



California State Board of Pharmacy

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

Phone: (916) 574-7900

Fax: (916) 574-8618

www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

SENATE BILL 493 IMPLEMENTATION COMMITTEE

Stan Weisser, RPh, Board President and Committee Chair

Amy Gutierrez, Pharm D

Debbie Veale, RPh

Victor Law, RPh

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

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

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

Attachment 1

A proposed schedule for development, discussion and targeted completion dates for SB 493 components is provided in **Attachment 1**.

At this November 2014 meeting, the committee will work on the first drafts of the hormonal contraception protocol and nicotine replacement protocols.

Discussion will also include the board's first pathways for APP licensure.

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

Attachment 2

(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 the last SB 493 Committee Meeting, the committee held a lengthy discussion about reporting immunization into the immunization registry. At this meeting, we believe we will have someone from the CA Immunization Registry in the CA Department of Public Health available to do a presentation on this program.

The minutes from the August meeting (**Attachment 2**) provide details about this discussion.

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, representatives of several schools of pharmacy will provide a form and possible mechanism by which schools and pharmacists can track they possess the required training.

Also at this meeting, the board can resume discussion of topics from the last meeting (see **Attachment 2**, minutes from the meeting).

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

Attachment 3

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**).

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. 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>

Also at the last 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.

Attachment 3 contains a draft document that outlines travel meds that was prepared by a team of individuals from CSHP and CPhA.

At the last meeting President Weisser commented that self-treatable illnesses are very broad. President Weisser asked of 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.

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 as 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.

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

At the last meeting, Dr. Gutierrez asked how the board might handle cases of patients who have an adverse medical event that could have been prevented if the pharmacist would have ordered a test. She asked to hear from pharmacists, especially from independent pharmacies, on how this would affect their practice.

Ms. Herold commented that there are really two issues the board 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?

Dr. Gray, representing Kaiser, states 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.

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.

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

Attachment 4

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 4 contains a draft protocol for hormonal contraception. We believe that much of today's meeting will be discussion on this protocol.

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.

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

Attachment 5

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 5**. Review of this work product is another of the principal topics for this meeting.

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

Attachment 6

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.

Over 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.

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.

At the December 16 meeting of this committee, board staff will have a draft regulation language and an application form to bring to the board to initiate the first rulemaking to

establish APP licensure. On page 18 of **Attachment 7** there is a list of pharmacist programs certified by the NCCA.

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 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).

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

SB 493 Work Product Timeline

Targeted Completion Dates

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Attachment 2



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GOVERNOR EDMUND G. BROWN JR.

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

DATE: August 6, 2014

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

COMMITTEE MEMBERS

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

COMMITTEE MEMBERS

NOT PRESENT:

STAFF

PRESENT: Virginia Herold, Executive Officer
Kristy Schieldge, DCA Staff Counsel
Laura Hendricks, Staff Analyst

Call to Order

President Weisser called the meeting to order at 9:06 a.m.

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

President Weisser acknowledged current board member Lavanza Butler and former board president Stan Goldberg in the audience.

President Weisser stated that as the committee continues its activities to implement SB 493, questions have been raised about how to implement certain provisions. At the June 4, 2014, meeting of the committee, a number of questions and areas for further review were identified. President Weisser noted these questions were placed in the meeting materials and will be discussed at this meeting.

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

Senate Bill 493 allows pharmacists to practice at the full scope of their knowledge and experience and increases their involvement in direct patient care. The following three items are areas where pharmacists, who possess the minimum requirements for providing the services, may do so without specific board licensure.

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

President Weisser outlined the immunization requirements as follows.

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

To initiate immunizations, a pharmacist must:

- complete an immunization training program endorsed by the CDC,
 - be certified in basic life support,
 - comply with all state and federal recordkeeping requirements,
 - provide information to the patient’s primary care physician and into the CDPH’s immunization registry.
- A pharmacist may initiate and administer epinephrine or diphenhydramine by injection (section 4052.8)
 - Pharmacists who do such immunizations need to be trained to perform these functions.
 - The law recognizes the following process: complete an immunization training program endorsed by the CDC or the Accreditation Council for Pharmacy Education (ACPE) that, at a minimum, includes hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines, and shall maintain that training.
 - California’s law requires training in basic life support. This is a recommended supplement of both the ACPE and CPhA programs, but it is not part of the immunization training.

- Enforcement checks of practitioners in the future who provide immunizations under this provision will need to be able to provide the board with evidence they possess the required training and are submitting information to the immunization registry and the patient's primary care physician.

President Weisser asked if the public had any comments on immunizations.

Dan Robinson, dean of Western University, reported that on September 17, 2014 there will be a meeting with deans of the eight California accredited schools of pharmacy to determine what certification programs are currently available in each curriculum. Dr. Robinson noted that the programs are APHA approved and students will get a certificate upon completion. Dr. Robinson stated that a goal of the meeting will be to develop a standardized form to be submitted to the board showing completion of a certification program on immunization, travel meds, smoking cessation and hormonal contraception.

Ms. Herold noted she will be at the meeting to provide and can provide feedback to the deans and report back to the committee.

President Weisser asked how far back the board should accept certification from a graduate of a school of pharmacy. Ms. Veale expressed that perhaps the schools should need to decide how far back they would feel comfortable certifying that a graduate received education in these areas. Dr. Robinson responded that this is something that would be discussed at the September 17 meeting. The committee requested the results of this meeting be discussed at their next meeting.

Mr. Law asked if there is a reporting procedure for certification programs completed during school. Dr. Robinson responded that this item would be discussed at the September 17 meeting. Ms. Herold noted that the board does not want the paperwork coming into the board with the initial application, but it must be made available to the board upon request.

Steve Gray, individual, commented that at the NABP meeting there was a lot of discussion on SB 493. Many board members from other states who were present at the NABP meeting warned that the board should not be in the business of collecting and approving protocols. Dr. Gray added that in one state the protocol must be approved by both the medical board and pharmacy board and it created significant delays.

Dr. Gutierrez asked if locations that currently provide immunizations already meet the standards outlined in SB 493. This was confirmed by Rebecca Cupp, from Ralphs. Ms. Herold noted that many locations that just provide flu shots are currently working under protocols, she would expect these protocols to slowly go away as pharmacists gain the training to administer immunizations independently.

Ms. Veale commented that a new requirement in SB 493 is the reporting of immunizations to

the California Department of Public Health (CDPH). Ms. Herold confirmed. Rebecca Cupp, from Ralphs, commented that currently their pharmacists provide the immunization information to the doctor, but not to CDPH. She added that there are different opinions on this requirement due to HIPPA violations. Ms. Schieldge commented that the language is open to interpretation and if the board wants to make reporting to CDPH a requirement, they would need to do so via a regulation.

The committee asked if a physician is required to report immunization information to CDPH. They noted that if physicians are not required, then it does not seem that pharmacists should be held to a higher reporting standard.

Jeff Goad, from Chapman University, reported that in other states providers are required to report to The Department of Public Health; however, in California they are not required to report to CDPH. Dr. Goad stated that much of the pushback on reporting requirements comes from the medical community. Dr. Goad commented Kaiser and many chain pharmacies do report to CDPH.

Ms. Veale asked if there are any HIPPA concerns in reporting to CDPH. Dr. Goad responded that other states have not raised any HIPPA concerns. Ms. Cupp noted that if reporting is mandated, then there is no HIPPA problem.

Dr. Gutierrez and Ms. Veale asked if there are IT concerns for pharmacies trying to report to the CDPH database. Dr. Goad responded that in his experience it is an easy process. However he recommended that the board remember that independent pharmacies may have different IT constraints than large chains or health systems.

Ms. Veale commented that if the board decided to require reporting to CDPH then it should only be required for California patients. The committee agreed.

Mr. Law asked if patients have access to the information so that they can review their immunization records. Dr. Goad responded that currently the system is difficult to use; however, the new version is supposed to be easier for patients and providers to access the immunization information.

Ms. Veale made the following motion: Require immunization information be reported to CDPH for California patients at least quarterly.

Dr. Gutierrez asked if there are any independent pharmacies in attendance who could speak to any IT difficulties. Mr. Law commented that he does not see independent pharmacies having too much difficulty in obtaining any necessary software, especially since providing immunizations will increase their revenue.

Dan Robinson asked if in mass immunization programs the reporting requirements would be the same. He said reporting requirements could prevent pharmacists from participating in

these community programs. Dr. Goad stated that there are many things to consider for mass immunization events, such as who donated the vaccines.

Ms. Herold commented that perhaps the committee should invite a CDPH representative to their next meeting so that these types of questions could be discussed. Ms. Veale agreed that hearing from CDPH and independent pharmacies would be very helpful. Ms. Veale tabled her previous motion.

Brian Warren, from the California Pharmacists Association, commented that reporting requirements are different in each county and not all county databases communicate with each other.

President Weisser commented that it seems there should be some mechanism to allow patients, pharmacist and doctors to view immunization records.

Dr. Gray, representing Kaiser, commented that Kaiser uses a system called "KITS" so that doctors and patients within the system can view immunization records. Dr. Gray also reminded the committee that there are different reporting requirements for different types of vaccines.

Mr. Law commented that reporting to CDPH is good for the profession. It will allow the tracking of how many pharmacists have provided vaccines to see how SB 493 has improved patient health.

President Weisser asked Jon Roth, of CPHA, to provide an overview of their immunization training program. Mr. Roth reported that the program they use is actually the APHA program. Mr. Roth confirmed that the program provides 20 continuing education units.

Ms. Schiedge asked Mr. Roth if the training program was recognized by ACPE or the CDC. Mr. Roth confirmed that it is approved by ACPE. Ms. Herold noted that the CDC website links to the APHA training program.

Dr. Gutierrez asked if currently a pharmacist who has completed the APHA training and has had training in basic life support can conduct immunizations without a protocol. Ms. Herold responded that if they meet the training requirements then they can conduct immunizations. Ms. Schiedge noted that the board would want to make certain there are records showing that they have met the all the education requirements. Dr. Gutierrez commented that the board needs to clarify what is considered accurate record keeping as far as education requirements and records of the actual administration of the immunization.

Dr. Gray commented that SB 493 does not give a pharmacist the right to purchase immunizations. The pharmacist would need to give the owner of the vaccine a record of the immunization that were administered or discarded.

Ms. Herold noted the board doesn't want to discourage mass immunization programs, but

needs to make sure there are accurate records kept.

Dr. Goad commented that there is a form called the Vaccine Administration Record that collects information that is required to be reported to the federal government. He noted that there is no federal mandate to report the information, just that the information be collected when the immunization is administered.

Dr. Goad reported that there is a statewide immunization registry called CAIR (California Immunization Registry).

Stan Goldenberg, former board president, commented that it may be very difficult to have every entity that provides immunizations report them to CDPH, due to the sheer volume of immunizations provided and the different settings they are provided in.

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

President Weisser explained that pharmacists may furnish prescription medications not requiring a diagnosis recommended by the CDC for individuals traveling outside the U.S.

At the June 2014 committee meeting, it was noted that the category of travel medications is very broad. President Weisser commented that at the meeting a member of the audience asked if the legislation applied only to the administration of travel immunizations or does it go beyond that scope to include other medications a traveler may need such as antibiotics or anti-nausea medications.

Additionally, President Weisser stated that since the protocol provision for immunizations was left untouched by SB 493, a pharmacist could still provide ACIP routinely recommended travel vaccines, as long as they do so under protocol, which still requires physician involvement. He noted that the board is having its attorneys review this issue.

At the June 2014 committee meeting, it was reported that approximately 5 percent of the traveling population sees a healthcare professional before traveling. President Weisser explained that SB 493 makes the process of getting travel medications much easier in a travel clinic setting, something that has been historically difficult due to protocol requirements. However, the committee is concerned that a board-produced protocol could be difficult to maintain because with travel medications, things can change overnight based on outbreaks and protocols would take time to modify.

Ms. Veale asked if there is anything in the legislation that defines the difference between an immunization and a travel vaccine. Ms. Schieldge responded that there are two separate sections of the business and professions code, one that allows all pharmacists to administer a vaccine under a protocol and one that allows a pharmacist to initiate a vaccine pursuant to the CDC guidelines. The second type of vaccine would require additional training for the

pharmacist.

Ms. Scheildge commented that the committee should define what “not requiring a diagnosis” means and identify the CDC guidance document. She added that she does not believe that that board needs to create a protocol for travel medications. Ms. Veale agreed.

Dr. Gutierrez expressed concern that the lack of protocol will create a loophole in the law. Ms. Scheildge commented that by clarifying the CDC guidance document and “not requiring a diagnosis” no loophole would be created.

Dr. Goad clarified that the CDC Yellow-book is the guidance document that the legislation is refereeing to. He reported that there is a chapter in the CDC Yellow-book on self-treatable illnesses. Dr. Goad added that CHPA and CSHP worked together to create a document that outlines travel meds. President Weisser commented that self-treatable illnesses are very broad.

President Weisser asked of 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. President Weisser asked Dr. Goad if the documents created are clearer than the Yellow-book. Dr. Goad responded that the document they created is clearer than the CDC Yellow-book.

Dr. Steve Gray commented 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 as 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.

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.

Ms. Veale asked if a pharmacist can write a prescription for travel medications and have the patient fill it at another pharmacy. Ms. Scheildge responded that she does not see anything in the law that specifies where the patient needs to have their medication filled and does not feel that the committee needs to address this issue.

Stan Goldenberg commented that the payer might have an issue with who wrote the prescription and where it was filled.

Dr. Gutierrez asked that at the next meeting the committee look closely at the travel medications document that Dr. Goad discussed.

The committee commented that they did not want to overregulate travel medication.

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

President Weisser reported that at the June meeting CSHP distributed guidelines that one of their committees had developed for ordering and interpreting tests after the passage of SB 493. President Weisser stated that the committee had commented that any guidelines developed should identify the professional standards pharmacists should follow when ordering and interpreting tests for monitoring the efficacy and safety of drug therapy.

Dr. Gutierrez asked if pharmacists will now be required to order tests prior to dispensing a medication in order to fulfill their corresponding responsibly. Ms. Scheildge responded that a pharmacist should use professional judgment and noted that SB 493 was created to give pharmacists more independence to use their education. Ms. Scheildge also commented that the need for testing should be on a case by case basis and would be a tool a pharmacist could use to improve patient care rather than a requirement.

Dr. Gutierrez expressed concern that requiring testing could affect access to care if a patient is told he or she must be tested in order to receive the medication. Ms. Scheildge responded that 493 says that a pharmacist *may* order tests. She interprets this as granting additional authority to use professional judgment to order tests if pharmacists are worried about the efficacy or toxicity of a drug.

President Weisser reported that at the June meeting, Mr. Roth stated that the language in SB 493 sets two different requirements for regular pharmacists and APP pharmacists. Ms. Herold commented that she is unclear of the difference between the two requirements. Ms. Scheildge responded that the difference is only that an APP pharmacist can choose to adjust or discontinue the drug therapy based on the test results. Whereas, a regular pharmacist would need to consult with the doctor and the doctor would then adjust or discontinue the drug therapy. Ms. Herold commented that the committee may want to establish a time period in which the APP pharmacist must notify the doctor of the change in drug therapy.

Dr. Gutierrez explained that her concern is how the board will handle cases of patients who have an adverse medical event that could have been prevented if the pharmacist would have ordered a test. She commented that she would like to hear from pharmacists, especially

independent pharmacies, on how this would affect their practice. Ms. Herold commented that there are really two issues the board 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.

Dr. Gray, representing Kaiser commented that the intent was to give pharmacists a tool. He also commented that during the 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.

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 commented that the board needs to educate pharmacists on their expanded role in the healthcare team. She encouraged the board to use the *Script* to disseminate the information.

A fourth year pharmacy student at Western University commented that insurance companies will likely stop a pharmacist from ordering a test if they see that that patient has recently had the same test, which will address the concern raised about pharmacists ordering unnecessary tests.

The committee recessed for a break at 10:50 a.m. and resumed at 11 a.m.

2. Discussion on the Requirements for Pharmacists Who Furnish Self-Administered Hormonal Contraceptives and the Development of Draft Protocols

President Weisser reported that during the June 2014 meeting, the committee discussed the requirements for the development of a protocol for self-administered hormonal contraception that must be approved by the Medical Board and the Board of Pharmacy. President Weisser noted that board staff proposes that a series of at least two public meetings be scheduled to include the required groups and any other interested parties to develop the protocols, the self-assessment questionnaire and the fact sheet.

