



## **SENATE BILL 493 IMPLEMENTATION COMMITTEE**

For the Meeting of December 16, 2014

Stan Weisser, RPh, Board President and Committee Chair

Amy Gutierrez, Pharm D

Debbie Veale, RPh

Victor Law, RPh

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

The board has formed this committee to implement the multiple requirements of SB 493. This committee, called simply the Senate Bill 493 Implementation Committee, will work on components to implement the multiple provisions of this bill. The meetings where these deliberations will occur are public, and will be listed on the board's website. We invite interested individuals to attend. The recent enactment of AB 1535 (Bloom) has directed the board to develop a naloxone protocol through an emergency rulemaking process. For expediency, this task has been added to the agenda of this committee.

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The committee met November 5, 2014; the minutes of this meeting are provided as **Attachment 1**.

### **1. FOR POSSIBLE ACTION: Discussion on Application Requirements of the Advanced Practice Pharmacist License**

**Attachments 2**

The requirements a pharmacist must meet to become licensed as an advanced practice pharmacist are provided in California Business and Professions Code section 4210, and require applicants to:

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.

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

And

b. **Other Certification Programs (e.g., Commission for Certification in Geriatric Pharmacy**

Over prior meetings, this committee has heard presentations from the Board of Pharmacy Specialties. Background materials and excerpts of the minutes for meetings hosting these discussions are provided in **Attachment 2**.

At this meeting the committee will hear a presentation by Anjali Weber, PhD, executive director of the National Commission for Certifying Agencies. Dr. Weber will provide a review of what the NCCA does when it approves a certification program. Background material on this agency and its process is provided in **Attachment 3**.

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.

William Ellis, executive director of the Board of Pharmacy Specialties will attend this meeting. Mr. Ellis will be present to provide information to respond to questions about the BPS program. The BPS has certification programs for eight of the nine specialties listed in paragraph (A): specifically:

- ambulatory care,
- critical care,
- nuclear pharmacy,
- nutrition support pharmacy,
- oncology pharmacy,
- pediatric pharmacy,
- pharmacotherapy,
- psychiatric pharmacy

There is one additional component -- geriatric pharmacy -- that is listed in the statutory language of paragraph (A) that is not a BPS certification program, but it is accepted by NCCA. Minutes from the meeting were the Certification in Geriatric Pharmacy provided a presentation to the committee is provided in **Attachment 4**.

Again, 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. This language, fully encompassing a fee for APP licensure, and means to provide evidence of possessing qualifying experience will be available at the board January 2015 Board Meeting.

**c. Report on other Programs Envisioned or Under Development**

This portion of the agenda is available for open discussion on other proposals to fit the qualifying method specified in paragraph (A).

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

The executive officer is 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.

**2. FOR POSSIBLE ACTION: 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.

At prior committee meetings, the committee has discussed various aspects of immunizations, including required reporting into the immunization registry. At this meeting, we believe we will have someone from the Los Angeles Department of Public Health to provide information in this area.

Regarding another aspect of pharmacists providing immunizations: 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.

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 – how can they document they completed this training several years before?

At this meeting, the committee should hear from representatives of several schools of pharmacy who will provide the next iteration of a form and possible mechanism by which schools and pharmacists can track they possess the required training. Although not required, this would facilitate identification by board staff monitoring to ensure the pharmacists possess the required training.

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

**Attachment 5**

At this meeting, the committee will continue its discussions about the parameters for travel medications. The discussion held at the prior meeting is provided in the minutes from the November committee meeting (see **Attachment 1**). Some of the issues still outstanding from prior meetings is highlighted in the material below.

At a prior meeting, the board discussed “not requiring a diagnosis.” Dr. Goad indicated that the CDC Yellow-book is the guidance document that the legislation is references. He reported that there is a chapter in the CDC Yellow-book on self-treatable illnesses. Here is the link to the book and the specific chapter you need:

Book: <http://wwwnc.cdc.gov/travel/page/yellowbook-home-2014>

Self-treatable conditions: <http://wwwnc.cdc.gov/travel/yellowbook/2014/chapter-2-the-pre-travel-consultation/self-treatable-conditions>

At the August meeting, the board’s counsel, Kristy Scheildge, commented that the committee should define what “not requiring a diagnosis” means and specifically identify the CDC guidance document.

Also, **Attachment 5** contains a draft document that outlines travel meds that was prepared by a team of individuals from CSHP and CPhA.

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

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.

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

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

This item is on the agenda so the committee and audience may discuss it.

At prior meetings, comments made on this topic include 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.

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, the standard of care could evolve to a point where a pharmacist *must* order a test prior to dispensing a certain medication.

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

**Attachment 6**

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 CA Department of Public Health.

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 to develop draft components for board review. One such product is the development of a protocol for self-administered hormonal contraception.

**Attachment 6** contains a draft protocol for hormonal contraception. A major outcome of this meeting is to identify whether this protocol is ready for submission to the board and Medical Board of California for approval and adoption as a regulation by the Board of Pharmacy.

Board staff believes this draft is ready for final review and referral to adoption as a regulation. However, if the committee is not ready to make this decision, the committee should direct specific steps to finalize the protocol, including the scheduling of an additional meeting in mid-January 2015 – before the board’s January Meeting to resolve any outstanding issues.

**4. FOR POSSIBLE ACTION: Review and Discussion on a Draft Protocol for Pharmacists Who Furnish Nicotine Replacement Products and Development of Draft Protocols**

**Attachment 7**

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 in **Attachment 7**. Review of this protocol is another of the principal topics for this meeting. Staff believes that this protocol is ready for submission to the board and Medical Board of California for approval and adoption as a regulation by the Board of Pharmacy at its January 2015 board meeting, and then on to the Medical Board Meeting that immediately follows the Pharmacy Board meeting.

However, if the committee is not ready to make this decision, the committee should direct specific steps to finalize the protocol, including the scheduling of an additional meeting in mid-January 2015 – before the board’s January Meeting to resolve any outstanding issues.

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

**Attachment 8**

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.

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).

A draft protocol has been vetted with various experts and is being brought to this committee meeting in **Attachment 8** for the committee's review.

Staff believes that this protocol is ready for final review by the committee and is ready to be brought to the January 2015 Board Meeting for approval.

A major outcome of this meeting is to identify whether this protocol is ready for submission to the board and Medical Board of California for approval and adoption as a regulation by the Board of Pharmacy.

However, if the committee is not ready to make this decision, the committee should direct specific steps to finalize the protocol, including the scheduling of an additional meeting in mid-January 2015 – before the board's January meeting to resolve any outstanding issues.

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

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

# **Attachment 1**



**California State Board of Pharmacy**

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

**STATE BOARD OF PHARMACY  
DEPARTMENT OF CONSUMER AFFAIRS  
SB 493 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  
Deborah Veale, RPh  
Amy Gutierrez, PharmD.  
Victor Law, RPh

**COMMITTEE MEMBERS**

**NOT PRESENT:**

**STAFF**

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

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**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>
<b>Web (manual entry)</b>	<b>Clinical</b>	<b>~2,400</b>	
	<b>Read-Only (schools)</b>	<b>&gt;4,000</b>	
<b>Electronic</b>	<b>Clinical</b>	<b>&gt;2,000</b>	<b>~2,000</b>

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 [available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6205a1.htm](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](http://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.

# **Attachment 2**

December 31, 2013

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

Dear Ms. Herold,

The Board of Pharmacy Specialties (BPS) was organized in 1976 as an independent certification agency of the American Pharmacists Association (APhA) with a mission to improve patient care by promoting the recognition and value of specialized training, knowledge, and skills in pharmacy and specialty board certification of pharmacists.

Toward this mission, BPS has recognized eight specialty practice areas including ambulatory care pharmacy, nuclear pharmacy, nutrition support pharmacy, pharmacotherapy, psychiatric pharmacy, oncology pharmacy, and the newest specialties – critical care pharmacy and pediatric pharmacy.

These eight areas of practice are also identified as part of eligibility criteria for individuals who seek recognition as an “advanced practice pharmacist” in legislation recently signed by California Governor Jerry Brown.

Enclosed is a document that provides background on and describes the rigorous process utilized by BPS to develop psychometrically sound and defensible certifications.

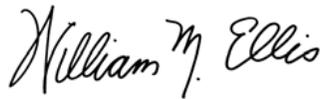
Of the more than 18,000 pharmacist specialists that are currently certified by BPS, over 10% reside in the State of California. BPS encourages the California State Board of Pharmacy to consider recognizing BPS, its specialty certification programs, and certificants as the Board develops and approves regulations to implement the provisions.

If you have any questions or require any additional background, please let us know. BPS would be happy to present information on its rigorous, nationally-accredited specialty certification programs to the California State Board of Pharmacy.

Sincerely,



Joseph J. Saseen, PharmD, BCPS  
2013 Chair, Board of Directors



William M. Ellis, RPh, MS  
Executive Director

Enclosure

cc: BPS Board of Directors  
Brian Lawson, PharmD, BPS Director, Professional Affairs

Board of Pharmacy Specialties  
2215 Constitution Avenue, NW  
Washington, DC 20037-2985  
[www.bpsweb.org](http://www.bpsweb.org)

*Ambulatory Care Pharmacy • Critical Care Pharmacy • Nuclear Pharmacy • Nutrition Support Pharmacy  
Pediatric Pharmacy • Pharmacotherapy • Psychiatric Pharmacy • Oncology Pharmacy*

### **Mission and Purpose**

The Mission of the Board of Pharmacy Specialties (BPS) is to improve patient care by promoting the recognition and value of specialized training, knowledge, and skills in pharmacy and specialty board certification of pharmacists

The Purpose of BPS certification programs is:

1. To grant recognition of appropriate pharmacy practice specialties based on criteria established by the Board of Pharmacy Specialties;
2. To establish standards for certification and recertification of pharmacists in recognized pharmacy practice specialties;
3. To grant qualified pharmacists certification and recertification in recognized pharmacy practice specialties;
4. To serve as a coordinating agency and informational clearing house for organizations and pharmacists in recognized pharmacy specialties;
5. To enhance public/consumer protection by developing effective certification programs for specialty practices in pharmacy.

### **Governance**

The BPS Board of Directors provides oversight for each of the eight Specialty Councils, staff, and test administrator / psychometric consultants in the administration of psychometrically sound and defensible certification processes.

### **NCCA Accreditation**

The National Commission for Certifying Agencies (NCCA) was created in 1987 to help ensure the health, welfare, and safety of the public through the accreditation of a variety of certification programs/organizations that assess professional competence. Certification programs that receive NCCA Accreditation demonstrate compliance with the NCCA's Standards for the Accreditation of Certification Programs, which were the first standards for professional certification programs developed by the industry.

NCCA accredited programs certify individuals in a wide range of professions and occupations including nurses, automotive professionals, respiratory therapists, counselors, emergency technicians, crane operators and more. To date, NCCA has accredited approximately 300 programs from more than 120 organizations.

The NCCA standards require demonstration of a valid and reliable process for development, implementation, maintenance, and governance of certification programs. NCCA uses a rigorous 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. The NCCA Standards are comprehensive and cover all aspects of the certification program(s), including administration, assessment development and recertification. NCCA standards are consistent with *The Standards for Educational and Psychological Testing (AERA, APA, & NCME, 1999)* and are applicable to all professions and industries.

BPS Specialty Certification Programs in Nuclear Pharmacy, Nutrition Support Pharmacy, Oncology Pharmacy, Pharmacotherapy and Psychiatric Pharmacy are recognized as accredited certification programs by the National Commission for Certifying Agencies, (NCCA). The Ambulatory Care Pharmacy specialty certification program

applied for accreditation in 2013. Per NCCA policies and procedures, the Critical Care Pharmacy and Pediatric Pharmacy specialty certification programs will be eligible for accreditation in 2018.

### **About the BPS Exam**

A BPS specialty certification examination samples the knowledge required to perform the tasks in each of the major areas of responsibility of the specialty as defined through a validated role delineation study (RDS). The RDS is developed through a nationwide study of the work pharmacy specialists perform in a variety of practice settings.

Mastery of the knowledge and skills involved in the defined scope of specialized practice is necessary for board certification, regardless of the particular practice in which an applicant is currently involved. Technical support in conducting task analyses, establishing test specifications, and constructing examinations is provided by an independent testing company that specializes in the assessment of the knowledge, skills, and abilities of professionals.

A content outline, listing the domains, tasks, and knowledge statements specific to each specialty practice, is provided for the information of prospective candidates on the BPS website or upon request. The content outline also notes the percentage of items per domain. Examinations are not structured domain by domain. Instead, test questions for each domain are distributed randomly throughout the total examination.

New regulations, drugs, and therapies are incorporated annually into the examinations. All BPS specialty certification examinations reflect current, best practices, at the time they are constructed – approximately six months prior to test administration. Official United States Adopted Name (USAN) generic names are used on all BPS examinations for all drug products, when possible.

### **Eligibility Criteria**

BPS specialty certifications are post-licensure credentials that document the knowledge, skill, and experience of pharmacists. Each BPS Specialty Certification Program has specific eligibility requirement related to practice experience. In general, the requirements for specialty certification are:

- Graduation from a pharmacy 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.
  - Practice Experience:
    - Completion of two (2) to four (4) years of practice experience with at least 50% of time spent in the pharmacy specialty practice activities (as defined by the applicable BPS Specialty Content Outline)
    - OR
    - Completion of a PGY1 residency\*, specialty PGY2 residency\*, and/or one additional year of practice with at least 50% of time spent in the pharmacy specialty practice activities (as defined by the BPS Ambulatory Care Content Outline)
- \*Effective January 1, 2013, only residency programs accredited by the American Society of Health-System Pharmacists (ASHP) or new residency programs granted Candidate Status for accreditation by ASHP are creditable for this purpose.
- Achieving a passing score on the BPS Specialty Certification Examination

### **Exam Test Dates and Sites**

BPS works with its testing provider to administer the specialty certification exams via internet-based testing. Candidates must schedule the date, time within two scheduled test administration windows (Spring and Fall). Candidates can schedule their examination at more than 450 test sites within the United States. **The test provider offers 26 locations in California.**

## **Examination Schedule**

Initial certification candidates will be permitted a total timed testing period of five (5) hours, scheduled as follows:

- Examination Part 1 (100 multiple-choice items): 2.5 hour testing period
- Optional break: Up to 45 minutes
- Examination Part 2 (100 multiple-choice items): 2.5 hour testing period

## **Examination Scoring**

The passing standards used in BPS examinations were established using criterion-referenced procedures that are widely used in certification. Criterion referenced passing standards link the score required to pass a test to the minimum level of knowledge required for specialty certification. Each BPS specialty certification program has its own passing standard.

BPS creates new versions, or forms, of all of its tests on a regular basis. In assembling the new forms, BPS and its testing consultants follow best practices in certification testing so that all forms are comparable in content and difficulty. Once the examination forms have been equated, a procedure called *scaling* is used to convert the actual number of correct answers, or raw scores, to a uniform scale. These converted scores are called scaled scores. Equated, scaled scores ensure that all candidates for a BPS specialty certification demonstrate at least the same level of knowledge in order to pass the examination.

## **Recertification**

Recertification assures the public and the profession that certified practitioners undergo periodic evaluation. Participating in continuing education opportunities or preparing for the recertification exam also offers the opportunity for certificants to increase knowledge in a specialty area and to stay up-to-date with current developments in the field. The Board of Pharmacy Specialties requires all board-certified specialists to recertify every seven years.

If a BPS-certified specialist does not apply for recertification, the individual will be removed from the official roster of board certified specialists. If a certified pharmacist fails to successfully complete the recertification process, extension of certification may be granted for a one-year period, at the sole discretion of BPS, while the individual seeks to successfully complete the process. Once a BPS-certified specialist has been deleted permanently from the roster, that individual may no longer use the designation or initials associated with that specialty (e.g., Board Certified Nuclear Pharmacist, BCNP) nor display the BPS certificate. Reinstatement can be achieved only by the successful completion of the entire certification process.

Each specialty area has its own approved continuing education programs and requirements designed to assess a practitioner's knowledge in their particular subject area. Continuing education credit earned through an approved professional development program will only be counted towards that specific specialty area. There is no overlap in continuing education programs between specialty areas.

A current, active license to practice pharmacist is required for recertification. Most BPS Board Certified Pharmacists have two options to maintain their certification by completing one of the professional development activities:

- Achieving a passing score on the 100-item, multiple choice objective recertification examination, based on the content outline for that particular specialty.
- Earning prescribed number hours of continuing education credit provided by a professional development program approved by BPS.

# BOARD OF PHARMACY SPECIALTIES

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## Content Outline for the AMBULATORY CARE PHARMACY SPECIALTY CERTIFICATION EXAMINATION January 2010 (Systems & Patient Care Problems updated May 2010)

The following domains, tasks and knowledge statements were delineated by the BPS Specialty Council on Ambulatory Care Pharmacy and validated through a role delineation study in 2007. The proportion of examination items allotted to each domain was determined through analysis and discussion of the results of the role delineation study by the Specialty Council.

Each of the major areas/domains of Ambulatory Care Pharmacy practice noted below will be tested. Questions will not be grouped by domain. Rather, items testing each domain are distributed throughout the total examination. Please note this examination will **SAMPLE** a candidate's knowledge rather than try to test all of his/her knowledge.

The test items in Domain 1 that deal with direct patient care focus on the therapeutic areas listed in the *Systems and Patient-Care Problems* section of this document, which begins on page 11 (e.g., Cardiovascular, Endocrine, Infectious Diseases). Test items in Domain 1 that deal with age-specific problems are reflected across all organ systems and patient-care problems. There is a mixture of chronic and acute care problems, with several questions that are not specific to a patient acuity level.

### **DOMAIN 1: Direct Patient Care (50% of the examination)**

#### **Tasks:**

1. Establish a caregiver relationship with the patient that fosters trust and open communication, and encourages patient self-management.
2. Interview patient/caregiver to obtain information relevant to the patient's care (for example, chief complaint, history of present illness).
3. Obtain the patient's medication history, including over the counter (OTC) medications, prescription medications, herbal and non-herbal dietary supplements, adherence, allergies, and previous adverse drug reactions.
4. Reconcile medications based on information obtained from patient/caregiver interview, patient's healthcare provider(s), patient's documented medication profiles, and medical records.
5. Obtain pertinent patient history (for example, family, medical, psychosocial, lifestyle, substances of abuse, diagnostic test results).

6. Perform pertinent physical assessments as they relate to patient's current condition and/or therapies (for example, vital signs, weight, palpation, auscultation, visual inspection).
7. Perform point of care testing (for example, blood glucose, cholesterol, INR, bone mineral density, peak flow).
8. Determine patient's willingness to work with an ambulatory care pharmacy specialist on health and medication-related issues.
9. Assess patient's self-management knowledge, understanding, skills, and willingness and ability to actively participate in his/her own care.
10. Assess benefits and risks of drug therapy for patients considering concomitant disease states, other medication, and other patient specific factors.
11. Assess the available information to identify drug related problems (for example, no drug, wrong drug, wrong dose, side effects, drug interactions) and response to therapy.
12. Assess the information gathered to identify non-drug factors that may affect patient outcomes (for example, tobacco, activity level, nutrition).
13. Identify and refer (i.e. triage) patients with needs beyond the scope of the ambulatory care pharmacy specialist.
14. Recognize patient-specific barriers to successful drug therapy (for example, social situations, patient denial, literacy, mental capacity, culture, language) and implement a plan to overcome these (for example, home visits, interpreter, picture-based education).
15. Provide drug-related patient education/counseling (for example, purpose of medication, proper administration, directions for use, foods or drugs to avoid while taking the medication, potential side effects and when to report problems).
16. Evaluate the patient's administration technique for medications that are not administered orally (for example, nasal inhalers, oral inhalers, eye drops, ear drops, subcutaneous injections).
17. Provide disease-related patient education/counseling (for example, diabetes, asthma, hypertension, dyslipidemia).
18. Provide wellness and prevention education/counseling (for example, lifestyle modifications, immunizations).
19. Recommend appropriate immunizations to specific patients.
20. Immunize patients by administering appropriate vaccines.
21. Provide OTC education/counseling (for example, herbals, non-herbal dietary supplements, vitamins, non-prescription drugs).
22. Perform collaborative drug therapy management via protocol or signed collaborative agreements with healthcare providers.
23. Provide integrated disease-state management (for example, pharmacotherapy clinics, primary care clinics where more than one disease may be addressed in a visit).

24. Provide focused disease-state management (for example, diabetes, hypertension, asthma, heart failure, anticoagulation, dyslipidemia, mental health, chronic pain).
25. Provide wellness and preventive programs for individual patients (for example, weight management program, tobacco cessation program, immunization program).
26. Identify situations in which OTC treatment may be appropriate, and recommend treatment options.
27. Make recommendations to manage drug therapy which may include initiation, modification, or discontinuation of medication therapy as appropriate.
28. Recommend appropriate self-care devices for monitoring chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors).
29. Teach patients how to use self-care devices for monitoring chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors).
30. Recommend appropriate health-related screening tests (for example, home pregnancy tests, hemoccult tests)
31. Define treatment goals in collaboration with the patient and other healthcare providers.
32. Determine patient's ability and willingness to pay for services (for example, insurance coverage, out of pocket expenses).
33. Emphasize affordability and cost-effectiveness when recommending drug therapy or designing a drug treatment plan.
34. Develop a patient-specific plan to address prioritized patient needs and identified drug-related problems to improve patient outcomes.
35. Implement a patient-specific plan to address prioritized patient needs and identified drug-related problems to improve patient outcomes.
36. Develop a patient-specific monitoring and follow-up plan in order to assess response to both drug and non-drug therapy and assure safety.
37. Communicate patient-specific findings and treatment recommendations to other healthcare professionals involved in the care of the patient.
38. Communicate patient-specific findings and treatment recommendations to the patient/caregiver in language they can understand (includes both written and verbal communication).
39. Conduct follow-up visits in order to assess response to both drug and non-drug therapy and assure safety.
40. Interpret follow-up laboratory (for example, potassium, sodium, creatinine, INR, liver function tests, cholesterol results) and other diagnostic results (for example, ECHO results, pulmonary function tests) to determine if and when adjustments to drug therapy are warranted.
41. Modify patient-specific treatment plan based on follow up assessment.
42. Determine patient-specific reasons for lack of adherence to recommended treatment and in collaboration with the patient develop a plan for improving adherence to therapy.

43. Document all patient care activities (for example, patient-specific findings, detailed treatment recommendations and communications with patient and other healthcare providers).

