
 - Dysphagia
 - Failure to Thrive
 - Falls
 - Frailty
 - Vision and Hearing Impairment
9. Infectious Diseases
 - Bone and Joint Infections
 - Drug Resistance
 - Gastrointestinal Infections
 - Genitourinary Tract Infection
 - Herpes Zoster
 - HIV/ AIDS
 - Immunizations
 - Influenza
 - Nosocomial Infections
 - Ophthalmic Infections
 - Pneumonia
 - Skin and Soft Tissue Infections
 - Tuberculosis



Effective Date: 01/01/2014

10. Musculoskeletal Disorders

- Acute and Chronic Pain
- Gout
- Osteoarthritis
- Osteoporosis
- Rheumatological Diseases

11. Nutrition/Hydration Disorders

- Dehydration
- Fluid and Electrolyte Disorders
- Malnutrition
- Weight Loss

12. Respiratory Disorders

- Allergic Rhinitis
- Asthma
- Chronic Obstructive Pulmonary Disease

Low Priority Conditions

13. Dermatologic Disorders

- Dermatitis and Pruritus
- Drug Induced Skin Disorders
- Fungal Infections
- Pressure Ulcers
- Xerosis

14. Oncology

- Breast Cancer
- Leukemias
- Prostate Cancer
- Skin Cancer

15. Ophthalmology

- Blepharitis
- Cataracts
- Dry Eyes
- Glaucoma
- Macular Degeneration

The table below shows the approximate percent of examination questions devoted to each therapeutic area:

Category	%
Low	5
Medium	35
High	60

**Certificate or Certification:
Which Option Is Best for Accomplishing Your Goals?**

**Submitted by
Lenora G. Knapp, PhD and Jennifer Naughton, SPHR**

There has been much confusion about the distinctions between certificate and certification programs both among the public and within the credentialing industry itself. The industry has taken a number of steps over the last several years to clarify *what* the distinctions are between these programs (see ICE's *Defining Features of Quality Certification and Assessment-Based Certificate Programs*), but it has not yet published any guidance on *when* to develop one vs. the other. In this article, we provide some answers to this important question.

Why Should You Care?

Certifiers are often asked by stakeholders to create new credentialing programs or they begin to explore the idea on their own, perhaps in the pursuit of additional revenue. Too frequently (and often inadvisably), the default response is to develop another certification program when in fact, a certificate or other type of product or program may be better choice.

Certificate and certification programs have distinctly different purposes and are designed to meet different stakeholder needs, a point emphasized in both of the national standards for certificate programs (*ASTM E2659-09* and *ICE 1100: 2010*) And both standards also distinguish certificates of attendance from other types of certificate programs [see sidebar 1]. (Further information about the standards and accreditation processes for both certificate and certification programs can be found in sidebar 2.)

Create the wrong type of program (certificate or certification) and you will wind up wasting considerable financial and people resources on a program that fails to deliver. Develop the right type of program and you can effectively satisfy stakeholder needs and accomplish your desired outcomes.

What's in a Name?

So, what makes certificate and certification programs different (see Table 1). In short, a certificate program is a learning event, whereas, a certification program provides validation that learning has occurred and typically results in an awarded credential.

Which Option is Best?

Here are some tips which will help you decide which type of program to create.

Certificate programs make sense when one (and probably more) of the following is true:

1. *Ongoing Learning Gaps in Particular Areas* - **There are, on an ongoing basis, a substantial number of individuals with knowledge/skill/performance gaps in a particular area.** Conversely, it likely would not be feasible to develop a certificate program for only a few individuals or to address sporadic or unpredictable knowledge/skill/performance gaps.
2. *High-Impact Job Functions* - **The gap directly affects critical or high-impact job functions, which if performed improperly, can have substantial negative consequences for the learner's employer or recipients of products/services provided by the learner.** For instance, a certificate program might provide technical skills, which if not mastered, could lead to an employer incurring financial losses or could create a safety hazard for customers.
3. *Cohesive Learning Program Is Required* - **A substantive and cohesive program of learning is needed to close the knowledge/skill/performance gap.** That is, a variety of integrated learning experiences covering a broad scope of inter-related knowledge/skills/competencies are required to achieve intended learning outcomes. Certificate programs can provide an organizing framework for the learning process, encouraging the alignment of all the learning components and assessments. A certificate program may not be advisable, if, for example, learners can master required knowledge simply by participating in a 1-hour, online course. That need is probably best addressed through a webinar or other means.
4. *Learning Outcome Evidence Is Valuable* - **Stakeholders desire or require that a rigorous evaluation be conducted to confirm that the intended learning outcomes have been achieved.** By definition, a certificate is not awarded until the learner has accomplished the intended learning outcomes. At a minimum, an assessment would be required to confirm that the instruction/training has provided participants with the desired knowledge and skills. Stakeholders may also require verification that participants can apply the newly acquired knowledge/skills on the job.

Certification programs may be the best option when:

1. *Validating Existing Competencies* - **The primary goal is to confirm that an individual possesses a desired set of knowledge/skills/competencies *previously acquired* through academic or other formal education, internal or external training programs, prior work experience, etc.**
2. *Assuring Baseline Competencies* - **It is beneficial or necessary to ensure that individuals serving in a particular job role possess a uniform, baseline set of knowledge/skills/competencies.** One example would be when the purpose of the certification is to protect the public from physical harm by an unqualified healthcare provider and thus, it is necessary to confirm that practitioners are minimally competent. In other situations, ensuring that individuals possess baseline competencies may provide employers with some assurance that they will be able to "hit the ground running." Also, if mastery of the baseline knowledge/skills/competencies is confirmed through

certification, then future training need not include these basics, but rather can focus on what is unique to the industry or the employing organization (e.g., products, services, processes), and in so doing, resources will be used more efficiently.

3. ***Assessment Is Desirable*** - The process through which individuals acquire critical knowledge/skills/competencies does not include a rigorous or uniform/standardized assessment to validate that skills acquisition has occurred AND such confirmation is desired or required by key stakeholders. For example, it may be that on-the-job experience is the primary means of mastering a particular set of skills and employers require that individuals demonstrate their ability before they are assigned to perform a particular function which relies on these skills. Or, it could be that there are disparate training programs which aid individuals in acquiring required knowledge/skills and stakeholders (e.g., employers, regulators) want a uniform yardstick by which to judge the effectiveness of these programs and to verify that the knowledge, skills, or competencies have been acquired.
4. ***Independent Validation Equals Credibility*** - Recognition of an individual's knowledge/skills/competencies through a certification process would enhance credibility and this benefit is of particular value to the recipient of the certification or his/her employer.

When is a Certificate of Attendance or Participation the Best Choice?

Note also that there are certain situations where a program awarding a certificate of attendance or participation may be a better solution than either a certificate or certification program. This may be the case when:

- There are a small number of potential participants and/or one cannot count on having a sufficient number of participants on a routine basis to make a certificate or certification program feasible.
- The scope of the knowledge/skills/competencies to be addressed is very narrow.
- The knowledge/skills/competencies do not directly affect critical or high-impact job functions.
- A rigorous assessment to confirm that participants have accomplished the intended learning outcomes is not required or not feasible (perhaps due to low volumes).

There is a sea of confusion out there. We hope we have provided you with some tools that can help you to navigate through muddy waters.

The authors welcome feedback on this article.

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This article was adapted from one originally published by the co-authors in the American Society for Training & Development's T+D Magazine.

Table 1 Distinctions Between Certificate and Certification Programs

Characteristic	Certificate	Certification
Primary purpose	Provide instruction/training to aid in the acquisition of knowledge/skills/competencies (learning through instruction)	Assess knowledge/skills/competencies that have already been acquired (validation through testing)
Eligibility	Occasionally has eligibility or prerequisite requirements to enroll	Has eligibility requirements to enroll
Purpose and scope of assessment	Evaluate accomplishment of intended learning outcomes of a specific education/training program	Confirm mastery of the knowledge/skills/competencies required to effectively perform a job function or occupational/professional role
Duration of program	Ends when certificate is awarded	Ongoing; requirements must be met on a routine basis to maintain credential (recertification)
Recognition of program completion	No acronym or letters are used after the recipient's name to reference the certificate OR the letters "CH" (for "Certificate Holder") precede the acronym/letters	Recipient uses an acronym or letters after his/her name to highlight certified status

[SIDEBAR 1] Certificates of Attendance/Participation vs. Certificate Programs

ASTM E2659-09 and *ICE 1100: 2010* distinguish “certificates of attendance” and “certificates of participation” from “certificate programs.” The former signify that the participant was present for the learning program or event, but do **not** indicate that the intended learning outcomes have been accomplished by the participant, as there is no assessment process to verify this. By contrast, in a certificate program, the certificate is awarded only after it has been confirmed, through an assessment process, that the learner has indeed accomplished the intended learning outcomes.

[SIDEBAR 2] National Standards and Accreditations for Certificate and Certification Programs

Certificate Programs

ASTM E2659 – 09, Standard Practice for Certificate Programs was developed by ASTM International, a voluntary standards development organization. The American National Standards Institute currently offers an accreditation process based on this standard.

ICE 1100: 2010 (E) – Standard for Assessment-Based Certificate Programs was created by the Institute for Credentialing Excellence (ICE), an organization dedicated to setting quality standards for credentialing organizations. ICE is currently finalizing an accreditation process based on this standard.

Both *ASTM E2659-09* and *ICE 1100: 2010* have undergone a rigorous review and approval process and have been recognized by the American National Standards Institute as American National Standards.

Certification Programs

The *Standards for the Accreditation of Certification Programs* (commonly referred to as the *NCCA Standards*) are published by the National Commission for Certifying Agencies (NCCA), the independent, accrediting arm of ICE. NCCA also administers a process for accrediting programs based on the standards.

ISO/IEC 17024 Conformity assessment – General requirements for bodies operating certification of persons was developed by the International Organization for Standardization and the International Electrotechnical Commission. Accrediting bodies in several countries offer accreditation services based on the standard.

**Example: Information about the Board of
Pharmaceutical Specialties Ambulatory Care
Pharmacist Certification Program**

CERTIFICATION PROGRAMS FOR PHARMACISTS

PHARMACIST-ONLY CERTIFICATIONS

AMBULATORY CARE PHARMACY		
1. Name of credential(s): Board Certified Ambulatory Care Pharmacist (BCACP)		
2. Responsible Organization: Board of Pharmacy Specialties (BPS)	Address:	Board of Pharmacy Specialties 2215 Constitution Avenue, NW Washington, DC 20037
	Telephone:	202-429-7591
	Fax:	202-429-6304
	E-mail:	info@bpsweb.org
	Web site:	www.bpsweb.org
3. Certification Body Accredited? Yes	By what organization? The National Commission for Certifying Agencies (NCCA) -but ambulatory care credential is ineligible for coverage until 2012	
4. Disciplines certified (in addition to pharmacists): None		
5. Eligibility criteria for pharmacists: <ul style="list-style-type: none"> • Graduation from a pharmacy degree program accredited by the Accreditation Council for Pharmacy Education (ACPE) or a program outside the U.S. that qualifies the individual to practice in the jurisdiction. • Current, active license to practice pharmacy in the U.S. or another jurisdiction. • Achieving a passing score on the Ambulatory Care Specialty Certification Examination • Completion of four (4) years of practice experience with at least 50% of time spent in ambulatory care activities (as defined by the BPS Ambulatory Care Pharmacy Content Outline) <p style="text-align: center;">OR</p> <p>Completion of a PGY2 Ambulatory Care Pharmacy residency. (Effective January 1, 2013, only residencies accredited by the American Society of Health-System Pharmacists or other recognized bodies are creditable for this purpose.)</p> <p style="text-align: center;">OR</p> <p>Completion of a PGY1 residency. (Effective January 1, 2013, only residencies accredited by the American Society of Health-System Pharmacists or other recognized bodies are creditable for this purpose); plus one (1) year of practice experience with at least 50% of time spent in ambulatory care activities (as defined by the BPS Ambulatory Care Pharmacy Content Outline).</p>		
6. Duration of initial certification: 7 years		

The list of certification programs open to pharmacists was compiled by the Council on Credentialing in Pharmacy in July 2012 from publicly available information. It is not necessarily an exhaustive list, as programs and their contact information change frequently.

CERTIFICATION PROGRAMS FOR PHARMACISTS

7. Recertification requirements:

A current, active license to practice pharmacy is required for recertification. In addition, recertification for Board Certified Ambulatory Care Pharmacists (BCACP) is an assessment of a practitioner's knowledge and skills through one of two methods:

- Achieving a passing score on the 100-item, multiple-choice objective recertification examination, based on the content outline of the certification examination in their 7th year following initial certification

OR

Earning approved continuing education credit provided by a professional development program approved by BPS (details unavailable at this time). Earning 100 hours of continuing education credit provided by the professional development programs offered by American College of Clinical Pharmacy (ACCP) and/or the joint program offered by the American Society of Health-System Pharmacists (ASHP) and the American Pharmacists Association (APhA). No more than 50 hours will be accepted by BPS during the first 3 years of the certification cycle.

- Further, Ambulatory Care Pharmacy Preparatory Review and Recertification Courses offered by either of the approved providers may only be completed for recertification up to two times, in nonconsecutive years, during the 7-year recertification cycle.
- All candidates for recertification must have a current active license to practice pharmacy

8. Examination specifics:

- **Paper & Pencil or computer-based:**

Paper and pencil

- **Number of questions:**

200

- **Question format:**

The multiple-choice format is used exclusively. Four possible answers are provided for each question, with only ONE designated as the correct or best choice. It is to the candidate's advantage to answer every question on the examination, since the final score is based on the total number of questions answered correctly. There is no penalty for selecting an incorrect choice.

- **Cost:**

- Certification Application Fee=\$600
- Recertification Application Fee=\$400
- Certification Retake Fee (Within 2 Years)=\$300
- Recertification Retake Fee (Within 1 Year)=\$200
- Annual Fee for All BPS-Certified Pharmacists=\$100 (not required for the year of recertification)

- **Frequency of exam:**

Once yearly. BPS will establish test sites in approximately 77 cities worldwide for administration of its specialty certification examinations. Alternate sites could be identified and requested as per the guidelines in <http://www.bpsweb.org/apply/altersiterequest.cfm>

- **Exam Pass Rate:**

Undetermined. First administration scheduled for 2011.

The list of certification programs open to pharmacists was compiled by the Council on Credentialing in Pharmacy in July 2012 from publicly available information. It is not necessarily an exhaustive list, as programs and their contact information change frequently.

CERTIFICATION PROGRAMS FOR PHARMACISTS

<p>9. Certification associated with specific training programs? No</p>	<p>Offered by whom? N/A</p>
<p>10. Certification exam prep courses/materials available? Yes</p>	<p>Offered by whom? BPS does NOT provide review information, preparatory courses, or study guides. However, such materials are available from outside organizations, state or local professional associations and colleges of pharmacy. The American College of Clinical Pharmacy, American Pharmacists Association, and the American Society of Health-system Pharmacists plan to provide resources to aid in test preparation. Suggested preparation: Could include residency or other formal training; study of journal articles, textbooks, or other publications related to the content outline; continuing education programs and courses in specialized pharmacy practice; study groups and examination preparation courses (see above); and reviewing sample test questions on the BPS website.</p>
<p>11. Other Pertinent Information:</p> <ul style="list-style-type: none"> • BPS is an autonomous division of the American Pharmacists Association (APhA) organized in 1976 as an independent certification agency of APhA. • Each specialty exam has a separate Content Outline (available online) validated through a national survey of pharmacist specialists. • Content Outlines provide details on major areas of responsibility for a specialist, the tasks required to fulfill these responsibilities, and the knowledge that underlies the performance of these tasks. • Each exam question is linked to a specific domain, task, and knowledge statement. • BPS utilizes the psychometric and exam administration services of Professional Examination Service of New York City in administration of its specialty certification programs. 	