Dr. Gutierrez noted at the June meeting, Dr. Hill-Besinque suggested that the board protocols should not be too prescriptive and should reference the CDC guidelines. Dr. Gutierrez asked if the board could reference the CDC guidelines in their regulation. Ms. Scheildge suggested that the board follow the same procedure as was used in the creation of the emergency contraception protocol with the Medical Board. President Weisser agreed that the joint effort with the Medical Board was successful.

Dr. Gutierrez asked if the protocol would need to reference a list of medications or could just

address the procedure. Ms. Scheildge responded that she did not see that the language required a list of medications to be included.

Ms. Veale and President Weisser asked if the board would have to update the regulation each time the CDC updated their guidelines. Ms. Scheildge responded that it would need to be updated each time a revision was made to the guidelines.

Kathy Hill-Besinque reported that the CDC guidelines are updated annually. She also noted that the guidelines are not really a protocol. Instead, they are more of a safety guideline, so the board would need to create a protocol to supplement the CDC guidelines.

Dr. Hill- Besinque stated that there is no universally accepted self-screening document and she also reported that there is an FDA requirement to hand out a fact sheet each time hormonal contraception is dispensed. She encouraged the board not to create an additional fact sheet.

President Weisser asked if the board could word the regulation in a way that would make all future updates of the CDC guidelines acceptable in order to avoid having to update the regulation each time. Ms. Scheildge responded that the Office of Administrative Law requires the title, date and edition of any document referenced in the regulation. This would require the regulation to be updated any time the CDC guidelines are updated.

Brian Warren commented that the statute does not say that the protocol needs to be adopted in regulation; it only says it needs to be developed by the Medical Board and Board of Pharmacy. Ms. Herold responded that it needs to be in regulation to use for enforcement purposes. Ms. Scheildge added that the Administrative Procedure Act requires this to be done via regulation.

Dr. Gray commented that the committee shouldn't hesitate to reference a document. He added that the board can use judgment to determine if the change in the document is significant enough to update the regulation.

Ms. Veale asked if the board could create a high-level draft prior to the meeting with the Medical Board and use it to start the process with them. Ms. Herold responded that she would recommend going into the meeting with a draft to modify. She added that it will be the staff's duty to create a draft for the board to review, modify and approve.

The committee discussed the scheduling of the workgroup meetings to develop the protocol. It was decided that the committee should create a high-level draft before the workgroup has their first meeting.

Alejandro Huerta, from the California Family Health Council, commented that the goal should be to champion and promote sexual health and improve access to all. He suggested that the committee get the public involved in the development of the protocol. Ms. Herold responded that the committee meetings and workgroup meetings would be open to the public and noticed

on the website.

3. Discussion on the Requirements for Pharmacists Who Furnish Nicotine Replacement Products and Development of Draft Protocols

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

- Certification of the pharmacist in smoking cessation therapy by an organization recognized by the board
- Development of a protocol developed and approved by this board and the Medical Board of California 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.

President Weisser noted that as with the hormonal contraception protocol, board staff proposes that a series of at least two public meetings be scheduled and should include the required groups.

Ms. Veale asked if the board could allow recent graduation from pharmacy school to qualify the pharmacist to begin furnishing nicotine replacement products, rather than making them take a certification program. Ms. Herold responded that this could be clarified in the protocol if the board agrees that recent graduation is an appropriate qualification method.

President Weisser asked if the board could require that *all* pharmacists take one hour of CE for each renewal period. Ms. Veale expressed that she would not like to require all pharmacists to take an hour of smoking cessation CE.

Ms. Scheildge commented that the board needs to determine what organizations they would like to recognize as certification programs for smoking cessation. Dr. Gutierrez asked if there is a list of certification programs available. Ms. Herold commented that she is not aware of any other than the CDC.

Dr. Gray asked if the board must adopt criteria that an organization must meet in order to be certified by the board. Ms. Scheildge responded that the committee could choose to create an application process or could just list the organizations in the regulation.

Robin Corelli, from the University of California, San Francisco commented that the Rx for

Change tobacco cessation curriculum has been the training that is the standard of care in California since 2000. Ms. Scheildge asked if upon completion of the program pharmacists are given a certificate of completion. Dr. Corelli responded that they do not currently, but they would be willing to in order to comply with 493.

President Weisser asked if the curriculum is used in schools outside of California. Dr. Corelli responded that the curriculum was distributed nationwide in 2005. However, she could not speak as to what schools outside of California are currently using.

Ms. Veale asked if the RX for Change program was available to current licensees, as well as students. It was confirmed that while Rx for Change was initially designed for training students, it is also used for training licensed health professionals.

Mr. Law asked if their program was required for a school to receive ACPE accreditation. Dr. Corelli explained that is not a requirement for ACPE accreditation.

Jon Roth commented that professional associations would be willing to work with the schools of pharmacy to expand the certification programs available for licensed pharmacists. He noted that there are numerous programs available for the one hour of ongoing CE.

Mr. Roth asked if the board could state in the regulation that the board would recognize any certification program that was approved by the ACPE, rather than listing an actual organization name. Ms. Scheildge was unsure if this would be appropriate; however, it was something that could be researched and discussed.

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

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

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

President Weisser also outlined the requirements a pharmacist must meet to become licensed as follows:

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.

Mr. Law noted that an APP pharmacist must have an active pharmacist license that is in good standing. He asked for clarification of the term “good standing.” Ms. Herold responded a pharmacist who is on probation would not be in good standing. She noted that a citation and fine and letter of admonishment are not considered discipline. Ms. Scheildge stated that the board could clarify “good standing” on the application so that those seeking to become an APP would understand the requirement.

Ms. Scheildge encouraged the committee to determine if they would like to require certification programs to apply to the board or if the board would simply list the entities they will recognize.

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

Alex Charge, a PIC for a small hospital system, asked for a definition of a collaborative practice agreement. He noted that his colleagues in the hospital setting feel that most inpatient pharmacists have been working under protocols and will therefore fulfill item (C). The committee agreed that most inpatient pharmacists have been working under practice agreements and would fulfill item (C).

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

Lisa Kroon, from the University of California, San Francisco, commented that not all inpatient pharmacists work in a collaborative practice agreement. Dr. Kroon briefly explained the residency program at UCSF.

The committee expressed their desire to ensure that any direct patient care experience has occurred recently relative to the application date to ensure that the pharmacist is truly ready to

practice as an APP.

A student at Western University commented that the current language does not restrict an applicant from counting hours completed during residency as part of the year of experience required in item (C).

Dr. Gutierrez commented that she sees the requirements in item (C) as a way to grandfather in people who have already been operating under a collaborative practice agreement.

Sarah McBane commented that there is an expectation of ownership and responsibility for residents, even though they operate under a preceptor. She also directed the committee's attention to a recent legal precedent that has been set from a case in Utah, where a pharmacist was held responsible for a recommendation they made for an over-the-counter drug.

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

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

Annetta Racelian, a residency program director, commented that most of the ambulatory care, residency care programs focus heavily on patient care.

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

Ms. Veale asked that staff compile a list of accreditation programs for the committee to review.

a. Board of Pharmacy Specialties Certification Programs and Commission for Certification in Geriatric Pharmacy

Ms. Veale reported that at the February 2014 Licensing Committee Meeting, the board heard a lengthy presentation by the Board of Pharmacy Specialties on their certification programs.

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

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

Ms. Veale noted that the Licensing Committee felt that the requirements for BPS certification are high and recertification is required every seven years.

Ms. Veale reported that at the June SB 493 Implementation Committee meeting the board heard a presentation from the Commission for Certification in Geriatric Pharmacy (CCGP) on their certification program.

Ms. Veale reported that the BPS and CCGP programs are not accredited by ACPE, as ACPE does not accredit certification programs. Both certification programs are accredited by NCCA. Ms. Veale noted that the *continuing education* that BPS offers is accredited by ACPE.

President Weisser asked if a legislation change would be required to accept NCCA accreditation. Ms. Scheildge responded that it would not require a legislative change; the board would simply need to recognize them.

A member of the public offered to provide the committee with a list of agencies that provide certification.

Mr. Roth reported that CPHA created a document that outlined elements they felt that a certification program must contain in order to be recognized by the board. Developing criteria would allow the board to accept applications from certification programs that wish to be recognized by the board.

The committee asked that at the next meeting they receive information on existing accreditation programs in order to determine if they should list specific ones, such as NCCA or create an application process for certification programs based on criteria developed by the board.

Dan Robinson, dean of Western University, expressed his concern that the existing accredited certification programs are not geared toward community pharmacists and generalists. Dr. Robinson reported that there is a certification program offered by the Canadian Pharmacists Association that applies specifically to community pharmacists. President Weisser expressed his concern that the program is not accredited. Ms. Veale asked if the program could apply to become accredited by NCCA. Dr. Robinson stated that the program may already be accredited by ACPE, he will verify and report back to the committee.

Megan Coder asked if an APP who was certified in one of the eight specialties offered by BPS could choose to practice in a different area, i.e., if a pharmacist originally was certified in oncology through BPS and in the future chose to work in pediatric pharmacy as an APP. It was clarified that once a pharmacist become licensed as an APP they could choose to practice in any area, as long as their CE was in the area which they are *currently* practicing.

Dr. Kroon briefly described the certification program offered by the Canadian Pharmacists Association and encouraged the board to consider the program.

Dr. Hill-Besinque asked to clarify that certification is an entry threshold not a renewal threshold; therefore after someone becomes licensed as an APP he or she could let the BPS certification expire and still be licensed as an APP. Ms. Herold and Ms. Scheildge confirmed that pharmacists could let their BPS certification expire as long as they met the CE requirements.

Dr. Gray expressed his opinion that the board would need to recognize specific certification programs not NCCA. Ms. Scheildge disagreed with Dr. Gray's interpretation of the language.

5. Development of Elements for Other Certification (or Certificate?) Programs

President Weisser reported that at the June 2014 meeting the committee identified that it may be best for the board to create objective criteria that programs must meet to be considered for board approval as an avenue to APP licensure.

At the June 2014 meeting Dr. Kroon described the Canadian Pharmacists Association's program. Dr. Kroon again provided the committee with a brief overview of the program and expressed that the program very suitable for community pharmacists. Mr. Roth added that the Canadian model is in discussion with APHA to bring the program to the United States.

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

President Weisser asked if there were any public comments for items not on the agenda. Mr. Roth asked if the board could put out a schedule for the oral contraception and smoking

cessation workgroups so that interested parties could make arrangements.

Adjournment

3:10 p.m.

Attachment 3

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.¹ 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

¹ 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)**

Prepared by: Jeff Goad, Pharm.D., MPH, FAPhA, FCPHA, FCSHP
Professor and Chair, Department of Pharmacy Practice
Chapman University School of Pharmacy

Appendix A. Conditions for Pharmacist Medication Furnishing

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

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

Condition	Considerations	Exclusions to Pharmacist Furnishing*	Medications
	<ul style="list-style-type: none"> Agents that increase gastric pH 		
Urinary tract infections (UTI)	<ul style="list-style-type: none"> For patients previously diagnosed with frequent uncomplicated UTIs and who can determine when to self-treat 	<ul style="list-style-type: none"> Not previously diagnosed 	Typical medications used: Macrochantin Ciprofloxacin Sulfamethoxazole/trimethoprim DS Pyridium (for associated pain)
Vaginal yeast infections	<ul style="list-style-type: none"> Female in whom a vaginal yeast infection has been previously diagnosed Long-term use of certain antimicrobials 	<ul style="list-style-type: none"> A co-morbid conditions that would make self-recognition unreliable Complicated VVC (e.g. comorbid DM, immune suppression, hx of systemic azole therapy) 	Typical medications used: 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 4

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.

SELF-SCREENING TOOL

Part 1: To be completed by patient

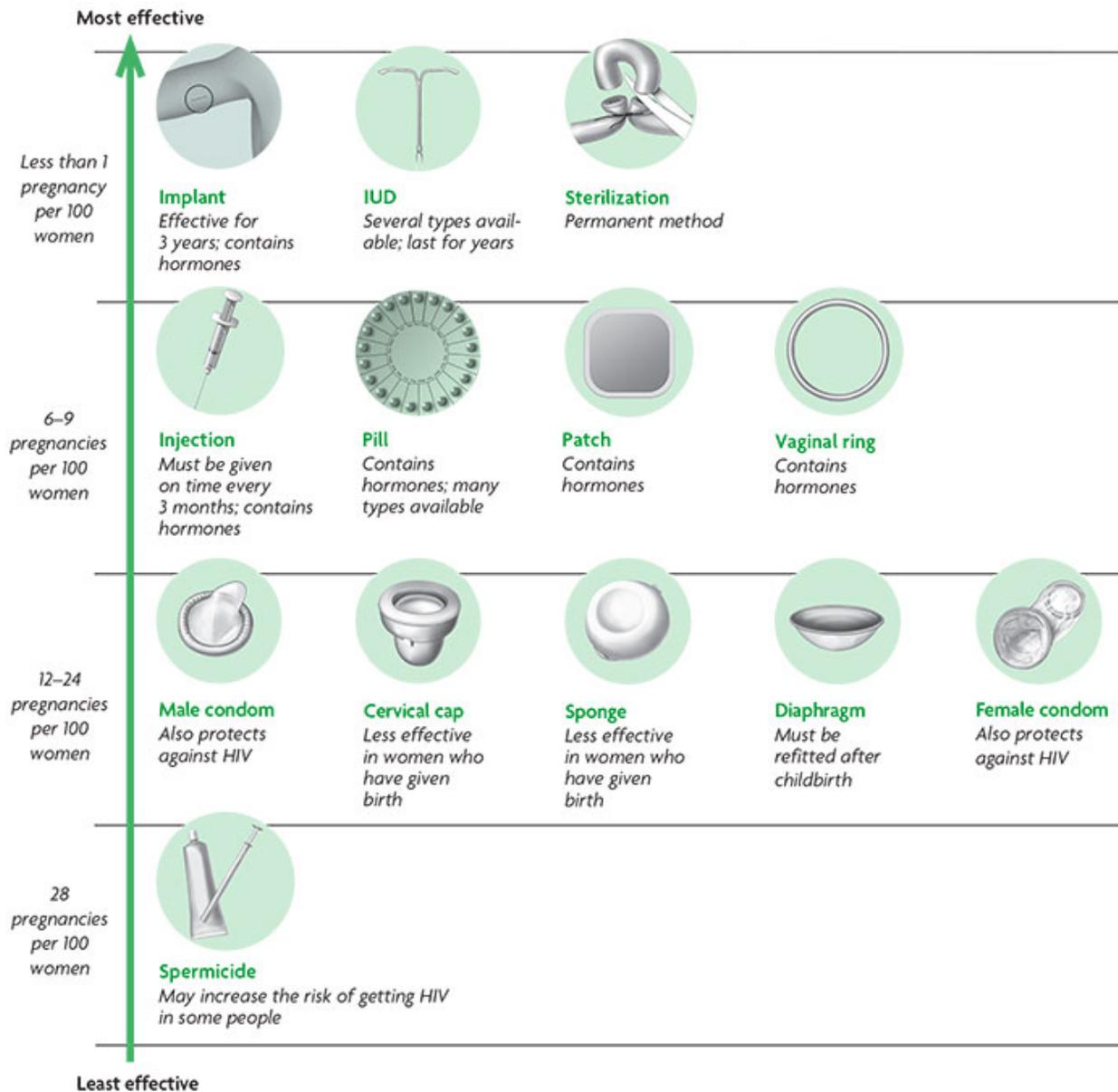
1	Do you or have you ever had breast cancer?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
2	Do you or have you ever had hepatitis, liver disease, liver cancer, or gall bladder disease, or do you have jaundice (yellow skin or eyes)?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
3	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
4	Do you smoke cigarettes? (If no, got to question 5)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	Are you 35 years of age or older?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	Do you smoke more than 15 cigarettes a day?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
5	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"/>
6	Do you think you might be pregnant now? (If yes, a pregnancy test is advised)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
7	Have you given birth within the past 6 weeks?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
8	Are you currently breastfeeding an infant who is less than 6 months of age?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
9	Do you have high blood pressure, hypertension, or high cholesterol?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
10	Do you have diabetes?	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	Has your parent or sibling ever had blood clots?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
14	Do you have lupus, rheumatoid arthritis, or any blood disorders?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
15	Are you in a wheelchair?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
16	Have you had bariatric surgery or stomach reduction surgery?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
17	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"/>
18	Have you ever been told by a medical professional not to take hormones?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
19	Have you ever taken birth control pills or used a birth control patch or ring? (If no, go to question 20)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	Did you ever experience a bad reaction to using birth control?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	Are you currently using birth control pills or a birth control path or ring?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
20	Do you usually get your period every month?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	If no, describe briefly:		
21	Do you have any other medical problems or take regular medication that could prevent you from using hormonal birth control?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	If yes, list them here:		
22	Do you weigh more than 200 lbs.?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
22 (alt.)	What is your current weight and height?	_____ lbs.	____' ____"

SELF-SCREENING TOOL

Part 2: To be completed by pharmacist

24	What is the patient's current blood pressure?	/	mm Hg
25	Are you recommending self-administered hormonal contraception to this patient?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
26	Are you providing self-administered hormonal contraception to this patient?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

YOUR BIRTH CONTROL OPTIONS



What things should I think about when choosing a birth control method?