**Knowledge of:**

- 01 anatomy and physiology
- 02 pathophysiology
- 03 laboratory and disease/drug monitoring parameters and their interpretation as they relate to drug therapy
- 04 the clinical assessment process
- 05 physical assessment techniques
- 06 pharmacology
- 07 pharmacotherapy
- 08 the principles of both focused and integrated disease-state management
- 09 the principles of and regulations governing collaborative drug therapy management
- 10 OTC medications
- 11 the principles of self-care
- 12 herbal medications, non-herbal dietary supplements, and treatments used in complementary and alternative medicine
- 13 common immunizations
- 14 clinical practice guidelines (for example, JNC 7 guidelines, NCEP ATP III guidelines, NIH Asthma guidelines, GOLD guidelines, ACIP guidelines)
- 15 the principles and practice of evidence-based medicine
- 16 recent advances related to pharmacotherapy in ambulatory practice
- 17 factors affecting medication and treatment adherence
- 18 effective interventions to address medication and treatment nonadherence
- 19 the techniques for use of point of care testing (for example, blood glucose, cholesterol, INR)
- 20 patient interviewing skills
- 21 motivational interviewing techniques
- 22 how to assess the patient's readiness and/or willingness to participate in their own care
- 23 how to develop effective collaborative partnerships with individual patients in order to maximize trust, encourage patient self-management, and optimize treatment outcomes
- 24 barriers to patient education and interventions to overcome them

- 25 cultural diversity and how it may impact the care of the patient
- 26 humanistic factors (e.g., quality of life, end of life), and how they may impact the care of the patient
- 27 how to obtain a medication history
- 28 the principles and process of medication reconciliation
- 29 how to develop effective collaborative relationships with other healthcare professionals in order to access health-related patient information essential to the care of the patient
- 30 how to collaborate with other healthcare professionals to optimize patient care outcomes
- 31 how to prioritize patient needs and/or drug-related problems
- 32 the scope of practice of the ambulatory care pharmacy specialist
- 33 how to apply pharmacoeconomic principles when designing a treatment plan
- 34 how to develop an effective, individualized treatment plan
- 35 how to implement an effective, individualized treatment plan
- 36 patient education principles and techniques (for example, group classes, individual patient counseling).
- 37 the format for documentation of patient care activities, plans and recommendations (for example, SOAP notes)
- 38 the types, indications, and uses of health-related screening tests (for example, home pregnancy tests, hemoccult tests)
- 39 the types, indications, and uses of self-care devices for monitoring chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors)
- 40 the process of determining appropriateness of over-the-counter treatments for individualized patients
- 41 how to effectively communicate treatment recommendations to the appropriate healthcare provider(s)
- 42 how to effectively communicate with the patient
- 43 the principles and practices of wellness and prevention
- 44 lifestyle behaviors which impact chronic diseases (for example, dietary factors, exercise, tobacco use) and appropriate modifications
- 45 the proper administration techniques for various drugs and immunizations (for example, eye drops, inhalers, injections)
- 46 State and Federal regulations regarding protection of patient information
- 47 the steps involved in continuity of care between healthcare settings (i.e., transitioning)
- 48 appropriate writing techniques for composing patient education materials

- 49 appropriate presentation techniques (for example, audiovisual aids, handouts) for delivering educational programs

## **DOMAIN 2: Practice Management (20% of the examination)**

### **Tasks:**

1. Identify the need for ambulatory clinical pharmacy services in response to patient care needs and/or business potential (for example, Medication Therapy Management, focused or integrated disease-state management programs/clinics).
2. Establish new ambulatory clinical pharmacy services in response to patient care needs and/or business potential (for example, Medication Therapy Management, focused or integrated disease-state management programs/clinics).
3. Establish relationships and/or collaborative practice agreements with other health care providers.
4. Promote and market patient care services to patients and health care providers.
5. Establish and maintain a system for patient referral.
6. Establish and maintain a system for patient follow up.
7. Develop systems for ongoing quality improvement, patient safety, and provision of cost-effective care (for example, medication use evaluation, ADR reporting, incident report evaluation).
8. Perform ongoing evaluations of quality, value, and need to justify, modify, disband, or expand ambulatory care pharmacy services.
9. Participate as an integral member of an interdisciplinary health care team.
10. Assure time, space and resources necessary to provide patient care services (for example, patient education materials, immunization supplies, office equipment and space, ancillary personnel, staff).
11. Organize the practice in a manner that supports efficient work flow, integration of care, and assures timely patient visits and follow-up (for example, use of ancillary personnel, group visits, disciplined appointment system, use of technology, coordination of care between clinical and medication dispensing functions).
12. Manage a financially viable practice (for example, cash flow management, cash payment systems, insurance contracting, accounting systems, pricing, expense analysis).
13. Develop systems to obtain reimbursement for ambulatory clinical pharmacy services.
14. Develop or obtain scope of practice guidelines and protocols accepted by the provider and/or institution, and in accordance with legal and regulatory requirements.
15. Develop and implement policy and procedures that are in accordance with accepted guidelines and standards of practice.
16. Manage point of care testing in accordance with regulatory requirements (for example, OSHA, CLIA).

17. Provide a system for drug procurement (for example, contracts, buying groups, special order drugs, patient assistance programs).
18. Ensure timely and accurate delivery of medication to patients.
19. Participate in formulary management (for example, participate on P&T committee, develop criteria for use protocols, design cost-effective treatment protocols, develop system for obtaining prior authorization and nonformulary drugs based on medical necessity).
20. Report medication errors and develop systems to track and analyze these for possible intervention measures.

**Knowledge of:**

- 01 the collaborative care relationships necessary in fulfillment of the pharmacist's role in a successful ambulatory care practice
- 02 effective interdisciplinary communication strategies
- 03 the regulations surrounding collaborative drug therapy agreements
- 04 the strategies and resources necessary for establishing a collaborative care agreement and referral process
- 05 needs assessment techniques for prospective ambulatory care pharmacy services
- 06 development and implementation strategies for ambulatory care pharmacy services
- 07 the continuous quality improvement process
- 08 business principles to effectively manage the practice (for example, accounting, purchasing, resource utilization, work flow, profit analysis)
- 09 procedures for coding and billing as relevant to pharmacy practice
- 10 tasks involved in managing the implementation of a new service or program
- 11 effective marketing strategies for initiating or expanding ambulatory pharmacy services
- 12 systems for patient referral and follow up
- 13 special order drug systems (for example, patient assistant programs, Accutane®, Enbrel®, Clozaril®, thalidomide)
- 14 regulations with regard to point of care testing (for example, OSHA, CLIA, state Board of Pharmacy, other state laws)
- 15 how to integrate patient care services within an ambulatory dispensing pharmacy practice (for example, medication adherence programs, Medication Therapy Management services, and disease management clinics)
- 16 formulary management systems (for example, P&T committee function, therapeutic interchange, prior authorization, nonformulary process)
- 17 cost-effective alternative and therapeutic interchange options

- 18 State and Federal regulations regarding protection of patient information
- 19 scope of practice for ambulatory care pharmacy practice
- 20 process necessary for evaluation, analysis, and justification of services
- 21 compensation strategies and funding sources
- 22 the literature evaluating medication errors and patient safety (for example, IOM report, Beers criteria)
- 23 legislative and regulatory issues that impact the practice of ambulatory care pharmacy

### **DOMAIN 3: Public Health (5% of the examination)**

#### **Tasks:**

1. Provide general information to the public regarding preventive health issues (for example, cardiovascular disease, tobacco cessation, immunizations).
2. Provide information to, and/or collaborate with other healthcare professionals to design intervention strategies that address preventive health issues.
3. Advise and direct the public and consumers to appropriate resource groups, organizations, and agencies (for example, Alzheimer's Association, American Cancer Society).
4. Participate in community health screening programs.
5. Serve as a public advocate regarding preventive health issues.
6. Advocate to ensure appropriate healthcare policy for ambulatory care pharmacy practice.
7. Facilitate appropriate care for patients affected by public health threats and disasters.
8. Participate in disaster response preparation and planning.

#### **Knowledge of:**

- 01 the role of ambulatory care pharmacists in public health
- 02 resources available through relevant groups, organizations, and agencies (for example, ADA, AHA, NIH, CDC, AAAAI)
- 03 disease prevention strategies
- 04 disease screening guidelines
- 05 legislative and regulatory issues that impact the prevention and treatment of diseases (e.g., immunization regulations, Medicare Part D)
- 06 information that is accessible to the public regarding the prevention and treatment of diseases (for example, reliable internet websites, toll-free information hotlines)
- 07 prevention and treatment of public health threats

**DOMAIN 4: Retrieval, Generation, Interpretation and Dissemination of Knowledge (15% of the examination)**

**Tasks:**

1. Stay current with the biomedical literature applicable to ambulatory care pharmacy practice.
2. Practice ongoing self-managed continuing professional development (for example, continuing education programs, practice self-evaluation, attend study or journal clubs).
3. Retrieve and interpret biomedical literature with regard to study design methodology, statistical analysis, and significance and applicability of reported data and conclusions.
4. Respond to drug information requests from patients and healthcare professionals.
5. Educate pharmacists, physicians, other allied health care professionals, students, and residents in the principles and practice of evidence-based medicine.
6. Provide health and medication-related education to healthcare professionals.
7. Provide experiential training to pharmacy students and residents in ambulatory care pharmacy practice.
8. Conduct research as principal investigator or co-investigator to generate knowledge applicable to ambulatory care pharmacy practice
9. Prepare and disseminate results of investigations (for example, case reports, abstracts, reviews, monographs) through publications and presentations to local, regional, and national audiences.
10. Document and report adverse drug-related events as appropriate (for example, adverse reactions, drug interactions, drug/device/assay defects) to add to the body of knowledge.
11. Participate in local, state, and/or national professional organizations.
12. Provide ongoing staff training and development, and opportunities/support for credentialing and continuing education.

**Knowledge of:**

- 01 principles of evidence-based medicine
- 02 common resources of biomedical literature applicable to ambulatory pharmacy practice
- 03 primary (for example, original research reports), secondary (for example, indexing and abstracting services), and tertiary (for example, textbook review articles) references
- 04 how to formulate a search strategy to retrieve information from the biomedical literature
- 05 process for identifying educational needs of healthcare professionals in ambulatory care practice
- 06 principles and methods of educating health care students, residents, and professionals
- 07 research methodology to interpret study validity (for example, study design, population selection, blinding, statistical analysis)

- 08 strengths and limitations of various study methods
- 09 clinical versus statistical significance in order to interpret medical literature
- 10 appropriate research methodology to design studies to assess a research hypothesis
- 11 regulatory requirements for the coordination of research (for example, HIPAA, IRB, OSHA)
- 12 methods for dissemination of research findings
- 13 the process/procedures for reporting appropriate adverse drug/vaccine events and problems observed with drug/vaccine products to appropriate governmental entities
- 14 the role and benefits of professional organizations for ambulatory care pharmacy practice
- 15 staff development principles and avenues for providing continuing education
- 16 certifications available to the ambulatory care pharmacy specialist (for example, Certified Diabetes Educator, Board Certified Pharmacotherapy Specialist, Certified Geriatric Pharmacist, Certified Anticoagulation Pharmacy Specialist, Certified Asthma Educator).
- 17 the existence and use of evidence-based treatment guidelines and protocols in the ambulatory care environment

#### **DOMAIN 5: Patient Advocacy (10% of the examination)**

##### Tasks:

1. Communicate patient-related information to healthcare professionals that advocates for optimal patient outcomes.
2. Facilitate access to Patient and/or Medication Assistance Programs.
3. Assist patients with understanding of prescription drug plans that provide optimal prescription drug coverage and facilitate best outcomes.
4. Resolve formulary issues to ensure access to cost-effective drug therapy.
5. Ensure appropriateness and accessibility of drug therapy during transitioning of care (for example, transition from acute to ambulatory care setting).
6. Ensure the patient has access to and understands the importance of maintaining an up-to-date medication list and emphasize the importance of sharing the list with all healthcare providers.
7. Establish a system for two-way communication between the pharmacist and the patient's healthcare providers in order to exchange vital patient information necessary to provide patient care.
8. Collaborate with other healthcare professionals to provide case management (for example, assess, plan, implement, coordinate, monitor, and evaluate the options and services required to meet the patient's health and human service needs).
9. Facilitate referrals for patients with needs beyond the scope of the ambulatory care pharmacist.
10. Advocate to ensure appropriate healthcare policy for optimal patient outcomes.

11. Manage conflict and differences of opinions with other healthcare professionals to optimize care for the patient.
12. Encourage patients to openly communicate health and medication related concerns with all healthcare providers (for example, patient disagreement with outlined treatment plan, use of herbal remedies or non-traditional treatments).

**Knowledge of:**

- 01 assertive and persuasive communication techniques for representing a patient’s healthcare needs and interests
- 02 patient-specific factors which may impact access to medications (for example, socioeconomic)
- 03 the structure, guidelines, and process of patient and/or medication assistance programs
- 04 the structure, including benefits and limitations, of prescription drug plans/formularies for patients in ambulatory care
- 05 resources for medication reconciliation necessary to transition patients to and from the ambulatory care setting
- 06 medication reconciliation skills and techniques
- 07 the healthcare resources and services available to ambulatory care patients (for example, disease specific websites, medication assistance programs social services)
- 08 collaborative relationships necessary to enable case management of ambulatory care patients
- 09 the scope and limitations of ambulatory care pharmacy practice
- 10 legislative and regulatory issues that impact patient outcomes
- 11 conflict management and negotiation skills

**SYSTEMS AND PATIENT-CARE PROBLEMS**

***Bone/Joint and Rheumatology***

- Fibromyalgia
- Osteoarthritis
- Gout/Hyperuricemia
- Osteoporosis
- Psoriatic arthritis
- Rheumatoid arthritis
- Systemic Lupus Erythematosus
- Bone/Joint and Rheumatology miscellaneous

***Cardiovascular***

- Arrhythmias
- Cardiopulmonary resuscitation

- Coronary artery disease
- Dyslipidemia
- Heart failure
- Hypertension
- Peripheral arterial disease
- Primary pulmonary hypertension
- Thromboembolic disorders
- Valvular heart disease
- Cardiovascular miscellaneous

***Dermatologic***

- Acne
- Burns
- Dermatitis
- Decubitus ulcers
- Infestations (Lice, Scabies, Fleas)
- Psoriasis
- Urticaria
- Dermatologic miscellaneous

***Endocrine***

- Adrenal disorders
- Diabetes mellitus
- Hormone disorders (Growth Hormone, Testosterone Deficiency, Acromegaly)
- Metabolic syndrome
- Obesity
- Parathyroid disorders
- Polycystic ovary syndrome
- SIADH
- Thyroid disorders
- Endocrine miscellaneous

***Eyes, Ears, Nose, and Throat***

- Allergic rhinitis
- Dry eye
- Glaucoma
- Macular degeneration
- Vertigo
- EENT miscellaneous

***Fluid and Electrolyte/Nutrition***

- Electrolyte abnormalities
- Nutritional deficiencies
- Nutritional supplementation
- Fluid and Electrolyte/Nutrition miscellaneous

***Gastrointestinal***

- Constipation
- Diarrhea
- Chronic liver disease and cirrhosis

- Gastroesophageal reflux disease
- Gastrointestinal bleeding
- Hepatitis
- Inflammatory bowel disease
- Irritable bowel syndrome
- Malabsorption syndrome
- Nausea/vomiting
- Pancreatitis
- Peptic ulcer disease
- Gastrointestinal miscellaneous

***Genitourinary***

- Prostatic hyperplasia
- Sexual dysfunction
- Urinary incontinence
- Genitourinary miscellaneous

***Hematologic***

- Anemias
- Sickle cell disease
- Thrombocytopenia
- Hematologic miscellaneous

***Immunologic***

- Allergy/anaphylaxis
- Angioedema
- Organ transplantation
- Immunologic miscellaneous

***Infectious Diseases***

- Antimicrobial prophylaxis
- Bone and joint infections
- Central nervous system infections
- Ear infections
- Fungal infections
- Gastrointestinal infections
- Gynecologic infections
- Human Immunodeficiency Virus infection
- Infectious endocarditis
- Intra-abdominal infections
- Non-HIV viral infection
- Ophthalmic infections
- Prostatitis
- Respiratory tract infections
- Sexually transmitted diseases
- Sinusitis
- Skin and soft tissue infections
- Tick borne infections
- Tuberculosis

- Urinary tract infections
- Infectious Diseases miscellaneous

### ***Neurological***

- Central nervous system hemorrhage
- Cerebral ischemia (including ischemic stroke)
- Dementia
- Epilepsy
- Headache/migraine
- Neuromuscular diseases
- Pain
- Parkinson's disease
- Peripheral neuropathy
- Spinal-cord injuries/abnormalities
- Traumatic brain injury
- Tremors
- Neurological miscellaneous

### ***Obstetrics/Gynecology***

- Chronic disease in pregnancy
- Contraception
- Endometriosis
- Infertility
- Lactation
- Menopausal symptoms
- Menstrual disorders
- Pregnancy-related disease
- Obstetrics/Gynecology miscellaneous

### ***Oncology***

- Breast cancer
- Colon cancer
- Gynecological cancers
- Leukemia
- Lung cancer
- Prostate cancer
- Skin cancer
- Supportive care (e.g., preventing / treating complications associated with malignancy or treatment)
- Oncology miscellaneous

### ***Psychiatric***

- Anxiety disorders
- Attention deficit disorders
- Bipolar disorders
- Depressive disorders
- Drug/alcohol overdose/withdrawal
- Schizophrenia
- Sleep disorders

- Substance abuse
- Psychiatric miscellaneous

### ***Renal***

- Acute renal failure
- Chronic kidney disease
- Dialysis (managing associated complications and drug dosing)
- Nephrolithiasis
- Renal miscellaneous

### ***Pulmonary***

- Asthma
- Chronic obstructive lung disease
- Sleep apnea
- Pulmonary miscellaneous

### ***Health Maintenance/Public Health***

- Bioterrorism
- Complementary/Alternative medicines
- First Aid
- Health advice, education, or instruction
- Immunizations
- Lifestyle modification
- Palliative care
- Patient safety
- Routine health screening
- Tobacco cessation
- Toxicology/Poisoning
- Health Maintenance/Public Health miscellaneous

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**Content Outline for the  
CRITICAL PHARMACY  
SPECIALTY CERTIFICATION EXAMINATION**  
**Developed April 2012 for Use on the Fall 2015 Exam**

The following domains, tasks and knowledge statements were delineated by the BPS Critical Care Practice Analysis Taskforce and validated through a role delineation study, conducted in 2012. The proportion of examination items allotted to each domain was determined through analysis and discussion of the results of the role delineation study by the BPS Critical Care Practice Analysis Taskforce and approved by the BPS Board of Directors.

Each of the major areas/domains of Critical Care Pharmacy practice noted below will be tested beginning in Fall 2015. Questions will not be grouped by domain on the exam. Rather, items testing each domain are distributed throughout the total examination. Please note this examination will **SAMPLE** a candidate's knowledge rather than trying to test all of his/her knowledge. Examination items will address problems and situations reflective of the full range of practice.

**Domain 1: Clinical Skills and Therapeutic Management (66% of exam)**

**Tasks**

*Tasks related to the comprehensive management of a critically ill patient including collecting, interpreting, and integrating pertinent clinical data; and designing, implementing, monitoring, and modifying patient-specific plans of care for critically ill patients in collaboration with the healthcare team.*

- 1.1 Collect and organize the medical history of a critically ill patient including history of present illness, past medical history, past surgical history, social history, family history, and allergies.
- 1.2 Perform comprehensive review and assessment of a critically ill patient's current and past medications, including prescription, over the counter (OTC), and complementary and alternative medicines.
- 1.3 Perform or obtain physical examination results and other pertinent assessments (e.g., pain, sedation, delirium) to comprehensively assess a critically ill patient's physiological condition and severity of illness.

- 1.4 Collect and organize relevant patient vital signs and physical exam findings for a critically ill patient.
- 1.5 Collect and organize relevant data from laboratory studies (e.g., chemistry, microbiology, pathology, hematology, serum drug concentration), imaging studies, procedures (e.g., biopsies, drain placements, therapeutic taps, bronchoscopy), and advanced critical care monitoring (e.g., ICP measurements, hemodynamic monitoring parameters, mechanical ventilator settings, ECGs).
- 1.6 Interpret, analyze, and integrate collected information for a critically ill patient.
- 1.7 Identify and prioritize current or potential patient-specific medical, medication, and nutrition-related problems for a critically ill patient.
- 1.8 Design, recommend and implement therapeutic regimens for a critically ill patient utilizing patient-specific data and best available evidence.
- 1.9 Collaborate as a member of a multidisciplinary team to establish and prioritize patient-specific therapeutic goals and plans for a critically ill patient.
- 1.10 Design and recommend a monitoring plan to assess a critically ill patient's response to therapeutic regimens and progress toward therapeutic goals.
- 1.11 Monitor a critically ill patient and evaluate therapeutic and adverse outcomes.
- 1.12 Modify plans of care for a critically ill patient based on therapeutic and adverse outcomes, and progress toward therapeutic goals.
- 1.13 Facilitate the administration of medications to critically ill patients including assessment of available administration routes, intravenous compatibilities, stabilities, and available medication delivery technologies (e.g., smart pumps, patient controlled analgesia, nebulizers).
- 1.14 Participate in the management of the medical emergencies and resuscitation events.
- 1.15 Facilitate continuity of care by communicating pertinent patient information to healthcare professionals within the ICU and when transitioning into or out of the ICU.
- 1.16 Document direct patient care activities as appropriate.

**Knowledge of:**

- k1.1 Diagnosis, pathophysiology, epidemiology, risk factors, and treatment of conditions in critically ill patients in the following therapeutic areas:
  - a) Pulmonary
  - b) Cardiovascular
  - c) Neurology and Neurological Injuries
  - d) Psychiatry
  - e) Renal
  - f) Hepato-Gastrointestinal
  - g) Immunology

- h) Endocrine
  - i) Hematology
  - j) Infectious diseases
  - k) Toxicology
  - l) Surgery
- k1.2 Sedation, analgesia, delirium, and neuromuscular blockade
  - k1.3 Nutrition support in the critically ill patient
  - k1.4 Alterations of pharmacodynamics and pharmacokinetics in the critically ill (e.g., effects of hypothermia, mechanical ventilation, volume resuscitation, organ dysfunction)
  - k1.5 Drug interactions and adverse drug events common in critical care
  - k1.6 Pharmacoeconomics (e.g., cost effectiveness, cost minimization)
  - k1.7 Sepsis/SIRS
  - k1.8 Advanced Cardiac Life Support (ACLS) principles
  - k1.9 Devices commonly utilized in critical care (e.g., balloon pump, left ventricular assist device [LVAD], cooling devices, extracorporeal membrane oxygenation [ECMO])
  - k1.10 Procedures commonly performed in critical care (e.g., bronchoscopy, central line placements, intubation, therapeutic hypothermia)
  - k1.11 Renal replacement therapy
  - k1.12 Mechanical ventilation principles and monitoring techniques
  - k1.13 Critical care monitoring techniques (e.g., hemodynamic, neurologic, cardiovascular)
  - k1.14 Impact of alterations in anatomy and physiology due to trauma, surgery or congenital causes on medication therapy
  - k1.15 Routes of administration for medications in critically ill patients
  - k1.16 Routes of administration for nutrition (enteral vs. parenteral) and alterations in absorption of nutrients in critically ill patients
  - k1.17 Preventative and supportive care measures used in the care of critically ill patients
  - k1.18 Fluid, electrolyte, and acid/base management in ICU patients
  - k1.19 Agents used for acute volume resuscitation and hemostasis (e.g., crystalloids, colloids, blood products, hemostatic agents)
  - k1.20 Parenteral vasoactive and inotropic agents
  - k1.21 End of life care
  - k1.22 Impact of critical illness on pre-existing conditions (e.g. endocrine disorders, cardiovascular diseases, infectious diseases, respiratory diseases)
  - k1.23 Application of evidence-based critical care literature and clinical practice guidelines in designing a patient-specific plan of care

k1.24 Outcome indicators for pharmacotherapy of disease states common to ICU patients

k1.25 Documentation processes used for critical care pharmacy services

**Domain 2: Practice Administration and Development. (15% of exam)**

**Tasks**

*Tasks related to advancing critical care pharmacy practice establishing implementing, and monitoring systems and policies to optimize the care of critically ill patients.*

2.1 Develop, promote and expand pharmacy services to optimize drug-related outcomes for critically ill patients.

2.2 Develop and implement institutional policies and guidelines (including disease and drug therapy protocols, critical care pathways, formulary proposals) to meet identified needs and facilitate the care of critically ill patients.