The list of certification programs open to pharmacists was compiled by the Council on Credentialing in Pharmacy in July 2012 from publicly available information. It is not necessarily an exhaustive list, as programs and their contact information change frequently.

**Appendix C: Credentialing Programs for
Pharmacists, which displays the pharmacy
programs approved by NCCA**

Appendix C: Credentialing Programs for Pharmacists

CERTIFICATION PROGRAMS AVAILABLE TO PHARMACISTS^{1,2}

Program	Certification Body	Credential Earned	Certification Body Accredited By
Ambulatory Care Pharmacy	Board of Pharmacy Specialties (BPS)	Board Certified Ambulatory Care Pharmacist (BCACS) ^{3,4}	National Commission for Certifying Agencies (NCCA)
Anticoagulation Care	National Certification Board for Anticoagulation Providers (NCBAP)	Certified Anticoagulation Care Provider (CACP)	
Asthma Education	National Asthma Educator Certification Board (NAECB)	Certified Asthma Educator (AE-C)	
Cardiology (Pharmacotherapy Added Qualifications)	Board of Pharmacy Specialties (BPS)	Board Certified Pharmacotherapy Specialist (BCPS) with Added Qualifications in Cardiology ³	National Commission for Certifying Agencies (NCCA)
Cardiovascular/Life Support	American Heart Association	Advanced Cardiovascular Life Support (ACLS)	
	American Heart Association	Pediatric Advanced Life Support (PALS)	
Clinical Pharmacology	American Board of Clinical Pharmacology (ABCP)	Accredited in Applied Pharmacology (AP)	
Diabetes Education	National Certification Board for Diabetes Educators (NCBDE)	Certified Diabetes Educator (CDE)	
Diabetes Management - Advanced	American Nurses Credentialing Center (ANCC)	Board Certified-Advanced Diabetes Management (BC-ADM)	
Geriatric Pharmacy	Commission for Certification in Geriatric Pharmacy (CCGP)	Certified Geriatric Pharmacist (CGP) ⁵	
Health Information Technology	Health IT Certification	Certified Professional in Electronic Health Records (CPEHR)	
	Health IT Certification	Certified Professional in Health Information Technology (CPHIT)	
	Health IT Certification	Certified Professional in Health Information Exchange (CPHIE)	
HIV/AIDS	American Academy of HIV Medicine (AAHIVM)	HIV Expert (AAHIVE) ⁵	
	American Academy of HIV Medicine (AAHIVM)	HIV Specialist (AAHIVS) ⁵	
Infectious Diseases (Pharmacotherapy Added Qualifications)	Board of Pharmacy Specialties (BPS)	Board Certified Pharmacotherapy Specialist (BCPS) with Added Qualifications in Infectious Diseases ³	National Commission for Certifying Agencies (NCCA)
Lipids	Accreditation Council for Clinical Lipidology	Clinical Lipid Specialist (CLS)	
Nuclear Pharmacy	Board of Pharmacy Specialties (BPS)	Board Certified Nuclear Pharmacist (BCNP) ³	National Commission for Certifying Agencies (NCCA)
Nutrition Support Pharmacy	Board of Pharmacy Specialties (BPS)	Board Certified Nutrition Support Pharmacist (BCNSP) ³	National Commission for Certifying Agencies (NCCA)
Nutrition Support	National Board of Nutrition Support Certification (NBNSC)	Certified Nutrition Support Clinician (CNSC)	
Oncology Pharmacy	Board of Pharmacy Specialties (BPS)	Board Certified Oncology Pharmacist (BCOP) ³	National Commission for Certifying Agencies (NCCA)
Pain Education	American Society of Pain Educators (ASPE)	Certified Pain Educator (CPE)	
Pain Management	American Academy of Pain Management (AAPM)	Credentialed Pain Practitioner (CPP)	
Pharmacotherapy	Board of Pharmacy Specialties (BPS)	Board Certified Pharmacotherapy Specialist (BCPS) ³	National Commission for Certifying Agencies (NCCA)
Poison Information	American Association of Poison Control Centers	Certified Specialist in Poison Information (CSPI)	
Psychiatric Pharmacy	Board of Pharmacy Specialties (BPS)	Board Certified Psychiatric Pharmacist (BCPP) ³	National Commission for Certifying Agencies (NCCA)
Toxicology	American Board of Applied Toxicology (ABAT)	Diplomat of the American Board of Applied Toxicology (DABAT)	

Notes:

1. Inclusion of a certification program in the above table does not necessarily indicate endorsement of the credential by CCP
2. CCP believes that information is correct at time of publication; all information should, however, be confirmed with the applicable certification body
3. Pharmacist-only certification
4. Under development; anticipated first administration 2011; certification is ineligible for NCCA coverage until 2012
5. Pilot program 2008-2010

NCCA-Accredited Certification Programs

You may search this directory by partial or full organization, or by industry category. Multiple industries may be selected by holding down the <ctrl> key.

If you do not select any search criteria, all organizations will be returned in the results. Also, some organizations who may not have completed their entire profiles may not show up in acronym or industry searches, so you may search again using a partial or full organization name. Please be sure to use the most current version of your preferred browser for faster loading.

Disclaimer:

Every effort has been made to compile complete and accurate information for this directory. If you believe that there has been an error or omission, please contact ICE staff. The information contained herein lists individual certification programs that have been accredited by the NCCA but should not be construed as an endorsement of the entire organization, company, or individuals. This information is provided for your convenience and may not be used to populate a marketing database or in a direct marketing campaign.

Search For:

Industry:

- Administration/Management
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- Arts
- Construction
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- Education

Organization Name:

Organization Acronym:

Accredited Program or Acronym:

Organization Name	Industry	NCCA Accredited Programs
Association of Clinical Research Professionals (ACRP)	Healthcare: Nursing Healthcare: Pharmacy Healthcare: Other	Clinical Research Associate (CCRA), Accredited through 4/30/2015 Clinical Research Coordinator (CCRC), Accredited through 4/30/2015 Certified Physician Investigator (CPI), Accredited through 9/30/2017
Board of Pharmacy Specialties (BPS)	Healthcare: Pharmacy	Board Certified Nuclear Pharmacist (BCNP), Accredited through 11/30/2018 Board Certified Nutrition Support Pharmacist (BCNSP), Accredited through 11/30/2018 Board Certified Oncology Pharmacist (BCOP), Accredited through 11/30/2018 Board Certified Pharmacotherapy Specialist (BCPS), Accredited through 11/30/2018 Board Certified Psychiatric Pharmacist (BCPP), Accredited through 11/30/2018 Board Certified Ambulatory Care Pharmacist (BCACP), Accredited through 11/30/2018
Commission for Certification in Geriatric Pharmacy (CCGP)	Healthcare: Pharmacy	Certification in Geriatric Pharmacy (CGP), Accredited through 1/31/2017
Pharmacy Technician Certification Board (PTCB)	Healthcare: Pharmacy	Certified Pharmacy Technician (CPhT), Accredited through 11/30/2016



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Attachment 3

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 properly and 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 for a period of at least three years from the date when the last self-administered hormonal contraception product was furnished.

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 review any questions the patient may have regarding self-administered hormonal contraception.

Pharmacists are encouraged to provide the patient with a copy of the current consumer-friendly birth control guide, and method-specific factsheet from the Association of Reproductive Professionals, all available on the Board of Pharmacy's website.

(7) Follow-Up Care: Upon furnishing a self-administered hormonal contraceptive, or if it 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 contraceptive 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 a physician of the patient's choice.

(9) Referrals and Supplies: If self-administered hormonal contraception services are not immediately available at the pharmacy or the pharmacist declines to furnish pursuant to conscience clause, the pharmacist shall refer the patient to another self-administered hormonal contraception provider. The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.

(10) Product Selection: The pharmacist may select any hormonal contraceptive listed in the current version of the USMEC 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. Furthermore, 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 for a period of at least three years from the date when the last self-administered hormonal contraceptive was furnished. 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'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 2010 in a 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 shall operate under the pharmacy'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 <input type="checkbox"/>	No <input type="checkbox"/>
	Did you ever experience a bad reaction to using hormonal birth control?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	Are you currently using birth control pills, or a birth control patch, ring, or shot/injection?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
3	Have you ever been told by a medical professional not to take hormones?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
4	Do you smoke cigarettes?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
5	Do you think you might be pregnant now?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
6	Have you given birth within the past 6 weeks?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
7	Are you currently breastfeeding an infant who is less than 1 month of age?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
8	Do you have diabetes?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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 <input type="checkbox"/>	No <input type="checkbox"/>
10	Do you have high blood pressure, hypertension, or high cholesterol?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
11	Have you ever had a heart attack or stroke, or been told you had any heart disease?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
12	Have you ever had a blood clot in your leg or in your lung?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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 <input type="checkbox"/>	No <input type="checkbox"/>
14	Have you had bariatric surgery or stomach reduction surgery?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
15	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
16	Do you have or have you ever had breast cancer?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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 <input type="checkbox"/>	No <input type="checkbox"/>
18	Do you have lupus, rheumatoid arthritis, or any blood disorders?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
19	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	If yes, list them here:		
20	Do you have any other medical problems or take regular medication?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	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>.

This document from the CDC offers guidance on how to use contraceptive methods most effectively. It is adapted from a World Health Organization (WHO) publication, and endorsed by the American College of Obstetricians and Gynecologists (ACOG).

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.

December 16, 2014

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 Depot 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).

This research concludes that reading the leaflet did not greatly affect adherence but aroused anxiety and decreased adherence in some patients.

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.

Most Effective



Least Effective

Methods	Number of pregnancies expected per 100 women*	Use	Some Risks
Sterilization Surgery for Women	less than 1	Onetime procedure Permanent	<ul style="list-style-type: none"> Pain Bleeding Infection or other complications after surgery Ectopic (tubal) pregnancy
Surgical Sterilization Implant for Women	less than 1	Onetime procedure Waiting period before it works Permanent	<ul style="list-style-type: none"> Mild to moderate pain after insertion Ectopic (tubal) pregnancy
Sterilization Surgery for Men	less than 1	Onetime procedure Waiting period before it works Permanent	<ul style="list-style-type: none"> Pain Bleeding Infection
Implantable Rod	less than 1	Inserted by a healthcare provider Lasts up to 3 years	<ul style="list-style-type: none"> Changes in bleeding patterns Weight gain Breast and abdominal pain
IUD Copper	less than 1	Inserted by a healthcare provider Lasts up to 10 years	<ul style="list-style-type: none"> Cramps Bleeding Pelvic inflammatory disease Infertility Tear or hole in the uterus
IUD w/ Progestin	less than 1	Inserted by a healthcare provider Lasts up to 3-5 years, depending on the type	<ul style="list-style-type: none"> Irregular bleeding No periods Abdominal/pelvic pain Ovarian cysts
Shot/Injection	6	Need a shot every 3 months	<ul style="list-style-type: none"> Bone loss Bleeding between periods Weight gain Nervousness Abdominal discomfort Headaches
Oral Contraceptives (Combined Pill) "The Pill"	9	Must swallow a pill every day	<ul style="list-style-type: none"> Nausea Breast Tenderness Headache Rare: high blood pressure, blood clots, heart attack, stroke
Oral Contraceptives (Progestin only) "The MiniPill"	9	Must swallow a pill every day	<ul style="list-style-type: none"> Irregular bleeding Headache Breast tenderness Nausea Dizziness
Oral Contraceptives Extended/Continuous Use "The Pill"	9	Must swallow a pill every day.	<ul style="list-style-type: none"> Risks are similar to other oral contraceptives (combined) Light bleeding or spotting between periods
Patch	9	Put on a new patch each week for 3 weeks (21 total days). Don't put on a patch during the fourth week.	<ul style="list-style-type: none"> Exposure to higher average levels of estrogen than most oral contraceptives
Vaginal Contraceptive Ring	9	Put the ring into the vagina yourself. Keep the ring in your vagina for 3 weeks and then take it out for one week.	<ul style="list-style-type: none"> Vaginal discharge Discomfort in the vagina Mild irritation Risks are similar to oral contraceptives (combined)
Diaphragm with Spermicide	12	Must use every time you have sex.	<ul style="list-style-type: none"> Irritation Allergic reactions Urinary tract infection Toxic shock
Sponge with Spermicide	12-24	Must use every time you have sex.	<ul style="list-style-type: none"> Irritation Allergic reactions Hard time removing Toxic shock
Cervical Cap with Spermicide	17-23	Must use every time you have sex.	<ul style="list-style-type: none"> Irritation Allergic reactions Abnormal Pap test Toxic shock
Male Condom	18	Must use every time you have sex. <i>Except for abstinence, latex condoms are the best protection against HIV/AIDS and other STIs.</i>	<ul style="list-style-type: none"> Allergic reactions
Female Condom	21	Must use every time you have sex. <i>May give some protection against STIs.</i>	<ul style="list-style-type: none"> Irritation Allergic reactions
Spermicide Alone	28	Must use every time you have sex.	<ul style="list-style-type: none"> Irritation Allergic reactions Urinary tract infection
Emergency Contraception — If your primary method of birth control fails			
Plan B Plan B One Step Next Choice	7 out of every 8 women who would have gotten pregnant will not become pregnant after taking Plan B, Plan B One-Step, or Next Choice	Swallow the pills within 3 days after having unprotected sex.	<ul style="list-style-type: none"> Nausea Vomiting Abdominal pain Fatigue Headache
Ella	6 or 7 out of every 10 women who would have gotten pregnant will not become pregnant after taking Ella.	Swallow the pill within 5 days after having unprotected sex.	<ul style="list-style-type: none"> Headache Nausea Abdominal pain Menstrual pain Tiredness Dizziness

*effectiveness of the different methods during typical/actual use (including sometimes using a method in a way that is not correct or not consistent) <http://www.fda.gov/birthcontrol>

¿Qué es el parche anticonceptivo?

El parche anticonceptivo es un parche hormonal semanal muy efectivo que se pone sobre la piel para prevenir el embarazo. El parche se usa por una semana y se cambia siempre el mismo día cada semana durante tres semanas. La cuarta semana esta "libre de parche".

¿Que tan efectivo es el parche anticonceptivo?

El parche anticonceptivo es 99 por ciento efectivo cuando se usa correctamente.

¿Cómo previene el embarazo el parche anticonceptivo?

El parche anticonceptivo previene el embarazo de la misma forma que las píldoras anticonceptivas. Funciona principalmente previniendo la ovulación, o que el ovario no libera un óvulo que pueda ser fertilizado. El parche también causa cambios en el moco cervical (haciendo más difícil para que el espermatozoide entre en el útero).

¿Dónde puedo usar el parche anticonceptivo?

Usted puede usar el parche en una de las siguientes cuatro áreas de su cuerpo: las nalgas o caderas, el abdomen, la parte superior del tronco (pecho y espalda, excluyendo los senos o pechos) o en la parte superior externa del brazo. Usted no debería colocar el parche sobre piel que esté roja, irritada o tenga alguna cortada. No debería colocarlo en áreas de su cuerpo donde se vaya a aplicar maquillaje, lociones, cremas, polvos u otros productos.

¿Como se mantiene pegado el parche?

El parche anticonceptivo tiene una capa que contiene tanto la medicina como un adhesivo que mantiene el parche pegado a la piel durante una semana entera.

¿Cuáles son los beneficios de usar el parche anticonceptivo?

Mujeres que usan el parche anticonceptivo pueden beneficiarse en tener un periodo mas liviano y menos doloroso. El parche anticonceptivo puede proteger contra algunos cánceres y enfermedades de los senos.

¿Quien no debe de usar el parche anticonceptivo?

Algunas mujeres no deben de usar el parche anticonceptivo, incluyendo mujeres que tengan coágulos de sangre, ciertos cánceres, o que tengan antecedentes de ataques del corazón o de cerebro, y aquellas mujeres que podrían estar embarazadas.