To choose the right birth control method for you, consider the following:

- How well it prevents pregnancy
- How easy it is to use
- Whether you need a prescription to get it
- Whether it protects against *sexually transmitted diseases (STDs)*
- Whether you have any health problems

Do I need to have a pelvic exam to get birth control from my health care provider?

A *pelvic exam* is not needed to get most forms of birth control from a health care provider except for the intrauterine device (IUD), diaphragm, and cervical cap. If you have already had sex, you may need to have a pregnancy test and STD test before birth control can be prescribed.

Which birth control methods also protect against sexually transmitted diseases (STDs)?

The male latex or polyurethane condom gives the best protection against STDs. The female condom provides some protection. With all other methods, you also should use a male or female condom to protect against STDs.

What is the birth control pill?

The birth control pill is a pill that you have to take every day at the same time each day. It contains *hormones* that prevent pregnancy. There are many types of birth control pills. Your health care provider can help you choose the right one for you.

If you miss a pill, you need to know what to do. Read the directions that came with your pack of pills. You also may want to contact your health care provider.

What is the skin patch?

The patch is a small (1.75 square inch) adhesive patch that is worn on the skin. It contains hormones that are slowly released into your body through the skin. A new patch is worn for a week at a time for 3 weeks in a row. During the fourth week, a patch is not worn, and you will have your menstrual period.

What is the vaginal ring?

The ring is a flexible plastic ring that you insert into the upper *vagina*. It releases hormones into your body. It is worn inside the vagina for 21 days and then removed for 7 days. During those 7 days, you will have your menstrual period. Then you insert a new ring.

If you have further questions, contact your health care provider.

Adopted from 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>.

Protocol Sources

Centers for Disease Control and Prevention, "United States Medical Eligibility Criteria (USMEC) for Contraceptive Use," *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 is referenced under "Procedures" as offering 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). Pages 55-56 describe why weight measurement is not needed. Page 20 discusses providers giving injections.

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

Citing the WHO's Medical Eligibility Criteria, this research article states the accurate medical history and blood pressure assessments are needed for the safe provision of hormonal contraceptives. This article also provided a Medical History Questionnaire that was used in the development of the protocol's self-assessment tool. The research found 96% overall 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.

World Health Organization, "Medical Eligibility Criteria for Contraceptive Use" (2009) 18, *available at*

http://www.who.int/reproductivehealth/publications/family_planning/9789241563888/en/.

This document presents evidence that obesity led to greater experience of adverse effects with oral contraceptives. "Limited evidence is inconsistent regarding whether [oral contraceptive] effectiveness varies by body weight or BMI." It recommends a measurement of blood pressure before prescription of contraceptives, but no mention of weight measurement.

Reproductive Health Access Project, "Your Birth Control Choices" (June 2014), *available at* http://www.reproductiveaccess.org/fact_sheets.htm.

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

Reproductive Health Access Project , “How To Switch Birth Control Methods” (Feb. 2013), available at http://www.reproductiveaccess.org/fact_sheets.htm.

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

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

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, omitting the mention of “especially for teens,” is recommended as the model for the Board’s fact sheet. SB 493 specifically states that the provision of an existing publication developed by nationally recognized medical organizations may fulfill the fact sheet requirement.

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.

The American College of Obstetricians and Gynecologists, “Progestin-Only Hormonal Birth Control: Pill and Injection,” FAQ186 (Jul. 2014), available at <http://www.acog.org/Patients/FAQs/Progestin-Only-Hormonal-Birth-Control-Pill-and-Injection>.

This fact sheet states that a health care provider must give the injection, making it incompatible with the term “self-administered.”

The New York City Department of Health and Mental Hygiene, “Quick Guide to Contraception: For Clinicians in Any Specialty,” available at <http://www.nyc.gov/html/doh/downloads/pdf/ms/contra-guide.pdf>.

This guide recommends checking weight only for the contraceptive patch, because if weight is greater than or equal to 198 pounds, the patch may be less effective.

Attachment 5

(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.

Protocol Sources

Centers for Disease Control and Prevention, "Quitting Smoking," *available at* http://www.cdc.gov/tobacco/data_statistics/fact_sheets/cessation/quitting/index.htm.

This resource describes the methods of quitting smoking and their effectiveness.

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

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

Frank Vitale, "Brief Intervention Protocol for Assisting Patients with Tobacco Cessation," 64 AM. J. HEALTH-SYST PHARM. 2583 (2007).

This commentary provides important resources and specific dialogue for a pharmacists' procedure for assisting patients with tobacco cessation.

Nicole Van Hoey, "Opportunities for Smoking Cessation Services in Emerging Models of Care," *America's Pharmacist* (Oct. 2014).

This Continuing Education provided helpful referral resources, especially smartphone resources.

University of California, San Francisco, "Smoking Cessation Leadership Center,"

<http://smokingcessationleadership.ucsf.edu/>.

This site offers evidence-based resources for providers as well as continuing education opportunities in smoking cessation for CME and CEU credit.

University of California, San Francisco, "Rx for Change," <http://rxforchange.ucsf.edu/>.

This site offers evidence-based resources for providers and non-providers.

Accreditation Council for Pharmacy Education, "Basic Tobacco Intervention Workshop,"

P.L.A.N. Search Detail, *available at* [https://www.acpe-](https://www.acpe-accredit.org/pwtool/plan/DetailResultsPLAN.aspx?progtype=1&id=267501&cosp=289079&fromdate=10/27/2014)

[accredit.org/pwtool/plan/DetailResultsPLAN.aspx?progtype=1&id=267501&cosp=289079&fromdate=10/27/2014](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.



PHARMACOLOGIC PRODUCT GUIDE: FDA-APPROVED MEDICATIONS FOR SMOKING CESSATION

		NICOTINE REPLACEMENT THERAPY (NRT) FORMULATIONS					BUPROPION SR	VARENICLINE
		GUM	LOZENGE	TRANSDERMAL PATCH	NASAL SPRAY	ORAL INHALER		
PRODUCT	<p>Nicorette¹, Generic OTC 2 mg, 4 mg original, cinnamon, fruit, mint, orange</p>	<p>Nicorette Lozenge,¹ Nicorette Mini Lozenge,¹ Generic OTC 2 mg, 4 mg cherry, mint</p>	<p>NicoDerm CO¹, Generic OTC (NicoDerm CO, generic) Rx (generic) 7 mg, 14 mg, 21 mg (24-hour release)</p>	<p>Nicotrol NS² Rx Metered spray 0.5 mg nicotine in 50 mL aqueous nicotine solution</p>	<p>Nicotrol Inhaler² Rx 10 mg cartridge delivers 4 mg inhaled nicotine vapor</p>	<p>Zyban¹, Generic Rx 150 mg sustained-release tablet</p>	<p>Chantix² Rx 0.5 mg, 1 mg tablet</p>	
PRECAUTIONS	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Temporomandibular joint disease Pregnancy³ and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Pregnancy³ and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Pregnancy³ (Rx formulations, category D) and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Underlying chronic nasal disorders (rhinitis, nasal polyps, sinusitis) Severe reactive airway disease Pregnancy³ (category D) and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Bronchospastic disease Pregnancy³ (category D) and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Concomitant therapy with medications or medical conditions known to lower the seizure threshold Severe hepatic cirrhosis Pregnancy³ (category C) and breastfeeding Adolescents (<18 years) <p>Warning:</p> <ul style="list-style-type: none"> BLACK-BOXED WARNING for neuropsychiatric symptoms⁴ <p>Contraindications:</p> <ul style="list-style-type: none"> Seizure disorder Concomitant bupropion (e.g., Wellbutrin) therapy Current or prior diagnosis of bulimia or anorexia nervosa Simultaneous abrupt discontinuation of alcohol or sedatives/benzodiazepines MAO inhibitor therapy in previous 14 days 	<ul style="list-style-type: none"> Severe renal impairment (dosage adjustment is necessary) Pregnancy³ (category C) and breastfeeding Adolescents (<18 years) <p>Warning:</p> <ul style="list-style-type: none"> BLACK-BOXED WARNING for neuropsychiatric symptoms⁴ 	
DOSING	<p><i>1st cigarette ≤ 30 minutes after waking:</i> 4 mg <i>1st cigarette >30 minutes after waking:</i> 2 mg</p> <p>Weeks 1–6: 1 piece q 1–2 hours Weeks 7–9: 1 piece q 2–4 hours Weeks 10–12: 1 piece q 4–8 hours</p> <ul style="list-style-type: none"> Maximum, 24 pieces/day Chew each piece slowly Park between cheek and gum when peppery or tingling sensation appears (~15–30 chews) Resume chewing when tingle fades Repeat chew/park steps until most of the nicotine is gone (tingle does not return; generally 30 min) Park in different areas of mouth No food or beverages 15 minutes before or during use Duration: up to 12 weeks 	<p><i>1st cigarette ≤ 30 minutes after waking:</i> 4 mg <i>1st cigarette >30 minutes after waking:</i> 2 mg</p> <p>Weeks 1–6: 1 lozenge q 1–2 hours Weeks 7–9: 1 lozenge q 2–4 hours Weeks 10–12: 1 lozenge q 4–8 hours</p> <ul style="list-style-type: none"> Maximum, 20 lozenges/day Allow to dissolve slowly (20–30 minutes for standard; 10 minutes for mini) Nicotine release may cause a warm, tingling sensation Do not chew or swallow Occasionally rotate to different areas of the mouth No food or beverages 15 minutes before or during use Duration: up to 12 weeks 	<p><i>>10 cigarettes/day:</i> 21 mg/day x 4 weeks (generic) 6 weeks (NicoDerm CO) 14 mg/day x 2 weeks 7 mg/day x 2 weeks</p> <p><i>≤ 10 cigarettes/day:</i> 14 mg/day x 6 weeks 7 mg/day x 2 weeks</p> <ul style="list-style-type: none"> May wear patch for 16 hours if patient experiences sleep disturbances (remove at bedtime) Duration: 8–10 weeks 	<p>1–2 doses/hour (8–40 doses/day) One dose = 2 sprays (one in each nostril); each spray delivers 0.5 mg of nicotine to the nasal mucosa</p> <ul style="list-style-type: none"> Maximum <ul style="list-style-type: none"> – 5 doses/hour or – 40 doses/day For best results, initially use at least 8 doses/day Do not sniff, swallow, or inhale through the nose as the spray is being administered Duration: 3–6 months 	<p>6–16 cartridges/day Individualize dosing; initially use 1 cartridge q 1–2 hours</p> <ul style="list-style-type: none"> Best effects with continuous puffing for 20 minutes Initially use at least 6 cartridges/day Nicotine in cartridge is depleted after 20 minutes of active puffing Inhale into back of throat or puff in short breaths Do NOT inhale into the lungs (like a cigarette) but “puff” as if lighting a pipe Open cartridge retains potency for 24 hours No food or beverages 15 minutes before or during use Duration: 3–6 months 	<p>150 mg po q AM x 3 days, then 150 mg po bid</p> <ul style="list-style-type: none"> Do not exceed 300 mg/day Begin therapy 1–2 weeks prior to quit date Allow at least 8 hours between doses Avoid bedtime dosing to minimize insomnia Dose tapering is not necessary Duration: 7–12 weeks, with maintenance up to 6 months in selected patients 	<p>Days 1–3: 0.5 mg po q AM Days 4–7: 0.5 mg po bid Weeks 2–12: 1 mg po bid</p> <ul style="list-style-type: none"> Begin therapy 1 week prior to quit date; alternatively, the patient can begin therapy and then quit smoking between days 8–35 of treatment Take dose after eating and with a full glass of water Dose tapering is not necessary Dosing adjustment is necessary for patients with severe renal impairment Duration: 12 weeks; an additional 12-week course may be used in selected patients 	

NICOTINE REPLACEMENT THERAPY (NRT) FORMULATIONS							BUPROPION SR	VARENICLINE			
GUM		LOZENGE		TRANSDERMAL PATCH	NASAL SPRAY	ORAL INHALER					
ADVERSE EFFECTS	<ul style="list-style-type: none"> ▪ Mouth/jaw soreness ▪ Hiccups ▪ Dyspepsia ▪ Hypersalivation ▪ Effects associated with incorrect chewing technique: <ul style="list-style-type: none"> – Lightheadedness – Nausea/vomiting – Throat and mouth irritation 		<ul style="list-style-type: none"> ▪ Nausea ▪ Hiccups ▪ Cough ▪ Heartburn ▪ Headache ▪ Flatulence ▪ Insomnia 		<ul style="list-style-type: none"> ▪ Local skin reactions (erythema, pruritus, burning) ▪ Headache ▪ Sleep disturbances (insomnia, abnormal/vivid dreams); associated with nocturnal nicotine absorption 	<ul style="list-style-type: none"> ▪ Nasal and/or throat irritation (hot, peppery, or burning sensation) ▪ Rhinitis ▪ Tearing ▪ Sneezing ▪ Cough ▪ Headache 	<ul style="list-style-type: none"> ▪ Mouth and/or throat irritation ▪ Cough ▪ Headache ▪ Rhinitis ▪ Dyspepsia ▪ Hiccups 	<ul style="list-style-type: none"> ▪ Insomnia ▪ Dry mouth ▪ Nervousness/difficulty concentrating ▪ Rash ▪ Constipation ▪ Seizures (risk is 0.1%) ▪ Neuropsychiatric symptoms (rare; see PRECAUTIONS) 	<ul style="list-style-type: none"> ▪ Nausea ▪ Sleep disturbances (insomnia, abnormal/vivid dreams) ▪ Constipation ▪ Flatulence ▪ Vomiting ▪ Neuropsychiatric symptoms (rare; see PRECAUTIONS) 		
	ADVANTAGES	<ul style="list-style-type: none"> ▪ Might satisfy oral cravings ▪ Might delay weight gain ▪ Patients can titrate therapy to manage withdrawal symptoms ▪ Variety of flavors are available 		<ul style="list-style-type: none"> ▪ Might satisfy oral cravings ▪ Might delay weight gain ▪ Easy to use and conceal ▪ Patients can titrate therapy to manage withdrawal symptoms ▪ Variety of flavors are available 		<ul style="list-style-type: none"> ▪ Provides consistent nicotine levels over 24 hours ▪ Easy to use and conceal ▪ Once daily dosing associated with fewer compliance problems ▪ FDA-approved for use in combination with bupropion SR 	<ul style="list-style-type: none"> ▪ Patients can titrate therapy to rapidly manage withdrawal symptoms 	<ul style="list-style-type: none"> ▪ Patients can titrate therapy to manage withdrawal symptoms ▪ Mimics hand-to-mouth ritual of smoking (could also be perceived as a disadvantage) 	<ul style="list-style-type: none"> ▪ Easy to use; oral formulation might be associated with fewer compliance problems ▪ Might delay weight gain ▪ Can be used safely with NRT; FDA-approved for use in combination with nicotine transdermal patch ▪ Might be beneficial in patients with depression 	<ul style="list-style-type: none"> ▪ Easy to use; oral formulation might be associated with fewer compliance problems ▪ Offers a new mechanism of action for patients who have failed other agents 	
		DISADVANTAGES	<ul style="list-style-type: none"> ▪ Need for frequent dosing can compromise compliance ▪ Might be problematic for patients with significant dental work ▪ Patients must use proper chewing technique to minimize adverse effects ▪ Gum chewing may not be socially acceptable 		<ul style="list-style-type: none"> ▪ Need for frequent dosing can compromise compliance ▪ Gastrointestinal side effects (nausea, hiccups, heartburn) might be bothersome 		<ul style="list-style-type: none"> ▪ Patients cannot titrate the dose to acutely manage withdrawal symptoms ▪ Allergic reactions to adhesive might occur ▪ Patients with dermatologic conditions should not use the patch 	<ul style="list-style-type: none"> ▪ Need for frequent dosing can compromise compliance ▪ Nasal/throat irritation may be bothersome ▪ Patients must wait 5 minutes before driving or operating heavy machinery ▪ Patients with chronic nasal disorders or severe reactive airway disease should not use the spray 	<ul style="list-style-type: none"> ▪ Need for frequent dosing can compromise compliance ▪ Initial throat or mouth irritation can be bothersome ▪ Cartridges should not be stored in very warm conditions or used in very cold conditions ▪ Patients with underlying bronchospastic disease must use with caution 	<ul style="list-style-type: none"> ▪ Seizure risk is increased ▪ Several contraindications and precautions preclude use in some patients (see PRECAUTIONS) ▪ Patients should be monitored for potential neuropsychiatric symptoms⁴ (see PRECAUTIONS) 	<ul style="list-style-type: none"> ▪ May induce nausea in up to one third of patients ▪ Patients should be monitored for potential neuropsychiatric symptoms⁴ (see PRECAUTIONS)
			COST/DAY ⁵	2 mg or 4 mg: \$1.90–\$3.70 (9 pieces)		2 mg or 4 mg: \$2.66–\$4.10 (9 pieces)		\$1.52–\$3.48 (1 patch)	\$5.00 (8 doses)	\$8.51 (6 cartridges)	\$2.72–\$6.22 (2 tablets)

¹ Marketed by GlaxoSmithKline.