2.3 Monitor and evaluate compliance with, and impact of, policies and guidelines (e.g., institutional, evidence based).

2.4 Establish and sustain collaborative professional relationships with other members of the interdisciplinary critical care team.

2.5 Justify and document clinical and financial value of critical care pharmacy services.

2.6 Perform quality improvement activities aimed at enhancing the safety and effectiveness of medication-use processes in the critical care area.

2.7 Promote the role and optimal use of critical care pharmacists to key stakeholders.

**Knowledge of:**

k2.1 Needs assessment techniques (e.g., gap analysis, medication use survey, best practices survey)

k2.2 Metrics for evaluating quality of critical care pharmacy services (e.g., lengths of ICU stay, mortality, cost-effectiveness)

k2.3 Quality assurance and process improvement methods

k2.4 Evidence-based literature supporting the value of critical care pharmacy

k2.5 Application of evidence-based critical care literature in designing institutional guidelines

k2.6 Communication strategies

k2.7 Resources (e.g., financial, technological, human) necessary to care for critically ill patients

k2.8 Medication safety principles pertinent to patients requiring care in the ICU

**Domain 3: Information Management and Education. (19% of exam)****Tasks**

*Tasks related to retrieval, generation, interpretation, and dissemination of knowledge related to critical care pharmacy, and the education of healthcare providers and trainees.*

- 3.1 Educate healthcare professionals and other stakeholders concerning issues related to the care of critically ill patients.
- 3.2 Educate critically ill patients and caregivers on issues related to medications and nutrition support.
- 3.3 Provide critical care education and training for practicing pharmacists, fellows, residents, student pharmacists, or students in other health professions.
- 3.4 Mentor pharmacists, fellows, residents, or students in critical care pharmacy practice.
- 3.5 Participate in continuous professional development related to critical care pharmacy practice (e.g., professional organizations, continuing education, clinical pharmacy networks).
- 3.6 Retrieve and critically evaluate biomedical literature with regard to study design methodology, statistical analysis, and applicability of study results in the critical care population.
- 3.7 Contribute to the critical care body of knowledge (e.g., participate in research, deliver poster/platform presentations, publish, participate in the peer review process).

**Knowledge of:**

- k3.1 Principles and methods of educating pharmacists, fellows, residents, students, and other healthcare professionals
- k3.2 Techniques for educating critically ill patients/caregivers
- k3.3 Published documents from professional societies (e.g., American Society of Health-System Pharmacists [ASHP], American College of Clinical Pharmacy [ACCP], Society of Critical Care Medicine [SCCM]) regarding the education and training of critical care pharmacists
- k3.4 Research design, methodology, and statistical analysis
- k3.5 Clinical application and limitations of published data and reports
- k3.6 Regulatory/IRB requirements relative to conducting critical care research
- k3.7 Continuing professional development opportunities in critical care (e.g., professional organization membership, committee involvement, sources of continuing education, mentorship)
- k3.8 Mentorship principles, techniques, and strategies

k3.9 Medical literature publication and review process

k3.10 Opportunities for disseminating critical care knowledge and scholarly activity (e.g., presentations, manuscripts, newsletters, abstracts, posters)

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### **Content Outline for the NUCLEAR PHARMACY SPECIALTY CERTIFICATION EXAMINATION March 2007**

The following domains, subdomains, tasks and knowledge statements were identified by the BPS Specialty Council on Nuclear Pharmacy and validated through a role delineation study, most recently updated in 2007. The proportion of examination items allotted to each domain was determined through analysis and discussion of the results of the role delineation study by the Specialty Council.

Each of the major areas/domains of Nuclear Pharmacy practice noted below will be tested. Questions will not be grouped by domain. Items testing each domain are distributed throughout the total examination. Please note that this examination will SAMPLE a candidate's knowledge rather than trying to test all of his/her knowledge.

#### **Domain 1: Drug Order Provision: (66% of the examination)**

##### ***Subdomain A. Procurement (8% of the examination)***

##### **Task:**

1. Determine product specifications and inventory (such as quantity, concentration, date and time of delivery, calibration time, and specific delivery instructions) for both radioactive and nonradioactive materials

##### **Knowledge of:**

- 01 Cost, source, and availability/delivery of radiopharmaceuticals, ancillary medications, and related products and services
- 02 Specifications and requirements related to placement of product orders, including manufacturer or regulatory requirements
- 03 USP standards for pharmaceutical ingredients, precursors, reagents, tests and assays, vendor certificates of purity or physical/chemical means of identification and other materials
- 04 Radiopharmaceutical class, including regulatory status, vendors, availability/delivery, formulation, components (e.g., antioxidants, stabilizing agents, buffers), expiration, storage
- 05 Analytical supplies and other materials needed for radiopharmaceuticals quality control procedures (e.g., solvents, chromatography strip/columns, sterility test media, endotoxin test media)
- 06 Supplies needed to practice nuclear pharmacy including needles and syringes, disinfectants, gloves, sharps containers, and other disposable/consumable supplies

- 07 Use patterns (e.g., amounts/rate of use) of radioactive and nonradioactive drugs, components and supplies

**Task:**

2. Store and maintain both radioactive and nonradioactive material to maintain drug integrity and security of material using safe handling procedures

**Knowledge of:**

- 01 Storage requirements for radioactive and nonradioactive drugs, components, and supplies (e.g., light, temperature, and humidity)
- 02 Consequences of improper storage conditions on the physical and/or chemical integrity of the material
- 03 Shielding requirements for radioactive materials
- 04 Federal regulations and standards regarding inspections of drug storage areas (e.g., Joint Commissions, JCAHO, ASHP, USP, APhA)

***Subdomain B. Compounding (26% of the examination)***

**Task:**

1. Review prescription orders for radiopharmaceuticals and interventional agents

**Knowledge of:**

- 01 Indications and dosage recommendations for radiopharmaceuticals and interventional agents based on patient specific characteristics

**Task:**

2. Select products, components, supplies, and equipment for compounding prescription orders

**Knowledge of:**

- 01 Ingredients/components of reagent kits and radiopharmaceuticals, including the purpose of each
- 02 Record-keeping procedures to ensure traceability of all drugs and related components for manufacturer or FDA recall procedures
- 03 Physiochemical and kinetic properties, mechanisms of localization, pharmacologic and/or therapeutic effects of radiopharmaceuticals and ancillary medications
- 04 Half-lives, modes of decay, gamma ray, etc., constants associated with clinically-used radionuclides
- 05 Factors that affect the stability and shelf life of reagent kits and radiopharmaceuticals, including radionuclidic contamination
- 06 Formulation factors that might adversely affect product performance
- 07 Compounding concepts, techniques and parameters required for optimal preparation of radiopharmaceuticals (e.g., volumes activities, pH, temperature, order of mixing, excipients, specific activity)
- 08 General synthetic radiolabeling methods (e.g. redox reactions, chelation, substitution, radioiodination, template synthesis) as well as methods for optimizing yield of radiolabeled product

**Task:**

3. Compound sterile and non-sterile preparations using appropriate aseptic, biological, and radiation safety techniques

**Knowledge of:**

- 01 Appropriate aseptic and ALARA techniques
- 02 Professional standards for compounding sterile and non-sterile products
- 03 Blood labeling procedures and universal precautions for blood borne pathogens
- 04 Containers, closures, and other packaging materials used in the compounding and dispensing of radiopharmaceuticals

**Task:**

4. Elute radionuclide generators for use in radiopharmaceutical preparations

**Knowledge of:**

- 01 Physical and chemical characteristics of available generators
- 02 Generator kinetics, elution techniques, and quality assurance techniques

**Task:**

5. Produce accelerator-based radionuclides

**Knowledge of:**

- 01 USP or other standard and regulations regarding the proper compounding of radiopharmaceuticals
- 02 Physical and chemical characteristics of components including incompatibilities
- 03 Product verification methods and applications
- 04 Components including precursors, reagents, target solutions and gases, containers and closures, transfer lines and membrane filters
- 05 Production methods, including parameters of nuclear reactions

**Task:**

6. Verify the identity, integrity, concentration, labeling, and proper storage of the final product

**Knowledge of:**

- 01 USP standards for drugs, pharmaceutical ingredients, reagents, tests and assays, and other materials

***Subdomain C. Quality Assurance (9% of the examination)***

**Task:**

1. Implement and follow procedures and maintains records for radionuclidic purity, radiochemical purity, chemical purity, pH, pharmaceutical integrity (e.g., particle size, isotonicity, sterility, apyrogenicity), biological integrity (e.g., leukocytes, platelets, antibodies), and other characteristics (e.g., specific activity, isomeric purity)

**Knowledge of:**

- 01 Principles of chemical, radiochemical, and radionuclidic purity and the maximum permissible limits
- 02 Analytical methods used to assess the chemical, radiochemical, and radionuclidic purity of radiopharmaceuticals
- 03 Pharmaceutical integrity (e.g., analytical methods for estimating particle size and number, calculations and analytical methods for determining isotonicity)
- 04 Analytical methods for the determination of biological integrity, including USP tests for sterility and apyrogenicity and the impact on the patient
- 05 Proper storage of quality control materials
- 06 Acceptable results ranges/action levels and reporting protocols

**Task:**

2. Check the function of instruments, equipment, and devices and maintain records as appropriate

**Knowledge of:**

- 01 Principles of operation and procedures for quality control of the nuclear pharmacy instruments, equipment, and devices
- 02 NRC regulations and standards regarding the possession, use, calibration, and quality control of the instruments, equipment, and devices used in the nuclear pharmacy

***Subdomain D. Dispensing (23% of the examination)*****Task:**

1. Determine dosage levels based on patient history, age, weight, body surface area, and/or other factors

**Knowledge of:**

- 01 Indications and dosage recommendations for radiopharmaceuticals
- 02 Situations when pharmacologic interventions are clinically indicated
- 03 Factors that affect dosage selection as well as methods used to calculate/determine dosages of radiopharmaceuticals for specific patients, including breastfeeding and pregnant patients
- 04 Proper sequencing when multiple imaging procedures or modalities are required as part of a patient's diagnostic workup
- 05 Mechanisms by which selected interventions can enhance the utility, safety, or efficacy of specific nuclear medicine procedures

**Task:**

2. Dispense prescriptions and maintains appropriate records

**Knowledge of:**

- 01 Applicable rules and regulations pertaining to radiopharmaceutical recordkeeping and traceability

02 Healthcare Health Insurance Portability and Accountability Act (HIPAA)

**Task:**

3. Supervise and review the activities of nonpharmacist personnel under the pharmacist's supervision

**Knowledge of:**

- 01 Current pharmacy law pertaining to supervisory tasks and ancillary staff

**Domain 2: Health and Safety: (24% of the examination)**

**Task:**

1. Comply with applicable rules and license requirements regarding radiation and radiopharmaceuticals (e.g., ALARA)

**Knowledge of:**

- 01 Radiation protection principles, techniques, and standards (e.g., those issued by NRC, NCRP, ICRP, OSHA, EPA, or DOT)
- 02 Appropriate shielding techniques as well as attenuation coefficients, half-value layers
- 03 Applicable regulations and standards related to the receipt, storage, handling, clinical application and disposal of radioactive materials used in medical and pharmacy practice
- 04 USP standards for sterility and apyrogenicity, drugs, pharmaceutical ingredients, reagents, tests and assays, and other materials

**Task:**

2. Comply with all applicable regulations concerning packaging, labeling, and transportation of radioactive, biohazardous and hazardous substances

**Knowledge of:**

- 01 Regulations concerning packaging, labeling, and transportation of radioactive and biohazardous materials from own facility or from other facilities
- 02 Proper procedures and use of equipment necessary to verify that package meets DOT requirements
- 03 OSHA and CDC standards for providing a safe working environment
- 04 Radioactive and biohazardous waste disposal policies and methods

**Task:**

3. Implement and maintain policies and procedures to provide a safe working environment with respect to health risks other than radiation (e.g., chemical or biohazard risks)

**Knowledge of:**

- 01 Types of risk involved and accepted techniques for minimizing such risks
- 02 OSHA and CED standards for providing a safe working environment

**Task:**

4. Implement and maintain policies and procedures for equipment and sealed sources and maintain appropriate records

**Knowledge of:**

- 01 Principles of operation, storage, possession, transfer, use, calibration, and quality control procedures for nuclear pharmacy equipment and devices
- 02 Operation, calibration, and quality control of instrumentation used to measure radioactivity and radiation exposure rates
- 03 Federal regulations governing the storage, possession, testing, and use of sealed sources

**Task:**

5. Implement and maintain policies and procedures to ensure proper storage, disposal, and transport of waste material and maintain appropriate records

**Knowledge of:**

- 01 Rules and regulations governing the storage, disposal, and transport of waste materials
- 02 Radioactive and biohazardous waste disposal policies and methods

**Task:**

6. Implement and maintain policies and procedures concerning recognition and investigation of regulatory and medical events, corrective/preventative actions, notification of proper authorities, and maintenance of appropriate records

**Knowledge of:**

- 01 Regulations governing medical events and notification of proper authorities
- 02 Procedures used in response to spills or other accidents involving radioactive material

**Domain 3: Drug Information Provision: (10% of the examination)**

**Task:**

1. Provide information and consultation on all aspects of nuclear pharmacy

**Knowledge of:**

- 01 Significance of quality control procedures and the interpretation of test results as they relate to product
- 02 Mechanisms by which medications can alter the kinetics of radiopharmaceuticals, the biodistribution patterns which result from these altered kinetics, and the clinical significance of the resulting alterations
- 03 Requirements and techniques for the administration of radiopharmaceuticals and ancillary medications
- 04 Parameters that can and/or should be monitored when a patient is receiving a specific medication or drug regimen, or when a patient undergoes a specific surgical intervention or receives some other specific therapeutic measure

**Task:**

2. Provide information on the type and incidence of adverse reactions and assist in developing guidelines for the prevention, recognition, treatment, and reporting of adverse reactions

**Knowledge of:**

- 01 Nature and incidence of previously-reported adverse reactions to radiopharmaceuticals and ancillary medications
- 02 Mechanisms and symptomatology associated with adverse reactions to medications in general and radiopharmaceuticals specifically
- 03 Methods to treat or alleviate adverse drug reactions
- 04 Existing adverse reaction investigation and reporting systems
- 05 Type, incidence, mechanism/cause, and methods for the prediction, recognition, investigation, and reporting of factors that may cause unusual or unanticipated nuclear medicine imaging or therapy results
- 06 Factors that can alter radiopharmaceutical biodistribution
- 07 Other quality assurance failures associated with the clinical use of radiopharmaceuticals and ancillary medications

**Task:**

3. Analyze records and reports information regarding product defects or clinical problems associated with the use of radiopharmaceuticals and ancillary medications

**Knowledge of:**

- 01 Factors that cause product defects and /or clinical problems with radiopharmaceuticals and ancillary medications, and the mechanisms involved
- 02 Existing reporting systems which can be used to document product problems and/or clinical problems associated with radiopharmaceuticals and ancillary medications

**Task:**

4. Provide consultative services to practitioners to ensure proper utilization of molecular imaging and radiopharmaceuticals in patient care

**Knowledge of:**

- 01 Organ systems and pathophysiologic disorders evaluated and/or treated with radiopharmaceuticals
- 02 Role of molecular imaging in the diagnosis or management of specific disorders (relative to other diagnostic and therapeutic modalities)
- 03 Molecular imaging procedures used to monitor the safety and efficacy of therapeutic drug regimens or other therapeutic, surgical, or interventional procedures
- 04 Mechanisms by which selected medications can enhance the utility, safety, or efficacy of specific molecular imaging procedures
- 05 Economic ramifications of radiopharmaceutical care
- 06 Design and interpretation of drug use evaluation studies
- 07 Rational radiopharmaceutical and ancillary medication usage

- 08 Normal and atypical performance parameters (e.g., radiopharmaceutical biodistribution, image quality, dosimetry, therapeutic effect, likelihood of untoward effects) associated with the therapeutic use of radiopharmaceuticals
- 09 Patient factors that may interfere with the outcome of the molecular imaging procedure
- 10 Preparatory requirements and techniques to improve the safety or efficacy of the molecular imaging procedure (e.g., fasting, hydration, sedation, thyroid blockade)
- 11 Pregnancy and breast feeding guidelines for molecular imaging procedures
- 12 Patient education needs, requirements, methods, and aids
- 13 Availability and interpretation of nuclear medicine and radioimmunoassay procedures used to monitor drug efficacy and toxicity

**Task:**

- 5. Participate in the design, formulation, quality control testing, and evaluation of new radiopharmaceuticals or modified preparation of existing radiopharmaceuticals

**Knowledge of:**

- 01 Principles of pharmaceutical product formulations and drug dosage for design and evaluation
- 02 Pharmaceutical chemistry and radiochemistry
- 03 Pharmacology including localization, metabolism, and excretion
- 04 Physical and chemical properties of radiopharmaceuticals
- 05 Dosage form characteristics
- 06 Principles of quality control testing
- 07 Potential radiochemical, chemical, and pharmaceutical impurities

**Task:**

- 6. Participate in the clinical trials of new radiopharmaceuticals or the new formulations of existing radiopharmaceuticals, including the preparation and submission of radiopharmaceutical INDs to FDA and applications to local committees (e.g., IRB)

**Knowledge of:**

- 01 Stochastic and nonstochastic risks associated with exposure to low-level radiation
- 02 Radiation doses to specific organs which result from the administration of radiopharmaceuticals
- 03 Methods used to determine/estimate radiation absorbed doses, dose equivalents, and effective dose equivalents
- 04 Applicable record-keeping requirements

**KEY TO ACRONYMS:**

ALARA	As Low As Reasonably Achievable
ASHP	American Society of Health-System Pharmacists (formerly the American Society of Hospital Pharmacists)
CDC	Centers for Disease Control
DOT	Department of Transportation
EPA	Environmental Protection Agency

FDA	Food and Drug Administration
ICRP	International Commission on Radiological Protection
IND	Investigational New Drug
IRB	Institutional Review Board
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
NABP	National Association of Boards of Pharmacy
NRC	Nuclear Regulatory Commission
NCRP	National Council on Radiation Protection and Measurements
OSHA	Occupational Safety and Health Administration
USP	United States Pharmacopoeia
USP/NF	United States Pharmacopoeia/national Formulary

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## **Content Outline for the NUTRITION SUPPORT PHARMACY SPECIALTY CERTIFICATION EXAMINATION March 2007**

The following domains, subdomains, tasks and knowledge statements were delineated by the BPS Specialty Council on Nutrition Support Pharmacy Practice and validated through a role delineation study, conducted in 2006. The proportion of examination items allotted to each domain and subdomain was determined through analysis and discussion of the results of the role delineation study by the Specialty Council.

Each of the major areas/domains of Nutrition Support Pharmacy practice noted below will be tested. Questions will not be grouped by domain. Rather, items testing each domain are distributed throughout the total examination. Please note this examination will **SAMPLE** a candidate's knowledge rather than trying to test all of his/her knowledge. Examination items will address problems and situations reflective of the full range of practice sites (e.g., home care, hospital).

### **Domain 1: Clinical Practice/Provision of Individualized Nutrition Support to Patients** **(68% of the examination)**

#### ***Subdomain A. Assessment (21% of the examination)***

##### **Tasks:**

1. Interview the patient and/or designated caregiver to obtain medical, nutritional, psychosocial, and socioeconomic history in order to assess nutritional status
2. Review the medical history for disease states, clinical conditions, medical/surgical therapies, laboratory findings, imaging studies, and physical findings in order to assess nutritional status
3. Measure and/or interpret physical assessment parameters relevant to nutritional status
4. Evaluate subjective and objective data to identify a patient who is, or may become, overnourished or undernourished
5. Identify interactions between drugs, dietary supplements, and nutrients
6. Estimate daily micro/macro nutrient requirements
7. Evaluate educational needs of the patient, health-care providers, and caregivers regarding specialized nutrition support (SNS)
8. Evaluate the indications for and suitability of the patient for SNS
9. Identify available nutrition support access
10. Evaluate eligibility for reimbursement of SNS (e.g., diagnosis, formulations, services, supplies)

**Knowledge of:**

- 01 Components of a nutritionally adequate diet (e.g., dietary reference intake [DRI])
- 02 Normal ingestion, digestion, absorption, metabolism, and excretion of nutrients
- 03 Relationship between nutrient intake and nutritional status
- 04 Effects of psychosocial and socioeconomic factors on nutritional status
- 05 Effects of education level, comprehension, home environment, and disabilities on educational needs
- 06 Diagnostic tests and findings used to assess nutrition status
- 07 Physical assessment techniques and findings used to evaluate nutritional status
- 08 Effects of disease states, clinical conditions or altered metabolism on nutritional status
- 09 Effects of medical and/or surgical therapies on nutritional status (e.g., renal replacement therapies, cardiopulmonary bypass, mechanical ventilation)
- 10 Effects of nutritional status on disease states
- 11 Interactions between drugs, dietary supplements, and nutrients
- 12 Effects of drugs and dietary supplements on nutritional status
- 13 Effects of nutritional status or specialized nutrition support (SNS) on drug pharmacokinetics and pharmacodynamics
- 14 Indications, risks, and benefits of SNS
- 15 Guidelines for nutrient requirements
- 16 Methods to determine patient-specific nutrient requirements
- 17 Effects of disease states, clinical conditions, and altered metabolism on the determination of patient-specific nutrient requirements
- 18 Types of vascular and enteral access devices
- 19 Regulations and guidelines for eligibility, coverage, and reimbursement for parenteral and enteral nutrition therapies

***Subdomain B. Develop and Implement a Therapeutic Plan of Care (21% of the examination)*****Tasks:**

1. Define the goals of specialized nutrition support (SNS)
2. Recommend/select the preferred route for the administration of SNS
3. Recommend/select an appropriate feeding formulation
4. Evaluate the appropriate pharmacologic use of adjunctive agents
5. Recommend/select the administration method for feeding formulations (e.g., cyclic, bolus, continuous)
6. Recommend/select the delivery system for feeding formulations
7. Recommend/select the feeding regimen to include initiation, advancement, and discontinuation of SNS
8. Design and implement a plan to monitor the clinical nutritional and metabolic responses to SNS
9. Design and implement a plan to prevent or manage complications of SNS
10. Design and implement a plan to prevent or manage interactions between drugs, dietary supplements and nutrients
11. Design and implement a plan to educate the patient, health-care professionals, and other caregivers regarding the prescribed SNS to maintain continuity of care

**Knowledge of:**

- 01 Outcome indicators of nutrition therapy (e.g., wound healing, overall length of stay, length of intensive care stay, number of ventilator days, morbidity, mortality, nutritional status)
- 02 Anatomy, physiology, and metabolism related to specialized nutrition support (SNS)
- 03 Disease states and clinical conditions which affect ingestion, digestion, absorption, metabolism, or excretion of nutrients
- 04 Effects of nutritional status that influence the nutrient requirements (e.g., maintenance, repletion, weight loss) of SNS
- 05 Effects of disease states and clinical conditions that influence the selection of the type of SNS
- 06 Indications for and limitations of vascular access devices used to administer parenteral nutrition
- 07 Indications, limitations, and contraindications for the use of parenteral nutrient components (e.g., dextrose, fat emulsion, amino acids, minerals, vitamins)
- 08 Composition and physical and chemical properties of parenteral nutrient components
- 09 Methods to initiate, advance, and discontinue parenteral feeding formulations (e.g., order writing/prescribing)
- 10 Appropriate methods for administering parenteral feeding formulations (e.g., continuous, cyclic)
- 11 Types of administration and filtration devices (e.g., pumps, bags, tubing, filters) used to administer parenteral feeding formulations
- 12 Indications, limitations and contraindications for the use of enteral nutrition or for enteral access devices used to administer enteral nutrition
- 13 Appropriate use of enteral feeding formulations
- 14 Composition and physical properties of enteral feeding formulations (e.g., protein, carbohydrate, fat, water, vitamins, minerals, osmolality)
- 15 Methods for initiation, advancement, and discontinuation of enteral feeding formulations (e.g., order writing/prescribing)
- 16 Appropriate methods for administering enteral feeding formulations (e.g., intermittent, continuous, bolus)
- 17 Types of devices (e.g., pumps, bags, tubing) used to administer enteral feeding formulations
- 18 Sources and use of specialized nutrition support (SNS) education materials for patients, health care professionals, and other caregivers
- 19 Methods to assess the clinical, nutritional, and metabolic responses to SNS
- 20 Methods to prevent and manage complications of SNS
- 21 Therapeutic and compatibility considerations for co-administration of adjuvant drugs with SNS (Specialized Nutrition Support)