¿Cuáles son las desventajas?

Algunas mujeres usando el parche anticonceptivo pueden sentir leves dolores en los senos, dolor de cabeza, y reacciones dermatológicas en el lugar donde ha colocado el parche. La mayoría de efectos secundarios no son serios, y los que son, no son muy comunes. La prevención de un embarazo no planeado con anticonceptivos aprobados

por el FDA es mas sano que un parto or el aborto. Fumar cigaros aumenta los riesgos seriamente.

Algunas drogas pueden hacer los anticonceptivos hormonales, incluyendo el parche anticonceptivo, menos efectivos. Al igual que con cualquier otro producto pharmaceutico, usted debe informar su proveedor o proveedora de la salud de cualquier otro medicamento que usted este tomando. Es posible que usted tenga que usar un anticonceptivo adicional como el condón, espermicida, o diafragma si usted toma medicamentos que pueden reducir la efectividad del parch anticonceptivo.

¿Dónde puedo conseguir el parch anticonceptivo?

Un proveedor or proveedora de servicios de salud (doctor o doctora, enfermera o asistente médico) te puede dar una receta para el parche anticonceptivo.

What is the contraceptive patch?

The contraceptive patch is a highly effective, weekly hormonal birth control patch that is worn on the skin to prevent pregnancy. The patch is worn for one week and replaced on the same day of the week for three consecutive weeks, with the fourth week “patch-free.” Your menstrual period should start during the “patch-free” week. The contraceptive patch available in the United States is called OrthoEvra®.

How effective is contraceptive patch?

The contraceptive patch is 99 percent effective when used correctly.

How does it work?

The contraceptive patch prevents pregnancy the same way that birth control pills do. It works primarily by preventing the ovary from releasing an egg to be fertilized. The patch also causes changes to the cervical mucus (making it more difficult for sperm to enter the uterus).

The contraceptive patch keeps you from becoming pregnant by delivering hormones (norelgestromin and ethinyl estradiol) through the skin and into the bloodstream. This is called transdermal administration.

Where can I wear the contraceptive patch?

You can wear the contraceptive patch on one of four areas of the body: your buttocks, abdomen, upper torso (front and back, excluding the breasts), or upper outer arm. The patch should not be worn on any other areas of the body. You should not place the patch on skin that is red, irritated, or cut. You should not place it on areas of your skin where makeup, lotions, creams, powders, or other products are or will be applied.

How does the patch stay on?

The contraceptive patch has a layer containing both the medication and an adhesive that keeps the patch on the skin for an entire week. The patch adheres well to the skin, allowing you to perform your daily activities such as bathing, showering, swimming, and exercising without interruption.

What are the benefits of using the contraceptive patch?

Women who use the contraceptive patch are likely to have lighter and less painful periods. The contraceptive patch may protect against some cancers and breast disease.

Who should not use the contraceptive patch?

Some women should not use the contraceptive patch, including women who have blood clots, certain cancers, or a history of heart attack or stroke, as well as those who are or may be pregnant.

What are the downsides?

Some women using the contraceptive patch experience breast tenderness, headache, and reactions at the application. Most side effects are not serious, and those that are, are very rare. Prevention of an unintended pregnancy with FDA-approved contraceptives is always safer than childbirth or abortion. Serious risks are increased if you smoke cigarettes.

Certain drugs may interact with hormonal birth control, including the contraceptive patch, to make them less effective in preventing pregnancy. As with all prescription products, you should tell your health care professional about any other medications you are taking. You may need to use a non-hormonal backup contraceptive, such as a condom, spermicide, or diaphragm, when you take drugs that can make the contraceptive patch less effective.

Where can I get the contraceptive patch?

A trained health care professional (including doctors, nurses, and nurse midwives) can provide you with the contraceptive patch.

ASUNTOS DE SALUD

Las píldoras anticonceptivas

¿Qué son las píldoras anticonceptivas?

Las píldoras anticonceptivas son una medicina que tomas todos los días para prevenir el embarazo. A veces se les llama “la píldora” o anticonceptivos orales. La mayoría de mujeres que usan la píldora toman “píldoras combinadas”. Estas contienen dos hormonas —estrógeno y progestina—.

Alguna píldoras anticonceptivas contienen solo una hormona, la progestina. Estas son llamadas a veces “mini píldoras”. Las píldoras solo de progestina son buenas para las mujeres que no pueden usar el estrógeno.

¿Qué tan efectivas son las píldoras anticonceptivas?

Si las píldoras anticonceptivas se usan correctamente siempre, menos de 1 de cada 100 mujeres que las usen quedará embarazada cada año. Si no siempre se usan correctamente, 8 de cada 100 mujeres que las usen quedarán embarazadas cada año.

Las píldoras anticonceptivas funcionan mejor si las tomas a la misma hora todos los días. Puedes encontrar que te ayude tomar la píldora cuando hagas algo más cada día —como cepillarte los dientes o cenar—. Esto es muy importante con la píldora solo de progestina.

Cuando comiences a tomar la píldora, esta puede tomar varios días para comenzar a funcionar. Asegúrate de usar un anticonceptivo de respaldo (como un condón) durante los primeros 7 días de la píldora combinada o 2 días de la píldora solo de progestina.

¿Cómo funcionan?

Las hormonas en la píldora impiden que tus ovarios liberen óvulos y espesan tu moco cervical para impedir que el esperma entre al útero.

¿Cuáles son los beneficios del uso de las píldoras anticonceptivas?

- Las píldoras anticonceptiva son seguras, convenientes y muy efectivas.
- No tienes que pensar en el control de la natalidad cada vez que tengas relaciones sexuales.
- La mayoría de mujeres pueden quedar embarazadas rápidamente cuando dejan de usar la píldora.
- Tus menstruaciones puede hacerse más ligeras y menos dolorosas si tomas la píldora.
- Las hormonas en las píldoras ofrecen beneficios a la salud. La píldora puede ofrecer cierta protección contra el acné, los tumores no cancerosos del pecho, el embarazo ectópico, los cánceres endometrial y ovárico, la anemia por deficiencia de hierro, los quistes en los ovarios, la enfermedad inflamatoria pélvica, los síntomas del síndrome premenstrual y las migrañas relacionadas con la menstruación.

¿Cuáles son los aspectos negativos del uso de las píldoras anticonceptivas?

- Las píldoras anticonceptivas no protegen contra las infecciones de transmisión sexual (ITS).

- Necesitas una receta para obtener las píldoras anticonceptivas. Esto requiere una visita a tu proveedor de atención a la salud.
- Algunas mujeres pueden tener efectos secundarios al uso de las píldoras anticonceptivas. Estos incluyen sangrado entre las menstruaciones, sensibilidad en los pechos y náusea. Algunos de los efectos más comunes solo duran los primeros meses.
- Es fácil olvidarse de tomar la píldora todos los días. Podrías necesitar usar anticoncepción de respaldo o tomar anticoncepción de emergencia si te olvidas de tomar una píldora o la tomas tarde. Asegúrate de hablar con tu proveedor de atención a la salud si te olvidas de tomar alguna píldora.
- Mujeres con ciertas condiciones de salud no deberían usar píldoras combinadas. Tu proveedor de atención a la salud te ayudará a decidir si la píldora es apropiada para ti.

¿Dónde puedo obtener las píldoras anticonceptivas?

Un proveedor de atención a la salud puede darte una receta para las píldoras anticonceptivas. Las puedes comprar con una receta en una farmacia, un centro de salud o una clínica.

¿Dónde puedo obtener más información?

Para mayor información sobre las píldoras anticonceptivas, habla con tu proveedor de atención a la salud.

Compara las píldoras anticonceptivas con otras opciones anticonceptivas y ve un corto video sobre cada método, en inglés o en español, en Method Match de ARHP (www.arhp.org/MethodMatch).

What are birth control pills?

Birth control pills are a medication you take every day to prevent pregnancy. They are sometimes called “the pill” or oral contraception. Most women using the pill take “combination pills.” These contain two hormones - estrogen and progestin.

Some birth control pills contain only one hormone - progestin. These are sometimes called “mini-pills”. Progestin-only pills are good for women who cannot use estrogen.

How effective are birth control pills?

If birth control pills are always used correctly, less than 1 out of 100 women using them will get pregnant each year. If they are not always used correctly, 8 out of 100 women using them will get pregnant each year.

Birth control pills work best if you take them at the same time every day. You might find it helpful to take the pill when you do something else every day — like brushing your teeth or eating dinner. This is very important with the progestin-only pill.

When you first start the pill, it takes several days to begin working. Be sure to use backup birth control (like a condom) for the first 7 days on the combination pill or 2 days with the progestin-only pill.

How do they work?

The hormones in the pill keep your ovaries from releasing eggs and thicken your cervical mucus to block sperm from getting into the uterus.

What are the benefits of using birth control pills?

- Birth control pills are safe, convenient, and very effective.
- You don't have to think about birth control each time you have sex.
- Most women can get pregnant quickly when they stop using the pill.
- Your periods may become lighter and less painful if you take the pill.
- The hormones in pills offer health benefits. The pill can offer some protection against acne, non-cancerous breast growths, ectopic pregnancy, endometrial and ovarian cancers, iron deficiency anemia, ovarian cysts, pelvic inflammatory disease, PMS symptoms, and menstrually-related migraine headaches.

What are the downsides of using birth control pills?

- Birth control pills do not protect against sexually transmitted infections (STIs).
- You need a prescription to get birth control pills. This requires a visit to a health care provider.
- Some women may have side effects while using birth control pills. They include bleeding between periods, breast tenderness, and nausea. Some of the most common side effects only last for the first few months.

- It is easy to forget to take the pill every day. You may need to use backup birth control or take emergency contraception if you miss a pill or take it late. Make sure to talk with your health care provider if you miss any pills.
- Women with certain health conditions should not use combination pills. Your healthcare provider will help you decide if the pill is right for you.

Where can I get birth control pills?

A health care provider can give you a prescription for birth control pills. You can purchase birth control pills at a drugstore, health center, or clinic with a prescription.

Where can I get more information?

For more information on the birth control pill, talk to your health care provider.

Compare the pill to other birth control options using ARHP's Method Match at www.arhp.org/MethodMatch.

ASUNTOS DE SALUD

La inyección anticonceptiva

www.arhp.org/healthmatters

¿Qué es la inyección?

La inyección anticonceptiva es una inyección de una hormona llamada progestina. Cada inyección previene el embarazo por aproximadamente tres meses.

¿Qué tan efectiva es la inyección?

La inyección anticonceptiva es muy efectiva. Si se usa correctamente siempre, menos de 1 de cada 100 mujeres quedarán embarazadas usando la inyección. Si no siempre se usa correctamente, 3 de cada 100 mujeres quedarán embarazadas cada año usando la inyección.

Cuando comiences a usar la inyección, esta toma varios días para comenzar a funcionar. Usa otra forma de anticoncepción de respaldo durante 7 días después que recibas la inyección.

¿Cómo funciona?

Un proveedor de atención a la salud te administrará la inyección en el brazo cada 12 semanas. La hormona en la inyección impide que tus ovarios liberen óvulos y espesa tu moco cervical para impedir que el espermatozoides entre al útero.

¿Cuáles son los beneficios del uso de la inyección?

- La inyección es segura, conveniente y muy efectiva.
- Si usas la inyección, no tienes que pensar en el control de la natalidad cada día o cada vez que tengas una relación sexual.
- La progestina en la inyección ofrece varios beneficios a la salud, incluyendo menos calambres menstruales y menstruaciones más ligeras, o ausentes del todo. También reduce el riesgo de enfermedad inflamatoria pélvica y cáncer endometrial.
- La inyección puede ser un buen método anticonceptivo para mujeres que no pueden usar el estrógeno.

¿Cuáles son los aspectos negativos del uso de la inyección?

- La inyección no protege contra las infecciones de transmisión sexual (ITS).
- Debes visitar a tu proveedor de atención a la salud cada 12 semanas.
- Algunas mujeres pueden tener efectos secundarios al usar la inyección. El sangrado irregular es el efecto secundario más común, especialmente en los primeros 6 a 12 meses. Otros efectos secundarios menos comunes incluyen cambios de apetito o aumento de peso, sensibilidad en los pechos y náusea y vómitos.
- Las mujeres que usan la inyección anticonceptiva pueden tener adelgazamiento temporal de los huesos. El crecimiento de los huesos comienza nuevamente cuando dejas de usar la inyección. Tú puedes ayudar a proteger tus huesos haciendo ejercicio regularmente y tomando suplementos de calcio y vitamina D.
- Las mujeres pueden quedar embarazadas al dejar de usar la inyección, pero esto puede tomar aproximadamente un año después de la última inyección.

- Mujeres con ciertas condiciones (cáncer del pecho, anorexia y uso de esteroides actuales o historia de los mismos) no deberían usar la inyección.

¿Dónde puedo obtener la inyección?

Un profesional de atención a la salud puede administrarte la inyección en un consultorio médico o una clínica.

¿Dónde puedo obtener más información?

Para mayor información sobre la inyección anticonceptiva, habla con tu proveedor de atención a la salud.

Compara la inyección con otras opciones anticonceptivas y ve un corto video sobre cada método, en inglés o en español, en Method Match de ARHP (www.arhp.org/MethodMatch).

What is the shot?

The birth control shot is an injection of a hormone called progestin. Each shot prevents pregnancy for about three months.

How effective is the shot?

The birth control shot is very effective. If always used correctly, less than 1 out of 100 women will get pregnant each year using the shot. If not always used correctly, 3 out of 100 women will get pregnant each year using the shot.

When you first start on the shot, it takes several days to begin working. Use a backup form of birth control for 7 days after you get the first shot.

How does it work?

A health care provider will give you the shot in your arm every 12 weeks. The hormone in the shot keeps your ovaries from releasing eggs and thickens your cervical mucus to block sperm from getting into the uterus.

What are the benefits of using the shot?

- The shot is safe, convenient, and very effective.
- If you use the shot, you don't have to think about birth control every day or each time you have sex.
- The progestin in the shot offers several health benefits, including fewer menstrual cramps, lighter or no periods. It also reduces the risk of pelvic inflammatory disease and endometrial cancer.
- The shot can be a good birth control method for women who cannot use estrogen.

What are the downsides of using the shot?

- The shot does not protect against sexually transmitted infections (STIs).
- You must visit your health care provider every 12 weeks.
- Some women may have side effects while using the shot. Irregular bleeding is the most common side effect, especially in the first 6 to 12 months. Other, less common, side effects include changes in appetite or weight gain, breast tenderness, and nausea and vomiting.
- Women who use the birth control shot may have temporary bone thinning. Bone growth begins again when you stop using the shot. You can help protect your bones by exercising regularly and getting extra calcium and vitamin D.
- Women can get pregnant after they stop using the shot, but it may take about a year after the last shot.
- Women with certain conditions (history of or current breast cancer, anorexia, and steroid use) should not use the shot.

Where can I get the shot?

A health care professional can give you the shot in a medical office or clinic.

Where can I get more information?

For more information on the birth control shot, talk to your health care provider.

Compare the shot to other birth control options using ARHP's Method Match at www.arhp.org/MethodMatch.

¿Qué es el anillo vaginal?

El anillo vaginal es un pequeño anillo flexible que tú pones en tu vagina una vez al mes para prevenir el embarazo. El anillo es fácil de poner y un tamaño le queda a la mayoría de mujeres. El anillo contiene hormonas llamadas estrógeno y progesterina. Estas son las mismas hormonas que tienen la mayoría de píldoras anticonceptivas.

¿Qué tan efectivo es el anillo vaginal?

Si se usa correctamente siempre, menos de 1 de cada 100 mujeres quedará embarazada usando el anillo. Si no siempre se usa correctamente, 8 de cada 100 mujeres quedarán embarazadas usando el anillo.