² Marketed by Pfizer.

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

⁴ In July 2009, the FDA mandated that the prescribing information for all bupropion- and varenicline-containing products include a black-boxed warning highlighting the risk of serious neuropsychiatric symptoms, including changes in behavior, hostility, agitation, depressed mood, suicidal thoughts and behavior, and attempted suicide. Clinicians should advise patients to stop taking varenicline or bupropion SR and contact a healthcare provider immediately if they experience agitation, depressed mood, and any changes in behavior that are not typical of nicotine withdrawal, or if they experience suicidal thoughts or behavior. If treatment is stopped due to neuropsychiatric symptoms, patients should be monitored until the symptoms resolve.

⁵ Wholesale acquisition cost from Red Book Online. Thomson Reuters, August 2014.

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

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

Attachment 6



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

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

APPLICATION FOR ADVANCED PRACTICE PHARMACIST

Print or type

Name:	Last	First	Middle	Former	CA Pharmacist License No:
**Address of record:	Number	Street		City	State Zip Code
Residence Address: <small>(if different from above)</small>	Number	Street		City	State Zip Code
Home telephone number: ()	Work telephone number: ()			Fax Number: ()	
Email address:	Date of Birth:			Social Security Number: ***	
Qualification Methods: (Check all that apply)					
<input type="checkbox"/> Certification in a relevant area of practice as specified in B&PC 4210 (a)(2)(A) <u>What type of documentation?</u>					
<input type="checkbox"/> Completion of postgraduate residency program – <u>What type of documentation?</u>					
<input type="checkbox"/> Worked under a collaborative practice agreement or protocol for one year <u>What type of documentation?</u>					
Type of Services to be provided: (check all that apply)					
<input type="checkbox"/> Order and Interpret tests for medication management and monitoring					
<input type="checkbox"/> Initiate or Adjust controlled substances therapy –Enter DEA licensure number _____					
Location(s) where services will be provided: (attach additional sheets, if needed)					
Name	Street Address		City	State	Zip
Name	Street Address		City	State	Zip
Name	Street Address		City	State	Zip

Please read carefully and sign below.

I understand that falsification of the information on this form may constitute grounds for denial or revocation of the license. I hereby certify under penalty of perjury under the laws of the State of California to the truth and accuracy of all statements, answers and representations made in this application, including all supplementary statements. I also certify that I personally completed this application and have read and understand the instructions attached to this application.

Signature of applicant (in full—no initials)

Date signed

DO NOT WRITE BELOW THIS LINE

Certification No. _____ Application fee no. _____

Date Issued _____ Amount _____

Date Cashiered _____

Attachment 7



Council on Credentialing in Pharmacy

Guiding Principles for Post-licensure Credentialing of Pharmacists

The Council on Credentialing in Pharmacy (CCP) provides leadership, guidance, public information, and coordination for the pharmacy profession's credentialing programs. CCP has previously published resource papers describing credentialing in pharmacy, the scope of practice of pharmacists and pharmacy technicians, and guiding principles for certification of individuals and accreditation organizations, sites or programs.^{1,4}

Credentials serve to document the knowledge, skills, and experience of pharmacists and are part of a comprehensive framework that includes professional education, licensure, formal post-licensure training, experience, and certification. To ensure optimal patient outcomes, specific post-licensure credentials are required of some pharmacists based on the complexity of the care they provide and/or to obtain specific patient care privileges.

CCP believes that structured processes for the credentialing and privileging of pharmacists can contribute to the safe and effective delivery of patient care and the *CCP Guiding Principles for Post-licensure Credentialing of Pharmacists* are offered with this intended goal.

For the purposes of this document, definitions for key terms are provided as follows:

Credential: Documented evidence of professional qualifications. Academic degrees, state licensure, residency certificates, and certification are all examples of credentials.

Credentialing: a) The process of granting a credential (a designation that indicates qualifications in a subject or area), (noted as ^a below); b) The process by which an organization or institution obtains, verifies, and assesses an individual's qualifications to provide patient care services (noted as ^b below).

Privileging: The process by which a health care organization, having reviewed an individual health care provider's credentials and performance and found them satisfactory, authorizes that person to perform a specific scope of patient care services within that organization.

1. Licensure of pharmacists should assure entry-level knowledge, skills, attitudes, and values for the provision of services and information regarding medications and their proper use. All licensed pharmacists should be capable of serving a wide variety of patients with different conditions and diseases when the complexities of the patient's pharmacotherapeutic and medical care needs and/or the technologies utilized in the delivery of care are limited. Post-licensure credentials for pharmacists should build on this foundation.

2. To ensure sustained program quality and viability over time and to protect the public and holders of the credentials, credentialing^a programs should be established through an efficient and effective profession-wide, consensus-building process. Credentials should be based on demonstrated patient/societal need, sustained demand within the pharmacy profession, and the availability of appropriate education and training programs to support the achievement and maintenance of the credential.
3. Within the pharmacy profession, there should be active coordination of and alignment between professional education, postgraduate education and training, and credentialing^a programs as outlined in the CCP Framework for Credentialing in Pharmacy Practice described in the Council's Scope of Contemporary Pharmacy Practice resource paper.²
4. Postgraduate education and training programs involve structured activities that should meet established professional standards. All credentialing^a programs should be accredited.^{3,4} Certification programs must be psychometrically sound, legally defensible, and should be accredited by the National Commission for Certifying Agencies (NCCA), American National Standards Institute (ANSI), or other recognized national or international accreditation body.
5. All postgraduate education, training and credentialing^a programs should include assessments that measure the knowledge and skills gained from these programs and/or provide evidence that holders of credentials have achieved the required level of competence. These assessments serve to document and assure ongoing program quality for all stakeholders within the health care system.
6. There should be a planned, coordinated effort by the pharmacy profession to educate pharmacists, other health professionals, employers, payers, and the public about all credentials held by pharmacists and their value to patients and the health care system. This effort should also advocate for the effective integration of pharmacists with post-licensure credentials into current and evolving health care delivery systems. Credentials should enable pharmacists to obtain specific patient care privileges and should not create barriers to the provision of any services pharmacists provide to their patients.
7. **Due to the variability in complexity of care and increasing differentiation of pharmacy practice, CCP believes that pharmacists—like many other patient care providers—should be expected to participate in credentialing^b and privileging processes to ensure they have attained and maintain competency to provide the scope of services and quality of care that are required in their respective practices.**
8. For all practice settings, employers and payers should be encouraged to adopt and implement their own credentialing^b and privileging processes for pharmacists to determine and authorize the patient care responsibilities appropriate for particular patient populations and care delivery.

Adopted by the Council on Credentialing in Pharmacy
Washington, DC
February 2011

References:

1. Credentialing in Pharmacy. November 2010. Council on Credentialing in Pharmacy, Washington, DC. <http://www.pharmacycredentialing.org/ccp/Files/CCPWhitePaper2010.pdf>
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http://www.pharmacycredentialing.org/ccp/Contemporary_Pharmacy_Practice.pdf
3. Guiding Principles for Certification of Individuals in Pharmacy. January 2006. Council on Credentialing in Pharmacy, Washington, DC.
<http://www.pharmacycredentialing.org/ccp/Files/CCP%20Guiding%20Principles%20for%20Certification%20Adopted%20January%202006.pdf>
4. Guiding Principles for Accreditation of Organizations, Sites or Programs in Pharmacy. January 2006. Council on Credentialing in Pharmacy, Washington, DC.
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CREDENTIALING IN PHARMACY: A RESOURCE PAPER

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The Council on Credentialing in Pharmacy

Washington, DC, November 2010¹

Mission: The Council on Credentialing in Pharmacy provides leadership, guidance, public information, and coordination for the profession of pharmacy's credentialing programs.

Vision Statement: The vision of the Council on Credentialing in Pharmacy is that all credentialing programs in pharmacy will meet established standards of quality and contribute to improvement in patient care and the overall public health.

INTRODUCTION

The credentialing of pharmacists and pharmacy technicians is an important topic in the pharmacy profession. Discussions about credentialing, inherently complex, have been further complicated by the lack of a common lexicon. Many different words are used to describe the process by which health care practitioners are educated, trained, licensed, and otherwise recognized for their competence and achievements. In addition, many different organizations, public and private, are involved in assessing pharmacists' and pharmacy technicians' knowledge and skill, granting credentials, and accrediting educational programs and institutions.

As pharmacy becomes more integral to the therapy decision-making and patient monitoring activities within the health care system (institutional and community based), employers, other care providers, patients, and health care payers need to better understand and appreciate the breadth and depth of pharmacist and pharmacy technician education and training and the myriad postgraduate education and training

opportunities available to pharmacists. More importantly, those within and outside the profession must share a common language and understanding of credentials so they can make educated, rational decisions regarding scope of practice, privileging, referral, and eligibility for compensation. A clear understanding of the knowledge, skill, attitudes, and values of contemporary pharmacists and pharmacy technicians and the meaning of the various credentials held by them will lead to a more effective health care workforce deployment, appropriate privileging and responsibility assignments, equitable compensation mechanisms, and improved quality of patient care.

Council on Credentialing in Pharmacy

Founded in 1999, the Council on Credentialing in Pharmacy (CCP) is a coalition of 12 national pharmacy organizations committed to providing leadership, guidance, public information, and coordination for credentialing programs in or relevant to pharmacy. Current CCP member organizations are as follows:

- Academy of Managed Care Pharmacy (AMCP)
- Accreditation Council for Pharmacy Education (ACPE)
- American Association of Colleges of Pharmacy (AACP)
- American College of Apothecaries (ACA)
- American College of Clinical Pharmacy (ACCP)
- American Pharmacists Association (APhA)
- American Society of Consultant Pharmacists (ASCP)
- American Society of Health-System Pharmacists (ASHP)
- Board of Pharmacy Specialties (BPS)
- Commission for Certification in Geriatric Pharmacy (CCGP)
- Institute for the Certification of Pharmacy Technicians (ICPT)
- Pharmacy Technician Educators Council (PTEC)

Purposes of the Resource Paper

This resource paper provides for those within and outside the profession an overview of the spectrum and current status of education and credentialing

¹ The November 2010 version updates and supersedes the version published in July 2006.

activities and processes for pharmacy personnel (pharmacists and pharmacy technicians). It also provides a common frame of reference and understanding for discussions concerning pharmacist and pharmacy technician credentialing and seeks to identify issues to consider as the credentialing of pharmacy professionals evolves and matures.

The resource paper begins with definitions of several terms that are essential to any discussion of credentialing, followed by a short section highlighting the importance of credentialing in pharmacy. The next three sections, which form the body of the paper, discuss in detail the three categories of credentials that pharmacists may earn:

- credentials needed to prepare for practice (i.e., academic degrees);
- credentials needed to enter practice (i.e., licensure) and to update professional knowledge and skill (i.e., re-licensure) under state law; and
- credentials voluntarily earned by pharmacists to document their specialized or advanced knowledge and skill (i.e., postgraduate degrees, certificates, and certification).

Each section contains, as applicable, information about the credential awarded, the training site, whether the credential is voluntary or mandatory, the credentialing body, and the agency that accredits the organization, site, or program. Particular attention is given to pharmacist certification programs, an area that has engendered much of the current interest in pharmacist credentialing.

The paper also includes a brief section on the credentialing of pharmacy technicians. It concludes with six appendices. Appendix A contains a comprehensive glossary of key terms applicable to credentialing. Appendix B is an alphabetic list of the organizations involved in credentialing and the organization, site, or program accreditation. The list contains names, addresses, and URLs (uniform resource locators).

Appendix C provides a tabular overview of various voluntary credentialing programs available to pharmacists as of the last revision of this paper. Appendix D contains the educational outcomes, goals, and objectives for 18 postgraduate year two (PGY2) pharmacy residencies. Appendix E contains a list of the specialties recognized by the Board of Pharmacy Specialties (BPS). Finally, Appendix F provides information on CCP's framework for the education, training, and certification of pharmacy technicians.

A separate resource paper, titled "Scope of Contemporary Pharmacy Practice: Roles, Responsibilities, and Functions of Pharmacists and Pharmacy Technicians," was developed and published by CCP in 2009. This resource paper is available at http://www.pharmacycredentialing.org/ccp/Contemporary_Pharmacy_Practice.pdf.

Taken together, these two resource papers seek to provide the most current and comprehensive description of the interconnected topics of the contemporary scope of practice of the profession and the credentialing framework that supports the practice.

Essential Definitions

Discussions of credentialing are often complicated by a lack of common understanding of key terms and the contexts in which they are used. To clarify these misunderstandings, it is essential to distinguish between processes (e.g., credentialing) and titles (a credential). Distinctions must also be made between processes that focus on individuals (e.g., credentialing and certification) and those that focus on organizations, sites, or programs (accreditation). Finally, it is essential to understand that for practicing pharmacists, some credentials are required (e.g., an academic degree or a state license), whereas others are earned voluntarily (e.g., certification).

Beyond these distinctions, it is also necessary to understand the definitions

of the words that commonly occur in discussions of credentialing and to be able to distinguish the sometimes-subtle differences among them. A comprehensive glossary of such words and their definitions appears in Appendix A. The following definitions are provided because an understanding of these terms is a prerequisite to any meaningful discussion of credentialing in pharmacy.

- A **credential** is documented evidence of professional qualifications. Credentials include diplomas, licenses, certificates, and certifications. Credentials are reflected in a variety of abbreviations that individuals place after their names. For instance, Pharm.D. is used for doctor of pharmacy, which is an earned academic degree, and R.Ph. is for registered pharmacist, which indicates state licensure. Acronyms such as BCNSP are for Board-Certified Nutrition Support Pharmacist, which indicates that an individual has demonstrated advanced knowledge or skill in a specialized area of pharmacy, and CPhT indicates that a pharmacy technician has passed a national certification examination).
- **Credentialing** is (1) the process of granting a credential (a designation that indicates qualifications in a subject or an area) and (2) the process by which an organization or institution obtains, verifies, and assesses an individual's qualifications to provide patient care services. (See also Privileging.)
- **Accreditation** is the process by which an association, organization, or governmental agency grants public recognition to an organization,² site, or program that meets certain established qualifications or standards, as determined through initial and periodic evaluations.

² The term *organization* is used in a broad sense, and it includes, for example, institutions, corporations, universities, colleges, schools, and health systems.

- A **certificate** is a document issued to an individual after the successful completion of a predetermined level of performance of a certificate program or of a pharmacy residency or fellowship.
- A **statement of continuing education credit** is a document issued to an individual after the completion of a continuing education (CE) program provided by an organization accredited by the Accreditation Council for Pharmacy Education (ACPE).
- **Certification** is a voluntary process by which a nongovernmental agency or an association grants recognition to an individual who has met certain predetermined qualifications specified by that organization. This formal recognition is granted to designate to the public that the individual has attained the requisite level of knowledge, skill, and/or experience in a well-defined, often specialized, area of the total discipline. Certification usually requires initial assessment and periodic reassessments of the individual's knowledge, skill, and/or experience.
- **Privileging** is the process by which a health care organization, having reviewed an individual health care provider's credentials and performance and found them satisfactory, authorizes that individual to perform a specific scope of patient care services within that organization.