***Subdomain C. Monitoring and Clinical Management (26% of the examination)*****Tasks:**

1. Monitor and evaluate clinical, nutritional, and metabolic responses to specialized nutrition support (SNS)
2. Prevent, identify, and manage complications of SNS
3. Revise the therapeutic plan (plan of care) based on changes in the patient's status

4. Revise drug therapy used in conjunction with SNS
5. Revise SNS based on drug therapy

**Knowledge of:**

- 01 Fluid, electrolyte, and acid-base balance
- 02 Metabolic, nutritional, and clinical responses to specialized nutrition support (SNS)
- 03 Mechanical complications associated with SNS and methods to prevent and manage them
- 04 Metabolic complications associated with SNS and methods to prevent and manage them
- 05 Infectious complications associated with SNS and methods to prevent and manage them
- 06 Gastrointestinal complications associated with SNS and methods to prevent and manage them
- 07 Psychosocial complications associated with SNS and methods to prevent and manage them
- 08 Pathophysiologic complications (e.g., altered organ function) associated with SNS and methods to prevent and manage them
- 09 Techniques and methods to monitor and manage interactions between drugs and nutrients
- 10 Effect of SNS on pharmacotherapy
- 11 Effect of pharmacotherapy on SNS
- 12 Methods to maintain or restore patency to feeding access devices

**Domain 2: Management of Nutrition Support Operations (20% of the examination)**

***Subdomain A. Patient Care Management (12% of the examination)***

**Tasks:**

1. Develop policies and procedures for patient-care aspects of specialized nutrition support (SNS) (e.g., nutritional assessment, monitoring, patient selection, ordering procedures)
2. Coordinate, manage or participate in activities of interdisciplinary SNS teams or committees (e.g., rounds, human and fiscal resources, educational programs)
3. Design and integrate nutrition support protocols into disease state management (e.g., critical pathways, clinical practice guidelines)
4. Design, implement, and evaluate systems and processes for the safe and effective use of SNS

**Knowledge of:**

- 01 Methods to determine patient care nutrient requirements
- 02 Methods to maintain patency of parenteral and enteral access devices
- 03 Costs associated with provision of specialized nutrition support (SNS)
- 04 Skills and information necessary for the patient, health-care professionals, and other caregivers to provide SNS
- 05 Methods used to monitor and enhance patient compliance

***Subdomain B. Compounding Operations (8% of the examination)***

**Tasks:**

1. Develop policies and procedures for operational aspects of SNS (e.g., labeling of feeding formulations, compounding, storage, beyond-use date, expiration)
2. Participate in development and management of nutrition product formulary
3. Participate in evaluation and selection of infusion-control devices and supplies for SNS
4. Maintain compliance with federal/state regulations and accreditation standards
5. Perform or supervise the compounding and dispensing of parenteral or enteral feeding formulations

**Knowledge of:**

- 01 Sources of information regarding compatibility, stability, and physical and chemical properties of parenteral and enteral feeding formulations
- 02 Guidelines (e.g., JCAHO, A.S.P.E.N., ASHP, OSHA, USP) for health systems related to specialized nutrition support (SNS)
- 03 United States Pharmacopeia Chapter 797
- 04 Components of a nutrition product formulary
- 05 Aseptic and clean technique for compounding parenteral and enteral feeding formulations and risk level assessment
- 06 Quality control procedures (e.g., infection control, end-product analysis) related to the preparation, dispensing, monitoring, storage, and use of parenteral and enteral feeding formulations
- 07 Indications and limitations of infusion and filtration devices (e.g., pumps, bags, tubing, filters) used to administer parenteral feeding formulations
- 08 Indications and limitations of enteral access devices used to administer enteral nutrition
- 09 Pharmaceutical calculations used in compounding feeding formulations
- 10 Guidelines for parenteral admixture compounding and dispensing
- 11 Compatibility and stability of parenteral feeding formulations (e.g., nutrients, drugs)
- 12 Preparation, compatibility, and stability of enteral feeding formulation (e.g., nutrients, drugs)
- 13 Storage, beyond-use date, expiration and hang time – limitations for SNS feeding formulations

**Domain 3: Advancement of Nutrition Support Practice (12% of the examination)**

**Tasks:**

1. Retrieve and evaluate available scientific literature regarding specialized nutrition support (SNS) to advance individual patient care, management of services, and education of patients, health-care providers, and caregivers
2. Design and/or conduct and communicate research (e.g., performance improvement, clinical, and outcomes) in the area of nutrition support

**Knowledge of:**

- 01 Scientific literature and other resources pertaining to nutrition and the provision of specialized nutrition support (SNS)
- 02 Research design, statistics, and data analysis

- 03 Research methodologies specific to SNS (e.g., bioelectric impedance analysis, total urinary nitrogen) used to design, conduct or evaluate scientific investigations
- 04 Pertinent professional organizations, publications, and other resources that transmit nutrition support knowledge
- 05 Procedures for obtaining professional privileges (e.g., writing orders, drug administration)
- 06 SNS use evaluations and other continuous quality improvement techniques related to the provision of SNS (e.g., system outcome indicators such as error rates associated with administration and compounding)
- 07 Communication technologies for the monitoring and clinical management of SNS
- 08 Patient outcome indicators of nutrition therapy (e.g., wound healing, length of stay, morbidity, mortality, nutritional status)

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## **Content Outline for the ONCOLOGY PHARMACY SPECIALTY CERTIFICATION EXAMINATION December 2006**

The following domains, tasks and knowledge statements were delineated by the BPS Specialty Council on Oncology Pharmacy and validated through a role delineation study, and most recently updated in 2006. The proportion of examination items allotted to each domain was determined through analysis and discussion of the results of the role delineation study by the Specialty Council.

Each of the major areas/domains of Oncology Pharmacy practice noted below will be tested. Questions will not be grouped by domain. Items testing each domain are distributed throughout the total examination. Please note that this examination will SAMPLE a candidate's knowledge rather than trying to test all of her/his knowledge.

**Domain 1: Clinical Skills and Therapeutic Management: Optimize drug therapy for patients with cancer through the design, recommendation, implementation, monitoring, and modification of individualized pharmacotherapeutic plans in collaboration with the healthcare team. (60% of the examination)**

### **Tasks:**

- 1 Collect and assess comprehensive patient information necessary to design a pharmacotherapeutic plan.
- 2 Establish therapeutic goals in collaboration with the patient/caregivers and the healthcare team.
- 3 Design, communicate/document, implement, and modify a pharmacotherapeutic plan for patient-specific problem(s) through the integration of pathophysiological, pharmacogenomic, pharmacokinetic, pharmacodynamic, age-related, socioeconomic, ethical/legal, and cultural considerations.
- 4 Design, communicate/document, implement, and modify a monitoring plan to assess patient-specific outcomes to the therapeutic plan, including outcomes related to concomitant disease states (e.g., symptom evaluation, adverse-effect evaluation, physical and laboratory assessment, frequency and duration of follow-up).
- 5 Assess outcomes relative to therapeutic goals (e.g., effectiveness, drug-related issues, adherence).
- 6 Predict, prevent, identify, and resolve treatment- or disease-related problems.

- 7 Provide education and counseling to patients/caregivers regarding the pharmacotherapeutic plan, concurrent drug therapies, and outcomes.

**Knowledge Statements:**

- 01 Pathology
- 02 Anatomy and physiology
- 03 Molecular biology
- 04 Etiology and pathophysiology of cancer and cancer treatment related complications
- 05 Cancer pharmacotherapies, including chemotherapies, biologic therapies, hormonal therapies, labeled and off-label uses
- 06 Non-pharmacological treatments (for example, radiation therapy, surgery, observation, radiopharmaceuticals)
- 07 Hematopoietic stem cell transplants
- 08 Alternative/complementary therapies (for example, herbals, vitamins, acupuncture), and non-prescription medications
- 09 Drug interactions
- 10 Use of clinical trials as a treatment option
- 11 Cancers, including staging, diagnosis, prognosis, and treatment outcomes by stage
- 12 Expected response rates based on patient-specific factors
- 13 Complications of cancer or cancer treatment, including both early and late effects
- 14 Toxicity assessment and grading
- 15 Factors that may influence treatment and outcomes, including age, organ function, biology of the disease, genetics, co-morbidities
- 16 Pharmacology/Pharmacokinetics, pharmacodynamics, and pharmacogenetics of anticancer and supportive care agents.
- 17 Drug-delivery technology
- 18 Drug administration and routes of delivery
- 19 Diagnostic and monitoring tests
- 20 Social and cultural factors impacting treatment and outcomes
- 21 Pain/Palliative care and end-of-life care
- 22 Issues related to supportive care, including growth factors, chemoprotectants, anti-emetics, anti-infectives, etc.

**Domain 2: Generation, Interpretation, and Dissemination of Information: Contribute to the care of patients with cancer through research, the application of research results, and education. (20% of the examination)**

**Tasks:**

- 1 Evaluate the literature with regard to study design, methodology, and significance of findings
- 2 Integrate new information with existing information to establish recommendations for clinical use.
- 3 Develop, modify, and evaluate patient and public educational materials for approved

- and investigational therapies
- 4 Provide education and consultation to the healthcare team.
  - 5 Participate in the drug development process and clinical research activities (for example, research protocol development, data collection and analysis, recruitment and monitoring of patients, investigational drug management, ensure adherence to the research protocol).
  - 6 Contribute new knowledge to the profession (e.g., case reports, adverse drug event reports, medication safety, review articles, abstracts)

**Knowledge Statements:**

- 01 Literature and information retrieval systems
- 02 Study design and methodology, including strengths and limitations
- 03 Common study endpoints (e.g., response, adverse events, economics, quality of life, pharmacokinetics, pharmacodynamics, pharmacogenomics)
- 04 Generalizability (application) of research results
- 05 Statistical methods
- 06 Educational and counseling methods
- 07 Information resources for education and counseling
- 08 Regulatory and ethical issues related to research (including confidentiality, informed consent, and patient rights)
- 09 Drug development process

**Domain 3: Guidelines, Policies, and Standards: Ensure the safe, effective, and appropriate use of medications in patients with cancer through the implementation of guidelines and the development and modification of pharmacy policies and systems. (15% of the examination)**

**Tasks:**

- 1 Design, implement, evaluate, and modify pharmacy services appropriate to the needs of patients across the continuum of care.
- 2 Establish and modify systems to ensure the safe use of medications.
- 3 Ensure that oncology-related pharmacy services comply with established regulations and standards.
- 4 Ensure that care is consistent with appropriate clinical practice guidelines.
- 5 Incorporate patient rights and ethical standards into pharmacy policies and procedures (e.g., confidentiality/HIPAA, age-appropriate informed consent, right of refusal)
- 6 Develop appropriate drug use policies in collaboration with other providers and/or agencies.

**Knowledge Statements:**

- 01 Clinical practice guidelines (for example, ASCO, ASHP, NCCN)
- 02 Methods for developing and evaluating clinical practice guidelines
- 03 Professional practice standards (e.g., ASHP, USP, ASCO)

- 04 National accreditation and regulatory standards (e.g., JCAHO, CMS, HIPAA, NIOSH, USP 797, OSHA, OBRA, DEA, ASHP Oncology Pharmacy Practice Residency Standards) and their impact on the care of patients
- 05 Reimbursement policies of federal and private agencies
- 06 Quality improvement strategies to avoid medication misadventures (e.g., processing of chemotherapy orders, protocol reviews)
- 07 Methods for handling cytotoxic drugs and related materials (administration, compounding, and disposal)
- 08 Investigational drug management

**Domain 4: Public Health and Advocacy: Raise awareness among the public and healthcare providers regarding cancer-related issues. (5% of the examination)**

**Tasks:**

- 1 Provide information to the public regarding cancer-related issues, including cancer risk factors, prevention, screening, and treatment.
- 2 Serve as a public advocate regarding treatment-related issues that pertain to the prevention, treatment, and palliation of cancer.
- 3 Refer the public to appropriate sources of information, cancer-support organizations, and agencies.

**Knowledge Statements:**

- 01 Resources available through groups, organizations, agencies, and pharmaceutical industry (e.g.: American Cancer Society, National Cancer Institute, Leukemia and Lymphoma Society, National Coalition of Cancer Survivors)
- 02 Cancer risk factors
- 03 Cancer prevention strategies
- 04 Cancer screening guidelines
- 05 Cancer treatment strategies
- 06 Clinical trial options

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**Content Outline for the  
PEDIATRIC PHARMACY  
SPECIALTY CERTIFICATION EXAMINATION**  
**Developed April 2012 for Use on the Fall 2015 Exam**

The following domains, tasks and knowledge statements were delineated by the BPS Pediatric Pharmacy Practice Analysis Taskforce and validated through a role delineation study, conducted in 2012. The proportion of examination items allotted to each domain was determined through analysis and discussion of the results of the role delineation study by the BPS Pediatric Pharmacy Practice Analysis Taskforce and approved by the BPS Board of Directors.

Each of the major areas/domains of Pediatric Pharmacy practice noted below will be tested beginning in Fall 2015. Questions will not be grouped by domain on the exam. Rather, items testing each domain are distributed throughout the total examination. Please note this examination will **SAMPLE** a candidate's knowledge rather than trying to test all of his/her knowledge. Examination items will address problems and situations reflective of the full range of practice.

**Domain 1: Patient Management (58% of exam)****Tasks**

Tasks related to the comprehensive management of a pediatric patient including collecting, interpreting, and integrating pertinent clinical data; and designing, implementing, monitoring, and modifying patient-specific plans of care for pediatric patients in collaboration with the healthcare team.

For the Pediatric Patient:

1.1 Obtain pertinent patient information (e.g., weight, height and/or body surface area, age, allergies, disease states, medication history including herbal and dietary supplements, current medications, dose form preference, immunization status, nutritional status, and social/family history) via medical record, discussion with healthcare colleagues and/or patient/parent/caregiver interview.

1.2 Obtain relevant clinical and laboratory data and results of diagnostic procedures.

1.3 Analyze and interpret collected patient information.

1.4 Identify and prioritize current or potential patient-specific medical, medication, and nutrition related problems.

1.5 Establish therapeutic goals with healthcare team and patient/parents/caregivers.

1.6 Design, recommend and/or implement an age-appropriate therapeutic regimen with healthcare team and patient/parents/caregivers.

1.7 Design and implement a plan to monitor the safety and efficacy of a therapeutic regimen, and adjust as necessary.

1.8 Participate in the management of pediatric emergencies.

1.9 Reconcile medications as necessary across the continuum of care including on admission, transfer, discharge, and during outpatient encounters.

1.10 Identify and refer patients with needs beyond the scope of the pediatric pharmacy specialist to an appropriate alternative level of care.

**Knowledge of:**

k1.1 Normal growth and development of the pediatric population

k1.2 Age-appropriate interviewing techniques for patients, parents, and caregivers

k1.3 Essential components of a medical history including maternal and birth history and childhood immunization status, if appropriate

k1.4 Essential components of a social history, including day care attendance, siblings, smoke exposure, home environment

k1.5 Pathophysiology, epidemiology, risk factors, diagnosis, prevention, and evidence-based treatment of common diseases and conditions in pediatric patients

k1.6 Equations to calculate body surface area, creatinine clearance, fluid requirements, and ideal body weight from birth to adult

k1.7 Pediatric populations for which standard calculated methods of assessment of renal impairment are not reliable

k1.8 Urine output calculation for body weight and appropriate output per age

k1.9 Methods for assessment of hepatic function in pediatric populations

k1.10 Normal laboratory values and vital signs from birth to adult

k1.11 Age-associated differences in pathophysiology and clinical manifestations of disease across patient populations

k1.12 Age-specific pharmacokinetic differences in neonates, infants, children, and adolescents:

k1.13 Age-specific pharmacodynamic differences in neonates, infants, children, and adolescents:

k1.14 Pharmacogenomic considerations in pediatric patients

k1.15 Appropriate use of off-label medications to treat pediatric patients

- k1.16 Pediatric-specific drug interactions (e.g., ceftriaxone and calcium-containing products in the neonate, calcium and phosphorous in parenteral nutrition)
- k1.17 Clinical or therapeutic implications in the fetus and neonate of placental transfer of medications or other substances (e.g., antenatal steroids, neonatal abstinence syndrome [NAS], anticonvulsant withdrawal)
- k1.18 Influence of medications on the production of breast milk
- k1.19 Excretion of medications and other substances in breast milk
- k1.20 Appropriate dosing based on age and body size (e.g., body surface area, post-menstrual age, gestational age, dosing weight)
- k1.21 Medication dosing in extracorporeal membrane oxygenation (ECMO) and in renal replacement therapy (e.g., continuous renal replacement therapy [CRRT], PD, HD)
- k1.22 Medication dose adjustment in pediatric patients with renal and hepatic impairment
- k1.23 Essential components of medication reconciliation in pediatric patients (e.g., concentration, dose in mg, palatability)
- k1.24 Pediatric-specific adverse effects (e.g., liver failure with valproate, tetracycline and tooth discoloration):
- k1.25 Differences in laboratory sampling for pediatric patients (e.g., blood volume; method, frequency and timing of sampling)
- k1.26 Differences in the management of pediatric emergencies (e.g., respiratory distress, neonatal seizures, cardiopulmonary arrest)
- k1.27 Nutritional and fluid requirements for infants and children for normal growth and disease
- k1.28 Childhood immunization schedules
- k1.29 Factors affecting adherence to the treatment regimen
- k1.30 Specialty needs of pediatric patients requiring referral to other providers (e.g., infant with signs of dehydration, patient needs compounded oral formulation)

## **Domain 2: Practice Management (20% of exam)**

### **Tasks**

Tasks related to advancing pediatric pharmacy practice; and recommending, designing, implementing, and monitoring systems and policies to optimize the care of pediatric patients.

- 2.1 Develop and implement systems to assure appropriate drug delivery (e.g., extemporaneous compounding, standardized concentrations) for pediatric patients.
- 2.2 Participate in decision-making regarding selection and implementation of equipment/technology and decision support involved in the medication use process (e.g. infusion pumps, CPOE, bar coding).

2.3 Develop and maintain a preferred formulary for pediatric patients and ensure appropriate pediatric dosing is incorporated in all formulary monographs.

2.4 Adopt, adapt or develop evidence-based practice guidelines and protocols for the management of pediatric patients in accordance with health-system policies and procedures.

2.5 Establish processes to anticipate, prevent, review, and report medication use events (e.g., trigger review, root cause analysis, failure mode and effects analysis, MedWatch, Vaccine Adverse Event Reporting System [VAERS]).

2.6 Perform continuous quality improvement activities aimed at enhancing safety and effectiveness of medication use.

2.7 Develop policies and direct the medication use process for investigational drugs (including compassionate use agents) in the pediatric population.

2.8 Justify and document the clinical and financial value of pediatric pharmacy services.

**Knowledge of:**

k2.1 Medication safety considerations (e.g., Institute for Safe Medication Practices [ISMP] and Joint Commission recommendations, Food and Drug Administration [FDA] alerts)

k2.2 Position statements, white papers, and national guidelines as an aid to the development of health-system policies and procedures

k2.3 Pediatric-specific considerations (e.g., age and body size) in the design or improvement of medication use processes (e.g., computerized physician order entry [CPOE], infusion pumps, electronic medical record [EMR])

k2.4 Routes of administration (e.g., intraosseous, oral/enteral, parenteral, IM, transdermal, intranasal, intraventricular)

k2.5 Impact of medication administration techniques on drug delivery in pediatric patients (e.g., inhalers, dead space in IV tubing, overfill, j-tip device)

k2.6 Medication administration technology (e.g., infusion pumps, subcutaneous needle devices, intranasal administration devices, aerosols)

k2.7 Appropriate references to support the preparation of pediatric formulations (e.g., IV dilutions, extemporaneously compounded preparations)

k2.8 Considerations when selecting pediatric-appropriate dosage formulations

k2.9 Metrics for evaluating quality of pediatric pharmacy services (e.g., patient/parent/caregiver satisfaction, length of stay, readmission, medication errors)

**Domain 3: Information Management and Education (18% of exam)****Tasks**

Tasks related to retrieval, generation, interpretation, and dissemination of knowledge related to pediatric pharmacy, and the education of healthcare providers, trainees, patients and caregivers.

3.1 Provide pediatric pharmacy-specific education and training for pharmacists, pharmacy technicians, pharmacy fellows, pharmacy residents, or student pharmacists.

3.2 Educate healthcare professionals or students in other health professions concerning safe and effective use of medications and other issues related to the care of the pediatric patient.

3.3 Educate and provide counseling to patients/parents/caregivers regarding the safe and effective use of medications, the treatment regimen, the monitoring of side effects, and the importance of adherence to the treatment regimen.

3.4 Contribute to the pediatric body of knowledge (e.g., participate in research, deliver presentations, participate as peer reviewer, publish).

3.5 Retrieve and interpret biomedical literature with regard to study methodology, statistical analysis, study results and applicability to pediatric pharmacy practice.

3.6 Develop and maintain a pediatric-specific medical reference library (electronic or print).

**Knowledge of:**

k3.1 Principles and methods of educating pharmacy staff, fellows, residents, student pharmacists and/or other healthcare professionals regarding pediatric health-related issues

k3.2 Age-appropriate patient education principles and methods

k3.3 Health literacy and cultural considerations in educating patients/parents/caregivers:

k3.4 Tools, methods and counseling techniques to increase adherence to the treatment regimen :

k3.5 Research design, methodology, and statistical analysis:

k3.6 Clinical application and limitations of published data and reports

k3.7 Regulatory/IRB/human subjects safety requirements and concerns for conducting research in the pediatric population

k3.8 Medical literature publication and review process

k3.9 Opportunities for disseminating pediatric knowledge and scholarly activity (e.g., presentations, manuscripts, newsletters, abstracts, posters)

k3.10 Appropriate pediatric-specific references

**Domain 4: Public Health and Patient Advocacy (4% of exam)****Tasks**

Tasks related to providing preventive health services, public health information, and advocacy for the pediatric patient population healthcare policy.

4.1 Advocate for public health initiatives to promote health, safety, and wellness in infants, children and adolescents.

4.2 Advocate for the availability of age-appropriate formulations, safety and efficacy studies in the pediatric population, and product labeling in pediatric patients.

4.3 Educate the public regarding the importance of health, safety, and wellness in infants, children and adolescents (e.g., poison prevention, vaccination, safe and effective medication use, substance abuse/misuse).

4.4 Participate in professional organizations related to pharmacy and pediatric practice.

4.5 Facilitate access to care and treatment for pediatric patients in times of financial need, disaster, drug shortage, or public health threat.