Cuando comienzas a usar el anillo, este toma varios días para comenzar a funcionar. Asegúrate de usar un anticonceptivo de respaldo (como un condón) durante los primeros siete días.

¿Cómo funciona?

Las hormonas en el anillo vaginal impiden que tus ovarios liberen óvulos y espesan tu moco cervical para impedir que el espermatozoide entre al útero.

Introduce el anillo en tu vagina. El anillo permanece en su lugar durante tres semanas seguidas. Tú lo extraes en la cuarta semana y tienes tu menstruación. Después de la semana de descanso, simplemente insertas un nuevo anillo y comienzas el ciclo de nuevo.

Si deseas, puedes saltarte la semana de descanso y mantener el anillo por cuatro semanas seguidas. Esto eventualmente hará que tus menstruaciones sean muy ligeras o desaparezcan del todo. Esto se llama anticoncepción de uso continuo. Si estás interesada en esta opción, habla con tu proveedor de atención a la salud.

Algunas veces el anillo puede salirse de la vagina al remover un tampón, al ir al baño o al tener relaciones sexuales. La mayoría de mujeres usan el anillo durante la relación sexual sin problemas y sin que lo sientan sus parejas. Si el anillo se sale o tú lo sacas, lávalo con agua tibia y pónelo de nuevo en las primeras tres horas.

¿Cuáles son los beneficios del uso del anillo vaginal?

- El anillo vaginal es seguro, conveniente y muy efectivo.
- Si usas el anillo, no tienes que pensar en el control de la natalidad cada día o cada vez que tengas una relación sexual.
- Muchas mujeres que usan el anillo, tienen menstruaciones más ligeras, más cortas y más regulares.
- La mayoría de mujeres pueden quedar embarazadas rápidamente después de dejar de usar el anillo.
- Las hormonas en el anillo ofrecen beneficios a la salud. El anillo puede ofrecer cierta protección contra el acné, los tumores no cancerosos del pecho, el embarazo ectópi-

co, los cánceres endometrial y ovárico, la anemia por deficiencia de hierro, los quistes en los ovarios, la enfermedad inflamatoria pélvica, los síntomas del síndrome premenstrual y las migrañas relacionadas con la menstruación.

¿Cuáles son los aspectos negativos del uso del anillo vaginal?

- El anillo vaginal no protege contra las infecciones de transmisión sexual (ITS).
- Para obtener el anillo necesitas visitar a tu proveedor de atención a la salud por una receta.
- Algunas mujeres pueden tener efectos secundarios al usar el anillo. Algunos de los efectos secundarios más comunes generalmente desaparecen a los dos o tres meses. Estos incluyen, sangrado entre menstruaciones, sensibilidad en los pechos y náusea y vómitos. El anillo también puede aumentar el flujo vaginal.
- Puede ser difícil recordar retirar el anillo después de las tres semanas e insertar un anillo nuevo después de la semana de descanso. Para ayudarte a recordar, puedes programar la alarma en tu teléfono celular y marcar la "fecha de cambio" en tu calendario.

- Mujeres con ciertas condiciones de salud no deberían usar el anillo. Tu proveedor de atención a la salud te puede ayudar a decidir si el anillo es apropiado para ti.
- Algunas drogas pueden interactuar con el anillo y hacerlo menos efectivo para prevenir el embarazo. Habla con tu proveedor de atención a la salud sobre cualquier medicina, con o sin receta, que estés tomando.

¿Dónde puedo obtener el anillo vaginal?

Tu proveedor de atención a la salud te mostrará como colocar y extraer el anillo y te dará una receta para reemplazos mensuales. Tú puedes comprar el anillo con una receta en una farmacia, un centro de salud o una clínica.

¿Dónde puedo obtener más información?

Para mayor información sobre el anillo vaginal, habla con tu proveedor de atención a la salud.

Compara el anillo vaginal con otras opciones anticonceptivas y ve un corto video sobre cada método, en inglés o en español, en Method Match de ARHP (www.arhp.org/MethodMatch).

What is the vaginal ring?

The vaginal ring is a small, flexible ring that you put into your vagina once a month to prevent pregnancy. The ring is easy to put in and one size fits most women. The ring contains hormones called estrogen and progestin. These are the same hormones that are in most birth control pills.

How effective is the vaginal ring?

If always used correctly, less than 1 out of 100 women will get pregnant each year using the ring. If not always used correctly, 8 out of 100 women will get pregnant each year using the ring.

When you first start using the ring, it takes several days to begin working. Be sure to use backup birth control (like a condom) for the first seven days.

How does it work?

The hormones in the vaginal ring keep your ovaries from releasing eggs and thicken your cervical mucus to block sperm from getting into the uterus.

Insert the ring into your vagina. The ring stays in place for three weeks straight. You take it out the fourth week and you have your period. After the week off, you simply insert a new ring and start the cycle again.

If you want to, you can skip the one week break and keep the ring in for four weeks straight. This will eventually make your period very light or disappear totally. This is called continuous-use contraception. If you are interested in this option, talk to your health care provider.

The ring can sometimes fall out of the vagina when removing a tampon, going to the bathroom, or having sex. Most women wear the ring during sex with no problems and without their partners feeling it. If the ring falls out or you remove it, rinse it with warm water and put it back in within three hours.

What are the benefits of using the vaginal ring?

- The vaginal ring is safe, convenient, and very effective.
- If you use the ring, you don't have to think about birth control every day or every time you have sex.
- Many women who use the ring have lighter, shorter, and more regular periods.
- Most women can get pregnant quickly after they stop using the ring.
- The hormones in the ring offer health benefits. The ring can offer some protection against acne, non-cancerous breast growths, ectopic pregnancy, endometrial and ovarian cancers, iron deficiency anemia, ovarian cysts, pelvic inflammatory disease, PMS symptoms, and menstrually-related migraine headaches.

What are the downsides of using the vaginal ring?

- The vaginal ring does not protect against sexually transmitted infections (STIs).
- Getting the ring requires a visit to a health care provider for a prescription.
- Some women may have side effects while using the ring. Some of the most common side effects usually go away after two or three months. They include bleeding between periods, breast tenderness, and nausea and vomiting. The ring may also increase vaginal discharge.
- It can be challenging to remember to remove the ring after three weeks and then insert a new ring after the one-week break. To help you remember, you may want to set the alarm on your cell phone and mark the “change date” on your calendar.
- Women with certain health conditions should not use the ring. Your healthcare provider will help you decide if the ring is right for you.
- Certain drugs may interact with the ring to make it less effective in preventing pregnancy. Talk with your health care provider about any over the counter or prescription medications you are taking

Where can I get the vaginal ring?

Your health care provider will show you how to insert and remove the ring and give you a prescription for monthly refills. You can purchase the ring at a drugstore, health center, or clinic with a prescription.

Where can I get more information?

For more information on the vaginal ring, talk to your health care provider.

Compare the ring to other birth control options using ARHP’s Method Match at www.arhp.org/MethodMatch.

Attachment 5

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: Nicotine replacement products approved by the federal Food and Drug Administration and prescribed by a pharmacist for smoking cessation are covered under 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 be pregnant? (If yes, do not furnish and refer to an appropriate health care provider)
 - Have you had a recent 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)
- 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 review any questions the patient may have regarding smoking cessation therapy and/or nicotine replacement products.

(5) Product Selection: Based on the information gathered from the patient during the Procedure outlined above, the pharmacist 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. Furthermore, 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 prescribed 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 for a period of at least three years from the date when the last nicotine replacement product was furnished. 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'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 a Board-approved continuing education program specific to smoking cessation therapy and nicotine replacement therapy, or an equivalent curriculum-based training program completed on or after the year 2000 in a California School of Pharmacy.

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

(9) Patient Privacy: All pharmacists furnishing nicotine replacement products in a pharmacy shall operate under the pharmacy'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

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CPhA/CSHP, "Pharmacists Protocol for Dispensing Nicotine Replacement Products."
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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.

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December 16, 2014

<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						
	<p>Nicorette¹, Generic OTC 2 mg, 4 mg original, cinnamon, fruit, mint</p>	<p>Nicorette Lozenge,¹ Nicorette Mini Lozenge,¹ Generic OTC 2 mg, 4 mg cherry, mint</p>	<p>NicoDerm CQ¹, Generic OTC (NicoDerm CQ, generic) Rx (generic) 7 mg, 14 mg, 21 mg (24-hour release)</p>	<p>Nicotrol NS² Rx Metered spray 0.5 mg nicotine in 50 mL aqueous nicotine solution</p>	<p>Nicotrol Inhaler² Rx 10 mg cartridge delivers 4 mg inhaled nicotine vapor</p>	<p>Combinations with demonstrated efficacy Nicotine patch + nicotine gum Nicotine patch + nicotine lozenge Nicotine patch + nicotine nasal spray Nicotine patch + nicotine oral inhaler</p>
PRECAUTIONS	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Temporomandibular joint disease Pregnancy³ and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Pregnancy³ and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Pregnancy³ (Rx formulations, category D) and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> 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 Pregnancy³ (category D) and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Bronchospastic disease Pregnancy³ (category D) and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> See precautions for individual agents
DOSING	<p><i>1st cigarette ≤ 30 minutes after waking:</i> 4 mg <i>1st cigarette >30 minutes after waking:</i> 2 mg</p> <p>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</p> <ul style="list-style-type: none"> 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 	<p><i>1st cigarette ≤ 30 minutes after waking:</i> 4 mg <i>1st cigarette >30 minutes after waking:</i> 2 mg</p> <p>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</p> <ul style="list-style-type: none"> 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 	<p><i>≥ 10 cigarettes/day:</i> 21 mg/day x 4–6 weeks 14 mg/day x 2 weeks 7 mg/day x 2 weeks</p> <p><i>≤ 10 cigarettes/day:</i> 14 mg/day x 6 weeks 7 mg/day x 2 weeks</p> <ul style="list-style-type: none"> May wear patch for 16 hours if patient experiences sleep disturbances (remove at bedtime) Duration: 8–10 weeks 	<p>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</p> <ul style="list-style-type: none"> Maximum <ul style="list-style-type: none"> – 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 	<p>6–16 cartridges/day Individualize dosing: initially use 1 cartridge q 1–2 hours</p> <ul style="list-style-type: none"> 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 	<p><u>Reserve for patients smoking ≥ 10 cigarettes/day:</u> Long-acting NRT: to prevent onset of severe withdrawal symptoms</p> <ul style="list-style-type: none"> Nicotine patch 21 mg/day x 4–6 weeks 14 mg/day x 2 weeks 7 mg/day x 2 weeks <p style="text-align: center;">PLUS</p> <p>Short-acting NRT: used as needed to control breakthrough withdrawal symptoms and situational urges for tobacco</p> <ul style="list-style-type: none"> 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						
	GUM	LOZENGE	PATCH	NASAL SPRAY	INHALER	COMBINATION NRT
ADVERSE EFFECTS	<ul style="list-style-type: none"> ▪ Mouth/jaw soreness ▪ Hiccups ▪ Dyspepsia ▪ Hypersalivation ▪ Effects associated with incorrect chewing technique: <ul style="list-style-type: none"> – Lightheadedness – Nausea/vomiting – Throat and mouth irritation 	<ul style="list-style-type: none"> ▪ Nausea ▪ Hiccups ▪ Cough ▪ Heartburn ▪ Headache ▪ Flatulence ▪ Insomnia 	<ul style="list-style-type: none"> ▪ Local skin reactions (erythema, pruritus, burning) ▪ Headache ▪ Sleep disturbances (insomnia, abnormal/vivid dreams); associated with nocturnal nicotine absorption 	<ul style="list-style-type: none"> ▪ Nasal and/or throat irritation (hot, peppery, or burning sensation) ▪ Rhinitis ▪ Tearing ▪ Sneezing ▪ Cough ▪ Headache 	<ul style="list-style-type: none"> ▪ Mouth and/or throat irritation ▪ Cough ▪ Headache ▪ Rhinitis ▪ Dyspepsia ▪ Hiccups 	<ul style="list-style-type: none"> ▪ See adverse effects listed for individual agents
ADVANTAGES	<ul style="list-style-type: none"> ▪ Might satisfy oral cravings ▪ Might delay weight gain ▪ Patients can titrate therapy to manage withdrawal symptoms ▪ Variety of flavors are available 	<ul style="list-style-type: none"> ▪ Might satisfy oral cravings ▪ Might delay weight gain ▪ Easy to use and conceal ▪ Patients can titrate therapy to manage withdrawal symptoms ▪ Variety of flavors are available 	<ul style="list-style-type: none"> ▪ Provides consistent nicotine levels over 24 hours ▪ Easy to use and conceal ▪ Once daily dosing associated with fewer compliance problems ▪ FDA-approved for use in combination with bupropion SR 	<ul style="list-style-type: none"> ▪ Patients can titrate therapy to rapidly manage withdrawal symptoms 	<ul style="list-style-type: none"> ▪ Patients can titrate therapy to manage withdrawal symptoms ▪ Mimics hand-to-mouth ritual of smoking (could also be perceived as a disadvantage) 	<ul style="list-style-type: none"> ▪ 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 NRT monotherapy ▪ Attractive option for patients who have previously failed treatment with NRT monotherapy ▪ See advantages listed for individual agents
	<ul style="list-style-type: none"> ▪ Need for frequent dosing can compromise compliance ▪ Might be problematic for patients with significant dental work ▪ Proper chewing technique is necessary for effectiveness and to minimize adverse effects ▪ Gum chewing may not be acceptable or desirable for some patients 	<ul style="list-style-type: none"> ▪ Need for frequent dosing can compromise compliance ▪ Gastrointestinal side effects (nausea, hiccups, heartburn) might be bothersome 	<ul style="list-style-type: none"> ▪ 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) 	<ul style="list-style-type: none"> ▪ Need for frequent dosing can compromise compliance ▪ 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 	<ul style="list-style-type: none"> ▪ Need for frequent dosing can compromise compliance ▪ Cartridges might be less effective in cold environments ($\leq 60^{\circ}\text{F}$) 	<ul style="list-style-type: none"> ▪ Increased cost of therapy ▪ 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.

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Attachment 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 timely access to naloxone hydrochloride and to provide standardized procedures for pharmacists to educate on and furnish naloxone hydrochloride in order to decrease and prevent harm from opioid overdose.

(3) Screening: The pharmacist may provide naloxone hydrochloride to anyone who uses or has a history of using prescription opioids—especially long acting or extended release opioids—or illicit opioids, or anyone who has contact with someone who uses or has a history of using prescription or illicit opioids.

(4) 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:

- Ask whether the person to whom the naloxone hydrochloride would be administered has a known hypersensitivity to naloxone (If yes, do not furnish).
- Before furnishing naloxone hydrochloride, the pharmacist shall provide training in opioid overdose prevention, recognition, response, and administration of the antidote naloxone.
- When naloxone hydrochloride is furnished:
 - The recipient shall be provided with appropriate counseling and information on the product furnished, including dosing, effectiveness, potential side effects, storage conditions, shelf-life, and safety. The recipient is not permitted to waive the required consultation.
 - The pharmacist shall ask the recipient if he or she wants chemical dependency treatment, recovery services, or medication disposal resources at this time. If yes, the pharmacist shall provide the recipient with any informational resources on hand and/or referrals to appropriate resources.
- The pharmacist shall review any questions the recipient may have regarding naloxone hydrochloride.

(5) Refills: The pharmacist shall review indications for use and administration of naloxone hydrochloride upon refill.

(6) Product Selection: Naloxone hydrochloride for take-home use can currently be supplied as an intramuscular injection, intranasal spray, auto-injector, or other formulations. 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.

(7) Suggested Rx:

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

Prescriptions shall include an expiration date for the naloxone hydrochloride furnished.

(8) 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 recipients whose primary language is not English.

(9) 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.

(10) Documentation: Each naloxone hydrochloride product furnished by a pharmacist pursuant to this protocol shall be documented in a medication record for the person to whom naloxone is being furnished, and securely stored within the originating health care facility for a period of at least three years from the date when the last naloxone hydrochloride product was furnished. 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 facility's normal operating hours.