IMPORTANCE OF CREDENTIALS IN PHARMACY

"Credential" and "credentialing," like "creed" and "credence," derive from the Latin verb *credere*, which means "to trust," "to entrust," or "to believe." Credentials indicate that a pharmacist or pharmacy technician holds the qualifications needed to practice in the pharmacy profession and is therefore worthy of the trust of patients, other health care professionals, and society as a whole.

In the pharmacy profession, the interest in credentials has been catalyzed in recent years by several factors. First among them are the pace of change and the increasing complexity of health care. A second factor is the pharmacist's expanding patient-centered role. Interest in credentialing has likewise been stimulated by the growing trend toward specialization in pharmacy practice and the need to document the pharmacist's ability to provide specialty care. Another contributing factor has been the need to assure the public, employers, payers, other health providers, and other pharmacists that practitioners are competent no matter where they are in their careers or where they practice.

Finally, economic realities enter the picture. Pharmacists who provide cognitive services or specialized care should receive compensation for their services. Similarly, payers rightfully expect and deserve to receive validation that pharmacists are qualified to provide such services. Credentials, and in many cases, more specifically, certification, can help provide the documentation required by Medicare and Medicaid, managed care organizations, and other third-party payers of pharmacists today and in the future.

OVERVIEW OF CREDENTIALING IN PHARMACY – PHARMACISTS

Introduction

Pharmacist credentials may be divided into three fundamental categories.

- **College and university degrees** are awarded to mark the successful completion of a pharmacist's academic training and education.
- **Licensure** indicates that the pharmacist has met the minimum requirements established by the state in which he or she intends to practice.
- **Postgraduate degrees and certificates** are awarded to pharmacists

who have completed programs of various types (e.g., residencies) that are intended to develop and enhance their knowledge and skill or to those who have successfully documented a specialized level of knowledge and skill through an assessment process.

Figure 1 illustrates these three categories of pharmacist credentialing. The sections that follow provide information on each credential offered in pharmacy; the credentialing, certification, or accreditation body involved; whether the credential is mandatory or voluntary; and other related information.

Preparing for the Pharmacy Profession

- **Credential earned:** Doctor of pharmacy degree. Before June 2004, pharmacy graduates were eligible to sit for state licensing examinations with a bachelor's of science degree in pharmacy or a doctor of pharmacy degree from an accredited professional degree program. Since June 2004, only the doctor of pharmacy degree has been awarded by U.S. colleges and schools of pharmacy. A program leading to the doctor of pharmacy degree is the equivalent of 4 academic years and includes didactic, small group, laboratory, simulation, and experiential instruction. Admission to the doctoral-level program requires not less than 2 years of appropriate pre-professional, collegiate-level study, with some programs requiring a bachelor's of science degree.
- **Credential awarded by:** College or school of pharmacy
- **Accreditation body for professional programs in pharmacy:** ACPE (formerly the American Council on Pharmaceutical Education). The U.S. Department of Education has recognized the ACPE accreditation of the professional degree program in pharmacy. Until fall 2001, an individual who

wished to become a pharmacist could enroll in a program of study that would lead to one of two degrees: a bachelor's of science degree in pharmacy (B.S. Pharm. or Pharm. B.S.) or a doctor of pharmacy (Pharm.D.) degree.

Standards for the accreditation of programs leading to the Pharm.D. degree as the sole professional degree in pharmacy were adopted in July 1997 and were first effective in July 2000. Accreditation of baccalaureate degree programs in pharmacy ceased in June 2004. The most current accreditation standards for Pharm.D. programs became effective July 1, 2007. Accreditation standards for professional degree programs in pharmacy are revised on a regular basis, normally every 5-7 years.

Pharm.D. programs typically involve 4 academic years of doctoral-level study that follows appropriate collegiate-level, pre-professional study. A few programs offer the professional education over 3 calendar years of full-time education. Some colleges and schools of pharmacy admit students into a 6-year academic program that combines the pre-professional and professional elements of the Pharm.D. degree. The Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree may be found at <http://www.acpe-accredit.org/standards/standards1.asp>.

State boards of pharmacy require a Pharm.D. or B.S. degree from a program approved by the boards (usually an ACPE-accredited program) to satisfy the educational requirements for a candidate to be eligible to take the state licensing examination. A listing of accredited professional programs offered by colleges and schools of pharmacy is published by ACPE and is available on the ACPE Web site (www.acpe-accredit.org). Graduates with foreign pharmacy degrees may also be eligible for licensure as a pharmacist through the Foreign Pharmacy Graduate Examination Committee (FPGEC) certification

process of the National Association of Boards of Pharmacy (NABP). Full details of this process may be found on the NABP Web site, www.nabp.net.

Entering Practice and Updating Professional Knowledge and Skill

- Credentials earned: Licensure as an R.Ph.; re-licensure to continue practicing over time
- Credential awarded by: State board of pharmacy
- Licensure process overseen by: State regulatory authorities

Pharmacy, like medicine and the other health professions, is regulated at the state level by state boards of pharmacy. Candidates are licensed to practice after (1) graduating from a college or school of pharmacy approved by the board; (2) completing a minimum number of hours of experience in practice; and (3) passing licensing examinations.

Candidates for licensure in all states must pass the North American Pharmacist Licensure Examination (NAPLEX), a computer-adaptive, competency-based examination that assesses the candidate's ability to apply knowledge gained in pharmacy school to real-life practice situations. Most states also require candidates to take a state-specific pharmacy law examination. Currently, 46 jurisdictions employ the Multistate Pharmacy Jurisprudence Examination (MPJE), a computer-adaptive assessment that tailors each examination to address federal pharmacy law as well as the pharmacy law and regulations of the state in which the candidate is seeking licensure.

Both the NAPLEX and the MPJE are developed by NABP for use by the boards of pharmacy as part of their assessment of competence to practice pharmacy.³ Development of these

³ FPGEC also operates under the auspices of NABP. FPGEC oversees the development of the Foreign Pharmacy Graduate Equivalency Examination (FPGEE) and evaluates the

examinations is directly related to NABP's mission, which is to assist its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for protecting the public health. The NAPLEX and MPJE examinations are administered by appointment, daily, throughout the year at a system of test centers located in all 50 states.

In addition to the NAPLEX and MPJE, some states require a laboratory examination or an oral examination before licensure is conferred. All state boards also require that candidates complete an internship before being licensed. The internship may be completed during the candidate's academic training, after graduation, or as a combination process, depending on state requirements.

State licensure indicates that the individual has attained the basic (entry-to-practice) level of competence necessary to ensure that the public health and welfare will be reasonably well protected. Individuals who have received a license may use the abbreviation R.Ph. or other designation authorized by the board of pharmacy after their names.

All 50 state boards of pharmacy require that registered pharmacists complete a minimum number of hours or continuing education units (CEUs) as a condition for renewing their licenses. The hours or CEUs must be earned either through participating in a CE activity whose provider has been accredited by ACPE or through a program or activity that has been otherwise approved by the state board. The ACPE Accreditation Standards for Continuing Pharmacy Education may be found at <http://www.acpe-accredit.org/ceproviders/standards.asp>.

ACPE accredits *providers* of CE,

qualifications of foreign pharmacy graduates who apply for FPGEC certification. FPGEC certification is one of the prerequisites for foreign pharmacy graduates wishing to sit for NAPLEX and apply for licensure.

not individual CE activities. Hours or CEUs may be obtained by attending accredited or approved educational seminars, teleconferences, and meetings; reading journal articles; or completing traditional home study courses or computer-based educational activities. Achievement of a satisfactory score on an assessment that is created by and submitted to the CE provider is generally required as documentation that a CE activity has been completed. ACPE publishes a directory of accredited providers of continuing pharmacy education (CPE), available on the ACPE Web site (www.acpe-accredit.org).

Licensure and licensure renewal are mandatory for pharmacists who wish to continue practicing their profession. In their regulatory role, state boards of pharmacy are ultimately responsible to the administrative and legislative bodies of the state.

Developing and Enhancing Knowledge and Skill

Pharmacists who wish to broaden and deepen their knowledge and skill may participate in a variety of postgraduate education and training opportunities. They include the following.

- **Academic Postgraduate Education and Training Programs** – Pharmacists who wish to pursue a certain field of study in depth may enroll in a postgraduate master's or doctor of philosophy (Ph.D.) degree program. Common fields of study for master's degree candidates include pharmacy or business administration and public health. Common fields for Ph.D. degree studies include pharmacology, pharmaceuticals, pharmaceutical and medicinal chemistry, pharmacotherapeutics, pharmacy practice, and social and administrative sciences. For more information about graduate programs offered by U.S. colleges and schools of pharmacy, see <http://www.aacp.org/site/page.as>

p?VID=1&CID=71&DID=3078&TrackID.

Pharmacists holding bachelor's of science degrees in pharmacy who have been in the pharmacy workforce may also return to a college or school of pharmacy to earn the Pharm.D. degree. These programs, which are tailored to the individual's background and experience, may follow nontraditional pathways; however, they must produce the same educational outcomes as traditional Pharm.D. degree programs.

Residencies

- Credential earned: Residency certificate
- Credential awarded by: Residency training program
- Program accreditation: The American Society of Health-System Pharmacists (ASHP) (independently or in collaboration with other pharmacy organizations)

A postgraduate year one pharmacy residency (PGY1) training program is an organized, directed, accredited program that builds on the knowledge, skill, attitudes, and abilities gained from an accredited professional pharmacy degree program. The first-year residency program (PGY1) enhances general competencies in managing medication-use systems and supports optimal medication therapy outcomes for patients with a broad range of disease states. The PGY2 program follows a PGY1 pharmacy residency and increases the resident's depth of knowledge, skill, attitudes, and abilities to raise his or her level of expertise in medication therapy management and clinical leadership in a specialized area of focus. In practice areas where board certification exists, graduates are prepared to pursue such certification. Pharmacy residencies occur in a wide variety of settings and are usually 12 months in duration.

ASHP is the recognized accrediting body for residency programs in

pharmacy. The ASHP Commission on Credentialing (COC), which reports to the ASHP Board of Directors, is responsible for developing the standards for residency programs, administering the accreditation process, and making recommendations regarding the granting and continuation of accreditation. The COC consists of 18 appointed pharmacists who have served as residency program directors or preceptors and have represented a wide variety of practice settings, as well as two public members. ASHP has collaborated with several other pharmacy organizations to promote pharmacy residencies and to provide a wide variety of representation from the pharmacy community on the COC. Partner organizations include the Academy of Managed Care Pharmacy (AMCP), the American Pharmacists Association (APhA), the American College of Clinical Pharmacy (ACCP), and the American Association of Colleges of Pharmacy (AACP). Each of these organizations has a dedicated position on the COC.

Further information on accreditation standards for pharmacy residency training is available at <http://www.ashp.org/accreditation/>.

Most pharmacists who pursue residency training complete a PGY1 pharmacy residency. These residencies occur in a wide variety of settings such as hospitals, ambulatory care clinics, community/retail pharmacies, managed care organizations, home care, or long-term care organizations. However, all residents must meet six required outcomes of a PGY1 residency, and they are trained to be generalists in delivering patient-centered care and in providing pharmacy operations. Some of these residents will elect to continue their training and complete a PGY2 pharmacy residency in a specific area of focus (e.g., critical care, oncology, cardiology, pediatrics). Further information is provided in Appendix D.

The Centers for Medicare and

Medicaid Services (CMS), an agency of the federal government, recognizes ASHP in its role as the accrediting body for pharmacy residency training. Some ASHP-accredited residency programs may be eligible for pass-through funding from CMS as part of their cost accounting report for Medicare beneficiaries whose care is provided in hospitals (42 CFR 413.85 Hospital Inpatient Prospective Payment System Rules). The rules and regulations guiding this reimbursement policy are reviewed yearly by CMS and are subject to change.

• **Fellowships⁴**

- Credential earned: Fellowship certificate
- Credential awarded by: Fellowship training program
- Program accreditation: No accreditation body

A fellowship is a directed, highly individualized postgraduate program that prepares the participant to become an independent researcher in an area of pharmacy practice. Fellowship programs, like residencies, usually encompass 1–2 years. The programs are developed by colleges and schools of pharmacy, academic health centers, colleges and universities, and pharmaceutical manufacturers.

There is no accreditation body for fellowship programs; however, the ACCP Guidelines for Clinical Research Fellowship Training Programs provide a framework for peer review that

⁴ Several pharmacy organizations (e.g., AMCP, ACCP, APhA, ASHP) award the honorary title of “Fellow” to selected members as a means of publicly recognizing their contribution to the profession and/or their respective organizations. A “fellow of APhA,” for example, may use the letters “FAPhA” as a designation after his/her name and other credentials. The two differing uses of the word “fellow” – the one denoting an individual participating in a postgraduate research training program and the other denoting the receipt of an honorary title from an organization – should be understood and clearly distinguished.

fellowship programs may adopt voluntarily. The guidelines document is available at <http://www.accp.com/docs/positions/guidelines/pos15.pdf>.

• **Certificate Programs** (now officially referred to as practice-based CPE activities)

- Credential earned: Certificate of completion
- Credential awarded by: Educational institutions and companies, pharmacy organizations, and others
- Provider accreditation: ACPE

Under the supplementary accreditation standards in place from 1999 to 2008, ACPE defined a certificate program for pharmacists as a structured and systematic postgraduate CE experience that was smaller in magnitude and shorter in duration than degree programs. When ACPE implemented new accreditation standards for CPE in January 2009, the term *certificate program* was officially replaced with *practice-based CPE activities*, but providers were permitted to continue using the term for activities that met the criteria. In addition to didactic instruction, the design of certificate programs or practice-based CPE activities includes practice experiences, simulations, and/or other opportunities for demonstrating desired professional competencies. The length of any such activity is determined by its stated goals, desired professional competencies, and outcome measures, but it requires a minimum of 15 contact hours (1.5 CEUs). These activities are designed to instill, expand, or enhance practice competencies through the systematic acquisition of specified knowledge, skill, attitudes, and behaviors. Usually, they are relatively focused; for example, APhA offers programs in areas such as immunization delivery, medication therapy management, and the management of dyslipidemias, diabetes, and over-the-counter medications.

Practice-based CPE activities, often still referred to as certificate programs, are offered by national and state pharmacy organizations and by schools and colleges of pharmacy and other educational groups. These programs are often held in conjunction with the main educational meeting of an organization. ACPE accredits providers of such activities. The Accreditation Standards for Continuing Pharmacy Education are found at <http://www.acpe-accredit.org/ceproviders/standards.asp>.

• **Traineeships** – Traineeships, in contrast to certificate programs, are defined as intensive, individualized, structured postgraduate programs intended to equip the participant with the knowledge and skill needed to provide a high level of care to patients with various chronic diseases and conditions. Traineeships are generally of longer duration (about 5 days) and involve smaller groups of trainees than certificate programs. Some are offered on a competitive basis, with a corporate sponsor or other organization underwriting participants’ costs. Pharmacy organizations that offer traineeships include the American College of Apothecaries, the American Society of Consultant Pharmacists (ASCP), and ASHP’s Research and Education Foundation.

• **Certifications**

- Credential earned: Certification in area of practice
- Credential awarded by: BPS; Commission for Certification in Geriatric Pharmacy (CCGP)
- Provider accreditation: National Commission for Certifying Agencies (NCCA)

Certification is a credential granted to pharmacists and other health professionals who have demonstrated a level of competence in a specific and

relatively focused area of practice that exceeds the minimum requirements for licensure. Certification is granted on the basis of successful completion of rigorously developed eligibility criteria that include a written examination and, in some cases, an experiential component. Certification processes targeted exclusively to pharmacists are undertaken and overseen by BPS and CCGP.

The development of a certification program includes the following: (1) defining the area in which certification is offered (role delineation); (2) creating and administering a psychometrically valid examination; (3) identifying other criteria for awarding the credential (e.g., experience); and (4) identifying recertification criteria.

- *Role delineation.* First, define the area in which certification is to be offered. This is done through a process called role delineation or task analysis. An expert panel of individuals in the proposed subject area develops a survey instrument to assess how practitioners working in the area rate the importance, frequency, and criticality of specific activities in that practice. The instrument is then sent to a sample of pharmacists practicing in that field.
- *Development of content outline.* On the basis of responses to the survey, develop a content outline for the certification program.
- *Preparation of examination.* Develop the written examination component of the certification program on the basis of the content outline.
- *Other activities.* Take appropriate measures to ensure that the security and confidentiality of the testing process are maintained, that the examination and eligibility criteria are appropriate, and that the knowledge and skill of those who are certified do, in fact, reflect competence.