**Knowledge of:**

k4.1 Healthcare disparities in pediatric patients

k4.2 Access to care disparities in pediatric patients

k4.3 Emergency preparedness resources for pediatric patients

k4.4 Public health resources for pediatric patients (e.g., childhood immunizations, sexually transmitted disease [STD] treatment, free health clinics)

k4.5 Public health initiatives and legislation to improve the overall well-being of children (e.g., smoking cessation, child proof caps, poison prevention, Best Pharmaceuticals for Children Act)

k4.6 Resources that improve access to medications and other therapies necessary for the care of pediatric patients (e.g., WIC, patient assistance programs, specialty pharmacies, compounding pharmacies)

k4.7 Professional organizations and their roles and resources related to advocacy

k4.8 Appropriate avenues to advocate for safe and effective use of medications in the pediatric populations (e.g., pediatric-specific formulations, removal of dangerous substances from the market, pediatric-specific product labeling)

k4.9 Evidence demonstrating value of post doctoral pediatric training and the pediatric pharmacy specialist (e.g., decreasing medication errors, decreased cost, decreased length of stay, improved outcomes)

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**Content Outline for the**

**PHARMACOTHERAPY**

**SPECIALTY CERTIFICATION EXAMINATION**

**April 2010**

The following domains, tasks and knowledge statements were delineated by the BPS Specialty Council on Pharmacotherapy and validated through a role delineation study in 2010. The proportion of examination items allotted to each domain was determined through analysis and discussion of the results of the role delineation study by the Specialty Council.

Each of the major areas/domains of Pharmacotherapy practice noted below will be tested. Questions will not be grouped by domain. Rather, items testing each domain are distributed throughout the total examination. Please note this examination will **SAMPLE** a candidate's knowledge rather than try to test all of his/her knowledge.

The test items in Domain 1 that deal with patient-specific pharmacotherapy focus on the therapeutic areas listed in the *Systems and Patient-Care Problems* section of this document (e.g., Cardiovascular, Endocrine, Infectious Diseases, etc.). Test items in Domain 1 that deal with age-specific problems are reflected across all organ systems and patient-care problems. There is a mixture of chronic and acute care pharmacotherapy problems, with several questions that are not specific to a patient acuity level.

**Domain 1: Patient-specific Pharmacotherapy (60% of exam)**

**Tasks:**

1. Collect patient-specific data to identify problems and individualize care
  - a. Review patient data regarding history, physical assessment, working diagnosis, laboratory and other diagnostic tests, and orders regarding drug therapy
  - b. Perform patient assessments (for example, physical examination, point of care testing)
  - c. Obtain information from patient, family, and health-care team members
  - d. Obtain additional pertinent data
  
2. Interpret data to identify problems
  - a. Interpret subjective and objective data
  - b. Identify drug-related problems
  - c. Develop/update a problem list

3. Design an individualized therapeutic plan
  - a. Determine and prioritize prevention and treatment goals
  - b. Consider ethical, cultural, legal, economic, quality of life and safety issues
  - c. Select drug and/or non-drug interventions
  - d. Identify potential for drug-drug, drug-disease, drug-nutrient, drug-device, and/or drug-laboratory interactions
  
4. Implement a therapeutic plan in collaboration with other health care professionals
  - a. Evaluate and resolve patient or health-care-system problems in the implementation of a patient's therapeutic plan
  - b. Administer drugs
  - c. Order diagnostic and/or laboratory tests
  - d. Perform diagnostic and/or laboratory tests
  - e. Communicate a therapeutic plan to health care professionals
  - f. Document a therapeutic plan
  
5. Educate patient and/or caregiver regarding a therapeutic plan
  - a. Identify and prioritize patient education needs
  - b. Recognize patient education barriers
  - c. Select and use appropriate educational method(s)
  - d. Assess patient's knowledge/skill acquisition
  
6. Monitor and modify a therapeutic plan
  - a. Monitor a therapeutic plan by collecting and interpreting data
  - b. Modify a therapeutic plan as needed

**Knowledge of:**

- 01 Anatomy and physiology
- 02 Disease state knowledge (prognosis; pathophysiology; epidemiology; etiology; risk factors; pathogenesis; signs and symptoms; diagnostic criteria; pharmacotherapy; pharmacokinetics; pharmacodynamics; pharmacoeconomics; pharmacogenomic; pharmaceuticals; drug-drug, drug-laboratory, drug-nutrient, drug-device, and drug-disease interactions; adverse drug effects; non-drug treatment; drug administration)
- 03 Disease/drug monitoring parameters (physical examination, laboratory and point of care tests, diagnostic tests, therapeutic goals)
- 04 Evidence-based practice guidelines
- 05 Patient education principles and methods
- 06 Health literacy
- 07 Regulatory requirements related to prescribing and monitoring specific drugs (e.g., methadone, isotretinoin, REMS programs)
- 08 Federal regulations related to patients rights and protections (e.g., privacy, child/adult protective services, advance directives, living will, power of attorney, do not resuscitate)
- 09 Ethical issues
- 10 Formats used to document pharmacotherapy recommendations and follow-up

- 11 Humanistic factors or outcomes (e.g., patient satisfaction, quality of life)
- 12 Cultural competence and sensitivity
- 13 Health promotion and disease prevention
- 14 Complementary and alternative medicine

**Domain 2: Retrieval, Generation, Interpretation and Dissemination of Knowledge in Pharmacotherapy (25% of exam)**

**Tasks:**

- 1. Identify and retrieve relevant biomedical literature
- 2. Interpret biomedical literature with regard to study design and methodology, statistical analysis, and significance of reported data and conclusions
- 3. Educate health care professionals, students, patients, and the public
- 4. Conduct research to generate clinical, economic, humanistic or translational knowledge applicable to patient care
- 5. Prepare and disseminate new knowledge (e.g., original research, review articles, case reports, abstracts, reviews and monographs)

**Knowledge of:**

- 01 Primary, secondary, and tertiary references
- 02 Search strategies
- 03 Information resources
- 04 Biostatistical methods
- 05 Internal and external validity
- 06 Clinical and statistical significance
- 07 Principles and methods of educating health care students and professionals
- 08 Role modeling, mentoring, and coaching techniques
- 09 Knowledge/skills assessment techniques
- 10 Research hypothesis generation
- 11 Research design and methodology
- 12 Protocol and proposal development
- 13 Regulatory requirements for the conduct of research (e.g., HIPAA, IRB, OSHA, NIH)
- 14 Data management
- 15 Design of publications for dissemination of new knowledge

**Domain 3: Systems and Population-based Pharmacotherapy (15% of exam)**

**Tasks:**

- 1. Document and report new, unusual, or severe pharmacotherapeutic events (e.g., adverse reactions, drug interactions, medication errors, drug/device/assay defects)
- 2. Collect and interpret data to characterize/identify health system and/or public health related problems
- 3. Design, justify, and garner support for health system and/or public health-related initiatives
- 4. Implement health system and/or public health-related initiatives

5. Measure and monitor outcomes of health system and/or public health-related initiatives

**Knowledge of:**

- 01 National regulatory and accrediting agency requirements for preventing, tracking, and reporting new, unusual, or severe pharmacotherapeutic events
- 02 Process/procedures for reporting to the FDA and other organizations new, unusual or severe adverse events related to drugs and/or devices
- 03 Evidence-based clinical practice and patient-care standards
- 04 Comparative effectiveness research/reviews
- 05 Health system-based standards and Federal regulations (e.g., TJC, NCQA, OSHA, CMS, HEDIS, LEAPFROG, HIPAA, FDA)
- 06 Principles of medication-use evaluation and prevention of drug-related injury
- 07 Performance improvement process
- 08 Principles of formulary and drug use system management
- 09 Ethical issues (industry interactions, conflict of interest, disclosure)
- 10 Continuity of patient care (e.g., medication reconciliation, in-home medication use)

## SYSTEMS AND PATIENT-CARE PROBLEMS

### ***Bone/Joint and Rheumatology***

- Fibromyalgia
- Osteoarthritis
- Gout/Hyperuricemia
- Osteoporosis
- Rheumatoid arthritis
- Systemic Lupus Erythematosus

### ***Cardiovascular***

- Acute coronary syndromes
- Advance cardiac life support
- Arrhythmias
- Cardiopulmonary resuscitation
- Coronary artery disease
- Dyslipidemia
- Heart failure
- Hypertension
- Peripheral arterial disease
- Primary pulmonary hypertension
- Septic shock
- Thromboembolic disorders
- Valvular heart disease

### ***Dermatologic***

- Acne
- Burns
- Dermatitis
- Decubitus ulcers
- Psoriasis
- Urticaria

### ***Endocrine***

- Adrenal disorders
- Diabetes insipidus
- Diabetes mellitus
- Obesity
- Parathyroid disorders
- Polycystic ovary syndrome
- SIADH
- Thyroid disorders

### ***Eyes, Ears, Nose, and Throat***

- Allergic rhinitis
- Glaucoma
- Macular degeneration
- Vertigo

### ***Fluid and Electrolyte/Nutrition***

- Acid-base disorders

- Electrolyte abnormalities
- Nutritional deficiencies

### ***Gastrointestinal***

- Constipation
- Diarrhea
- Chronic liver disease and cirrhosis
- Gastroesophageal reflux disease
- Gastrointestinal bleeding
- Hepatitis
- Inflammatory bowel disease
- Irritable bowel syndrome
- Malabsorption syndrome
- Nausea/vomiting
- Pancreatitis
- Peptic ulcer disease
- Stress Ulcer Prophylaxis

### ***Genitourinary***

- Prostatic hyperplasia
- Sexual dysfunction
- Urinary incontinence

### ***Hematologic***

- Anemias
- Clotting factor disorder
- Disseminated intravascular coagulation
- Sickle cell disease
- Thrombocytopenia

### ***Immunologic***

- Allergy/anaphylaxis
- Angioedema
- Organ transplantation
- Stevens-Johnson syndrome

### ***Infectious Diseases***

- Antimicrobial prophylaxis
- Bone and joint infections
- Central nervous system infections
- Ear infections
- Febrile neutropenia
- Fungal infections
- Gastrointestinal infections
- Gynecologic infections
- Human Immunodeficiency Virus infection
- Infectious endocarditis
- Intra-abdominal infections
- Lung abscess
- Ophthalmic infections
- Prostatitis

- Respiratory tract infections
- Sepsis
- Sexually transmitted diseases
- Sinusitis
- Skin and soft tissue infections
- Tuberculosis
- Urinary tract infections

### ***Neurological***

- Central nervous system hemorrhage
- Cerebral ischemia (including ischemic stroke)
- Dementia
- Epilepsy
- Headache/migraine
- ICU sedation/paralysis/delirium
- Neuromuscular diseases
- Parkinson’s disease
- Pain
- Peripheral neuropathy
- Spinal-cord injuries/abnormalities
- Status epilepticus
- Traumatic brain injury
- Tremors

### ***Obstetrics/Gynecology***

- Chronic disease in pregnancy
- Contraception
- Endometriosis
- Infertility
- Lactation
- Menopausal symptoms
- Menstrual disorders
- Pregnancy-related disease

### ***Oncology***

- Breast cancer
- Colon cancer
- Gynecological cancers
- Leukemia
- Lung cancer
- Prostate cancer
- Skin cancer
- Supportive care (e.g., preventing / treating complications associated with malignancy or treatment)

### ***Psychiatric***

- Anxiety disorders
- Attention deficit disorders
- Bipolar disorders
- Depressive disorders

- Drug/alcohol overdose/withdrawal
- Schizophrenia
- Sleep disorders
- Substance abuse

***Renal***

- Acute renal failure
- Chronic kidney disease
- Dialysis (managing associated complications and drug dosing)
- Nephrolithiasis

***Pulmonary***

- Adult respiratory distress syndrome
- Asthma
- Chronic obstructive lung disease
- Respiratory failure
- Sleep apnea

***Health Maintenance/Public Health***

- Bioterrorism
- Health advice, education, or instruction
- Immunizations
- Lifestyle modification
- Patient safety
- Routine health screening

# BOARD OF PHARMACY SPECIALITIES

2215 Constitution Avenue, NW  
Washington, DC 20037-2985  
202-429-7591 · FAX 202-429-6304  
[bps@aphanet.org](mailto:bps@aphanet.org) · [www.bpsweb.org](http://www.bpsweb.org)

## Content Outline for the PSYCHIATRIC PHARMACY SPECIALTY CERTIFICATION EXAMINATION **Developed Fall/Winter 2011/12 for Use on the October 2013 Exam**

The following domains, tasks and knowledge statements were delineated by the BPS Specialty Council on Psychiatric Pharmacy practice and validated through a role delineation study, conducted in 2011. The proportion of examination items allotted to each domain was determined through analysis and discussion of the results of the role delineation study by the Specialty Council.

Each of the major areas/domains of Psychiatric Pharmacy practice noted below will be tested beginning in October 2013. Questions will not be grouped by domain on the exam. Rather, items testing each domain are distributed throughout the total examination. Please note this examination will **SAMPLE** a candidate's knowledge rather than trying to test all of his/her knowledge. Examination items will address problems and situations reflective of the full range of practice sites (e.g., home care, hospital).

### **Domain 1: Patient Management**

**Provide optimal medication therapy management for patients with psychiatric and co morbid disorders. (62% of the examination)**

#### **Tasks:**

1. Conduct and interpret results of psychiatric assessments (for example, mental status examination, BPRS, HAM-D, BDI, HAM-A).
2. Interpret the results of clinical data (for example, physical examination, laboratory data, pharmacogenetics tests, neurological, psychological testing) obtained by other providers.
3. Interview patient, family, and/or caregiver(s) to identify information necessary to design a treatment plan (for example, medication history, adverse effects, adherence, target symptoms, severity).
4. Identify and assess target symptoms that respond to pharmacotherapy and variables that influence medication effectiveness (for example, time to response, and duration of illness).
5. Assess and manage psychiatric illnesses in the context of medical co morbidities.
6. Identify and assess target symptoms that respond to non-pharmacologic interventions (for example, cognitive-behavior therapy, electroconvulsive therapy, VNS, alternative therapies).
7. Establish measurable therapeutic goals in collaboration with the treatment team, patient, family, and/or the caregiver(s).

8. Recommend, initiate, or modify pharmacotherapy treatment plan.
9. Recommend non-pharmacological treatment plan.
10. Recommend, design, or implement a medication-specific monitoring plan (for example,)
11. Assess outcomes of the medication treatment and monitoring plans relative to therapeutic goals (for example, effectiveness, drug-related problems, adherence) and revise, as required.
12. Anticipate, identify, and manage drug-related problems (for example, drug-drug interactions, sub-therapeutic dose, treatment non-adherence).
13. Document and communicate findings, recommendations, decisions, and outcomes regarding treatment.

**Knowledge of:**

- 01 Psychiatric and related disorders
  - diagnostic criteria
  - signs and symptoms
  - pathophysiology
  - etiology (including drug induced, disease induced)
  - risk factors
  - onset, course, and prognosis
  - epidemiology
  - common medical co morbidities
- 02 Treatment of psychiatric and related disorders
  - relative role of treatment options (pharmacologic and non-pharmacologic)
  - proposed mechanism of action and pharmacologic effects
  - pharmacokinetics, pharmacogenetics and pharmacodynamics
  - relative potency, dosage, schedule, route of administration, and delivery technology
  - relative effectiveness of treatment options, including complementary and alternative therapy
  - dosage initiation, titration, and discontinuation
  - potential adverse events, toxicities, and management strategies
  - relative and absolute contraindications
  - pharmacoeconomics
  - rationale for drug selection
  - drug interactions
  - special populations (for example, gender, ethnicity, pregnancy, lactation, co-morbidity, age, partial and non-responders)
  - risk factors for non-adherence and strategies to evaluate and improve adherence
- 03 Disease and medication-specific monitoring parameters for psychiatric and related disorders
  - interviewing methods (for example, mental status exam, psychiatric interview)
  - laboratory and diagnostic tests (including imaging)
  - therapeutic drug monitoring
  - physical assessment (for example, vital signs, movement disorders)

- therapeutic end points
- frequency and relative importance of monitoring parameters
- assessment measures (for example, rating scales, inventories, quality of life)

## **Domain 2: Information Management**

**Obtain, generate, interpret, and disseminate knowledge related to psychiatric pharmacy.**  
(25% of the examination)

### **Tasks:**

1. Select and evaluate sources for biomedical information appropriate for psychiatric pharmacy practice.
2. Critically evaluate a study with regard to design and methodology, sources of bias, and significance and applicability of findings.
3. Develop best practices based on evaluation of the primary literature.
4. Provide and assess medication education to patients, families, and caregivers in individual and group sessions.
5. Provide and assess education to students, residents, trainees, pharmacists, and other healthcare professionals.
6. Generate new knowledge (for example, conduct research, publish case reports) to foster the safe, effective, and economical use of pharmacologic agents.
7. Develop and disseminate information to the public regarding mental health issues and medication safety.

### **Knowledge of:**

- 01 Medical literature related to psychiatric and related disorders
- 02 Information resources and technologies
- 03 Study design and methodology (including strengths and limitations of various designs and statistical methods)
- 04 Applicability and generalizability of research findings
- 05 Clinical versus statistical significance
- 06 Education methods for patients and the public
- 07 Professional education methods and principles
- 08 Procedures to assess the effectiveness of medication education
- 09 Regulations and guidelines for dissemination of medication information (for example, REMS, medication guides)
- 10 Regulatory and ethical issues related to research in patients with psychiatric and related disorders (including competency, confidentiality, informed consent, and patient rights)

### **Domain 3: Health Policy and Practice Management**

**Collaborate with healthcare professionals, administrators, and the general public to promote health, safety and welfare of individuals and populations with mental illness. (13% of the examination)**

#### **Tasks:**

1. Develop and implement systems and policies that optimize the care of patients with psychiatric and co morbid disorders.
2. Evaluate psychiatric services for compliance with standards established by national accrediting and regulatory agencies as related to practice in healthcare settings (for example, mental health, developmental disorders, substance abuse, forensic settings).
3. Advocate for the health, safety and welfare of individuals and populations with mental illness.
4. Assess the appropriateness of prescribing patterns of psychotropic medications in specific patient populations.
5. Develop and implement medication use policies in collaboration with other healthcare providers and/or agencies to optimize patient outcomes.
6. Develop and implement strategies for providing psychiatric pharmacy services appropriate to the needs of patients.
7. Facilitate patient access to medications and healthcare services.
8. Evaluate the quality and effectiveness of mental health care provided to patients.

#### **Knowledge of:**

- 01 Clinical practice guidelines for treatment of patients with psychiatric and neurologic disorders
- 02 National accreditation and regulatory standards (for example, TJC, HIPAA, CMS, CARF, OHRP)
- 03 Reimbursement policies of federal, state, and private agencies as related to the provision of psychiatric healthcare
- 04 Performance improvement methods (for example, peer review, adverse event monitoring, medication use evaluation)
- 05 Organizations that advocate and provide resources for patients with mental illness (for example, National Alliance on Mental Illness, CPNP, American Psychiatric Association)
- 06 Patient assistance programs and alternative funding sources

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- 05 Organizations that advocate and provide resources for patients with mental illness (for example, National Alliance on Mental Illness, CPNP, American Psychiatric Association)
- 06 Patient assistance programs and alternative funding sources



**DOCUMENTATION of TRAINING/EXPERIENCE**

I have spent \_\_\_\_\_ years providing patient-care activities as a pharmacist.

The Board of Pharmacy Specialties (BPS) requires a candidate to have completed **three (3) years of practice experience following initial licensure with at least 50% of time spent in activities related to the domains of the specialty exam**, or completed a **PGY1 residency**. Please provide your eligibility criteria below.

*\*Effective January 1, 2013, only residencies accredited by the American Society of Health-System pharmacist (ASHP) or residency programs that are under active consideration for accreditation by ASHP are creditable for this purpose.*

**PRACTICE EXPERIENCE**

Using the chart below, estimate the percentage of time you have spent in each of the domains of pharmacotherapy practice, as well as in all other areas of pharmacy practice. Each period must be 12 consecutive months, but not necessarily January-December. The total percentage of time for each 12 month period must equal 100%. See the *Pharmacotherapy Content Outline for detail of activities included under each domain.*

DOMAINS	TIME PERIODS (based on a 12 month period)		
	1st period	2nd period	3rd period
	(month)_____, (yr)____	(month)_____, (yr)____	(month)_____, (yr)____
<b>from</b>			
<b>to</b>	(month)_____, (yr)____	(month)_____, (yr)____	(month)_____, (yr)____
<b>I.</b> Patient-Specific Pharmacotherapy			
<b>II.</b> Retrieval, Generation, Interpretation and Dissemination of Knowledge in Pharmacotherapy			
<b>III.</b> Health-System Related Pharmacotherapy			
<b>IV.</b> All other pharmacy practice activities			
<b>TOTAL</b>	100%	100%	100%

**RESIDENCY**

I have completed a PGY1 Residency in Pharmacotherapy Pharmacy.

YES  NO

Dates: \_\_\_\_\_ to \_\_\_\_\_

Site: \_\_\_\_\_

Major Preceptor: \_\_\_\_\_

**EMPLOYMENT INFORMATION**

---

Select Employer Category (check all appropriate boxes)

- Academia-affiliated/University-based Setting
- Ambulatory Care
- Acute Care
- Family Medicine/Primary Care/Private Office
- Government: Armed Services/NIH/Public Health Service/VA
- Hospital/Health-system based Setting
- Manage Care/Mail Order
- Hospital/Health-system based Setting
- Private Office
- Other, Describe: \_\_\_\_\_

---

Employer Name

---

Employer Address

---

Supervisor Name

---

Supervisor Title

(      )

---

Supervisor Phone

---

Supervisor Email Address

**PHARMACY DEGREE**

List below the pharmacy degree(s) which you have earned along with the conferring institution(s)/date(s).

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degree	institution	date conferred
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degree	institution	date conferred
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degree	institution	date conferred
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## **APPLICATION STATEMENT**

- I hereby apply to the Board of Pharmacy Specialties for certification as a specialist in Pharmacotherapy.
- I have enclosed the six hundred dollar (\$600) fee and a photocopy of my current state pharmacy license/registration certificate.
- I have read, comprehended, and agree to comply with all the information contained in the 2013 BPS ***Candidate's Guide***.
- I understand and agree that certification is contingent upon my successfully meeting all eligibility requirements, which include achieving a passing score on the examination.
- I understand and agree that my signature below constitutes written authorization for the test developer to release my scores to BPS and to myself ONLY.
- I further understand that BPS may release aggregate examination score data to individuals or organizations selected by BPS to study its testing program, on the condition that my identity will NOT be disclosed.
- I understand and agree that in the event any material statement made by me during this certification process is false, I will not be certified, or if such has been granted to me, that it will be revoked. I authorize BPS to verify the information I have provided.
- I understand and agree that my signature below authorizes BPS to publish my name via the BPS website, if the conditions of recertification are met.
- If certified by BPS, I agree to make claims regarding certification only in respect to the scope for which certification has been granted. Further, I agree to not use the certification in such a manner as to bring the Board of Pharmacy Specialties into disrepute and not make any statement regarding the certification which the Board of Pharmacy Specialties may consider misleading or unauthorized. Further, I agree to ensure that neither certificate nor any part thereof is used in a misleading manner.
- Upon suspension or withdrawal of certification, I agree to discontinue the use of all claims to certification that contains any reference to the Board of Pharmacy Specialties or its certifications, and to return any certificates issued by BPS.
- I hereby certify that the information given during this certification process is true and correct to the best of my knowledge and belief.