(11) Training: Prior to furnishing naloxone hydrochloride, pharmacists who participate in this protocol must have successfully completed a minimum of one hour of a Board-approved continuing education program specific to the use of naloxone hydrochloride, or an equivalent curriculum-based training program completed in an ACPE-accredited School of Pharmacy.

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

Protocol Sources

Scott Burris, et al., “Stopping an Invisible Epidemic: Legal Issues in the Provision of Naloxone To Prevent Opioid Overdose,” DREXEL L. REV. 1(2):273-339, 326 (2009).

This law review article recommends fostering naloxone distribution through pharmacies, and using EC statutes as a model.

Substance Abuse and Mental Health Services Administration, “Opioid Overdose Toolkit,” available at <http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2014/SMA14-4742>.

This resource provides materials to develop policies to prevent opioid overdose.

The Network for Public Health Law, “Legal Interventions To Reduce Overdose Mortality: Naloxone Access and Overdose Good Samaritan Laws” (Aug. 2014), available at https://www.networkforphl.org/_asset/qz5pvn/naloxone_FINAL.pdf.

This article describes naloxone access nationwide.

Harm Reduction Coalition, “Guide to Developing and Managing Overdose Prevention and Take-Home Naloxone Projects” (2012), available at <http://harmreduction.org/issues/overdose-prevention/tools-best-practices/manuals-best-practice/od-manual/>.

This manual outlines the process of developing an overdose prevention program, including with a take-home naloxone component.

Northeast Behavioral Health, “Opioid Overdose Prevention and Reversal via Peer-Administered Narcan” (2012), available at <http://harmreduction.org/wp-content/uploads/2012/02/od-train-the-trainer-parents.pdf>.

This PowerPoint presentation provides information to educate peers on opioid prevention and reversal.

CA Department of Health Care Services, “Pharmacist Protocol for Furnishing Naloxone for the Prevention of Opioid Overdose” (last updated Oct. 29, 2014).

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

World Health Organization, “Community Management of Opioid Overdose” (2014).

This resource provides materials to develop policies to prevent opioid overdose.

Drug Policy Alliance, “What Is Naloxone?” (Aug. 2014), available at <http://www.drugpolicy.org/resource/what-naloxone>.

This fact sheet provides comprehensive information on naloxone.

Massachusetts Department of Health and Human Services, “Dispensing of Naloxone by Standing Order” (2014), available at <http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/dhpl/pharmacy/dispensing-of-naloxone-by-standing-order-.html>.

This site contains a pamphlet recommended as the base for the Board’s factsheet.

N. Zaller, et al., "The Feasibility of Pharmacy-Based Naloxone Distribution Interventions: A Qualitative Study with Injection Drug Users and Pharmacy Staff in Rhode Island," 48 SUBST. USE MISUSE 8 (2013).

This research supports pharmacy-based naloxone intervention, but notes barriers including misinformation and costs.

Traci C. Green, et al., "Responding to Opioid Overdose in Rhode Island: Where the Medical Community Has Gone and Where We Need To Go," R.I. MED. J. 29-33 (Oct. 2014), available at <http://www.rimed.org/rimedicaljournal/2014/10/2014-10-29-dadt-green.pdf>.

This article gives an overview of opioid overdose, provides guidance resources, and emphasizes the importance of Good Samaritan Laws.

Attachment 6



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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 IMPLIMENTATION COMMITTEE MEETING
MINUTES**

DATE: November 5, 2014

LOCATION: Department of Consumer Affair
First Floor Hearing Room
1625 North Market Blvd.
Sacramento, Ca 95834

COMMITTEE MEMBERS

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

**COMMITTEE MEMBERS
NOT PRESENT:** Deborah Veale, RPh

STAFF

PRESENT: Virginia Herold, Executive Officer
Laura Hendricks, Staff Analyst
Michael Santiago, DCA Staff Counsel

Call to Order

President Weisser called the meeting to order at 10:19 a.m.

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

President Weisser acknowledged current board member Allen Schaad in the audience.

1. Proposed Schedule for Action on Provisions Established by SB 493 (Hernandez, Chapter 469, Statutes of 2013)

President Weisser introduced Liz McCaman, who will be working with the committee on drafting protocols. President Weisser explained that at today's meeting the committee would be reviewing the draft protocols for hormonal contraception and nicotine replacement.

President Weisser briefly reviewed that schedule of action that was provided in the meeting materials.

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

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

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

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

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

President Weisser noted that at the August SB 493 Committee Meeting, the committee held a lengthy discussion about reporting immunization into the immunization registry.

Dr. Steve Nickell, from California Immunization Registry (CAIR) provided a presentation via phone to the committee. Highlights from his presentation are below. The entire presentation follows these minutes.

Overview

- CAIR is a consortium of 9 regional registries
- 7 use same 'CAIR' software and are operated by CDPH
- 'CAIR 7' cover 48 of 58 CA counties; 87% of population

Benefits

- FOR PATIENTS:
 - Consolidate in one record all immunizations a patient has received.

- Provide an accurate, official copy of a child’s immunization history for personal, day care, school, or camp entry requirements.
- Help ensure that a patient’s immunizations are up to date.
- Help ensure timely immunization for children whose families move or switch healthcare providers.
- Prevent unnecessary (duplicative) immunizations.
- FOR PROVIDERS, PLANS AND PURCHASERS:
 - Provide definitive information on immunizations due or overdue.
 - Provide current recommendations and information on new vaccines.
 - Complete required school, camp, and day care immunization records.
 - Facilitate introduction of new vaccines or changes in the vaccine schedule.
 - Help manage vaccine inventories.
 - Generate coverage reports for managed care (e.g., Healthcare Effectiveness Data and Information Set [HEDIS®]) and other organizations.

CAIR Disclosure

- Patients must be informed that their information will be shared prior to the provider sharing the information with CAIR
- Patients have right to:
 - Refuse sharing with other CAIR users
 - Correct record
 - Request list of users who have viewed their record
- CAIR Disclosure (‘Immunization Registry Notice to Patients and Parents’) is available in multiple languages at: <http://cairweb.org/cair-forms/>

CAIR Participation

<i>Interface</i>	<i>Participant Type</i>	<i># Active</i>	<i># Pending</i>
Web (manual entry)	Clinical	~2,400	
	Read-Only (schools)	>4,000	
Electronic	Clinical	>2,000	~2,000

President Weisser asked if patients can access their own information. Dr. Nickell responded that the new version that is currently under development will have a patient portal.

President Weisser asked to clarify if the current system allows schools to see student information. Dr. Nickell responded that currently there are approximately 4,000 schools and daycare facilities that have read-only rights, allowing them to check student immunizations.

Mr. Law asked if they are concerned about the capacity of the system. Dr. Nickell responded that the system has plenty of room to expand and in the future they will be looking to delete entries for people who have passed away.

Dr. Gray, from the Institute for Community Pharmacy, asked how the CAIR system ensures that the practitioner has the correct patient. Dr. Nickell answered that the system uses algorithms. He noted that there are sometimes problems with patients not having a NPI.

Dr. Gray asked when a pharmacist gives a vaccine how will it be determined what exact pharmacy location gave the immunization. Dr. Nickell answered that there are ID's given to each pharmacy, which includes the exact location (address, store number, etc).

Dr. Gray asked if information is automatically uploaded to the Federal Database. Dr. Nickell responded that it is not.

Dr. Gray asked if Veterans Affairs is inputting data. Dr. Nickell answered that currently there is nothing coming from the VA.

Dan Robinson, Dean of Western University, commented that currently reporting to the registry is voluntary. He added that if the board makes it mandatory for pharmacists to report, they would be the only health care provider required to do so. President Weisser commented that the shift to vaccines being provided by pharmacists rather than doctors would justify them reporting to the database. Ms. Herold stated she doesn't think reporting is currently a requirement.

President Weisser reported that at the August meeting, there was considerable discussion about whether students who may have received this training in pharmacy school could use their training without retaking it somewhere else. The question arose as to how they could document they completed this training several years before.

Lisa Kroon, from the University of California, San Francisco, reported that several schools have created an affidavit. Dr. Kroon explained that the affidavit outlines the curriculum that was received by the student either in the core curriculum or in an elective. She explained that the student would keep this and provide it to the board with their application. She noted that the student signs under penalty of perjury that they did receive all of the education listed on the affidavit. The school will also fill out a portion of the affidavit confirming the students' enrollment and graduation date.

Ms. Herold commented that the board would like to see what dates the schools started teaching immunizations as part of their core curriculum. Dr. Kroon responded that this information could be researched and provided to the committee.

Ms. McCaman commented that the committee should also determine if the schools teach hormonal contraception to the US MEC standards.

Dr. Gutierrez asked if the school, rather than the student, could attest to the student receiving the education. Dr. Kroon responded that there was concern about the amount of paperwork the school would have to complete. Dan Robinson, Dean of Western University added that it may be difficult for the school to attest to the specific education received as much of it is received through experience.

Dr. Gray, commented that during the SB 493 hearings the Medical Board and AMA stated that they expected the Pharmacy Board to replicate the Medical Board's process for verifying education. The Medical Board does not require upfront documentation; rather the licensee must provide proof upon the request of the medical board.

The committee asked if the schools could provide information on when each component became part of the core curriculum at the December committee meeting.

(b) For Prescription Medications Not Requiring a Diagnosis that Are Recommended by the CDC for Travel Outside the US

President Weisser explained that at this meeting, the committee will continue its discussions about the parameters for travel medications. Below are excerpts from the August 6 meeting minutes (**Attachment 2**).

President Weisser reported that at the August committee meeting Dr. Goad indicated that the CDC Yellow-book is the guidance document that the legislation is referring to. He reported that there is a chapter in the CDC Yellow-book on self-treatable illnesses.

President Weisser stated that at the August committee meeting the board's counsel, Kristy Scheildge, commented that the committee should define what "not requiring a diagnosis" means and identify the CDC guidance document.

At the last meeting President Weisser commented that self-treatable illnesses are very broad. President Weisser asked if the board can refer to the CDC Yellow-book. Ms. Scheildge responded that the committee would need to review it in order to determine if it is appropriate and clear enough for licensees.

President Weisser reported that at the August meeting Dr. Steve Gray noted that the goal of SB 493 was to help alleviate the work of doctors and nurses. During the negotiations with the medical professionals, they asked that pharmacists follow the same guidelines that they do, which would be the CDC Yellow-book. Dr. Gray noted that in many other countries these travel medications are available over the counter.

President Weisser reported that at the August meeting Ms. Scheildge encouraged the committee to consider how quickly the primary care physicians need to be notified, and what information needs to be placed in the patient file after a pharmacist provides the travel medications.

President Weisser stated that a draft document on travel medications prepared by a team of individuals from CSHP and CPhA was provided in the meeting materials. President Weisser asked if anyone in the audience could comment on the document in Dr. Goad's absence.

Dr. Robinson clarified that travel medications do not apply to previously diagnosed disease; they are only for anticipated diseases that may occur during travel.

Dr. Gutierrez asked how long the "certificate of travel health" referenced in the document was valid for. Dr. Robinson responded that if pharmacists are going to provide travel medications they should follow the outline of the "travel health" education. The certificate is referenced in the document only to show that this training would be the gold standard of education for pharmacists wanting to provide travel meds.

President Weisser asked how a pharmacist would respond if someone came into a pharmacy saying they have jet-lag and asked for Ambien. Dr. Robinson responded that he would need to ask someone who works in travel medicine.

Dr. Gutierrez expressed her concern with patients trying to receive unnecessary antibiotics. Dr. Robinson responded that the pharmacist should be talking to the patient about their travel to determine what medications they actually require.

Dr. Gray commented that doctors are required to perform a good faith examination prior to prescribing travel meds. However, the exam does not need to be a physical examination. The Medical Board has specific requirements for when the exam must be physical.

Dr. Gray recommended that the committee have travel clinics come to a future meeting to discuss their process.

Dr. Gray suggested that the board create requirements for which records a pharmacist must have to show how they determined that the patient needed that travel medicine. Dr. Gray added that a pharmacist would need a personal DEA number to provide a controlled substance.

Sara McBane provided her personal experience regarding travel medicine when she traveled abroad.

Mr. Law commented that the burden should be on the traveler to prove that they will be traveling to an area that justifies the need for travel meds.

Brian Warren, from the California Pharmacists Association, suggested that the committee look at existing safeguards for travel clinics and doctors.

Andrew Lowe, a pharmacist, commented that he is concerned with documentation of travel and proof should be provided for the protection of the patient and pharmacists. Mr. Lowe added that he is also concerned with patients seeking controlled substances; he suggested that the committee create a quantity limit for the dispensing of controlled substances.

Ms. McCaman commented that documentation could be as simple as the traveler showing an electronic confirmation for their flight, hotel, etc.

(c) For Ordering and Interpreting Tests to Monitor and Manage Drug Therapies

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 enter the appropriate information in a patient record system shared with the prescriber, when available and as permitted by the prescriber. (CA B&P Code section 4052(a)(12))
- *APP licensed pharmacists can:*
Order and interpret drug-therapy related tests, and initiate or modify therapy

President Weisser reported that at the August committee meeting, Dr. Gutierrez asked how the board might handle cases of patients who have an adverse medical event which could have been prevented if the pharmacist would have ordered a test.

At the August committee meeting Ms. Herold commented that there are really two issues the committee should discuss:

1. Can the board discipline a pharmacist for not ordering a test; and
2. What is the pharmacist's civil liability in regards to testing?

President Weisser reported that at the August committee meeting, Dr. Gray commented that during creation of the legislation, doctors stated that they wanted pharmacists to have the ability to order tests in order to make recommendations on the patient's care based on actual data.

President Weisser reported that at the August committee meeting Lisa Kroon, from the University of California, San Francisco, commented at this time the language in SB 493 states that pharmacists *may* order tests to improve patient safety and access to care. However, she noted that in the future she could see the standard of care evolving to a point where a pharmacist *must* order a test prior to dispensing a certain medication.

Dr. Gutierrez expressed her concern that ordering tests may cause delays in patients receiving their medication, especially in an independent pharmacy.

Ms. Herold asked the committee to determine if they wanted to draft a regulation on ordering tests or create a guidance document.

Mr. Law commented that ordering tests should not be mandatory, but should be an option for pharmacists who feel it is in the patients' best interest.

Dr. Kroon commented that SB 493 *allows* a pharmacist to order tests, it does not require it. She added that until Healthcare Information Exchange (HIE) sharing is available in all pharmacies, ordering tests should not be required.

President Weisser commented that the committee should consider if there are any liability concerns for an independent pharmacist who decided not to order a test.

Dr. Gutierrez commented that the board should encourage the use of testing where appropriate, but not require it. She added that a pharmacist would need to use their professional judgment to determine if it is worth it to delay a patient's medication in order to conduct testing.

Ms. Herold stated that the committee could draft a policy statement for pharmacists. She noted that it would need to be drafted carefully so that it does not become a de facto regulation.

Mr. Law stated that he sees this applying more towards hospital pharmacies. President Weisser commented that he anticipates that it will expand to community pharmacies. Dr. Kroon agreed that the goal is for community pharmacies to have access to testing.

Dr. Gray and Dr. Robinson stated that the word *may* was used very deliberately when SB 493 was drafted.

Dr. Robinson commented that at previous meetings the committee had been provided a document with guidelines for ordering tests. Ms. Herold commented that this document had been provided in previous meeting materials.

Dr. Gray commented that coordination between a pharmacist and the physician will be very important as pharmacists begin ordering tests. Dr. Robinson agreed that the intent was for doctors and pharmacists to work in collaboration when ordering tests.

Dr. Robinson noted that prior to ordering tests, a pharmacist will need to find a way for the test to be paid for.