A professional testing company typically assists in developing both the role delineation and the examination to

ensure that the examination meets the professional standards of psychometric soundness and legal defensibility.

Certifying Agencies for Pharmacists Only—Two groups, BPS and CCGP, offer certification exclusively to pharmacists.

Board of Pharmacy Specialties (<http://www.bpsweb.org/>)—Established in 1976 by the APHA (then the American Pharmaceutical Association), the Board of Pharmacy Specialties (BPS) certifies pharmacists in six specialties: ambulatory care pharmacy, nuclear pharmacy, nutrition support pharmacy, oncology pharmacy, pharmacotherapy, and psychiatric pharmacy. Descriptions of each specialty area are provided in Appendix E. Pharmacists wishing to retain BPS certification must undergo recertification every 7 years. Since 2008, NCCA has accredited BPS specialty certification programs.

A new specialty is recognized by BPS after its review of a petition, usually submitted by one or more pharmacy organizations, which supports and justifies recognition of the specialty. This petition must meet criteria established by BPS. In making its decision, BPS obtains input from the profession and the public through a series of open hearings and other opportunities for comment.

An 11-member board that includes eight pharmacists, two health professionals who are not pharmacists, and one public/consumer member directs the work of BPS. A specialty council of six specialist members and three pharmacists not in the specialty directs the certification process for each specialty.

BPS examinations are administered with the assistance of an educational testing firm in a process that is psychometrically sound and legally defensible. Each of the six specialties has its own eligibility criteria, examination specifications, and recertification process. All six examinations occur on a single day once a year in about 50 sites worldwide.

In 1997, BPS introduced a method designed to recognize focused areas within recognized pharmacy specialties. A designation of “added qualifications” denotes that an individual has demonstrated an enhanced level of training and experience in one segment of a BPS-recognized specialty. Added qualifications are conferred on the basis of a portfolio review to qualified individuals who already hold BPS certification. Within the specialty of pharmacotherapy, infectious diseases and cardiology are the two areas of added qualifications approved by BPS.

Commission for Certification in Geriatric Pharmacy (<http://www.ccgp.org/>)

—In 1997, the ASCP Board of Directors voted to create CCGP (the Commission for Certification in Geriatric Pharmacy) to oversee a certification program in geriatric pharmacy practice. CCGP is a nonprofit corporation that is autonomous from ASCP. It has its own governing board of commissioners. The CCGP Board of Commissioners includes five pharmacist members, one physician member, one payer/employer member, one public/consumer member, and one liaison member from the ASCP Board of Directors.

To become certified, candidates are expected to be knowledgeable about the principles of geriatric pharmacotherapy and the provision of pharmaceutical care to the elderly. Pharmacists who meet CCGP’s requirements are entitled to use the designation Certified Geriatric Pharmacist, or CGP. Pharmacists who wish to retain their CGP credential must recertify every 5 years by successfully completing a written examination.

CCGP contracts with a professional testing firm to assist in conducting the role delineation or task analysis and in developing and administering the examination. The resulting process is psychometrically sound and legally defensible. CCGP is currently pursuing recognition of its examination and processes

by NCCA. The CGP certification examinations are administered twice a year at multiple locations in the United States, Canada, and Australia. CCGP publishes a candidate handbook that includes the content outline for the examination, eligibility criteria for taking the examination, and the policies and procedures of the certification program.

Multidisciplinary Certification Programs – An evolving array of certification programs is available to professionals from many health disciplines, including pharmacists. Areas in which such certification is available include diabetes education, anticoagulation therapy, pain management, lipid management, HIV/AIDS care, and asthma education. Some of these programs are in early stages of development.

Appendix C provides a listing of available pharmacist-specific and multidisciplinary certification programs available at the time of publication of this resource paper.

OVERVIEW OF CREDENTIALING IN PHARMACY – PHARMACY TECHNICIANS

A pharmacy technician assists in pharmacy activities that do not require the professional judgment of a pharmacist. For example, pharmacy technicians may accept prescription orders from patients, prepare labels, enter information in the pharmacy's computer system, and retrieve medications from inventory. The term *pharmacy technician* is used in a majority of states; however, other terms are also used to describe pharmacy support personnel carrying out functions similar to those previously described. As pharmacists assume a larger number of patient-centered roles, pharmacy technicians are increasingly responsible, under pharmacist supervision, for technical and distributive functions in pharmacies in all settings.

The exact functions and responsibilities of pharmacy technicians are defined by state laws and regulations and are also determined by the willingness of pharmacists to delegate the activities of their practice that do not require professional judgment. Pharmacy technicians always work under the supervision of a licensed pharmacist. The education and training, certification, and CE processes for pharmacy technicians are broadly similar in approach to those of pharmacists. There is, however, much wider variation among states in the regulation of and requirements for pharmacy technicians. There is also, at least presently, substantially less standardization in the education and training processes for pharmacy technicians than for pharmacists.

Education and Training

Most pharmacy technicians today have been trained on the job, either formally or informally. As the responsibilities of pharmacy technicians grow, however, more individuals are enrolling in formal training programs. These programs are generally affiliated with a vocational school, a community college, or a university, hospital, or another health care organization. Graduates of these programs may be awarded an associate's degree or a certificate of completion.

Not all states have education and training requirements for pharmacy technicians, but some states require board of pharmacy approval of the training program. ASHP is recognized within the pharmacy profession as offering programmatic accreditation of training programs for pharmacy technicians. Academic institutions that offer technician training programs are usually accredited by one or more institutional accreditors.

ASHP's Technician Training Programs Accreditation Regulations and Standards can be found at <http://www.ashp.org/technician/techregs.pdf>. Accreditation of technician training programs is voluntary in most states.

Regulation

State boards of pharmacy regulate the practice/work activities of pharmacy technicians. Regulatory approaches differ substantially among the states. Around 60% of states currently require registration or licensure of pharmacy technicians by the board of pharmacy. Virtually all state boards of pharmacy have amended their pharmacy practice acts and regulations in recent years, allowing an expanded role for pharmacy technicians in the delivery of pharmacy services. Further changes in the regulation of pharmacy technicians will inevitably occur as the practice of pharmacy continues to evolve.

Certification

• Pharmacy Technician Certification Board

The Pharmacy Technician Certification Board (PTCB) was established in 1995 as a national voluntary certification program for pharmacy technicians. It is governed by five organizations—APhA, ASHP, the Illinois Council of Health-System Pharmacists, the Michigan Pharmacists Association, and NABP.

In collaboration with testing experts, PTCB administers a national examination, the Pharmacy Technician Certification Examination (PTCE). The examination is designed to assess the candidate's knowledge and skill base for activities that are most commonly performed by a pharmacy technician, as determined by a national task analysis. Since 2006, the PTCB technician certification program has been accredited by NCCA.

PTCB administers the PTCE year-round Monday through Friday at Pearson Professional Centers nationwide. A technician who passes the PTCE is designated a Certified Pharmacy Technician (CPhT). To maintain PTCB certification, pharmacy technicians must recertify every 2 years. To

qualify for recertification, they must participate in at least 20 hours of approved pharmacy-related CE that includes 1 hour of pharmacy law. Information about PTCB and the PTCE is available at www.ptcb.org.

- **Institute for the Certification of Pharmacy Technicians**

In 2005, the Exam for the Certification of Pharmacy Technicians (ExCPT) was launched. This examination is offered in a computer-based format using on-demand testing at proctored test centers and is given more than 300 times a year at more than 550 locations across the country. The examination is designed to recognize pharmacy technicians who demonstrate proficiency in the knowledge and skill needed to assist pharmacists in safely, accurately, and efficiently preparing and dispensing prescriptions. The examination, which achieved NCCA accreditation in 2008, is based on a national job task analysis conducted on a regular basis, most recently in 2010. More information on the ExCPT examination is available at www.nationaltechexam.org.

A growing number of states require pharmacy technicians to be certified, and/or these states recognize certification in other ways in their regulations.

CCP has provided substantial leadership to the profession during the past 2 years with respect to technician education training, regulation, and certification. CCP's framework for consideration and use by organizations, regulatory bodies, and others appears in Appendix F of this document. It is also published separately on the CCP Web site at the following Web site:

http://www.pharmacycredentialing.org/ccp/Files/CCP%20technician%20framework_08-09.pdf.

CREDENTIALING - THE FUTURE

The pharmacy profession continues to evolve in response to changing patient needs and an increasingly complex health care system in the United States. This evolution creates opportunities for pharmacists to provide an expanded range of services within their defined and authorized scopes of practice. It is incumbent on the profession to assure the public, as well as employers, payers, other health professionals, regulatory agencies, and governmental agencies, that pharmacists and pharmacy technicians who provide specific services possess the knowledge, skill, attitudes, and values to safely and competently perform those services. Through an established and widely understood system of credentialing, including licensure to practice and recognition of skill evolved beyond general practice to specialty practice in defined areas, this assurance will be accomplished.

Figure 1: U.S. Pharmacy Credentials and Oversight Bodies^a

<u>Education</u>	<u>Entry into Practice</u>	<u>Practice</u>
Pharmacists		
<p>Doctor of pharmacy (Pharm.D.) degree (ACPE)</p>	<p>Licensure (R.Ph.) (state boards of pharmacy)</p>	<p>License renewal (state boards of pharmacy) State-specific criteria, including mandatory continuing education (ACPE)</p>
		<p>Postgraduate education (optional) Advanced degrees M.S., Ph.D. (colleges/schools of pharmacy) Postgraduate training (optional) PGY1 & PGY2 residency (ASHP) Traineeship (ASHP) Fellowship (ACCP, ASHP) Certificate programs (ACPE)^b Continuing education (ACPE)</p>
		<p>Certification (optional) Specialty (BPS) Non-specialty (CCGP) Multidisciplinary (various)</p>
Pharmacy technicians^c		
<p>Education/Training: Certificate of completion or associate's degree in some states (ASHP/state boards of pharmacy)</p>	<p>Registration/licensure in some states (boards of pharmacy)</p>	<p>Certification (PTCB, ICPT)</p>

^aOversight bodies are described in text.

^bEffective January 2008, certificate programs are referred to as practice-based CPE activities in ACPE standards.

^cState differences exist; refer to the main text.

Appendix A: Glossary⁵

Accreditation: The process whereby an association or agency grants public recognition to an organization, site, or program that meets certain established qualifications or standards, as determined through initial and periodic evaluations

Certificate: A certificate is a document issued upon successful completion of the predetermined level of performance of a certificate program or of a pharmacy residency or fellowship. (See also Statement of Continuing Education Credit.)

Certificate program: A structured, systematic education and CE experience that is generally smaller in magnitude and shorter in duration than a degree program. Certificate programs are designed to instill, expand, or enhance practice competencies through the systematic acquisition of specific knowledge, skill, attitudes, and performance behaviors. In ACPE accreditation standards, this term has been officially replaced with the term *practice-based CPE activities*; the former term, however, is still often used.

Certification: The voluntary process by which a nongovernmental agency or an association grants recognition to an individual who has met certain predetermined qualifications specified by that organization. This formal recognition is granted to designate to the public that this person has attained the requisite level of knowledge, skill, and/or experience in a well-defined, often specialized, area of the total discipline. Certification usually requires initial assessment and periodic reassessments of the individual's knowledge, skill, and/or experience.

Certified: Adjective used to describe an individual who holds certification that is incorporated into the name of the credential awarded that person. For example, someone who has earned BPS certification in oncology is a Board-Certified Oncology Pharmacist. A pharmacy technician who has passed a national certification examination is a CPhT.

⁵ These definitions have been collaboratively developed over several years by a variety of organizations involved in pharmacy credentialing and are generally accepted by those involved in both policy and operational management of the enterprise.

Clinical privileges: Authorization for a pharmacist to provide a specific range of patient care services (See Privileging.)

Competence: The ability of the individual to perform his/her duties accurately, make correct judgments, and interact appropriately with patients and colleagues. Professional competence is characterized by good problem-solving and decision-making abilities, a strong knowledge base, and the ability to apply knowledge and experience to diverse patient care situations.

Competency: A distinct knowledge, skill, attitude, or value that is essential to the practice of a profession. Individual competencies might include mastery of aseptic technique and achievement of a thought process that enable the person to identify therapeutic duplications. A pharmacist or pharmacy technician must master a variety of competencies to gain competence in his or her profession.

Continuing education: CE for the pharmacy profession is a structured educational activity designed or intended to support the continuing development of pharmacists and/or pharmacy technicians to maintain and enhance their competence. CPE should promote problem solving and critical thinking and be applicable to the practice of pharmacy.

Continuing professional development: The lifelong process of active participation in learning activities that assists individuals in developing and maintaining continuing competence, enhancing their professional practice, and supporting achievement of their career goals

Credential: Documented evidence of professional qualifications. Academic degrees, state licensure, residency certificates, and certification are all examples of credentials.

Credentialing: (1) The process of granting a credential (a designation that indicates qualifications in a subject or an area) and (2) the process by which an organization or institution obtains, verifies, and assesses an individual's qualifications to provide patient care services (See also Privileging.)

Fellowship: A directed, highly individualized postgraduate program designed to prepare a pharmacist to become an independent researcher

License: A credential issued by a state or federal body indicating that the holder is in compliance with the minimum mandatory governmental requirements necessary to practice in a particular profession or occupation

Licensure: The process of granting a license

Pharmacy technician: An individual who, under the supervision of a licensed pharmacist, assists in pharmacy activities not requiring the professional judgment of the pharmacist

Privileging: The process by which a health care organization, having reviewed an individual health care provider's credentials and performance and found them satisfactory, authorizes that person to perform a specific scope of patient care services within that organization

Registered: Adjective used to describe a pharmacist or pharmacy technician who has met state requirements for licensure and whose name has been entered on a state registry of practitioners who are licensed to practice in that jurisdiction

Residency: An organized and directed postgraduate training program in a defined area of pharmacy practice

PGY1 residency: The first year of postgraduate pharmacy residency training is an organized, directed, accredited program that builds on the knowledge, skill, attitudes, and abilities gained from an accredited professional pharmacy degree program. The first-year residency program enhances general competencies in managing medication-use systems and supports optimal medication therapy outcomes for patients with a broad range of disease states.

PGY2 residency: The second year of pharmacy residency training is an organized, directed, accredited program that builds on the competencies established in the PGY1 program. The second-year residency program is focused in a specific area of practice. The PGY2 program increases the resident's depth of knowledge, skill, attitudes, and abilities to raise the resident's level of expertise in medication therapy management and clinical leadership in the area of focus. In practice areas where board certification exists, graduates are prepared to pursue such certification.

Scope of practice: The boundaries within which a health professional may practice. The scope of practice is generally established by the board or agency that regulates the profession in a given state or organization.