Signature in full \_\_\_\_\_

Print Name \_\_\_\_\_ Date \_\_\_\_\_

Be sure you have:

- COMPLETELY** and **ACCURATELY** filled out the application.
- ENCLOSED \$600** – check, money order, Visa/MasterCard/American Express
- MAILED/FAXED** application no later than **AUGUST 1, 2013**.
- ATTACHED** photocopy of **PHARMACY REGISTRATION CERTIFICATE/LICENSE** to application



# GUIDELINES FOR PHYSICIAN DOCUMENTATION OF DISABILITY RELATED NEEDS

If you have a learning disability, a psychological disability, or other hidden disability that requires an accommodation in testing, please have your physician submit documentation to BPS on letterhead describing your disability and its severity and explain the need for requested accommodations. The report should include the following:

- A specific diagnosis of the disability using professionally recognized nomenclature, e.g., American Psychiatric Association Diagnostic and Statistical Manual
- A current evaluation (conducted no more than three years prior to the request for accommodations)
- Clear description of the specific diagnostic criteria and names of all diagnostic test used including dates(s) of evaluation
- Detailed description of the applicant's current functional limitations due to the diagnosed disability and an explanation of how the diagnostic test results relate to the identified functional limitations
- Recommendations of specific accommodations including assistive device, including a detailed explanation of why these accommodations or devices are needed and how they will reduce the impact of the identified functional limitations on the specific exam for which they are requested.
- List of any accommodations the applicant currently uses in daily functioning
- Physician's contact information and credentials



**CURRENT WORK EXPERIENCE**

Please note: Current employment is not a requirement to renew BPS certification. The information below is being gathered for informational purposes only.

Check all that apply:

- Direct Patient Care       Administrative Care       Retired       Unemployed

Employer: \_\_\_\_\_

Employer Type:

- |   |   |
|---|---|
| <input type="checkbox"/> Hospital/Health Center (Community or Teaching) | <input type="checkbox"/> Community Pharmacy/Ambulatory Clinic |
| <input type="checkbox"/> University/Academic                            | <input type="checkbox"/> Dept. of Veterans Affairs            |
| <input type="checkbox"/> Mail Services                                  | <input type="checkbox"/> Pharmaceutical Industry              |
| <input type="checkbox"/> Health Care System (Kaiser, etc.)              | <input type="checkbox"/> Admin./Mgmt./Association/Publishing  |
| <input type="checkbox"/> Dept. of Health and Human Services/USPHS       | <input type="checkbox"/> U.S. Army                            |
| <input type="checkbox"/> U.S. Navy                                      | <input type="checkbox"/> Chain Pharmacy                       |
| <input type="checkbox"/> Unemployed/retired                             | <input type="checkbox"/> U.S. Air Force                       |
| <input type="checkbox"/> Home Health/Infusion Service                   | <input type="checkbox"/> Independent Consultant/Self-employed |

Using the chart below, estimate the percentage of time you have spent in each of the domains of your specialty area of practice, as well as in all other areas of pharmacy practice, during this recertification period (2007-2013). See the Content Outline at [www.bpsweb.org](http://www.bpsweb.org) for details of activities included under each domain.

DOMAINS	percentage
I	_____ %
II	_____ %
III	_____ %
IV	_____ %
<i>All other pharmacy practice activities</i>	_____ %
<b>TOTAL</b>	100%

List your pharmacy work experience for 2007-2013 (for retired/unemployed BPS certificants, list last employer).

1. Employer: _____ _____	3. Employer: _____ (if applicable)
Your Position Title: _____	_____
Dates of Employment: _____	Your Position Title: _____
2. Employer: _____ (if applicable)	Dates of Employment: _____
_____	
Your Position Title: _____	
Dates of Employment: _____	

## **RECERTIFICATION FEEDBACK**

1. What are the primary benefits of maintaining Board Certification (check all that apply)?
  - Expand knowledge and skills in pharmacy
  - Attain more confidence in performing professional responsibilities
  - Gain personal satisfaction by accomplishing something professionally important
  - Gain greater credibility/status as a professional
  - Increase in income
  - Contribute to a faster career path
  - Enhance job mobility
  - Job requirement
  - Peer recognition
  - Attain greater job security
2. If recertifying via CE, what are the biggest benefits of choosing this recertification option (check all that apply)?
  - Expand knowledge and skills in pharmacy
  - Address areas of weakness in pharmacy practice
  - Able to plan recertification activities
  - Other (please specify) \_\_\_\_\_
3. If recertifying via CE, what are the biggest challenges in obtaining recertification (check all that apply)?
  - Time needed to complete requirements
  - Cost of completing requirements
  - Difficulty of post-tests
  - Amount of CE options available
  - Type of CE options available (live vs. online)
  - Lack of relevancy to my practice
  - Other (please specify) \_\_\_\_\_
4. If recertifying via exam, what are the biggest benefits in choosing this recertification option (check all that apply)?
  - Time (spent preparing for the exam vs. completing CE)
  - Cost (vs. purchasing CE modules)
  - Expand knowledge and skills in pharmacy practice
  - Other (please specify) \_\_\_\_\_
5. If recertifying via exam, what are the biggest challenges in obtaining recertification (check all that apply)?
  - Difficulty of exam
  - Scheduling of exam
  - Preparation time for exam
  - Relevancy to practice
  - Other (please specify) \_\_\_\_\_
6. What other activities have you participated in over the 7 year recertification cycle that you believe have strengthened your knowledge in your specialty area (check all that apply)?
  - Journal publications
  - Conference attendance
  - Conference presentations
  - Research
  - Other (please specify) \_\_\_\_\_
7. Does your employer provide reimbursement for the following (check all that apply):
  - BPS initial certification exam
  - BPS recertification fee
  - BPS annual maintenance fee
  - Continuing Education offered by BPS-approved providers
8. Does your employer provide additional compensation for BPS certification?
  - Yes
  - No
9. Do you believe the 7-year time period for recertification is appropriate?
  - Yes
  - No—should be shorter (please note, CE requirements would be prorated)
10. Are you considering becoming certified in another specialty area?
  - Yes
  - No
- 10a. If yes, which specialty or proposed specialty would you consider becoming certified in? \_\_\_\_\_
- 10b. If yes, do you plan on keeping your current certification?
  - Yes
  - No
  - Undecided

**APPLICATION STATEMENT**

I hereby apply to the Board of Pharmacy Specialties for recertification as a specialist in: (Check one)

Nuclear Pharmacy  Nutrition Support Pharmacy  Oncology  Pharmacotherapy  Psychiatric

- I have enclosed the four hundred dollar (\$400) fee and a photocopy of my current state pharmacy license/registration certificate.
- I have read, comprehended, and agree to comply with all the information contained in the 2013 BPS Recertification Guide.
- I understand and agree that recertification is contingent upon my successfully meeting all eligibility requirements.
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- I hereby certify that the information given during this certification process is true and correct to the best of my knowledge and belief.

Signature in full \_\_\_\_\_

Print Name \_\_\_\_\_ Date \_\_\_\_\_

Be sure you have:

- COMPLETELY** and **ACCURATELY** filled out the application.
- ENCLOSED \$400** – check, money order, Visa/MasterCard/American Express
- MAILED/FAXED** application no later than **AUGUST 1, 2013**.
- ATTACHED** photocopy of **PHARMACY REGISTRATION CERTIFICATE/LICENSE** to application



# GUIDELINES FOR PHYSICIAN DOCUMENTATION OF DISABILITY RELATED NEEDS

If you have a learning disability, a psychological disability, or other hidden disability that requires an accommodation in testing, please have your physician submit documentation to BPS on letterhead describing your disability and its severity and explain the need for requested accommodations. The report should include the following:

- A specific diagnosis of the disability using professionally recognized nomenclature, e.g., American Psychiatric Association Diagnostic and Statistical Manual
- A current evaluation (conducted no more than three years prior to the request for accommodations)
- Clear description of the specific diagnostic criteria and names of all diagnostic test used including dates(s) of evaluation
- Detailed description of the applicant's current functional limitations due to the diagnosed disability and an explanation of how the diagnostic test results relate to the identified functional limitations
- Recommendations of specific accommodations including assistive device, including a detailed explanation of why these accommodations or devices are needed and how they will reduce the impact of the identified functional limitations on the specific exam for which they are requested.
- List of any accommodations the applicant currently uses in daily functioning
- Physician's contact information and credentials



## February 12, 2014 Licensing Committee Meeting Minutes Expert

### **2. Presentation by Brian Lawson, PharmD, Director of Professional Affairs, Board of Pharmacy Specialties, and Andrea Iannucci, PharmD, Board of Directors, Board of Pharmacy Specialties, Regarding Development of Certification Programs and Existing Certification Programs for Pharmacists**

#### Background

The Board of Pharmacy Specialties (BPS), as its name implies, has developed eight pharmacy practice areas for which it has developed certification programs. The BPS literature provides 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

At the February 12, 2014, Licensing Committee meeting, Dr. Brian Lawson provided information about the certification programs BPS developed for pharmacists. Dr. Lawson also provided information about development of certification programs. Meeting materials included an overview of their processes, and then the content outlines for each of the specialties. These specialties are specifically listed in the new law (as section 4210) as qualifying routes for the advanced practice pharmacist licensure.

Dr. Lawson's presentation provides background for the committee as it moves forward with establishing qualifying components for advanced practice pharmacists.

Whereas the specific specialties listed in SB 493 are the programs certified by the BPS, this agency itself is not mentioned in the bill -- see "from an organization recognized by the Accreditation Council for Pharmacy Education or another entity recognized by the board" in section 4210(a)(2)(A). As such, the board will need to recognize this agency if this is the direction the board chooses to go.

#### Presentation

Chair Veale introduced and welcomed Brian Lawson, PharmD, and Andrea Iannucci, PharmD, from Board of Pharmacy Specialties (BPS) regarding the development of a certification program and the existing certification program for pharmacists.

Brian Lawson, PharmD, introduced himself as the Director of Professional Affairs for BPS and Andrea Iannucci, PharmD as a local specialist in oncology and serves on the Board of Directors for BPS.

Dr. Lawson congratulated the board on the accomplishment of establishing APP in California and thanked the committee for the opportunity to talk about pharmacist credentialing to the committee.

Dr. Lawson discussed the Council on Credentialing in Pharmacy (CCP) as a national coalition of about ten organizations as a forum to discuss credentialing activities in pharmacy. CCP directs the process to establish standards of quality, to improve patient care and overall public health. CCP meets on a quarterly basis to direct leadership guidance to provide public information and coordinate the pharmacy profession's credentialing activities. CCP is the only forum to set a framework for how that process works from graduation through to when someone becomes a practitioner.

Dr. Lawson continued to explain that CCP is comprised of 10 national pharmacy organizations including: American Association of Colleges of Pharmacy; American College of Clinical Pharmacy; Accreditation Council for Pharmacy Education; Academy of Managed Care Pharmacy; American Pharmacists Association; American Society of Consultant Pharmacists; American Society of Health-System Pharmacists; Board of Pharmacy Specialties; Commission for Certification in Geriatric Pharmacy; and Pharmacy Technician Educators Council.

Dr. Lawson explained one of the purposes of the group is to solidify the verbiage related to credentialing. BPS has a publication that frames the discussion between credentialing and privileging in pharmacy detailing there are three categories: prepare for practice, enter practice, and document voluntarily their specialized advanced knowledge and skills.

Chair Veale asked Dr. Lawson about the publication date of the paper being available March 2014. Dr. Lawson clarified there is a pre-publication draft available prior to publication.

Dr. Lawson continued that BPS did a paper in 2010 on credentialing in pharmacy to serve as a resource paper to give guidance and definition to the terms often used. Dr. Lawson clarified the terms "certificate program" and "certification" for the purposes of his presentation. Dr. Lawson defined a "certificate program" as a certificate provided upon completion awarded based on educational experience or continuing education gained. In most cases, a minimum of 15 hours of continuing education is awarded by an educational institution or pharmacy institution. A provider for these types of programs includes Accreditation Council for Pharmacy Education (ACPE). Certificate programs out in the market include the immunization and MTM certificate that are completed over the course of a weekend.

Dr. Lawson defined “certification” as a certification in an in area of practice that is recognizing an area of practice at a higher level of knowledge, skill set, and experience. Certifications focus on an area of practice such as cardiology, nutritional support, or pharmacotherapy. These certifications are currently awarded by BPS and Commission for Certification in Geriatric Pharmacy (CCGP) who administers the geriatric program. Dr. Lawson continued these certification programs are accredited by the National Commission for Certifying Agencies (NCCA).

Chair Veale asked Dr. Lawson if BPS is the only certification issuer in pharmacy. Dr. Lawson stated that there are two organizations that do pharmacy certifications. BPS offers eight certifications and CCGP offers one certification. Ms. Herold added that there is also a program for insulin in diabetics. Dr. Lawson indicated often times people with get additional certified as a diabetes educator or board certified and explained those are not specific to pharmacy but are multi-disciplinary credentials. Dr. Lawson provided the Web site to CCP of <http://www.pharmacycredentialing.org/> for resource documents.

Dr. Iannucci reported to the committee that she is an oncology pharmacist working at UC Davis Medical Center. Dr. Iannucci has been an oncology pharmacist for about 20 years and has been on for over 20 years as well as been a clinical professor with UCSF School of Pharmacy. Dr. Iannucci directs the PGY2 oncology residency training program at UC Davis Medical Center. Dr. Iannucci stated she has been involved with BPS in the past serving as the Chair for the Oncology Specialty Council and is rejoining BPS this year as a member of the Board of Directors.

Dr. Iannucci stated she would explain the services and BPS process. BPS was established in 1976 as a way to recognize specialty practice areas in pharmacy and define standards for recognized specialties as well as evaluating the knowledge and skills of pharmacy specialists. Dr. Iannucci reported to the committee that the vision and mission of BPS are aligned with the goals of SB 483. BPS’ mission is to be the premier post-licensure certification agency that will ensure board certified pharmacists are recognized within health care delivery systems while serving the needs of the public and the pharmacy profession. BPS’ vision is to improve patient care by promoting recognition and value of specialized training, knowledge and skills in pharmacy and specialty board certification of pharmacists.

Dr. Iannucci provided to the committee that BPS is represented by the Board of Directors which oversees the specialty councils. Currently, there are eight recognized specialty councils. Each council is represented by a panel of experts in the area of practice and they put the examinations together for each of the certifications.

Chair Veale inquired if there is a process for the future to add a new specialty if needed. Dr. Iannucci indicated there is a process. Just recently, groups were successful in petitioning BPS for recognizing critical care pharmacy and pediatric pharmacy as specialties. BPS has specialty councils developed now for these two newer specialties and will be launching examinations in 2015. The councils have been created now to develop the role delineation and examinations.

Dr. Iannucci indicated that is generally how the process is done. An organization sponsors a specialty group and petitions BPS.

Dr. Iannucci stated that in order for BPS to achieve the position of the premier post-licensure certification agency, BPS recognizes the importance of maintaining a validated and quality process. BPS maintains this by achieving accreditation of the BPS programs through the NCCA.

Dr. Iannucci shared with the Licensing Committee that NCCA was created in 1987 to ensure the health, welfare, and safety of the public through a variety of certification programs that assess professional competence. NCCA certifies a wide variety of programs including other health professionals, automotive professionals, and emergency technicians. NCCA has accredited more than 300 programs for approximately 120 organizations. In California, the Department of Drug Programs does require NCCA accreditation for qualified certification programs for alcohol and other drug program counselors.

Dr. Iannucci indicated NCCA standards require demonstration of a valid and reliable process for development, implementation, maintenance, and governance of certification programs. NCCA employs a rigorous peer review process to establish the accreditation standards, evaluate the plans for the standards, recognize organizations that demonstrate compliance, and serve as a resource for quality certification. The standards are comprehensive and cover all aspects of the certification process including administration, assessment development, and recertification. Dr. Iannucci reported currently 6 of the BPS certification programs are accredited by NCCA. BPS will be eligible for accreditation with the new programs in 2018.

Committee Member Law inquired as to the requirements for BPS to be certified by NCCA. Dr. Lawson provided there is a lot of documentation of standards required by NCCA provided in the handouts to the committee. New programs such as critical care and pediatrics cannot be added until 2018 because the process is a three-year cycle.

Chair Veale inquired if a pharmacist whose specialty is critical care/pediatrics but those haven't been approved yet, where would the pharmacist fall. Dr. Lawson indicated typically pharmacotherapy specialist, and can apply for the critical care/pediatrics if eligibility is met once the exam is rolled out in 2015.

Dr. Iannucci continued to explain the eligibility criteria for BPS examinations. Requirements include graduating from an accredited pharmacy program, and maintaining an active license to practice pharmacy. In addition to those requirements and similar to advanced practice requirements for California, BPS does require practice experience. Chair Veale inquired if BPS verifies good standing for the pharmacist license. Dr. Iannucci indicated yes. Dr. Iannucci explained experience requirements for the pharmacotherapy certification exam include 2-4 years experience with at least 50% of time spent in the specialty area or completion of PGY 1 residency program. Dr. Iannucci continued to explain the eligibility for the more advanced specialties such as oncology require additional years of practice experience and specialty PGY 2 residency training.

Dr. Iannucci reported BPS examination eligibility requirements are listed on the BPS Web site as well as an outline of the examination test content. BPS examinations are internet based and offered at over 650 national and international testing sites during two 17-day windows each year. An examination consists of 200 questions in a four option multiple choice format. The examination is administered 100 questions at a time over the course of two and one half hours for each 100 question set.

Chair Veale inquired if the BPS examinations are psychometrically sound as the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). Dr. Lawson responded NCCA accreditation requires BPS has a psychometrically sound legally defensible process. Dr. Lawson stated BPS also worked with a test consultant who works with the specialty councils and content experts to ensure the defensibility of the exams. Dr. Lawson stated BPS uses a criterion reference approach using the Agnoff method to determine the passing point for each exam. A threshold is set. Those who meet or exceed the threshold pass the exam; those who don't meet the threshold do not pass the exam. Passing the exam is not a guarantee.

Dr. Iannucci continued BPS recertification is required every seven years to document a specialist's current knowledge and skills. There are two options for recertification in most specialties (except nutritional support) to recertify by means of passing a 100 question recertification examination or completing 70-120 hours of BPS approved continuing education (CE). Currently for the nutritional support specialty, certification is only available by examination.

Chair Veale inquired how BPS determined seven years was the requirement for recertification. Dr. Lawson indicated the trend for recertification is 5-10 years. BPS selected the middle of the two trends. Dr. Lawson indicated this will be reevaluated.

Dr. Lawson continued that the CE option through BPS requires taking CE from BPS approved CE providers. Each BPS approved provider is required to administer an examination based on the BPS content outline for the specialty. The assessment questions must be passed the first attempts and aren't provided additional attempts if failed.

Chair Veale inquired to Executive Officer Herold if recertification every seven years would pose a problem given that the pharmacist license expires every two years. Ms. Herold indicated this would pose a bit of a problem and the board would have to decide how to handle this issue. Ms. Herold also indicated the board would have to determine if the APP was a one time certification for licensure or if it would have to be renewed in addition to renewal of the pharmacist license. Ms. Herold explained that the APP license will sync up with the RPH license which expires every two years. This could allow for a licensee to be renewed as an APP during the time in which the certification expires. Ms. Herold continued the committee and board will have to decide if APP is licensure once as long as the pharmacist license is maintained or if competence will have to be reestablished as some point in time. Dr. Lawson provided that

since there are CE options, and the CE can be used toward their licensure. Ms. Herold explained there is an additional CE requirement.

Dr. Iannucci provided an overview of the international board certification growth process. From 2002 to 2013, BPS' number of certified pharmacists tripled and almost quadrupled. Chair Veale inquired if there were pharmacists with specialty certifications in the United States versus international. Dr. Iannucci provided and Dr. Lawson confirmed a majority of those are within the United States. Chair Veale inquired as to what percent of the pharmacists in the United States are certified. Dr. Lawson provided the percentage was small but would further explain how this fits into the landscape of the pharmacy profession in the United States.

Dr. Iannucci provided international candidates who sit for BPS specialty illustrates the merit of the examination process because the candidates have to take this examination in English and are subject to all questions that are subject to United States regulatory domain. International candidates are committed to the process and furthering their career. Dr. Lawson indicated BPS has had inquiries from Hong Kong and Saudi Arabia to assist the countries in the development of creating a similar framework.

Committee Member Law inquired who selects the 200 questions required for a specialty examination and the selection process for the specialty council experts. Dr. Iannucci explained each specialty council maintains its own items bank based on domain specified content outline. As part of the review process, the specialty council ensures the question is still valid, and there is evidence to still support the validity of each question. Periodically, the item bank must be purged to allow for variety, accuracy, and currency. Committee Member Law further inquired how often the specialty councils meet. Dr. Iannucci provided specialty councils meets annually to assemble the examination as well as periodically via conference calls to finalize examination content. Dr. Lawson clarified specialty councils use remote item banking system to develop items to allow specialty council members to develop items remotely. Dr. Lawson indicated specialty councils are working year round to develop examinations. Dr. Lawson further provided a role review to determine the tasks performed by each specialty as well as a test analysis every five years to reassess the content outline and update questions in the item banks. Ms. Herold commented this is identical to the process used by the board for the CPJE as well as the process used by the National Association of Boards of Pharmacy (NABP) for the North American Pharmacist Licensure Examination (NAPLEX). Ms. Herold stated the board uses a criteria referenced based scoring but she was unsure if NABP used criteria referenced based scoring for the NAPLEX. The board conducts a job analysis every five years and adjusts the content outline based on the frequency and importance of the skill. Ms. Herold stated any examination selected by the board will have to meet the requirements of a job related examination.

Dr. Lawson continued in 2011, BPS conducted a group of stakeholders to determine the next steps in moving forward. BPS developed their strategic plan and white paper focusing on the growth of current specialties; the addition of new specialties; marketing the value of specialties; and assessing the model for recertification. BPS continues to meet with

stakeholders to look at the landscape of what other health care professions do in terms of assessing, certifying specialties, and re-certifying specialties. BPS will continue to have this discussion as the environment continues to change.

Chair Veale inquired if a pharmacist who was not actively practicing a specialty but kept abreast of the specialty could pass the re-certification examination and be re-certified with a specialty. Dr. Lawson responded that yes this is possible but there are certain thresholds of experience that have to be met. It is possible to have pharmacists certified who are not practicing their specialty but are nearing retirement or entering administration. BPS checked with the American Boards of Medical Specialties (ABMS) who only requires their certified to only see one patient a year in order to recertify. Dr. Lawson stated BPS meets that minimum threshold.

Dr. Lawson summarized BPS' white paper in that BPS mission/vision is that board certification will be an expectation pharmacists engaged in patient care. BPS wants to ensure that board certification is understood by other health care professionals. Growth in BPS should align with training opportunities for pharmacists. Dr. Lawson reviewed BPS approved certification programs: ambulatory care pharmacy, nuclear pharmacy, nutrition support, oncology, pharmacotherapy, and psychiatric. Both critical care and pediatrics are in process and looking to administer the first exam in the fall of 2015. BPS is currently conducting role delineation studies for cardiology, infections disease and pain/palliative care. Potential areas for future certification may include HIV, patient safety, sterile compounding, pharmacoinformatics, and transplantation.

Ms. Herold indicated the main issues the board is dealing with right now are pain management and sterile compounding. Dr. Lawson indicated pain management could fit under pediatric, ambulatory care, or oncology specialties. BPS also wants to look into sub-specialties where pain may be a sub-specialty of another specialty.

Dr. Lawson provided BPS believes board certification is critical to ensure stakeholders of the level of knowledge of practitioners. Dr. Lawson indicated he was available for questions.

Chair Veale inquired if there were any other states that have similar APP laws. Dr. Lawson indicated he believed North Carolina and New Mexico had similar requirements and Iowa was in the development stages. Chair Veale inquired if the other states embraced BPS certification. Dr. Lawson indicated BPS certification was not required in statute but BPS remains open to discuss.