Dr. Gutierrez stated that she is not concerned with pharmacists who are working as part of a health system; rather, her concern is for independent pharmacies which may have to significantly delay treatment to order a test.

Keith Yokishoka, pharmacist, commented that the intent for allowing pharmacists to order tests was to increase patient access and decrease the burden on physicians.

The committee recessed for a break at 12:11 p.m. and resumed at 1:04 p.m.

3. Review and Discussion on a Draft Protocol for Pharmacists who Furnish Self-Administered Hormonal Contraceptives

President Weisser explained that the California HealthCare Foundation provided support to the board to develop various components that the board needs to meet the requirements of SB 493. This support was in the way of a researcher to develop draft components for board review. One such component is the development of a protocol for self-administered hormonal contraception.

President Weisser reported that SB 493 requires the development of a protocol for self-administered hormonal contraception. The protocol must be developed and approved by both this board and the Medical Board, in consultation with the American Congress of Obstetricians and Gynecologists, the CA Pharmacists Association and other appropriate entities. It requires a self-screening tool for use by patients based on the current United States Medical Eligibility Criteria (USMEC). The pharmacist must also provide to the patient a fact sheet approved by the same group identified above and the California Department of Public Health.

Below is the draft protocol that was provided in the meeting materials. The self-screening tool and “birth control options” chart are provided following these minutes.

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 products with the following routes of administration are considered self-administered:

- Oral;
- Transdermal patch;
- Vaginal ring.

(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.
 - When a self-administered hormonal contraceptive is furnished:
 - The patient shall be provided with appropriate counseling and information on the product furnished, including dosing, potential side effects, safety concerns, and the FDA required patient product information leaflet.
 - The patient shall be advised of the importance of receiving recommended preventative health screenings.
 - The patient shall be informed that most contraceptive methods do not protect against sexually transmitted infections (STIs). Consistent and correct use of the latex condom reduces the risk of STIs and HIV.
 - When considering a specific clinical situation, pharmacists are encouraged to consult the Centers for Disease Control and Prevention's *U.S. Selected Practice Recommendations for Contraceptive Use, 2013*, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6205a1.htm> (or the most updated version or supplement); this document offers guidance on how to use contraceptive methods most effectively, and addresses common but sometimes complicated issues in contraceptive management.
- (5) Self-Screening Tool: The pharmacist shall provide the patient with a self-screening tool for use of self-administered hormonal contraceptives. The patient shall complete the self-screening tool, and the pharmacist shall use the answers to identify patient risk factors. The patient shall complete the tool annually, or whenever the patient indicates a major health change.

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 a copy of the current self-administered hormonal contraception fact sheet approved by the Board of Pharmacy as required by the Business and Professions code Section 4052.3(c). The pharmacist shall review any questions the patient may have regarding self-administered hormonal contraception.

This fact sheet should be made available in alternate languages for patients whose primary language is not English.

(7) Follow-Up Care: Upon furnishing a self-administered hormonal contraceptive, or if it 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 contraceptive 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, the pharmacist shall provide the patient with a written record of the drug(s) or device(s) furnished and advise the patient to consult a physician of the patient's choice.

(9) Referrals and Supplies: If self-administered hormonal contraception services are not immediately available at the pharmacy or the pharmacist declines to furnish pursuant to conscience clause, the pharmacist shall refer the patient to another self-administered hormonal contraception provider. The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.

(10) Product Selection: The pharmacist may select any hormonal contraceptive listed in the current version of the United States Medical Eligibility Criteria (USMEC) for Contraceptive Use as Category 1 or 2, based on the information reported in the self-screening tool and the blood pressure as recorded by the pharmacist. The USMEC shall be kept current and

maintained in the pharmacy. Furthermore, 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 as required by law. A patient medication record shall be maintained in an automated data processing or manual record mode such that the following information is readily retrievable during the pharmacy's normal operating hours:

(A) The patient's full name and address, telephone number, date of birth or age, and gender;

(B) For each self-administered hormonal contraceptive dispensed by the pharmacist:

(i) The name, strength, dosage form, route of administration, quantity, and directions for use;

(ii) The furnishing pharmacist's name and where appropriate, license number, DEA registration number, or other unique identifier;

(iii) The date on which the self-administered hormonal prescription was dispensed or refilled;

(iv) The prescription number for each self-administered hormonal contraception prescription;

(v) Any additional information required by title 16, sections 1717 and 1701.1 of the California Code of Regulations.

(C) Any of the following which may relate to the contraceptive therapy: patient allergies, idiosyncrasies, current medications and relevant prior medications including nonprescription medications and relevant devices, or medical conditions which are communicated by the patient or the patient's agent.

(D) Any other information that the pharmacist, in his or her professional judgment, deems appropriate.

The patient medication record and a copy of the completed self-screening tool shall be securely stored within the originating pharmacy for at least one year from the date when the last self-administered hormonal contraception product was furnished.

(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 ACPE- or ASHP-approved continuing education program specific to self-administered hormonal contraception and application of the USMEC, or an equivalent curriculum-based training program completed on or after 2010 in a California School of Pharmacy.

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

Ms. McCaman briefly reviewed the draft protocol. She then asked for input from experts in the profession, particularly regarding the weight of a patient.

President Weisser asked if an exam was needed for the vaginal ring. Ms. McCaman responded that no exam was needed.

President Weisser asked if the FDA requires a fact sheet. Ms. McCaman responded that the FDA requires a fact sheet be provided for each prescription, but it is specific to the specific medication being dispensed. She felt it was necessary to provide information on all types of contraception.

President Weisser asked why she used one hour for the training time. Ms. McCaman responded that there was no specific requirement for training time, so she used one hour. She asked that those with knowledge on appropriate training provide her with feedback.

Ms. Herold commented that if a pharmacist had a problem with providing hormonal contraception they would not take the one-hour training in order to provide this service, thus the conscience clause could be removed.

Dr. Gutierrez asked if the fact sheet would be translated. Ms. Herold commented that the board strives to translate all documents provided to the public in at least 5 languages.

Mr. Law asked if there is a continuing education requirement. Ms. McCaman responded that she did not include any because she did not see a continuing education requirement in the SB 493 language. She added that if the board felt it was necessary it could be added.

Dr. Kathy Hill-Besinque recommended that the board should make the FDA fact sheet the minimum requirement. She said if a pharmacist wants to provide additional information they can give the patient the fact sheet developed by the board. Ms. McCaman responded that her interpretation of SB 493 was that the board must create their own fact sheet. Dr. Hill-Besinque stated that she felt the FDA fact sheets would be sufficient and as information is constantly changing it would be difficult for the board to keep their fact sheet up-to-date.

Dr. Hill-Besinque commented that some of the language regarding record keeping is duplicative of existing California law. President Weisser agreed.

Dr. Hill-Besinque commented that medroxyprogesterone acetate by injection (Depo-Provera) is not required to be administered by a healthcare provider. Thus, it should be included as a self-administered option. Ms. McCaman commented that originally it did include the injection;

however, after her research she determined that an injection is not self-administered. She noted that she is not opposed to including it if she can

President Weisser asked if diaphragms are still used. Dr. Hill-Besinque commented that they are still used; however, they require fitting by a doctor.

Sally Raffi, from the University of California, San Diego, commented that she was encouraged that the board was open to including depo-injections as they are the most effective form of self-administered birth control.

Ms. Raffi recommended that the board remove “patch” and “ring” so that as products change the board will not have to update the language.

Dr. Hill-Besinque recommended reorganizing the self-screening tool so that the questions do not begin with “scary” questions that may discourage the use of contraception. She recommended removing the question about being older than 35 and the question about the patient being in a wheelchair.

Ms. Raffi recommended the removal of the question regarding the patient’s weight. A patient’s weight will not affect their eligibility to receive contraception or its safety. She noted that it may affect the medications efficacy, but that is not the purpose of the self-screening tool. Dr. Hill-Besinque commented that studies have shown that weight is not a factor in the efficacy for hormonal contraception. Ms. McCaman asked if they recommended removal of all questions about weight. Dr. Hill-Besinque and Ms. Raffi confirmed that weight should not be included on the self-screening tool.

Dr. Hill-Besinque and Ms. Raffi discussed the need for the pharmacist to take every patient’s blood pressure versus for only those who are taking medication that would affect their blood pressure.

President Weisser asked how a pharmacist deals with a young patient seeking birth control. Dr. Hill-Besinque commented that there is no minimum age for a patient seeking birth control. Hormonal contraception is only recommended for those who have started menstruating, so the pharmacist would need to discuss that with them.

Brianna Pitman, from Planned Parenthood, commented that she appreciated the inclusion of the conscience clause so that patients are not denied care. Ms. Pitman added that depo-injections were not discussed during the creation of SB 493; however, their inclusion should be researched and discussed. Ms. Pitman concluded that she would like to see a list created of clinics that a pharmacist could refer a patient to if they needed additional care or if the pharmacist conscientiously objected to dispensing birth control.

Shannon Smith-Crowley, American Congress of OBGYNs, commented that her main concern is preventing barriers to patients care. She added that she does not feel that a pharmacist needs to take a patient's blood pressure. It should be offered to the patient, but it should not prevent them from receiving care if they decline.

Ms. Herold commented that the fact sheet created by the board was meant to give women information on birth control options that they may not be aware of.

Dr. Hill-Besinque commented that hormonal contraception can be harmful for patients with high blood pressure, so taking blood pressure is necessary.

Dr. Hill-Besinque commented that she would eliminate question regarding regular menstrual cycles, she recommended instead asking when the last menstrual cycle occurred.

Ms. Raffi recommended removing the question about how many cigarettes a person smokes.

Ms. Raffi recommended removing the pregnancy test suggestion. Ms. McCaman responded that she would review this item.

Ms. Raffi commented that the language should be changed from "ACPE- or ASHP-approved continuing education program" to "board approved continuing education program."

Robert Stein, pharmacist, recommended that the board keep the conscience clause for clarity.

Brian Warren, representing the California Pharmacists Association, recommended changing the language to read "The pharmacist shall notify the patient's primary care provider, with patient consent..." Ms. McCaman responded that SB 493 states that the provider must be notified; however, she would like input from the board's legal counsel. Dr. Hill-Besinque commented that it is important for the board to protect a women's right to privacy in this area.

Mr. Warren stated that SB 493 allows the board to create a fact sheet or use a nationally recognized fact sheet. Ms. Herold commented that the FDA fact sheet comes in the medication packaging and is specific to the particular medication.

Mr. Warren asked if pharmacies could put the questions in their own formatting. Ms. Herold responded that she would ask legal counsel.

Ms. Raffi commented that SB 493 gives specific elements that must be included in the fact sheet, and some of the elements are missing from the current draft. Ms. McCaman agreed and noted she would be modifying it based on feedback received.

4. Review and Discussion on a Draft Protocol for Pharmacists Who Furnish Nicotine Replacement Products and Development of Draft Protocols

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

- Certification of the pharmacist in smoking cessation therapy by an organization recognized by the board
- Development of a protocol developed and approved by this board and the Medical Board of California with other “appropriate entities”
- The pharmacist maintain records of all prescription drugs and devices furnished for at least three years
- The patient’s primary care provider is notified of any drugs or devices furnished, or information is added to a shared patient record. If the patient has no primary care provider, the pharmacist provides the patient with a written record and advises the patient to consult a physician of the patient’s choice
- The pharmacist completes one hour of CE on smoking cessation therapy biennially

A draft protocol for nicotine replacement products is provided below.

Nicotine Replacement

(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 adequate information to successfully comply with smoking cessation therapy.

(3) Explanation of Covered Products: Prescription-only nicotine replacement products with the following routes of administration are covered by this protocol:

- Nicotine patch;

- Inhaler;
- Nasal spray.

The smoking cessation medications Bupropion SR (also marketed as Zyban) and Varenicline (also marketed as Chantix) are not covered by this protocol; these medications are not considered Nicotine Replacement Therapy, and therefore not authorized by Section 4052.9 of the California Business and Professions code.

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

- Ask the patient to explain his or her current illness and then clearly connect the illness with smoking. It is important to be specific because general statements like “smoking will kill you” may come across as nagging;
- Review the patients’ past quit attempts and examine three key questions:
 - What type of behavior-change techniques did the patient use in the past?
 - How did the patient use the smoking-cessation medication(s) of choice?
 - If the patient did not make any behavior changes or use medication(s), why not?
 - Did the patient experience any adverse effects during past quit attempts?
- Ask the patient the following screening questions:
 - Are you pregnant or plan to be pregnant? (If yes, do not furnish and refer to obstetrician)
 - Have you had a recent heart attack or any heart procedures within the last 2 weeks?
 - Do you have any history of arrhythmias?
 - Do you have any chest pain?
 - Have you been diagnosed with temporomandibular joint (TMJ) disorder, or do you wear dentures? (If yes, avoid gum)
 - Do you have any history of allergic rhinitis (e.g. nasal allergies)? (If yes, avoid nasal spray)
 - Do you have any history of asthma or COPD? (If yes, avoid inhaler and nasal spray).

Screening questions should be asked again annually, or whenever the patient indicates a major health change.

- When a nicotine replacement product is furnished:

- The pharmacist shall review the instructions for use with every patient using a nicotine replacement product.
- The patient shall be informed of the importance of coping with quitting; referring the patient to a behavior-change program will significantly increase his or her likelihood of success.
- The patient shall be provided with appropriate information on the national telephone quit line, 1-800-QUIT-NOW and/or the California telephone quit line, 1-800-NO-BUTTS.
- Pharmacists are encouraged to recommend the patient seek additional assistance, including but not limited to a formal cessation plan available for free through the quit lines. Pharmacists are also encouraged to research and refer patients to smartphone apps such as QuitSTART, QuitPal, and QuitGuide.
- The pharmacist shall review any questions the patient may have regarding smoking cessation therapy and/or nicotine replacement products.
- When considering a specific clinical situation, pharmacists are encouraged to consult the tools, resources, and publications from the University of California, San Francisco available at <http://rxforchange.ucsf.edu/registration.php> and <http://smokingcessationleadership.ucsf.edu/>.

(5) Product Selection: Based on the information gathered from the patient during the Procedure outlined above, the pharmacist may select any nicotine replacement products from the list of therapies specified in the Table “Pharmacologic Product Guide: FDA-Approved Medications for Smoking Cessation.” This list shall be kept current and maintained in the pharmacy. Furthermore, generic equivalent products may be furnished.

(6) Follow-Up Care: The pharmacist shall refer the patient to an appropriate health care provider for follow-up care in the following situations:

- Women who are pregnant or are planning to become pregnant.
- Patients with significant cardiac concerns, for example:
 - Myocardial infarction within the previous 2 weeks;
 - Serious underlying arrhythmias;
 - Serious or worsening angina pectoris.
- Patients with uncontrolled mental health conditions.

(7) 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, the pharmacist shall provide the patient with a written record of the drug(s) or device(s) furnished and advise the patient to consult a physician of the patient's choice.

(8) Referrals and Supplies: If smoking cessation services and/or nicotine replacement products are not immediately available, the pharmacist shall refer the patient to another nicotine replacement product provider and the National and/or California Smokers' Helpline.

(9) Documentation: Each smoking cessation drug or device furnished by a pharmacist pursuant to this protocol shall be documented in a patient medication record and securely stored within the originating pharmacy for a period of at least three years from the date when the last smoking cessation product was furnished; a patient medication record shall serve the purpose of notifying other health care providers and monitoring the patient. A patient medication record shall be maintained in an automated data processing or manual record mode such that the following information is readily retrievable during the pharmacy's normal operating hours:

(A) The patient's full name and address, telephone number, date of birth or age, and gender;

(B) For each nicotine replacement product dispensed by the pharmacist:

(i) The name, strength, dosage form, route of administration, quantity, and directions for use;

(ii) The furnishing pharmacist's name and where appropriate, license number, DEA registration number, or other unique identifier;

(iii) The date on which the nicotine replacement product was dispensed or refilled;

(iv) The prescription number for each nicotine replacement medication prescription;

(v) Any additional information required by title 16, sections 1717 and 1707.1 of the California Code of Regulations.