Statement of CE credit: A document issued to an individual upon completion of a CE activity provided by an organization accredited by ACPE or a comparable organization

Traineeship: A short, intensive, clinical, and didactic postgraduate educational program intended to equip the pharmacist with the knowledge and skill needed to provide a high level of care to patients with specific diseases or conditions

Appendix B: Referenced Pharmacy Organizations and Certification Bodies

Pharmacy organizations

Academy of Managed Care Pharmacy (AMCP)
100 North Pitt Street, Suite 400
Alexandria, VA 22314
(800) 827-2627
www.amcp.org

Accreditation Council for Pharmacy Education (ACPE)

20 North Clark Street, Suite 2500
Chicago, IL 60602-5109
(312) 664-3575
www.acpe-accredit.org

American Association of Colleges of Pharmacy (AACP)

1727 King Street
Alexandria, VA 22314
(703) 739-2330
www.aacp.org

American College of Apothecaries (ACA)

P.O. Box 341266
Memphis, TN 38184
(901) 383-8119
www.acainfo.org

American College of Clinical Pharmacy (ACCP)

13000 West 87th Street Parkway, Suite 100
Lenexa, KS 66215-4530
(913) 492-3311
www.accp.com

American Pharmacists Association (APhA)

2215 Constitution Avenue NW
Washington, DC 20037-2985
(202) 628-4410
www.aphanet.org

American Society of Consultant Pharmacists (ASCP)

1321 Duke Street
Alexandria, VA 22314-3563
(703) 739-1300
www.ascp.com

American Society of Health-System Pharmacists (ASHP)

7272 Wisconsin Avenue
Bethesda, MD 20814
(301) 657-3000
www.ashp.org

National Alliance of State Pharmacy Associations (NASPA)

2530 Professional Road, Suite 202
Richmond, VA 23235
(804) 285-4431

National Association of Boards of Pharmacy (NABP)

700 Busse Highway
Park Ridge, IL 60068
(847) 698-6227
www.nabp.net

National Association of Chain Drug Stores (NACDS)

413 North Lee Street, P.O. Box 1417-D49
Alexandria, VA 22313-1480
(703) 549-3001
www.nacds.org

National Community Pharmacists Association (NCPA)

100 Daingerfield Road
Alexandria, VA 22314
(703) 683-8200
www.ncpanet.org

Pharmacy Compounding Accreditation Board

c/o 2215 Constitution Avenue NW
Washington, DC 20037-2985, and
P.O. Box 282
Algona, IA 50511
(515) 341-1250

Pharmacy Technician Educators Council (PTEC)

P.O. Box 10118
Santa Ana, CA 92711-0118
(202) 567-7832
www.rpxptec.org

Certification bodies for pharmacists or pharmacy technicians (May be multidisciplinary)

Anticoagulation Forum
88 East Newton Street, E-113
Boston, MA 02118-2395
(617) 638-7265
www.acforum.org

Board of Pharmacy Specialties (BPS)

2215 Constitution Avenue NW
Washington, DC 20037-2985
(202) 429-7591
www.bpsweb.org

Commission for Certification in Geriatric Pharmacy (CCGP)

1321 Duke Street
Alexandria, VA 22314-3563
(703) 535-3038
www.ccgpg.org

Institute for the Certification of Pharmacy Technicians (ICPT)

2536 South Old Highway 94, Suite 224
St. Charles, MO 63303
(314) 442-6775
www.icpt.org

National Asthma Educator Certification Board

American Lung Association
1740 Broadway
New York, NY 10019-4374
(212) 315-8865
www.lungusa.org

National Certification Board for Diabetes Educators (NCBDE)

330 East Algonquin Road, Suite 4
Arlington Heights, IL 60005
(847) 228-9795
www.ncbde.org

Pharmacy Technician Certification Board (PTCB)

2215 Constitution Avenue NW
Washington, DC 20037
(202) 429-7576
www.ptcb.org

Appendix C: Credentialing Programs for Pharmacists

CERTIFICATION PROGRAMS AVAILABLE TO PHARMACISTS^{1,2}

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

Notes:

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

Appendix D: PGY2 Pharmacy Residencies

ASHP has developed educational outcomes, goals, and objectives for the following areas of PGY2 training:

- Ambulatory Care Pharmacy (PGY2)
- Cardiology Pharmacy (PGY2)
- Critical Care Pharmacy (PGY2)
- Drug Information (PGY2)
- Geriatric Pharmacy (PGY2)
- Health-System Pharmacy Administration (PGY2)
- Infectious Diseases Pharmacy (PGY2)
- Internal Medicine Pharmacy (PGY2)
- Medication-Use Safety (PGY2)
- Nuclear Medicine Pharmacy (PGY2)
- Nutrition Support Pharmacy (PGY2)
- Oncology Pharmacy (PGY2)
- Pain Management and Palliative Care (PGY2)
- Pediatric Pharmacy (PGY2)
- Pharmacotherapy Informatics (PGY2)
- Psychiatric Pharmacy (PGY2)
- Pharmacy Residency Training in an Advanced Area of Practice (PGY2)
- Solid-Organ Transplant Pharmacy (PGY2)

Appendix E: Specialties Recognized by BPS

I. Ambulatory care pharmacy practice is the provision of integrated, accessible health care services by pharmacists who are accountable for addressing medication needs, developing sustained partnerships with patients, and practicing in the context of family and community. The ambulatory care pharmacist accomplishes these services through direct patient care and medication management for ambulatory patients, long-term relationships, coordination of care, patient advocacy, wellness and health promotion, triage and referral, and patient education.

Domains of the BPS Ambulatory Care Pharmacy specialty examination include:

Domain 1: Direct Patient Care (50% of the examination)

Domain 2: Practice Management (20% of the examination)

Domain 3: Public Health (5% of the examination)

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

Domain 5: Patient Advocacy (10% of the examination)

II. Nuclear pharmacy seeks to improve and promote the public health through the safe and effective use of radioactive drugs for diagnosis and therapy. A nuclear pharmacist, as a member of the nuclear medicine team, specializes in procurement, compounding, quality assurance, dispensing, distribution, and monitoring of radiopharmaceutical drugs. In addition, the nuclear pharmacist monitors patient outcomes and provides information and consultation regarding health and safety issues, as well as the use of non-radioactive drugs and patient care.

Domains of the BPS Nuclear Pharmacy specialty examination include:

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

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

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

III. Nutrition support pharmacy addresses the care of patients who receive specialized nutrition support, including parenteral and enteral nutrition. The nutrition

support pharmacist is responsible for promoting the maintenance and/or restoration of optimal nutritional status, designing and modifying treatment according to the needs of the patient. This specialist in nutrition support pharmacy is responsible for direct patient care and often functions as a member of a multidisciplinary nutrition support team.

Domains of the BPS Nutrition Support Pharmacy specialty examination include:

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

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

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

IV. Oncology pharmacy specialists recommend, design, implement, monitor, and modify pharmacotherapeutic plans to optimize outcomes in patients with malignant diseases. The oncology pharmacist specialist recommends, designs, implements, monitors, and modifies pharmacotherapeutic plans to optimize outcomes in patients with malignant diseases.

Domains of the BPS Oncology Pharmacy specialty examination include:

Domain 1: Clinical Skill and Therapeutic Management (60% of the examination)

Domain 2: Generation, Interpretation, and Dissemination of Information (20% of the examination)

Domain 3: Guidelines, Policies, and Standards (15% of the examination)

Domain 4: Public Health and Advocacy (5% of the examination)

V. Pharmacotherapy is the pharmacy specialty responsible for ensuring the safe, appropriate, and economical use of drugs in patient care. The pharmacotherapy specialist is responsible for direct patient care, often functions as a member of a multidisciplinary treatment team, may conduct clinical research, and is often a primary source of drug information for other health care professionals.

Domains of the BPS Pharmacotherapy specialty examination include:

Domain 1: Patient-Specific Pharmacotherapy (55% of the examination)

Domain 2: Retrieval, Generation, Interpretation, and Dissemination of Knowledge in Pharmacotherapy (30% of the examination)

Domain 3: Health System-Related Pharmacotherapy (15% of the examination)

The term *added qualifications* is used by BPS to denote the demonstration of an enhanced level of training and experience and to document further differentiation of practitioners within specialties that BPS has already recognized. BPS's creation of this process in 1997 was in response to requests from several segments of the profession in view of the growing complexity of the profession and the needs of health care systems. As of June 2010, two areas of Added Qualifications had received approval within the Pharmacotherapy specialty: **Cardiology and Infectious Diseases**.

VI. Psychiatric pharmacy addresses the pharmaceutical care of patients with psychiatric disorders. As a member of a multidisciplinary treatment team, the psychiatric pharmacist specialist is often responsible for optimizing drug treatment and patient care by conducting patient assessments, recommending appropriate treatment plans, monitoring patient response, and recognizing drug-induced problems.

Domains of the BPS Psychiatric Pharmacy specialty examination include:

Domain 1: Clinical Skill and Therapeutic Management (65% of the examination)

Domain 2: Education and Dissemination of Information (25% of the examination)

Domain 3: Clinical Administration (10% of the examination)

Appendix F: CCP Pharmacy Technician Credentialing Framework

The following elements comprise the CCP framework for the education, training, certification, and regulation of pharmacy technicians.

See http://www.pharmacycredentialing.org/ccp/Files/CCP%20technician%20framework_08-09.pdf for the complete resource paper.

1. One valid national task analysis of entry-level pharmacy technicians in all pharmacy work settings will be used as the foundation for technician education, training, examination, and certification. This task analysis should be performed with the input and participation of all interested stakeholders in accordance with nationally accepted standards, and it should be administered and revised on a regular basis to ensure that its content reflects contemporary practice.
2. Educational outcomes and competencies based on the task analysis will be established for use in the education, training, examination, and certification of pharmacy technicians.
3. A model curriculum for the education and training of entry-level pharmacy technicians will be developed and adopted based on the outcomes and competencies identified from the national task analysis. The educational preparation will include both didactic and experiential components.
4. A national programmatic accreditation system will evaluate pharmacy technician education and training programs against the nationally established standards.
5. State boards of pharmacy will regulate pharmacy technicians and require them to complete a nationally accredited education and training program and pass a competency-based examination that is psychometrically sound, nationally accredited, and based on the task analysis.
6. State boards of pharmacy will develop a "pharmacy technician in training" category.
7. State boards of pharmacy will require pharmacy technicians to maintain their competency through ongoing and approved education, training, and development.
8. State boards of pharmacy will develop a method of reciprocity between states for pharmacy technicians.

**COUNCIL ON CREDENTIALING IN PHARMACY
GUIDING PRINCIPLES FOR ACCREDITATION OF ORGANIZATIONS, SITES
OR PROGRAMS IN PHARMACY**

The provision of leadership, guidance, public information and coordination regarding the development and application of accreditation standards for the pharmacy profession are integral components of the Council on Credentialing in Pharmacy (CCP) vision and mission statements. The *CCP Guiding Principles for Accreditation of Organizations, Sites or Programs in Pharmacy* are intended as guidelines for the development or assessment of new and established accrediting organizations (or systems of accreditation) serving organizations¹, sites or programs in pharmacy.

The Guiding Principles are based upon The Association of Specialized and Professional Accreditors (ASPA) "Member Code of Good Practice" (adopted March 21, 1995). This document is a companion piece to CCP's *Guiding Principles for Certification of Individuals in Pharmacy*.

The following definition is used in this guideline and is adapted from the **CCP Resource Paper "Credentialing in Pharmacy"**: *

Accreditation: is the process by which a private association, organization or government agency, after initial and periodic evaluations, grants recognition to an organization, site or program that has met certain established criteria.

Accreditation is to be differentiated from "certification" which is a voluntary process by which a non-governmental agency or an association grants recognition to an *individual* who has met certain predetermined qualifications specified by that organization.

* *CCP documents are posted at www.pharmacycredentialing.org.*

An accrediting organization serving organizations, sites or programs in pharmacy should adhere to the following guiding principles:

- 1. Pursues its mission, goals, and objectives, and conducts its operations in a trustworthy manner.**
 - Focuses primarily on educational, training or operational quality (as applicable), not narrow interests, or political action, or educational trends.
 - Demonstrates respect for the complex interrelationships involved in the pursuit of excellence by individual organizations, sites or programs.
 - Exhibits a system of checks and balances in its standards development and accreditation procedures. Includes input from a broad range of stakeholders.

¹ The term "organization" is used in a broad sense and includes, for example, institutions, corporations, universities, colleges, schools, and health-systems.

Council on Credentialing in Pharmacy: Guiding Principles for Accreditation of Organizations, Sites or Programs in Pharmacy (January 2006)

- Avoids relationships and practices that would provoke questions about its overall objectivity and integrity.
- Analyzes criticism carefully and responds appropriately by explaining its policies and actions and/or making changes.

2. Maximizes service, productivity, and effectiveness in the accreditation relationship.

- Recognizes that teaching, training, learning, operations, or systems - not accredited status - are the primary purposes of organizations, sites or programs.
- Respects the expertise and aspirations for high achievement already present and functioning in organizations, sites or programs.
- Uses its understanding of teaching, learning, operations, or systems and the presence of local expertise and aspirations as a basis for effective and accurate evaluation at individual organizations, sites or programs.
- Keeps the accreditation process as efficient and cost-effective as possible by minimizing the use of visits and reports, and by eliminating, whenever possible, duplication of effort between accreditation and other review processes.
- Works cooperatively with other accrediting bodies and or regulatory bodies to avoid conflicting standards, and to minimize duplication of effort in the preparation of accreditation materials and the conduct of on-site visits.
- Provides the organization, site or program with a thoughtful diagnostic analysis that assists the organization, site or program in finding its own approaches and solutions, and that makes a clear distinction between what is required for accreditation and what is recommended for improvement.

3. Respects and protects organizational, site or program autonomy.

- Works with issues of organizational, site, or program autonomy in light of the commitment to mutual accountability implied by participation in accreditation, while at the same time, respecting the diversity of effective organizational, site or programmatic approaches to common goals, issues, challenges, and opportunities.
- Applies its standards and procedures with profound respect for the rights and responsibilities of organizations, sites or programs to identify, designate, and control, where applicable: (a) their respective missions, goals, and objectives; (b) educational, operational or philosophical principles and methodologies used to pursue functions implicit in their various missions, goals, and objectives; (c) specific choices and approaches to content, policies, and procedures; (d) agendas and areas of study pursued through scholarship, research, and policy development; and (e) specific personnel choices, staffing configurations, administrative structures, and other operational decisions.
- With respect to organizations, sites and programs, recognizes the ultimate authority of each community for its own policies while maintaining fundamental standards and fostering consideration of evolving needs and conditions in the profession and the communities it serves.

4. Maintains a broad perspective as the basis for wise decision making.

- Gathers and analyzes information and ideas from multiple sources and viewpoints concerning issues important to organizations, sites, programs, professions, publics, governments, and others concerned with the content, scope, and effectiveness of its work.
- Uses the results of these analyses in formulating policies and procedures that promote effective teaching, learning, systems or operations that protect the autonomy of organizations, sites and programs, and that encourage trust and cooperation within and among various components of the larger community.

5. Focuses accreditation reviews on the development of knowledge and competence.

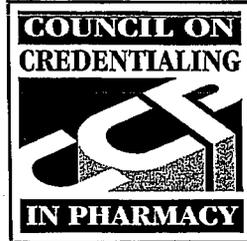
- Concentrates on results in light of specific organizational, site or programmatic missions, goals, objectives.
- Deals comprehensively with relationships and interdependence among purposes, aspirations, curricula, goals and objectives, operations, resources, and results.
- Considers techniques, methods, and resources primarily in light of results achieved and functions fulfilled rather than the reverse.
- Has standards and review procedures that provide room for responsible experimentation and encourage innovation.

6. Exhibits integrity and professionalism in the conduct of its operation.

- Creates and documents its scope of authority, policies, and procedures to ensure fair and consistent governance, decision making and implementation.
- Exercises professional judgment in the context of its published standards and procedures.
- Demonstrates continuing care with policies, procedures, and operations regarding due process, conflict of interest, confidentiality, and consistent application of standards.
- Presents its materials and conducts its business with accuracy, skill, and sophistication sufficient to produce credibility for its role as an evaluator of quality.
- Is quick to admit errors in any part of the evaluation process, and equally quick to rectify such errors.
- Maintains sufficient financial, personnel, and other resources to carry out its operations effectively.
- Provides accurate, clear, and timely information to the education community, the professions, and the public concerning standards and procedures for accreditation, and the status of accredited organizations, sites or programs.
- Corrects inaccurate information about itself or its actions.

7. Has mechanisms to ensure that expertise and experience in the application of its standards, procedures, and values are present in members of its visiting teams, commissions, and staff.

- Maintains a thorough and effective orientation, training, and professional development program for all persons involved in the accreditation processes, appropriate to their roles and responsibilities.
- Works with organizations, sites or programs to ensure that site teams represent a collection of expertise and experience appropriate for each specific review.
- Conducts evaluations of members of its visiting teams, commissions, and staff that involve responses from organizations, sites or programs that have experienced the accreditation process.
- Conducts evaluations of criteria and procedures that include responses from reviewers and those reviewed.



CREREDENTIALING AND PRIVILEGING OF PHARMACISTS

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Council on Credentialing in Pharmacy
Washington, DC
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Executive Summary

Processes for the credentialing and privileging of health professionals are of increasing importance and value to the U.S. health care system and to society. As efforts continue to provide, and reward, more efficient, affordable, and higher quality health care (the “triple aim” <http://content.healthaffairs.org/content/27/3/759.full>), the ability to assure the capabilities and competence of the health professionals, including pharmacists, who practice within an increasingly complex and sophisticated system has become both more relevant and essential.