Committee Member Law inquired as to the cost to participate in BPS certification. Dr. Lawson indicated the cost to sit for the examination is \$600 and \$100 annually to maintain the certification. If a candidate fails the examination, the cost is \$300 each time up to a year until the exam is passed. Dr. Lawson indicated if a candidate doesn't pass within the first few attempts, the candidate understands they may not be up to the level required for certification and stops taking the exam.

Committee Member Wong indicated his concern of a seven year certification process being too long and would like to see it at five years because of the changes in industry. Chair Veale requested even number year renewal to align with California. Dr. Lawson indicated it was difficult to find the number that would meet each states' requirements but BPS does reevaluate.

Assistant Executive Officer Anne Sodergren inquired what other types of professions does NCCA accredit and what are the passing rates of those examinations and if they vary on area of specialty. Dr. Lawson responded NCCA accredits over 300 organizations with over 120 programs. Dr. Lawson indicated they accredit oncology nurses and pharmacy technicians in addition to the many others. Ms. Sodergren inquired about the medical profession. Dr. Lawson indicated the medical profession allows for a grandfathering clause that didn't need recertification and does not meet the NCCA standards. Dr. Lawson indicated the pass rate varies based on specialty and pool of candidates as standards and not bell curves are used.

Chair Veale indicated the requirements seem very rigorous with the years of practice or completion of a residency program. Dr. Lawson provided that the purpose of the credential is to demonstrate over time a body of experience in a specialized area of practice. Dr. Iannucci indicated she didn't believe she could recertify by either examination or continuing education without practicing in the specialty area.

Chair Veale asked Dr. Iannucci if she tried to teach to the examination. Dr. Iannucci provided she doesn't try to teach to the examination. Dr. Iannucci provided that she develops her residency to the ASHP structure and standards. Chair Veale inquired about the affiliation with APHA. Dr. Lawson clarified that BPS is an autonomous division of APHA. Additionally, APHA has a non-voting board member on the BPS board. NCCA wouldn't allow BPS to operate without the distinction.

Ms. Herold inquired as to why effective 1/1/13 BPS is only accepting ASHP approved residency as experience. Dr. Lawson provided BPS is relying on ASHP to validate the residency programs to be of high quality and standards for the training program. Ms. Herold inquired if the belief is that there will be higher passing scores. Dr. Lawson responded in concept this should be the case but this has not been tracked. If a candidate has attended a non-ASHP residency program, this can be counted as one year of experience of practice.

Ms. Herold inquired to the percentage of people who recertify with examination versus continuing education. Dr. Iannucci indicated she believed this number to vary but the majority recertify by non-examination route. Ms. Herold inquired to the continuing education programs accepted for recertification. Dr. Iannucci provided there are designated programs that meet the qualifications for recertification. Dr. Lawson added that BPS approves providers who submit a curriculum or blueprint that is evaluated. It must provide a parallel to the certification content outline. Dr. Iannucci added the specialty councils provide feedback to the continuing education provider programs. This is done on an annual basis.

Dr. Lawson provided contact information to the committee and thanked them for their time.

Chair Veale asked if there were questions from the public.

CSHP Board Member Ryan Gates addressed the committee. Dr. Gates worked as the co-chair between CSHP and CPHA to draft the legislation for the APP. Dr. Gates indicated the task force looked at New Mexico and North Carolina laws. Specifically, North Carolina recognized in statute as certification from BPS.

Chair Veale thanked Dr. Gates for his comments and asked staff to look at the other states. Specifically, Chair Veale requested a comparison of states' statutes/regulations with regard to specific accreditation requirements.

Chair Veale asked for public comment. Hearing none Chair Veale continued with the agenda.

# **Attachment 3**

# National Commission for Certifying Agencies

## Standards for the Accreditation of Certification Programs



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Approved February 2002.  
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## Preamble

### INTRODUCTION

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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

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**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

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**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

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**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

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**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

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**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**

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**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**

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**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**

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**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

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**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

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**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**

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**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

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**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 appropriately 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**

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**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

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**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

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**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

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**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

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**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

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**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

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**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**

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**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.

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**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.

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**Discipline—**

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

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**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.

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**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.

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**Item Bank—**

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

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**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.

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**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.

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**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).

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Linda Althouse, Ph.D., Education Division, SAS Institute

Susan Caulk, CRNA, MA, Council on Certification of Nurse Anesthetists

Katherine Church, Dietary Managers Association

Denise M. Fandel, MS, ATC, National Athletic Trainers Association Board of Certification

Kathleen Guerra, Education Division, SAS Institute

Michael Martin, Commission for Certification in Geriatric Pharmacy

Maria Potenza, Ph.D., Psychometrics and Test Technology, Certification and Skills Assessment, Microsoft Corporation

Jan Towers, Ph.D., NPC, CRNP, American Academy of Nurse Practitioners

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Richard Cotton, MA, American Council on Exercise

Gary Smith, National Board for Respiratory Care

Ted Twardowski, Safety and Occupational Health Administration, US Department of Labor

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Dede Pahl, Certified Financial Planners Board of Standards, Inc.

Richard Young, REM, PE, National Registry of Environmental Professionals

Karen Zaglaniczny, Ph.D., CRNA, Department of Anesthetists, William Beaumont Hospital

END OF DOCUMENT

# **Attachment 4**



## June 4, 2014 Excerpt

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

Mr. Tom Clark, from the Commission for Certification in Geriatric Pharmacy (CCGP), provided the board with a presentation on its program. Below is an overview of the presentation, the entire PowerPoint can be viewed following these meeting minutes.

#### **Commission for Certification in Geriatric Pharmacy (CCGP)**

##### CCGP

- Board certification examination in geriatric pharmacy practice
- Certified Geriatric Pharmacist (CGP) credential
- Established in 1997 by American Society of Consultant Pharmacists

##### Accreditation

- CCGP is accredited by the National Commission for Certifying Agencies
- NCCA is the nationally recognized accrediting body for certification organizations and establishes standards
- NCCA accredits in a wide variety of nursing, health care & other industries
- CCGP is accredited by the National Commission for Certifying Agencies
- NCCA is the nationally recognized accrediting body for certification organizations and establishes standards
- NCCA accredits in a wide variety of nursing, health care & other industries

##### CCGP Overview

- About 2,500 Certified Geriatric Pharmacists today
- About 40 percent in LTC and about 40 percent hospital-based
- About 10 percent community pharmacy
- About 6 percent managed care, 7 percent academia

##### Recognition

- Australia – CGP credential recognized by Australian government as one of two pathways for pharmacists to qualify for payment for HMR and RMR
- North Carolina – CGP credential recognized as one of qualifications for Clinical Pharmacist Practitioner
- Missouri – CGP credential recognized as one of the eligibility criteria for pharmacists to qualify for “certificate of medication therapeutic authority from the Missouri State Board of Pharmacy to provide medication therapy services that include initiating or implementing a modification of a patient’s medication therapy or device usage.”

##### Development

- CCGP test partner is Applied Measurement Professionals (AMP)
- CCGP has Exam Development Committee to work with AMP on test development – rigorous standards

##### Administration

- CCGP exam is computer-based and administered in four test windows throughout the year
- AMP has network of test centers throughout the U.S., including 16 test centers in California
- Exam is 150 multiple-choice questions and takes three hours

#### Eligibility

- Current active pharmacist license
- Two years of experience as pharmacist
- Passing score on CCGP examination required to become Certified Geriatric Pharmacist

#### Recertification

- Certification cycle is five years
- Recertify by retaking exam or by Continuing Professional Development
- Complete 75 hours of designated geriatric continuing education over five years
- Complete part of CE midway thru cycle

#### Summary

- CCGP examination is a rigorous board certification examination that meets all applicable quality standards
- The CCGP examination is accessible to California pharmacists with 16 test centers and exam administration throughout the year
- The CCGP examination is particularly well suited to the requirements of the California legislation, with a good match to the CGP content outline

A member of the public asked how many of CCGP certified pharmacists are there in California. Mr. Clark stated that there are about 200 in California.

Ms. Herold asked how many pharmacists recertify after five years. Mr. Clark responded that their recertification rate is about 77 percent.

Dr. Gutierrez asked if the continuing education that is required for recertification is specific to their program. Mr. Clark provided that they require it to be taken through the American Society of Consultant Pharmacists.

Dr. Gutierrez asked what the cost is for pharmacists. Mr. Clark responded that the certification test is \$600 and if candidates pass the exam there is a \$250 administrative fee that covers the whole five years the certification is valid. He noted that there are payment plans available.

Dr. Gutierrez asked if continuing education is included in the \$800 cost. It was confirmed that the continuing education is not included and it is paid directly to the course provider.

A board-certified pharmacist in the audience commented that the cost to become certified and maintain the certification can be a burden to pharmacists.

Dr. Robinson commented that the language in SB 493 states that the certification program must be recognized by ACPE or the Board of Pharmacy. However, ACPE does not recognize

certification programs. Dr. Robinson concluded that in the future, perhaps there should be a legislative change to the requirement. President Weisser asked how difficult it would be to change the language. It was noted that an easier solution might be for the board to recognize NCCA as an appropriate accreditation body.



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  
1321 Duke Street  
Alexandria, VA 22314  
703-535-3036 / FAX: 703-739-1500  
[info@ccgp.org](mailto: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  
Alexandria, VA 22314  
703-535-3036  
[www.ccgp.org](http://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*

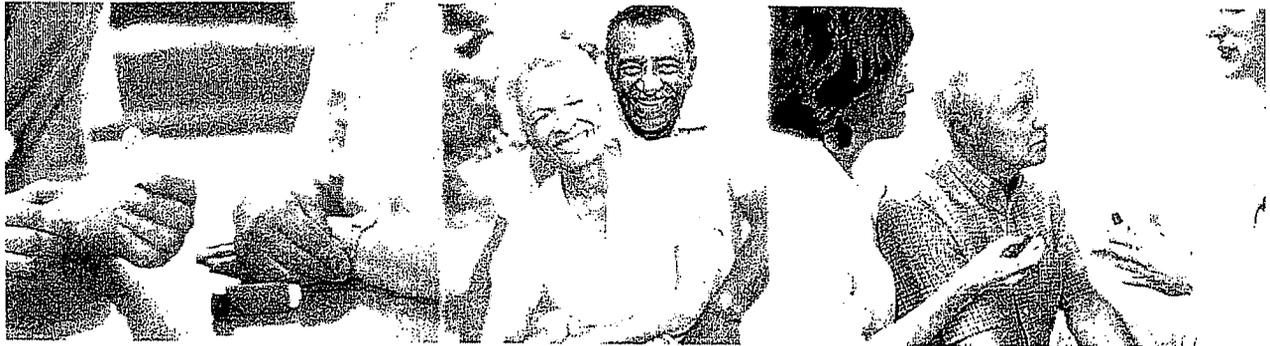


Commission for Certification  
in Geriatric Pharmacy

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## About the Certified Geriatric Pharmacist Examination

✉ | ☰

### 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 CGP 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 CGP 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](#)
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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.



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- 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



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**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**

<b>Characteristic</b>	<b>Certificate</b>	<b>Certification</b>
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.

# **Attachment 5**

## The Practice of Travel Health for Pharmacists

Joint California Pharmacists Association and California Society of Health-System Pharmacists Sub-Committee on SB493 Travel Medicine Provision

Jeff Goad (Chair)

Victoria Dudas (UCSF)

Tania Gregorian (Cedars-Sinai)

James McCabe (Safeway)

Karl Hess (Western U)

Sepi Soleimanpou (Walgreens)

### Background

The practice of travel medicine includes both pre-travel, known as travel health, and the ill returned traveler. The returned traveler is often seen by a medical provider who can provide diagnostic services. Travel Health requires providers skilled in risk communication, destination risk assessment, patient assessment, immunizations, medications and travel-related equipment. Physicians, nurses and more recently, pharmacists fulfill this role. Prior to January 2014, pharmacists could provide risk communication, limited patient assessment, immunization by physician protocol, and medications by patient-physician specific collaborative practice agreement and travel-related equipment. With the passage of SB493, pharmacists are now able to provide enhanced patient assessment, referrals to specialists, routine immunizations without a protocol, and furnish prescription medications for international travelers for conditions not requiring a diagnosis. Pharmacists are now able to nearly independently provide the full range of pre-travel medicine services. The traveling population already numbers in the millions and will likely only grow in the future. Most international travelers do not access travel medicine services. The expansion of pharmacists' ability to provide Travel Health services and to raise consumer awareness of the risks involved with international travel will have a tremendously positive impact on access and the health of the traveling population.

### Senate Bill 493 (Chaptered 10/1/2013) Travel Medicine and Immunization Language

Section B&P 4052 (a)(10)(A)(3) and (B), (11)

*Prescription medications not requiring a diagnosis that are recommended by the federal Centers for Disease Control and Prevention for individuals traveling outside of the United States.*

*The pharmacist shall notify the patient's primary care provider of any drugs or devices furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by 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 drugs or devices furnished and advise the patient to consult a physician of the patient's choice.*

*Administer immunizations pursuant to a protocol with a prescriber.*

4052.8.(a) In addition to the authority provided in paragraph (11) of subdivision (a) of Section 4052, a pharmacist may independently initiate and administer vaccines listed on the routine immunization schedules recommended by the federal Advisory Committee on Immunization Practices (ACIP), in compliance with individual ACIP vaccine recommendations, and published by the federal Centers for Disease Control and Prevention (CDC) for persons three years of age and older.

## Practice Standard

The Infectious Diseases Society of America has published guidelines to help travel medicine professionals understand the full spectrum of the specialty.<sup>1</sup> Pharmacists are being entrusted with new professional responsibilities that necessitate optimal practice standards to ensure the safety and quality of the services they provide to their patients. The law requires pharmacists to follow the Centers for Disease Control and Prevention's Health Information for International Travel ([The Yellow Book](#)) when determining what medications may be furnished. The following recommendations should serve as the peer standard for a pharmacist practicing Travel Health in California.

- **Training and Credentials**
  - Pharmacy School or accredited Post-graduate educational program that, at a minimum, encompasses the International Society of Travel Medicine's [Body of Knowledge](#)
  - Meets qualifications to administer vaccines in California (requires separate training)
  - Recommended credential: Certificate of Travel Health (from the International Society of Travel Medicine)
  - Ongoing annual post-graduate education
- **Setting**
  - Community pharmacy
    - Suitable patient care area for education and vaccination
    - All vaccines available and able to administer on site
      - Those vaccines not on the CDC routinely recommended vaccine list require a physician signed protocol
      - Yellow Fever vaccine requires special approval from the Department of Public Health (the Yellow Fever stamp requires a physician's license number)
    - Appropriate selection of non-prescription, prescription and equipment for travel
  - Ambulatory Care
    - Must be able to direct the care of the traveler, understanding some functions may be delegated
    - Offer all immunizations as part of coordinated care

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<sup>1</sup> Hill D, et al. [The Practice of Travel Medicine: Guidelines by the Infectious Diseases Society of America](#). CID 2006; 43:1499–539

- Vaccines may be administered by other qualified healthcare professionals
  - Those vaccines not on the CDC routinely recommended vaccine list require a physician signed protocol
  - Yellow Fever vaccine requires special approval from the Department of Public Health (the Yellow Fever stamp requires the protocol physicians license number)
- **Operation of the Travel Health Clinic**
  - Collect pertinent patient and destination specific information in paper or electronic format (See [CDC Yellow Book table 2-01](#))
  - Develop a plan for the patient that must include patient and destination specific education and when and what appropriate vaccination(s), medication and equipment are necessary
  - Provide or direct the implementation of the plan
    - Pharmacists must make appropriate vaccine selection, whether directly administering or indirectly by ordering it
    - Pharmacists must make appropriate prescription medicine selection, whether directly furnishing or indirectly by ordering it
    - Pharmacists must make appropriate recommendations for non-prescription products
  - For returned travelers, triage and refer as appropriate
  - Documentation
    - Patient encounters must be documented in an appropriate paper or electronic information management system
      - Standard patient care documentation should be used
      - When prescriptions are furnished, this documentation must be provided to the patient's primary care physician or document within an electronic health or medical record
    - Immunizations must also be documented in the California Immunization Registry (CAIR)
    - Patient documentation should, at a minimum, contain
      - Destination and destination-specific risks
      - Pertinent patient history
      - Patient specific risk assessment
      - Travel health plan for education and necessary medications, vaccinations and equipment
- **Proposed conditions and prescription medication allowed to be furnished by pharmacists (appendix A)**
- **Vaccines that may be initiated without protocol and those that need a physician signed protocol (Appendix B)**
- **Laboratory tests for travel medicine-related medications (Appendix C)**

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## Appendix A. Conditions for Pharmacist Medication Furnishing

Condition	Considerations	Exclusions to Pharmacist Furnishing*	Medications
<b>Altitude illness</b>	<ul style="list-style-type: none"> <li>• Ultimate altitude</li> <li>• Rate of ascent</li> <li>• <a href="#">CDC Table 2-07</a></li> </ul>	<ul style="list-style-type: none"> <li>• Treatment or prevention of HAPE or HACE</li> </ul>	<b>Typical medications used (<a href="#">CDC Table 2-08</a>):</b> Acetazolamide Dexamethasone
<b>Hepatitis A</b>	<ul style="list-style-type: none"> <li>• Hepatitis A protection when Hepatitis A vaccine is not indicated or is not expected to be effective</li> <li>• Short term protection</li> </ul>	<ul style="list-style-type: none"> <li>• 1-40 years with hepatic dysfunction</li> <li>• &gt; 2 weeks before departure</li> <li>• Known isolated immunoglobulin A deficiency</li> <li>• Known severe thrombocytopenia</li> </ul>	IGIM
<b>Influenza Prophylaxis</b>	<ul style="list-style-type: none"> <li>• Short term protection for those in whom the influenza vaccine is contraindicated</li> <li>• Hemisphere and time of year</li> </ul>	<ul style="list-style-type: none"> <li>• Use greater than 10 days</li> </ul>	<b>Typical medications used:</b> Oseltamivir Zanamivir
<b>Jet lag</b>	<ul style="list-style-type: none"> <li>• Time zones crossed</li> <li>• Patient specific factors</li> </ul>	<ul style="list-style-type: none"> <li>• Pharmacist must register with DEA to furnish controlled substances</li> </ul>	<b>Typical medications used</b> Non-prescription: Melatonin Rx: Zolpidem
<b>Leptospirosis</b>	<ul style="list-style-type: none"> <li>• Potential mucocutaneous exposure to contaminated water</li> </ul>	<ul style="list-style-type: none"> <li>• Children &lt; 8 years and pregnant women</li> </ul>	<b>Typical medications used</b> Doxycycline

Condition	Considerations	Exclusions to Pharmacist Furnishing*	Medications
<b>Malaria</b>	<ul style="list-style-type: none"> <li>• Prophylaxis</li> <li>• Presumptive Self-treatment</li> <li>• Resistance patterns at destination</li> <li>• Patient specific factors</li> </ul>	<ul style="list-style-type: none"> <li>• Not having G6PD results for primaquine</li> </ul>	<p><b>Typical medications used</b></p> <p>Chloroquine            Doxycycline            Atovaquone/Proguanil            Mefloquine</p> <p><a href="#">Choosing a drug for chemoprophylaxis</a>  <a href="#">Presumptive Self-Treatment</a></p>
<b>Motion sickness</b>	<ul style="list-style-type: none"> <li>• Previous patient experience</li> <li>• Duration of exposure</li> <li>• OTC drug of choice for short duration</li> </ul>		<p><b>Typical medications used:</b></p> <p>Scopolamine (primarily patch)            Promethazine (oral and suppository)            antidopaminergic drugs (such as prochlorperazine)            Multiple non-prescription (meclizine, dimenhydrinate, cyclizine)</p>
<b>HIV: Occupational exposure</b>	<ul style="list-style-type: none"> <li>• Destination with elevated rates of HIV</li> <li>• Potential contact with blood or bodily fluids in a medical clinic setting</li> <li>• Medical professionals</li> </ul>		<p><b>Use current recommended regimen:</b></p> <p><a href="http://aidsinfo.nih.gov/contentfiles/HealthCareOccupExpoGL.pdf">http://aidsinfo.nih.gov/contentfiles/HealthCareOccupExpoGL.pdf</a></p>
<b>Travelers' diarrhea (TD)</b>	<ul style="list-style-type: none"> <li>• Bacterial resistance patterns at destination</li> <li>• Patient specific factors</li> <li>• Self-treatment or prophylaxis</li> </ul>	<ul style="list-style-type: none"> <li>• Developed countries with safe food and water</li> </ul>	<p><b>Typical medications used:</b></p> <p>Ciprofloxacin            Azithromycin            Levofloxacin            Rifaximin</p>

Condition	Considerations	Exclusions to Pharmacist Furnishing*	Medications
	<ul style="list-style-type: none"> <li>Agents that increase gastric pH</li> </ul>		
<b>Urinary tract infections (UTI)</b>	<ul style="list-style-type: none"> <li>For patients previously diagnosed with frequent uncomplicated UTIs and who can determine when to self-treat</li> </ul>	<ul style="list-style-type: none"> <li>Not previously diagnosed</li> </ul>	<b>Typical medications used:</b> Macrochantin Ciprofloxacin Sulfamethoxazole/trimethoprim DS Pyridium (for associated pain)
<b>Vaginal yeast infections</b>	<ul style="list-style-type: none"> <li>Female in whom a vaginal yeast infection has been previously diagnosed</li> <li>Long-term use of certain antimicrobials</li> </ul>	<ul style="list-style-type: none"> <li>A co-morbid conditions that would make self-recognition unreliable</li> <li>Complicated VVC (e.g. comorbid DM, immune suppression, hx of systemic azole therapy)</li> </ul>	<b>Typical medications used:</b> Fluconazole OTC/Rx Topical/suppository antifungals

\* Exclusions to Pharmacist Furnishing is in addition to medical or pharmacologic precautions or contraindications for individual medications

## Appendix B. Vaccines

Routine (no protocol necessary) – 3 years of age and older	Travel Only (per protocol)
Td, DT, Tdap, DTaP	Typhoid
Hepatitis A	Japanese Encephalitis
Hepatitis B	Rabies
MCV4 and MPSV4	Yellow Fever
PPSV23 and PCV13	Hepatitis A/Hepatitis B
Influenza	
HPV2 and HPV4	
Polio	
MMR	

## Appendix C

Travel-Related Product	Laboratory Test	Considerations
Primaquine	G6PD	Must be ordered prior to medication initiation
Hepatitis A	Hep A Ab Total	Most appropriate for those born in developing countries who may already be immune to Hepatitis A
Hepatitis B	Hep B Surface Ag Ab Titer	For healthcare providers or others who need to know if they are immune to Hepatitis B. Further analysis of antigens or core antibodies should be done in consultation with a specialist
Rabies	Rabies Titer (Rabies Vaccine Response Endpoint Titer)	Used to determine need for booster doses of vaccine
Measles and Mumps	Rubeola Antibody IgG Mumps Antibody IgG	For those with uncertain vaccination or disease history to determine need for vaccination
Varicella	Varicella IgG Ab	For those with uncertain vaccination or disease history to determine need for vaccination

# **Attachment 6**

## Pharmacists Protocol for Dispensing Self-Administered Hormonal Contraception

Senate Bill 493 (Chapter 469, Statutes of 2013) permits pharmacists to furnish prescription self-administered hormonal contraception based on a statewide protocol adopted by the California State Board of Pharmacy and the Medical Board of California.

On the following page is the approved protocol. Pharmacists may use this protocol after they have completed one hour of continuing education credit specific to self-administered hormonal contraception, or an equivalent curriculum-based training program completed on or after the year 2010 in a California School of Pharmacy (a requirement of the new law).