(C) Any of the following which may relate to the smoking cessation therapy: patient allergies, idiosyncrasies, current medications and relevant prior medications including nonprescription medications and relevant devices, or medical conditions which are communicated by the patient or the patient's agent.

(D) Any other information that the pharmacist, in his or her professional judgment, deems appropriate.

(10) Training: Prior to furnishing nicotine replacement products, pharmacists who participate in this protocol must be certified in

smoking cessation therapy by an organization recognized by the Board of Pharmacy. The Board of Pharmacy recognizes ACPE-approved CE programs of at least four hours, and recognizes the graduates of California Schools of Pharmacy.

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

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

Sarah McBane, pharmacist, recommended removing the three forms listed (patch, inhaler and spray).

Ms. McBane recommended removing the four questions about prior attempts to quit and changing it to say: Review the patient's current tobacco use and discuss their prior quit attempts.

Ms. McBane asked why the draft language states that a four-hour course is required. Ms. McCaman responded that she did research and found an ACPE program that was four hours and she found that students received six hours of education. She noted that she was willing to discuss modifying this requirement based on feedback. Dr. Kroon commented that a two hour training course would be sufficient for practicing pharmacists (students receive more training).

Dr. Kroon and Ms. McBane recommended removing: "Ask the patient to explain his or her current illness and then clearly connect the illness with smoking. It is important to be specific because general statements like "smoking will kill you" may come across as nagging."

Dr. Kroon recommended removing: "Screening questions should be asked again annually..."

Dr. Kroon recommended not including specific smartphone applications.

Ms. McBane recommended removing the entire paragraph that begins with "The smoking cessation medications Bupropion SR..."

Michael Santiago, legal counsel asked if all nicotine replacement gums are prescription only. Ms. McBane explained that some gums are over-the-counter but can also be written in a prescription so the patient's insurance will cover it. Mr. Santiago indicated that SB 493 only covers those available via prescription. The committee discussed the logistics of payment for

over-the-counter medications that are written via prescription and agreed that this needs to be looked at further.

Dr. Gray commented that the intent of SB 493 was to allow pharmacists to furnish nicotine smoking cessation products. He added that the inclusion of over-the-counter options is important because patients need to be informed on all of their options.

Dr. Gray asked if there is a problem with a pharmacist providing smoking cessation products to someone under 18 years old. The committee agreed that this should be addressed so that teenagers can get help quitting. Ms. McCaman noted that she purposely didn't include an age in the draft.

Jennifer Samosa, from the California Medical Board, commented that the Medical Board is looking forward to working with the Board of Pharmacy on these protocols. Dr. Gutierrez asked if the Medical Board has been working on the draft protocols with board staff. Ms. Herold responded that the executive officer has seen them. Ms. Samosa added that after the drafts are edited based on today's feedback they would be provided to the Medical Board's legal counsel and a few Medical Board members to review.

The committee recessed for a break at 2:35 p.m. and resumed at 2:40 p.m.

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

President Weisser explained that the requirements a pharmacist must meet to become licensed as an advanced practice pharmacist are:

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 reported that at prior meetings, this committee has heard presentations from the Board of Pharmacy Specialties, and Commission for Certification in Geriatric Pharmacy as possible routes to criteria A.

President Weisser reported that at the October 2014 Board Meeting, the board approved a motion that directs staff to: Develop regulation language to recognize NCCA approved providers as a qualifying route to APP licensure, and to finalize the draft application form to collect information from applicants for APP licensure.

President Weisser noted that page 17 of Attachment 7 in the meeting materials is a list of pharmacist programs certified by the NCCA. The committee asked staff to identify what NCCA programs are applicable to SB 493.

Mr. Jon Roth, CEO of the California Pharmacist's Association, commented that at the last committee meeting members discussed approving accrediting agencies rather than reviewing and approving each individual program. He again expressed his support of this approach.

Dr. Gutierrez expressed that some of the programs accredited by NCCA do not seem to apply to an advanced practice pharmacist.

Dr. Hill-Besinque commented that if the board chooses to approve accreditation bodies, it does not mean that every course offered by the accreditation body would be acceptable for APP licensure. It would still need to be relevant to patient care.

Dr. Robinson commented that he also supports the board approving accreditation bodies rather than individual programs.

Ms. McBane suggested removing scope of practice section of the draft application. She also asked the committee to consider if the social security number was really needed on the application as the board would already have it on file. Dr. Gray agreed with Ms. McBane.

Ms. McBane also recommended that the application be updated to say "primary location," rather than having applicants list all of the possible places they may be working.

Dr. Gray recommended that the application include the NPI number if applicable.

Mr. Roth commented that in many of the documents in the meeting materials the term "APP license" is used. He stated that he doesn't believe that the board is creating a new license, rather they are granting a credential to an already existing license. Dr. Gray commented that perhaps the board could call it a registration. Ms. Herold responded that from the board's perspective it is a license. Mr. Santiago agreed that in department vernacular this is a license, not a credential or registration.

6. Discussion on the Development of Pharmacy Protocols for Naloxone, as Provided by AB 1535 (Bloom, Chapter 326, Statutes of 2014)

This year, AB 1535 authorizes the Board of Pharmacy to work with the Medical Board to develop a jointly approved protocol on naloxone for pharmacists. A draft protocol will be brought to the December Board meeting for the committee's review.

Section 4052.01 is added to the Business and Professions Code, to read:

4052.01.

- (a) Notwithstanding any other provision of law, a pharmacist may furnish naloxone hydrochloride in accordance with standardized procedures or protocols developed and approved by both the board and the Medical Board of California, in consultation with the California Society of Addiction Medicine, the California Pharmacists Association, and other appropriate entities. In developing those standardized procedures or protocols, the board and the Medical Board of California shall include the following:
- (1) Procedures to ensure education of the person to whom the drug is furnished, including, but not limited to, opioid overdose prevention, recognition, and response, safe administration of naloxone hydrochloride, potential side effects or adverse events, and the imperative to seek emergency medical care for the patient.
 - (2) Procedures to ensure the education of the person to whom the drug is furnished regarding the availability of drug treatment programs.
 - (3) Procedures for the notification of the patient's primary care provider with patient consent of any drugs or devices furnished to the patient, or entry of appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider, and with patient consent.
- (b) A pharmacist furnishing naloxone hydrochloride pursuant to this section shall not permit the person to whom the drug is furnished to waive the consultation required by the board and the Medical Board of California.
- (c) Prior to performing a procedure authorized under this section, a pharmacist shall complete a training program on the use of opioid antagonists that consists of at least one hour of approved continuing education on the use of naloxone hydrochloride.
- (d) The board and the Medical Board of California are each authorized to ensure compliance with this section. Each board is specifically charged with enforcing this section with respect to its respective licensees. This section does not expand the authority of a pharmacist to prescribe any prescription medication.
- (e) 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).

Dr. Gutierrez commented that she is pleased to see the board taking steps to help deal with the adverse effects of opioids. She asked if other states already have programs in place. Ms. Herold responded that California is very behind in this area.

Brian Warren commented that there was emergency language included because there is an urgent public health risk. Mr. Warren noted that New Mexico, Rhode Island, and Washington have programs in place.

Ms. Herold commented that, unfortunately, this is a very necessary service that needs to be provided.

Dr. Gray commented that some of the latest naloxone products actually talk to the patient. He added that a future product will even email the doctor when the product is used.

Keith Yokishoka commented that www.prescribetoprevent.org has a naloxone protocol that is used in Rhode Island.

Mike McQuitty, from Department of Healthcare Services, asked when the draft protocol would be reviewed by the committee. Ms. Herold responded that the language his department provided has been used as a source document and the draft would be reviewed at the December committee meeting.

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

There were no comments from the committee or the public.

President Weisser adjourned the meeting at 3:13 p.m.

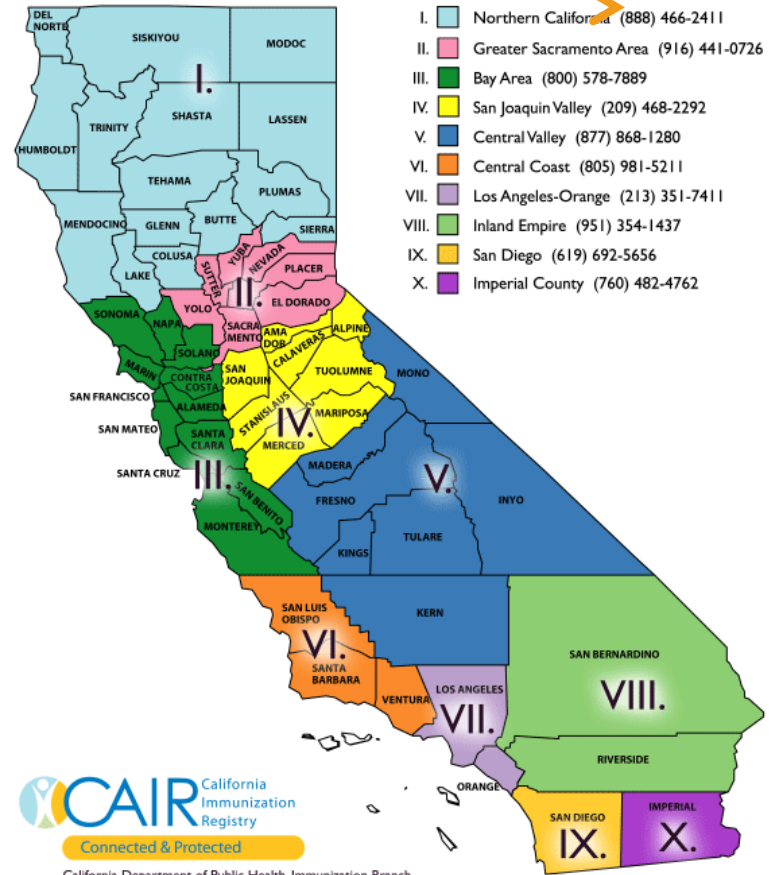


California Immunization Registry (CAIR) Update

Steve Nickell PhD
Chief, Registry & Assessment Section
Immunization Branch, CDPH
Pharmacy Board, 11/5/2014

Regional Immunization Registries in CA

- 10 regional or county immunization registries statewide
- All but Imperial County comprise the California Immunization Registry (CAIR) System



California Department of Public Health, Immunization Branch
850 Marina Bay Parkway, Building P, 2nd Floor, Richmond, CA 94804
www.ca-sils.org (510) 620-3737

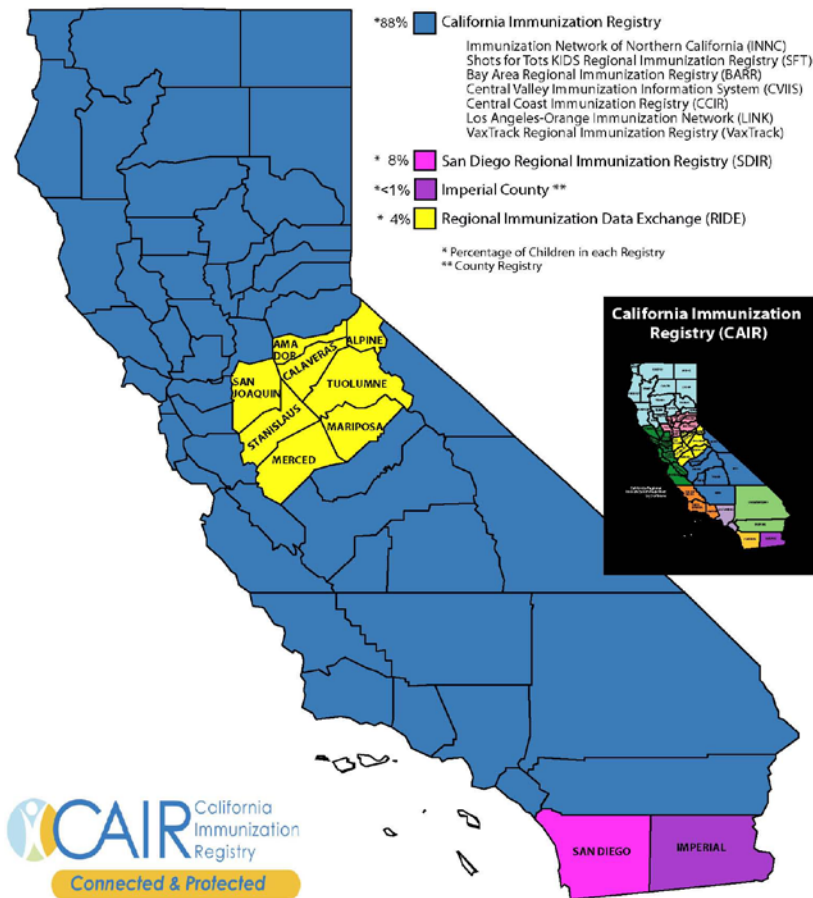
APRIL 2008



The California Immunization Registry (CAIR) System

- CAIR is a consortium of 9 regional registries
- 7 use same 'CAIR' software and are operated by CDPH
- 'CAIR 7' cover 48 of 58 CA counties; 87% of population

California Immunization Registry (CAIR) By Software Application



California Department of Public Health, Immunization Branch
850 Marina Bay Parkway, Building P, 2nd Floor, Richmond, CA 94804
www.ca-siis.org (510) 620-3737

June 2009



Benefits of IZ Registries

- **FOR PATIENTS:**

- Consolidate in one record all immunizations a patient has received.
- Provide an accurate, official copy of a child's immunization history for personal, day care, school, or camp entry requirements.
- Help ensure that a patient's immunizations are up to date.
- Help ensure timely immunization for children whose families move or switch healthcare providers.
- Prevent unnecessary (duplicative) immunizations.

- **FOR PROVIDERS, PLANS AND PURCHASERS:**

- Provide definitive information on immunizations due or overdue.
- Provide current recommendations and information on new vaccines.
- Complete required school, camp, and day care immunization records.
- Facilitate introduction of new vaccines or changes in the vaccine schedule.
- Help manage vaccine inventories.
- Generate coverage reports for managed care (e.g., Healthcare Effectiveness Data and Information Set [HEDIS®]) and other organizations.



Benefits of IZ Registries

- **FOR COMMUNITIES:**
 - Help control vaccine-preventable diseases.
 - Help identify high-risk populations and under-immunized populations.
 - Help prevent disease outbreaks.
 - Provide information on community and state coverage rates.
- **FOR PUBLIC HEALTH OFFICIALS:**
 - Provide information to identify pockets of need, target interventions and resources, and evaluate programs.
 - Ensure providers follow the most up-to-date recommendations for immunization practice.
 - Facilitate introduction of new vaccines or changes in the vaccine schedule.
 - Integrate immunization services with other public health functions.
 - Help to monitor adverse events.