The protocol was prepared with the intent to keep it simple and to comply with the statutory requirements established by Senate Bill 493.

The statutory provisions for pharmacists furnishing nicotine replacement products are found in California Business and Professions Code sections 4052(a)(10) and 4052.3.

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.

## **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>.

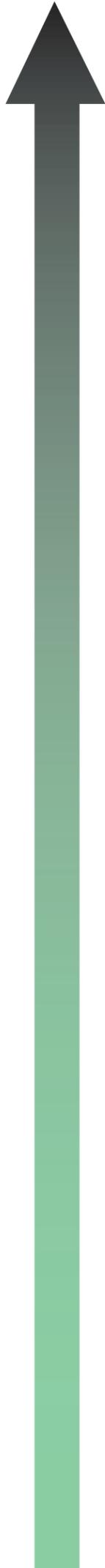
*These FDA regulations require manufacturers to include comprehensive patient leaflets in both prescription-only and OTC products.*

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 <b>1</b>	Onetime procedure Permanent	<ul style="list-style-type: none"> <li>Pain</li> <li>Bleeding</li> <li>Infection or other complications after surgery</li> <li>Ectopic (tubal) pregnancy</li> </ul>
Surgical Sterilization Implant for Women	less than <b>1</b>	Onetime procedure Waiting period before it works Permanent	<ul style="list-style-type: none"> <li>Mild to moderate pain after insertion</li> <li>Ectopic (tubal) pregnancy</li> </ul>
Sterilization Surgery for Men	less than <b>1</b>	Onetime procedure Waiting period before it works Permanent	<ul style="list-style-type: none"> <li>Pain</li> <li>Bleeding</li> <li>Infection</li> </ul>
Implantable Rod	less than <b>1</b>	Inserted by a healthcare provider Lasts up to 3 years	<ul style="list-style-type: none"> <li>Changes in bleeding patterns</li> <li>Weight gain</li> <li>Breast and abdominal pain</li> </ul>
IUD Copper	less than <b>1</b>	Inserted by a healthcare provider Lasts up to 10 years	<ul style="list-style-type: none"> <li>Cramps</li> <li>Bleeding</li> <li>Pelvic inflammatory disease</li> <li>Infertility</li> <li>Tear or hole in the uterus</li> </ul>
IUD w/ Progestin	less than <b>1</b>	Inserted by a healthcare provider Lasts up to 3-5 years, depending on the type	<ul style="list-style-type: none"> <li>Irregular bleeding</li> <li>No periods</li> <li>Abdominal/pelvic pain</li> <li>Ovarian cysts</li> </ul>
Shot/Injection	<b>6</b>	Need a shot every 3 months	<ul style="list-style-type: none"> <li>Bone loss</li> <li>Bleeding between periods</li> <li>Weight gain</li> <li>Nervousness</li> <li>Abdominal discomfort</li> <li>Headaches</li> </ul>
Oral Contraceptives (Combined Pill) "The Pill"	<b>9</b>	Must swallow a pill every day	<ul style="list-style-type: none"> <li>Nausea</li> <li>Breast Tenderness</li> <li>Headache</li> <li>Rare: high blood pressure, blood clots, heart attack, stroke</li> </ul>
Oral Contraceptives (Progestin only) "The MiniPill"	<b>9</b>	Must swallow a pill every day	<ul style="list-style-type: none"> <li>Irregular bleeding</li> <li>Headache</li> <li>Breast tenderness</li> <li>Nausea</li> <li>Dizziness</li> </ul>
Oral Contraceptives Extended/Continuous Use "The Pill"	<b>9</b>	Must swallow a pill every day.	<ul style="list-style-type: none"> <li>Risks are similar to other oral contraceptives (combined)</li> <li>Light bleeding or spotting between periods</li> </ul>
Patch	<b>9</b>	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"> <li>Exposure to higher average levels of estrogen than most oral contraceptives</li> </ul>
Vaginal Contraceptive Ring	<b>9</b>	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"> <li>Vaginal discharge</li> <li>Discomfort in the vagina</li> <li>Mild irritation</li> <li>Risks are similar to oral contraceptives (combined)</li> </ul>
Diaphragm with Spermicide	<b>12</b>	Must use every time you have sex.	<ul style="list-style-type: none"> <li>Irritation</li> <li>Allergic reactions</li> <li>Urinary tract infection</li> <li>Toxic shock</li> </ul>
Sponge with Spermicide	<b>12-24</b>	Must use every time you have sex.	<ul style="list-style-type: none"> <li>Irritation</li> <li>Allergic reactions</li> <li>Hard time removing</li> <li>Toxic shock</li> </ul>
Cervical Cap with Spermicide	<b>17-23</b>	Must use every time you have sex.	<ul style="list-style-type: none"> <li>Irritation</li> <li>Allergic reactions</li> <li>Abnormal Pap test</li> <li>Toxic shock</li> </ul>
Male Condom	<b>18</b>	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"> <li>Allergic reactions</li> </ul>
Female Condom	<b>21</b>	Must use every time you have sex. <i>May give some protection against STIs.</i>	<ul style="list-style-type: none"> <li>Irritation</li> <li>Allergic reactions</li> </ul>
Spermicide Alone	<b>28</b>	Must use every time you have sex.	<ul style="list-style-type: none"> <li>Irritation</li> <li>Allergic reactions</li> <li>Urinary tract infection</li> </ul>
<b>Emergency Contraception — If your primary method of birth control fails</b>			
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"> <li>Nausea</li> <li>Vomiting</li> <li>Abdominal pain</li> <li>Fatigue</li> <li>Headache</li> </ul>
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"> <li>Headache</li> <li>Nausea</li> <li>Abdominal pain</li> <li>Menstrual pain</li> <li>Tiredness</li> <li>Dizziness</li> </ul>

\*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 canceres y enfermedades de los cenos.

### ¿Quien no debe de usar el parche anticonceptivo?

Algunas mujeres no deben de usar el parche anticonceptivo, incluyendo mujeres que tengan cuagulos de sangre, ciertos canceres, o que tengan antecedentes de ataques del corazon o de cerebro, y aquellas mujeres que podrian estar embarazadas.

### ¿Cuáles son las desventajas?

Algunas mujeres usando el parche anticonceptivo pueden sentir leves dolores en los cenos, dolor de cabeza, y reacciones dermatologicas 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.

## HEALTH MATTERS

# Frequently Asked Questions About the Contraceptive Patch

### **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](http://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](http://www.arhp.org/MethodMatch).

## ASUNTOS DE SALUD

# La inyección anticonceptiva

### ¿Qué es la inyección?

La inyección anticonceptiva es una inyección de una hormona llamada progesterina. 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 progesterina 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](http://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](http://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 espermatozoides 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](http://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](http://www.arhp.org/MethodMatch).

# **Attachment 7**

## Pharmacists Protocol for Dispensing Nicotine Replacement Products

Senate Bill 493 (Chapter 469, Statutes of 2013) permits pharmacists to furnish prescription nicotine replacement medications based on a statewide protocol adopted by the California State Board of Pharmacy and the Medical Board of California.

On the following page is the approved protocol. Pharmacists may use this protocol after they have completed two hours of continuing education credit in 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. Ongoing continuing education is also required biennially (a requirement of the new law).

The protocol was prepared with the intent to keep it simple and to comply with the statutory requirements established by Senate Bill 493.

The statutory provisions for pharmacists furnishing nicotine replacement products are found in California Business and Professions Code sections 4052(a)(10) and 4052.9.

When considering a specific clinical situation, pharmacists are encouraged to consult the resources from the Agency for Healthcare Research and Quality available at <http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/tobacco/clinicians/index.html>; and from the University of California, San Francisco available at <http://rxforchange.ucsf.edu/registration.php>.

## **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

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

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

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

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

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

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

Agency for Healthcare Research and Quality, "Treating Tobacco Use and Dependence: 2008—Clinical Practice Guideline," *available at*

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						COMBINATION NRT
	GUM	LOZENGE	PATCH	NASAL SPRAY	INHALER	
PRODUCT	Nicorette <sup>1</sup> , Generic OTC 2 mg, 4 mg original, cinnamon, fruit, mint	Nicorette Lozenge, <sup>1</sup> Nicorette Mini Lozenge, <sup>1</sup> Generic OTC 2 mg, 4 mg cherry, mint	NicoDerm CO <sup>1</sup> , Generic OTC (NicoDerm CO, generic) Rx (generic) 7 mg, 14 mg, 21 mg (24-hour release)	Nicotrol NS <sup>2</sup> Rx Metered spray 0.5 mg nicotine in 50 mL aqueous nicotine solution	Nicotrol Inhaler <sup>2</sup> Rx 10 mg cartridge delivers 4 mg inhaled nicotine vapor	Combinations with demonstrated efficacy Nicotine patch + nicotine gum Nicotine patch + nicotine lozenge Nicotine patch + nicotine nasal spray Nicotine patch + nicotine oral inhaler
PRECAUTIONS	<ul style="list-style-type: none"> <li>Recent (<math>\leq 2</math> weeks) myocardial infarction</li> <li>Serious underlying arrhythmias</li> <li>Serious or worsening angina pectoris</li> <li>Temporomandibular joint disease</li> <li>Pregnancy<sup>3</sup> and breastfeeding</li> <li>Adolescents (&lt;18 years)</li> </ul>	<ul style="list-style-type: none"> <li>Recent (<math>\leq 2</math> weeks) myocardial infarction</li> <li>Serious underlying arrhythmias</li> <li>Serious or worsening angina pectoris</li> <li>Pregnancy<sup>3</sup> and breastfeeding</li> <li>Adolescents (&lt;18 years)</li> </ul>	<ul style="list-style-type: none"> <li>Recent (<math>\leq 2</math> weeks) myocardial infarction</li> <li>Serious underlying arrhythmias</li> <li>Serious or worsening angina pectoris</li> <li>Pregnancy<sup>3</sup> (Rx formulations, category D) and breastfeeding</li> <li>Adolescents (&lt;18 years)</li> </ul>	<ul style="list-style-type: none"> <li>Recent (<math>\leq 2</math> weeks) myocardial infarction</li> <li>Serious underlying arrhythmias</li> <li>Serious or worsening angina pectoris</li> <li>Underlying chronic nasal disorders (rhinitis, nasal polyps, sinusitis)</li> <li>Severe reactive airway disease</li> <li>Pregnancy<sup>3</sup> (category D) and breastfeeding</li> <li>Adolescents (&lt;18 years)</li> </ul>	<ul style="list-style-type: none"> <li>Recent (<math>\leq 2</math> weeks) myocardial infarction</li> <li>Serious underlying arrhythmias</li> <li>Serious or worsening angina pectoris</li> <li>Bronchospastic disease</li> <li>Pregnancy<sup>3</sup> (category D) and breastfeeding</li> <li>Adolescents (&lt;18 years)</li> </ul>	<ul style="list-style-type: none"> <li>See precautions for individual agents</li> </ul>
DOSING	<p>1<sup>st</sup> cigarette <math>\leq 30</math> minutes after waking: 4 mg</p> <p>1<sup>st</sup> cigarette <math>&gt; 30</math> minutes after waking: 2 mg</p> <p>Weeks 1–6: 1 piece q 1–2 hours</p> <p>Weeks 7–9: 1 piece q 2–4 hours</p> <p>Weeks 10–12: 1 piece q 4–8 hours</p> <ul style="list-style-type: none"> <li>Maximum, 24 pieces/day</li> <li>Chew each piece slowly</li> <li>Park between cheek and gum when peppery or tingling sensation appears (~15–30 chews)</li> <li>Resume chewing when tingle fades</li> <li>Repeat chew/park steps until most of the nicotine is gone (tingle does not return; generally 30 min)</li> <li>Park in different areas of mouth</li> <li>No food or beverages 15 minutes before or during use</li> <li>Duration: up to 12 weeks</li> </ul>	<p>1<sup>st</sup> cigarette <math>\leq 30</math> minutes after waking: 4 mg</p> <p>1<sup>st</sup> cigarette <math>&gt; 30</math> minutes after waking: 2 mg</p> <p>Weeks 1–6: 1 lozenge q 1–2 hours</p> <p>Weeks 7–9: 1 lozenge q 2–4 hours</p> <p>Weeks 10–12: 1 lozenge q 4–8 hours</p> <ul style="list-style-type: none"> <li>Maximum, 20 lozenges/day</li> <li>Allow to dissolve slowly (20–30 minutes for standard; 10 minutes for mini)</li> <li>Nicotine release may cause a warm, tingling sensation</li> <li>Do not chew or swallow</li> <li>Occasionally rotate to different areas of the mouth</li> <li>No food or beverages 15 minutes before or during use</li> <li>Duration: up to 12 weeks</li> </ul>	<p><math>\geq 10</math> cigarettes/day: 21 mg/day x 4–6 weeks 14 mg/day x 2 weeks 7 mg/day x 2 weeks</p> <p><math>\leq 10</math> cigarettes/day: 14 mg/day x 6 weeks 7 mg/day x 2 weeks</p> <ul style="list-style-type: none"> <li>May wear patch for 16 hours if patient experiences sleep disturbances (remove at bedtime)</li> <li>Duration: 8–10 weeks</li> </ul>	<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"> <li>Maximum <ul style="list-style-type: none"> <li>– 5 doses/hour or</li> <li>– 40 doses/day</li> </ul> </li> <li>For best results, initially use at least 8 doses/day</li> <li>Do not sniff, swallow, or inhale through the nose as the spray is being administered</li> <li>Duration: 3–6 months</li> </ul>	<p>6–16 cartridges/day Individualize dosing: initially use 1 cartridge q 1–2 hours</p> <ul style="list-style-type: none"> <li>Best effects with continuous puffing for 20 minutes</li> <li>Initially use at least 6 cartridges/day</li> <li>Nicotine in cartridge is depleted after 20 minutes of active puffing</li> <li>Inhale into back of throat or puff in short breaths</li> <li>Do NOT inhale into the lungs (like a cigarette) but “puff” as if lighting a pipe</li> <li>Open cartridge retains potency for 24 hours</li> <li>No food or beverages 15 minutes before or during use</li> <li>Duration: 3–6 months</li> </ul>	<p><u>Reserve for patients smoking <math>\geq 10</math> cigarettes/day:</u></p> <p><b>Long-acting NRT:</b> to prevent onset of severe withdrawal symptoms</p> <ul style="list-style-type: none"> <li><b>Nicotine patch</b> 21 mg/day x 4–6 weeks 14 mg/day x 2 weeks 7 mg/day x 2 weeks</li> </ul> <p style="text-align: center;"><b>PLUS</b></p> <p><b>Short-acting NRT:</b> used as needed to control breakthrough withdrawal symptoms and situational urges for tobacco</p> <ul style="list-style-type: none"> <li><b>Nicotine gum (2 mg)</b> 1 piece q 1–2 hours as needed OR</li> <li><b>Nicotine lozenge (2 mg)</b> 1 lozenge q 1–2 hours as needed OR</li> <li><b>Nicotine nasal spray</b> 1 spray in each nostril q 1–2 hours as needed OR</li> <li><b>Nicotine inhaler</b> 1 cartridge q 1–2 hours as needed</li> </ul>

NICOTINE REPLACEMENT THERAPY (NRT) FORMULATIONS USED AS MONOTHERAPY						
	GUM	LOZENGE	PATCH	NASAL SPRAY	INHALER	COMBINATION NRT
ADVERSE EFFECTS	<ul style="list-style-type: none"> <li>▪ Mouth/jaw soreness</li> <li>▪ Hiccups</li> <li>▪ Dyspepsia</li> <li>▪ Hypersalivation</li> <li>▪ Effects associated with incorrect chewing technique:               <ul style="list-style-type: none"> <li>– Lightheadedness</li> <li>– Nausea/vomiting</li> <li>– Throat and mouth irritation</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>▪ Nausea</li> <li>▪ Hiccups</li> <li>▪ Cough</li> <li>▪ Heartburn</li> <li>▪ Headache</li> <li>▪ Flatulence</li> <li>▪ Insomnia</li> </ul>	<ul style="list-style-type: none"> <li>▪ Local skin reactions (erythema, pruritus, burning)</li> <li>▪ Headache</li> <li>▪ Sleep disturbances (insomnia, abnormal/vivid dreams); associated with nocturnal nicotine absorption</li> </ul>	<ul style="list-style-type: none"> <li>▪ Nasal and/or throat irritation (hot, peppery, or burning sensation)</li> <li>▪ Rhinitis</li> <li>▪ Tearing</li> <li>▪ Sneezing</li> <li>▪ Cough</li> <li>▪ Headache</li> </ul>	<ul style="list-style-type: none"> <li>▪ Mouth and/or throat irritation</li> <li>▪ Cough</li> <li>▪ Headache</li> <li>▪ Rhinitis</li> <li>▪ Dyspepsia</li> <li>▪ Hiccups</li> </ul>	<ul style="list-style-type: none"> <li>▪ See adverse effects listed for individual agents</li> </ul>
ADVANTAGES	<ul style="list-style-type: none"> <li>▪ Might satisfy oral cravings</li> <li>▪ Might delay weight gain</li> <li>▪ Patients can titrate therapy to manage withdrawal symptoms</li> <li>▪ Variety of flavors are available</li> </ul>	<ul style="list-style-type: none"> <li>▪ Might satisfy oral cravings</li> <li>▪ Might delay weight gain</li> <li>▪ Easy to use and conceal</li> <li>▪ Patients can titrate therapy to manage withdrawal symptoms</li> <li>▪ Variety of flavors are available</li> </ul>	<ul style="list-style-type: none"> <li>▪ Provides consistent nicotine levels over 24 hours</li> <li>▪ Easy to use and conceal</li> <li>▪ Once daily dosing associated with fewer compliance problems</li> <li>▪ FDA-approved for use in combination with bupropion SR</li> </ul>	<ul style="list-style-type: none"> <li>▪ Patients can titrate therapy to rapidly manage withdrawal symptoms</li> </ul>	<ul style="list-style-type: none"> <li>▪ Patients can titrate therapy to manage withdrawal symptoms</li> <li>▪ Mimics hand-to-mouth ritual of smoking (could also be perceived as a disadvantage)</li> </ul>	<ul style="list-style-type: none"> <li>▪ Provides consistent nicotine levels over 24 hours and patients can titrate therapy to manage withdrawal symptoms and situational urges for tobacco</li> <li>▪ Research studies suggest combination therapy provides a small, but meaningful increase in success rates compared to NRT monotherapy</li> <li>▪ Attractive option for patients who have previously failed treatment with NRT monotherapy</li> <li>▪ See advantages listed for individual agents</li> </ul>
	<ul style="list-style-type: none"> <li>▪ Need for frequent dosing can compromise compliance</li> <li>▪ Might be problematic for patients with significant dental work</li> <li>▪ Proper chewing technique is necessary for effectiveness and to minimize adverse effects</li> <li>▪ Gum chewing may not be acceptable or desirable for some patients</li> </ul>	<ul style="list-style-type: none"> <li>▪ Need for frequent dosing can compromise compliance</li> <li>▪ Gastrointestinal side effects (nausea, hiccups, heartburn) might be bothersome</li> </ul>	<ul style="list-style-type: none"> <li>▪ When used as monotherapy, cannot be titrated to acutely manage withdrawal symptoms</li> <li>▪ Not recommended for use by patients with dermatologic conditions (e.g., psoriasis, eczema, atopic dermatitis)</li> </ul>	<ul style="list-style-type: none"> <li>▪ Need for frequent dosing can compromise compliance</li> <li>▪ Nasal administration might not be acceptable or desirable for some patients; nasal irritation often problematic</li> <li>▪ Not recommended for use by patients with chronic nasal disorders or severe reactive airway disease</li> </ul>	<ul style="list-style-type: none"> <li>▪ Need for frequent dosing can compromise compliance</li> <li>▪ Cartridges might be less effective in cold environments (<math>\leq 60^{\circ}\text{F}</math>)</li> </ul>	<ul style="list-style-type: none"> <li>▪ Increased cost of therapy</li> <li>▪ See disadvantages listed for individual agents</li> </ul>

<sup>1</sup> Marketed by GlaxoSmithKline.

<sup>2</sup> Marketed by Pfizer.

<sup>3</sup> 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 8**

## Pharmacists Protocol for Dispensing Naloxone Hydrochloride

Assembly Bill 1535 (Chapter 326, Statutes of 2014) permits pharmacists to furnish naloxone hydrochloride based on a statewide protocol adopted by the California State Board of Pharmacy and the Medical Board of California.

On the following page is the approved protocol. Pharmacists may use this protocol after they have completed one hour of continuing education credit specific to naloxone hydrochloride, or an equivalent curriculum-based training program completed in a California School of Pharmacy (a requirement of the new law).

Prior legislation (Assembly Bill 635, Chapter 707, Statutes of 2013), permits a licensed health care provider who is authorized by law to prescribe an opioid antagonist to prescribe and dispense to a person at risk of an opioid-related overdose or to a family member or friend. This protocol does not affect any prescriptions furnished under California Civil Code section 1714.22.

This protocol was prepared with the intent to keep it simple and to comply with the statutory requirements established by Assembly Bill 1535. The statutory provisions for pharmacists furnishing naloxone hydrochloride are found in California Business and Professions Code section 4052.01.

When considering a specific clinical situation, pharmacists are encouraged to consult the Substance Abuse Mental Health Services Administration's "Opioid Prevention Toolkit" (2014), available at <http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2014/SMA14-4742>; prescribers will find guidance for identifying patients at risk for overdose, engaging them in prevention and risk-reduction efforts, and accessing opioid-dependence treatment, including naloxone.

Other resources include Prescribe to Prevent, <http://prescribetoprevent.org/pharmacists>; and Harm Reduction Coalition, <http://harmreduction.org/issues/overdose-prevention/tools-best-practices/od-kit-materials>.

## **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 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 a patient requests naloxone hydrochloride, or when a pharmacist in his or her professional judgment decides to advise the patient of the availability and appropriateness of naloxone hydrochloride, the pharmacist shall complete the following steps:

- Ask the patient 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 ensure that patients are properly and appropriately trained in opioid overdose prevention, recognition, response, and administration of the antidote naloxone.
- When naloxone hydrochloride is furnished:
  - The patient shall be provided with appropriate counseling and information on the product furnished, including dosing, effectiveness, potential side effects, and safety. The patient is not permitted to waive the required consultation.
  - The pharmacist shall ask the patient if he or she wants drug treatment, recovery services, or medication disposal resources at this time. If yes, the pharmacist shall provide the patient with any informational resources on hand and/or referrals to appropriate resources.
- The pharmacist shall review any questions the patient may have regarding naloxone hydrochloride.

(5) Advanced Provision and Refills: The pharmacist may furnish naloxone hydrochloride for a patient in advance of the need for naloxone hydrochloride. 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. All formulations are effective. Additional formulations of naloxone hydrochloride may become available and can be furnished under this protocol. 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.	

(8) Fact Sheet: The pharmacist shall provide the patient a copy of the current naloxone fact sheet approved by the Board of Pharmacy.

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

(9) Notifications: The pharmacist, with the patient's verbal or written consent, shall notify the patient's primary care provider of any 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 the patient and that primary care provider. If the patient does not have a primary care provider, or chooses not to give notification consent, the pharmacist shall provide the patient with 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 patient medication record and securely stored within the originating pharmacy for a period of at least three years from the date when the last naloxone hydrochloride 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.

(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 a California School of Pharmacy.

(12) Patient Privacy: All pharmacists furnishing naloxone hydrochloride in a pharmacy shall operate under the pharmacy's policies and procedures to ensure that patient 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](https://www.networkforphl.org/_asset/qz5pvn/naloxone_FINAL.pdf).

*This article describes naloxone access nationwide.*

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

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

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*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.*