CAIR - Disclosure

- Patients must be informed that their IZ information will be shared prior to the provider sharing the information with CAIR
- Patients have right to:
 - Refuse sharing with other CAIR users
 - Correct record
 - Request list of users who have viewed their record
- CAIR Disclosure ('Immunization Registry Notice to Patients and Parents') is available in multiple languages at: <http://cairweb.org/cair-forms/>

CAIR 2.0 Project

- Consolidate 'CAIR 7' into single db - CDPH 'hub'
- Implement new state-of-the-art registry software (WIR used by 17 other states) that is state IT-compliant and supports interoperability (HL7)
- Connect to 3 independent via HL7 query/response messaging
- Due late 2016

CAIR IZ Portal (CAIR 7) - Electronic Data Submission

CAIR IZ Portal offers a simple online interface that allows electronic data submitters to:

- **Register** - automated email returns appropriate IDs and passwords
- **Test** - submit HL7 messages via SOAP for automated email feedback
- **Submit** - 'onboard' to full production data submission
- Register at: <https://igs.cdph.ca.gov/cair/>

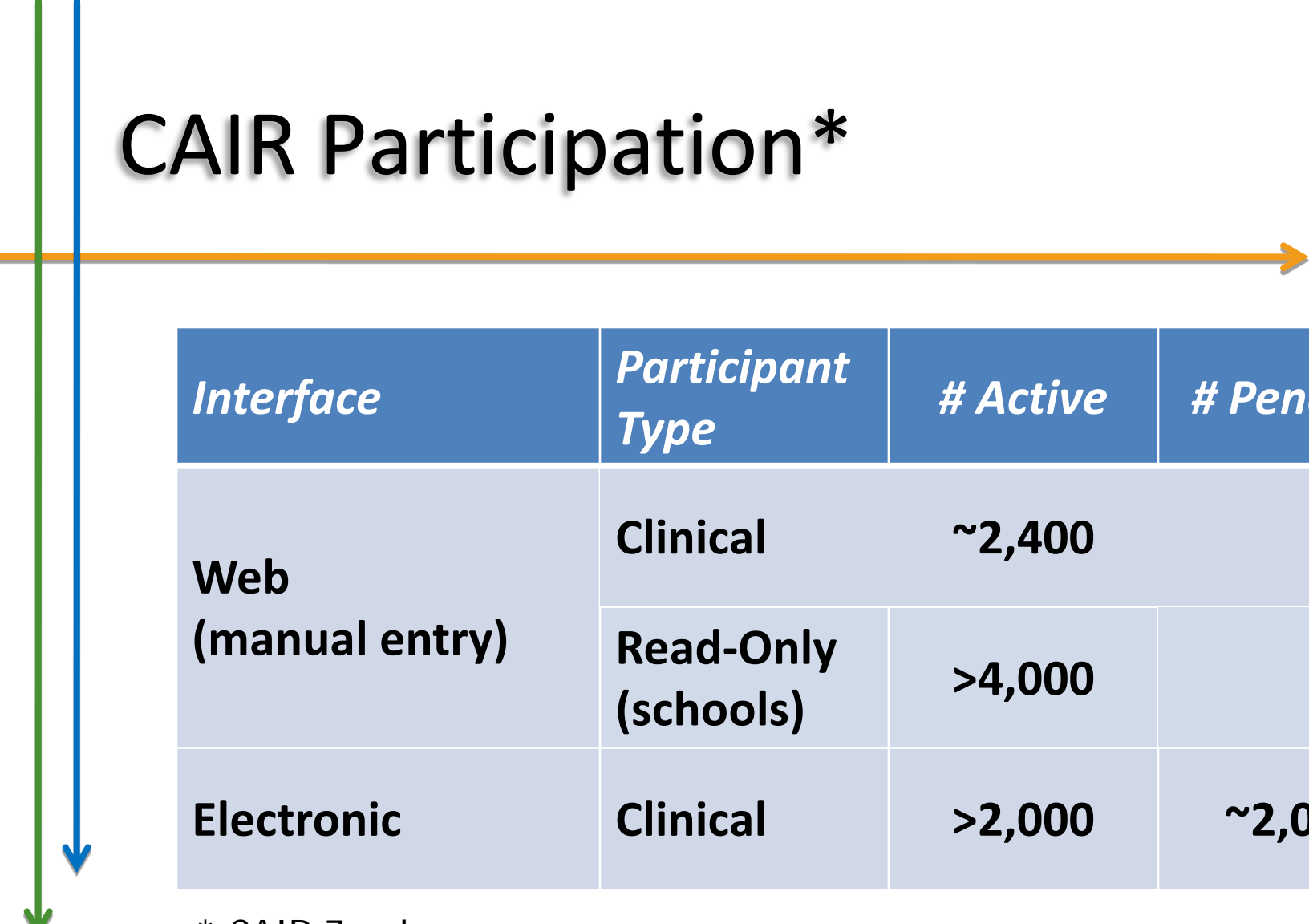
CAIR IZ Portal - Current Status*

<i>Site Type</i>	<i>Total</i>	<i>Data Submission Status</i>	
		<i># Testing</i>	<i># 'Production'</i>
1. Direct submission to CAIR		991	
2. Submits via HIE	2,935	960	
Total Data Owners	3,989	1,951	
3. HIEs	171	112	59
TOTAL Registrants			

* As of 11/4/2014. 'CAIR 7' only.



CAIR Participation*



<i>Interface</i>	<i>Participant Type</i>	<i># Active</i>	<i># Pending</i>
Web (manual entry)	Clinical	~2,400	
	Read-Only (schools)	>4,000	
Electronic	Clinical	>2,000	~2,000

* CAIR 7 only

Impact of MU Program

- In MU Stage 2, submission to IZ registry is *core* measure so is required

CAIR Portal Accts	#
Existing	1,781
New	2,208
Total Portal Accts	3,989

CAIR Participation - Pharmacies

- sFTP/Flat File process
 - Rite Aid
 - Safeway/Vons/Pavilion
 - Walgreens (>550 sites)
- CAIR IZ Portal Registrants (HL7)

Pharmacy	Sending Entity	Status
Clinicare	Practice Fusion	Testing
CVS	Surescripts	Pending
Safeway	Surescripts	Pending
Walmart	STC	Pending

Important Links

CAIR Home Page:

www.cairweb.org

5 Steps to Data Exchange:

[Cairweb.org/data-exchange-tech-support/](http:// Cairweb.org/data-exchange-tech-support/)

Data Exchange Specialists for questions:

CAIRDataExchange@cdph.ca.gov





Questions?



California State Board of Pharmacy

1625 N. Market Blvd, N219, Sacramento, CA 95834

Phone: (916) 574-7900

Fax: (916) 574-8618

www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

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

DATE: December 16, 2014

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

COMMITTEE MEMBERS

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

**COMMITTEE MEMBERS
NOT PRESENT:** Victor Law, RPh

STAFF

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

Call to Order

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

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

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

1. Discussion on Requirements of the Advanced Practice Pharmacist License

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

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

NCCA Mission

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

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

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

Application Process

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

Overview of NCCA Standards

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Approaches to Increasing Immunization Registry Usage

Rational

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

Examples of Other Jurisdictions

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

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

Policy Options

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

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

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

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

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

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

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

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

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

d. Report of Other Programs Envisioned or Under Development

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

• *All pharmacists can:*

Order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies. A pharmacist who orders and interprets tests pursuant to this paragraph shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescription, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or enter the appropriate information in a patient record system shared with the prescriber, when available and as permitted by the prescriber. (CA B&P Code section 4052(a)(12))

• *APP licensed pharmacists can:*

Order and interpret drug-therapy related tests, and initiate or modify therapy
This item is on the agenda so the committee and audience may discuss it.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

M/S: Veale/Gutierrez

Support: 3 Oppose: 0 Abstain: 0

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

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

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

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

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

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

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

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

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

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

M/S: Gutierrez/Veale

Support: 3 Oppose: 0 Abstain: 0

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

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

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

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

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

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

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

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

M/S: Gutierrez/Veale

Support: 3 Oppose: 0 Abstain: 0

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

M/S: Gutierrez/ Veale

Support: 3 Oppose: 0 Abstain: 0

6. General Discussion Concerning Implementation of SB 493

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

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

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

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

NCCA Accreditation Process

December 16, 2014



NCCA Mission

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

- Establish accreditation standards;
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Application Process

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

Application Status

- Primary reviewers responsible for formal written comments in online application.
- NCCA Commission meets in-person to discuss new and renewal applications
- Decisions: Approve, Deny, or Defer
- NCCA Chair notifies program sponsor of application status through online system

Applications - General

- Summative vs. formative evaluation
- Commissioners are encouraged to send formal inquiries to applicants through the online system for questions or clarifications.
 - Avoid consultation with the program
- Confidentiality of applicant and application status
- Annual reports for all accredited programs are due June 1 and reviewed during the July meeting.

Overview of NCCA Standards

- NCCA accredits certification programs, not organizations, agencies, or testing services
- Programs may be sponsored by non-profit or for-profit organizations
- Accreditation is generally awarded for five years
- NCCA Standards are intended to be consistent with the *Standards for Educational and Psychological Testing* (AERA, APA, & NCME, 2014), and others
- Purpose is to evaluate process and products (not content)

Components of Each Standard

✓ Standard Statement

- An accreditation requirement that must be met

✓ Essential Element

- Specifies what must be done to fulfill the requirements of the standard

✓ Commentary

- Clarifies terms, provides examples, or offers suggestions regarding evidence needed to document compliance

(Current) Structure of Standards

- Resources, structure, and governance of the sponsoring organization (5)
- Information required to be available to applicants, certificants, and the public (4)
- Characteristics of the program including administrative and psychometric concerns (9)
- Recertification initiatives (2)
- Ongoing compliance with standards (1)

Example: Purpose of the Certification Program

The purpose of the certification program is to conduct certification activities in a manner that upholds standards for competent practice in a profession, occupation, role, or skill.

- Greater emphasis on eligibility
- Greater emphasis on the intended purpose and target population

Example: Practice Analysis

The certification program must analyze, define, and publish performance domains and tasks related to the purpose of the credential, and the knowledge and/or skill associated with the performance domains and tasks, and use them to develop specifications for the assessment instruments.

- Greater emphasis on aligning method with program
- Greater emphasis on representativeness
- Greater emphasis on translation to blueprint process

Example: Recertification

The certification program must demonstrate that its recertification requirements measure or enhance the continued competence of certificants.

- Greater emphasis on the rationale/philosophy of the recertification (e.g., continued competence, enhanced competence)
- Greater emphasis on connecting recertification expectations with job related expectations

Questions?





Approaches to Increasing Immunization Registry Usage

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Overview

- Introduction
- Rationale
- Examples
- Policy Options
- Timelines



Introduction

- SB 493
 - Authorizes pharmacists to administer immunizations
 - Mentions registry usage: “Comply with all state and federal recordkeeping and reporting requirements, including ...entering information in the appropriate immunization registry.”
- Rationale for immunization registries and benefits of usage
- Strategies to increase usage of vaccine registries



Rationale

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



Rationale

- Healthy People 2020
 - IID–18: Increase the percentage of children under age 6 years of age whose immunization records are in a fully operational, population-based immunization information system (IIS).
 - Target: 95 percent.
 - Baseline: 75 percent of children under 6 years of age had two or more immunizations recorded in immunization information system (IIS) in 2008.

Rationale

Percentage of U.S. Children < 6 years with 2+ Immunizations in IIS

State/City	Percentage
Alabama	95.3%
Alaska	71.3%
Arizona	106.4%
Arkansas	109.6%
California	61.8%
Chicago, IL*	57.7%
Colorado	100%
Connecticut	58.8%
DC	No Data
Delaware	106.3%
Florida	107.3%
Georgia	116.7%
Hawaii	34.9%

National coverage: 86% (2012)

Percentage of U.S. Adults +19 years with 1+ Immunizations in IIS

State/City	Percentage
Alabama	31.4%
Alaska	52.6%
Arizona	30.4%
Arkansas	50.5%
California	8.7%
Chicago, IL*	2.2%
Colorado	32.4%
Connecticut	No Data
DC	No Data
Delaware	14.5%
Florida	35.3%
Georgia	71.6%
Hawaii	6.7%

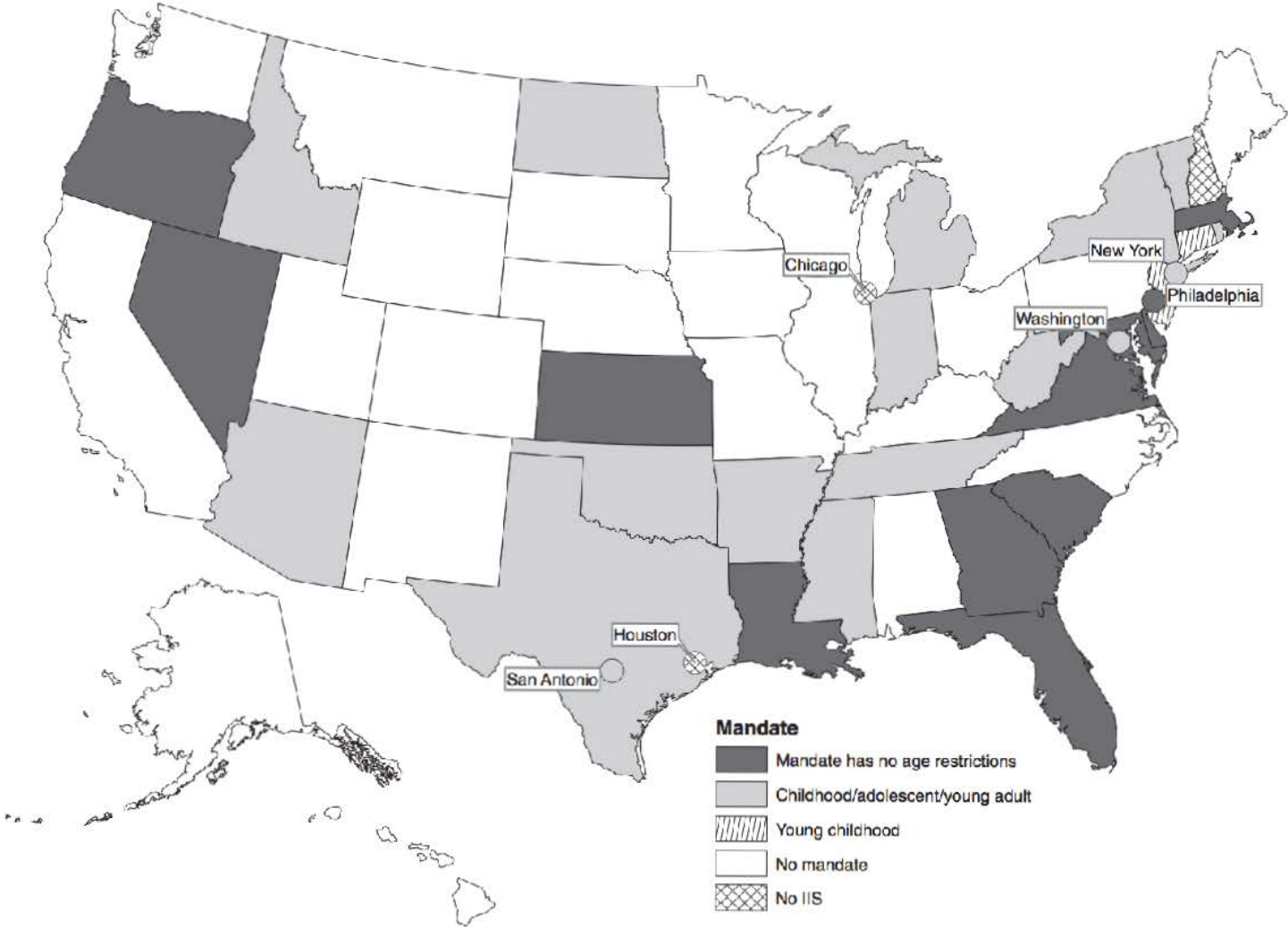
National coverage: 25% (2012)



Examples from Other Jurisdictions

- Minnesota: “Mark of Excellence” voluntary recognition program
- New Jersey: Requirement to enter information into the registry for children under 7
- Arizona: Requirement that all immunizations given to children must be recorded in the registry, but pharmacies must also enter information for adults
- Summary: In 2013, 31 jurisdictions currently mandate at least one type of provider report immunizations (up from 12 in 2000).

Examples from Other Jurisdictions





Policy Options

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



Immunization Providers

- Impacts of registry participation on providers
- Benefits of registry participation for providers



Timeline

- Activities that influence immunization registry usage in California (2014-2016)
 - Software update
 - Meaningful use
- Policy processes may be initiated concurrently, or subsequent to identifying the impact of the new technology



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