Currently, all U.S.-educated pharmacists attain a fundamental set of credentials to qualify to enter practice – an accredited professional pharmacy degree and a license awarded upon successful completion of a national, post-graduation examination administered by the National Association of State Boards of Pharmacy on behalf of state boards of pharmacy. This process provides an established framework to assure the ability of pharmacists to provide care and services that reflect sound, entry-level practice. However, evolving patient care and health system needs and demands have heightened the requisite skills needed by pharmacists to deliver more complex services. Ongoing professional development and competency assessment are integral parts of health professionals’ expectations to maintain a contemporary practice. This resource guide on the credentialing and privileging of pharmacists has been developed to supplement the Council on Credentialing in Pharmacy’s* **Guiding Principles for Post-licensure Credentialing of Pharmacists** (February 2011) and to assist those who are introducing or enhancing a credentialing and privileging system for pharmacists within their health care

*The Council on Credentialing in Pharmacy (CCP) provides leadership, guidance, public information, and coordination for the profession of pharmacy’s credentialing programs. CCP’s vision is that all credentialing programs in pharmacy will meet established standards of quality and contribute to improvement in patient care and the overall public health. As part of its core purpose, CCP provides resources to enhance both the profession’s and public’s understanding of these issues with respect to the pharmacy profession. CCP maintains a resource library of documents that provide information about the key elements of accreditation, certification, credentialing and privileging, including the language and taxonomy commonly used in these processes. In-depth discussion about these core concepts is found in previously published CCP papers at <http://www.pharmacvcredentialing.org/> as well as the reference listing in this guide.

settings. CCP does not provide the guide for use as a standard of practice, nor intends to represent the content as best or expected practices

Purpose of Credentialing and Privileging

The purpose of a "credentialing process" is to document and demonstrate that the health care professional being evaluated has attained the credentials and qualifications to provide the scope of care expected for patient care services in a particular setting. The purpose of a "privileging process" is to assure that the health care professional being considered for certain privileges has the specific competencies and experience for specific services that the organization provides and/or supports. Credentialing and privileging have distinct purposes but are closely related processes that may overlap or occur in a coordinated fashion (Galt, 2004a; Galt, 2004b). Credentialing and privileging are tailored to the complexity of services being provided at the setting.

Credentialing and privileging processes are also designed to foster and facilitate on-going quality improvement in individual performance using periodic peer review as a method of evidence-based evaluation. It is typical for peer experts to establish competencies at the local level for specific patient care services for which privileges are granted. Peer experts are also used to establish the performance review standards for these services and to continually update and maintain the current standards of performance for the specific services the credentials represent.

In addition to their professional degree program and licensure, many pharmacists attain further specific skills and expertise to provide patient care services through post-licensure education, residency training, and certification processes. It is in the context of this framework of such post-professional development that the processes of credentialing and privileging have increasing relevance and value.

Credentialing

What is a credential? A credential is documented evidence of professional qualifications. Academic degrees, state licensure, residency certificates, and board certifications are all examples of credentials. Credentials are most commonly earned within a professional domain, e.g., the license to practice a profession. Credentials are also earned by professionals with differing backgrounds who have attained focused expertise in a particular disease or knowledge domain. Examples include Certified Diabetes Educator, Certified Asthma Educator, or Certified Professional in Electronic Health Records. CCP has compiled a list of certification programs offered to pharmacists; see <http://www.pharmacycredentialing.org/Files/CertificationPrograms.pdf>

What is credentialing? Credentialing refers to one of two processes. The first is the process of granting a credential - a designation that indicates qualifications in a subject or area. Examples of this would be granting a practitioner the license to practice or granting board certification. The second is the process by which an organization or institution obtains, verifies, and assesses an individual's qualifications to provide patient care services. This may be as straight forward as verifying professional licensure; or it may be more complex, such as assessing the clinical experience and preparation for specialty practice beyond the assurances of professional licensure within a local organization, such as a hospital, community clinic, or home care service. The processes for credentialing vary by institution and organization.

Guiding Principles for Post-Licensure Credentialing of Pharmacists

CCP has identified eight guiding principles for post-licensure credentialing of pharmacists. The full statement is entitled, *CCP Guiding Principles for Post-licensure Credentialing of Pharmacists February 2011*, and is located at <http://www.pharmacycredentialing.org>. A summary of the principles is:

1. Licensure of pharmacists should assure entry-level knowledge, skills, attitudes, and values for the provision of services and information regarding medications and their proper use to a wide variety of patients. Post-licensure credentials for pharmacists should build on this foundation.
2. Credentialing programs should be established through a profession-wide, consensus-building process. Credentials should be based on demonstrated patient/societal need.
3. Within the pharmacy profession, there should be active coordination of and alignment between professional education, postgraduate education and training, and credentialing programs.
4. All credentialing (credential-granting) programs should be accredited. Certification programs must be psychometrically sound, legally defensible, and should be accredited.
5. All postgraduate education, training and credentialing programs should include assessments that measure the attainment of the required level of competence.
6. Through stakeholder education, credentials should enable pharmacists to obtain specific patient care privileges. Credentials should not create barriers to the provision of any services pharmacists provide to their patients.
7. Pharmacists should be expected to participate in credentialing and privileging processes to ensure they have attained and maintain needed competency.
8. Employers and payers should be encouraged to adopt and implement their own credentialing and privileging processes for pharmacists to determine and authorize the patient care responsibilities.

How Individuals are Credentialed

Health care organizations such as hospitals and health plans, as well as corporate and individual pharmacy operations, commonly have in place internal credentialing processes. Credentialing may occur through a department within an organization specifically tasked with this process, such as human resources; or it may occur at the time of hiring and documentation of performance review. No matter the model, the organization confirms the individual professional's information and makes an independent credentialing decision about each individual for the organization. Individuals who satisfy the credentialing requirements for employment are eligible then for hire or for specific job responsibilities. An overview of the basic credentialing process steps that could apply in any organization is shown in figure 1, adapted from *The Credentialing Handbook* (Deutsch & Mobley, 1999). Credentialing is not a one-off event at the time of hiring. As indicated, the steps apply to the initial as well as the recredentialing process.

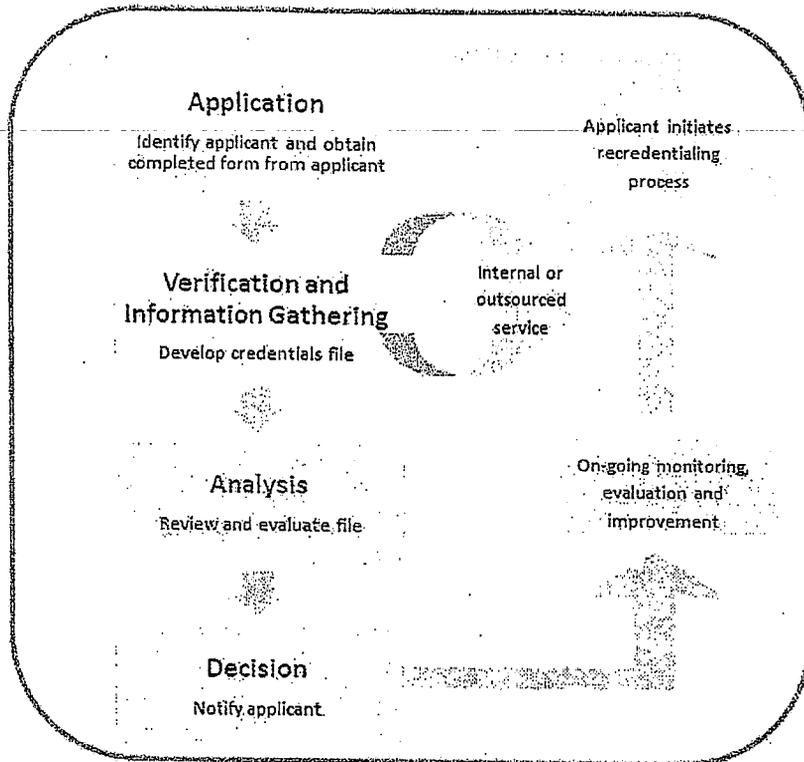


Figure 1. The Basic Credentialing Process Followed by Organizations

Application The credentialing process is commonly initiated using an application checklist. The individual pharmacist applies for employment or subsequently for recertification. The typical contents of the initial application for pharmacist employment might include:

- A completed application with all questions answered
- Proof of professional liability coverage, if required for the position
- Signed release allowing organization to verify credentials
- Signed and dated application attestation
- Education and work history

Professionals administering credentialing programs have recognized that allied health disciplines such as pharmacy generally practice in a dependent manner, within a scope of practice that can be described in a job description. A common tool used by multiprofessional organizations in allied health credentialing is to define the core competencies and skills and create a competency and skills assessment checklist. These checklists should be completed and retained by the organization (Gassiot, 2011; Searcy, 2011; Giles, 2011).

Verification The pharmacist's application is reviewed by human resources and/or a credentialing department and the primary sources of documentation of credentials are verified. Primary source verification is documentation from the original source of a specific credential that verifies the accuracy of a qualification reported by an individual health care practitioner. This can be documented in the form of a letter, documented telephone contact, or secure electronic communication with the original source. Information that is verified may include: licensure from licensing boards; professional liability coverage (if required); all levels of education/training/certification as applicable to the provider or facility type; investigating any disciplinary actions by state licensing boards. Some organizations will conduct this review themselves and some will outsource the verification process to experts who complete this process on behalf of the organization. In any case, this information is compiled and a credentialing file is established for each individual pharmacist who applies.

Analysis and Decision Once the credentialing file is complete, a process to review and evaluate the information occurs. Some organizations have created multidisciplinary committees to review and authorize the credentials of health professionals who are not physicians. A decision is made as to the candidate's success in meeting the minimum requirements for the credentials to become a member of the credentialed staff. This may serve to meet requirements for eligibility for hire or recredentialing. The pharmacist is notified of the decision.

Periodic Reappraisal Credentials are reappraised at specified intervals determined by the organization, and guided by various standards, i.e., accreditation, regulations, or laws. Performance monitoring and evaluation occur as an on-going activity throughout the practitioner's employment; however, a formal reappraisal is part of the quality improvement process and occurs commonly every two years in many organizations.

Individuals' rights during the credentialing process In general, applicants will have the right to review information gathered during the application process, ask about the status while in process, and correct any information that is not accurate. If there are major discrepancies between an individual's application and information obtained for verification from other sources, an opportunity should be provided to the individual to explain the discrepancy. Some processes include an appeal process if an unfavorable decision about credentialing is made from the organization. It is not lawful for information from the National Practitioner Data Bank or information that is considered to be peer-review protected to be released back to the individual during the credentialing process.

Assuring continuing competence Individual pharmacists and employers have a stake in assuring continuing competence. The individual pharmacist must be aware of the need for continuing professional development and must assume personal responsibility for currency of knowledge and skills. Pharmacists must be willing to have their practice and performance reviewed and evaluated by their peers. The employer carries out the requirements of accrediting bodies to assure the ongoing competencies of employees. The practice setting can influence the level of competencies that need to be maintained.

PRIVILEGING

What is a privilege? A privilege in this context is permission or authorization granted by a hospital or other health care institution to a health professional (e.g., physician, pharmacist, nurse practitioner) to render specific diagnostic, procedural, or therapeutic services. Privileges are often of different types, such as admitting privileges, which give the professional rights to admit patients, or clinical privileges, which give the professional the right to treat. Privileging examples for pharmacists include pharmacokinetic dosing in hospitals and monitoring and adjusting anticoagulants.

What is privileging? Privileging is the process by which a health care organization, having reviewed an individual health care provider's credentials and performance and found them satisfactory, authorizes that individual to perform a specific scope of patient care services within that organization.¹ Authority is granted based upon establishing that the person has demonstrated competence to provide these services, the services are within the scope of provision of the organization, and the organization can support their delivery.² Clinical privileges are both facility-specific and individual-specific. Privileging is usually a local process involving review of an individual professional's credentials and performance.

How Individuals are Granted and Retain Privileges

Initial Privileges The individual initiates privilege requests. Organizations provide an application to be completed. The applicant includes a request for the specific clinical privileges desired and establishes possession of the competencies to justify the clinical privileges request. The applicant's request for clinical privileges is reviewed. An established committee of peers or collaborators (often referred to as the Credentials Review or Privileging Committee) or an expert in the privileging area requested will typically perform the review. Upon completion of this assessment, the recommendation is forwarded as approval, disapproval, or a modification of the requested clinical privileges and the rationale for the conclusions provided. It is common that recommendations identify a time period of direct supervision by an appropriately-privileged practitioner when a practitioner has had a lapse in clinical activity, or for those procedures that are high risk as defined by the local organization policy. Clinical privileges are based on evidence of an individual's current competence, as well as relevant experience and credentials.

Reappraisal of Privileges Reappraisal is the process of evaluating the professional credentials, clinical competence, and health status (as it relates to the ability to perform the requested clinical privileges) of practitioners who hold clinical privileges within the facility or organization. Most processes include policies and procedures for reappraisal of privileges. These relate to the scheduled renewal, a change in privileges requested by the applicant, or denial, failure to renew, reduction, and revocation of clinical privileges. The process is based upon professional competence, professional misconduct, or substandard care, and is generally applied to all health care professionals who hold privileges. The process used for reappraisal is similar to the initial process used to grant privileges. Organization

¹ Scope of practice: The boundaries in which a health care provider may practice. For pharmacists, the scope of practice has traditionally been established by the board or agency that regulates the profession within a given state or organization.

² Competence: The ability to perform one's duties accurately, make correct judgments, and interact appropriately with patients and colleagues. Professional competence is characterized by good problem-solving and decision making abilities, a strong knowledge base, and the ability to apply knowledge and experience to diverse patient care situations

mission and clinical techniques change over time; therefore it is expected that clinical privileges also will change in response. Similarly, practitioners may not maintain practice or gain the experiences needed to assure competency. In these contexts, practitioners may need to submit a request for modification of clinical privileges.

Privileged Individuals' Obligations Individuals must take personal responsibility for determining if the activity or service to be rendered to patients is within their individual scope of practice. As pharmacists gain experience with participating in the privileging process, these decisions must be made explicitly and personally before rendering these services. Individuals must accept the organization's rules, regulations and bylaws and the noted professional obligations and responsibilities. Individuals are expected to be proactive about informing the organization whenever anything is going to affect or limit their ability to uphold the privileges. Individuals are expected to maintain records, e.g., in a personal professional development portfolio, to support documentation for a credentialing file (Goudreau, 2008).

Issues of Liability There are some issues of liability associated with these processes. The organization that employs professionals exposes itself to confidentiality issues, vicarious liability, potential violations of due process and negligence. However, these issues also exist through the normal employment process. Overall, the dual processes of credentialing and privileging should reduce risk rather than contribute to it (Youngberg, 1996).

Designing Pharmacy Credentialing and Privileging Processes

Who develops credentialing and privileging criteria? Expert technical knowledge makes the profession itself best suited to both design and drive the credentialing and privileging processes, locally and regionally within employment settings, or nationally. This means that pharmacist leadership at the local, regional and national levels is required to advance the adoption and oversight of the credentialing and privileging processes for all stakeholders. The direct involvement and leadership of the professions responsible for their own delivery of services is an established approach to controlling and maintaining credentialing and privileging, when combined with a strong peer review and performance review system. Pharmacists should cooperate, collaborate and integrate with existing processes, defining the quality of standards and competencies that credentialing and privileging processes will require of pharmacists. Where no processes exist, pharmacists should lead their development. There are some services that are provided by several professions. In these cases, pharmacists will need to meet established credentialing and privileging standards and processes.

Who manages the credentialing and privileging processes? Alignment of the credentialing and privileging processes should occur between those processes relevant to the professionals' scope and responsibilities of practice and the larger setting in which practice occurs. As such, pharmacist leaders should take the initiative to align their scope of responsibilities and services with the larger practice setting. Usually, a specific department is responsible for the credentialing and privileging process of an organization or institution. These departments are involved in basic human resources activities, as well as, organizing the assimilation and verification of credentials. It is typical for this department, or in some cases departments, to be overseen by a medical staff, quality assurance, or human resources office in larger health systems and organizations or corporations.

What is accreditation and how does it relate to credentialing and privileging? Accreditation is a process whereby a professional association or nongovernmental agency grants recognition to a school,

organization or health care institution for demonstrated ability to meet predetermined standards, such as: the accreditation of professional degree programs and providers of continuing education by the Accreditation Council for Pharmacy Education (ACPE), residency programs by the American Society of Health-System Pharmacists (ASHP), and hospitals by The Joint Commission. Professionals' credentials to offer advanced or specific services are earned through a certification process, e.g., an educational program that has been accredited. There are several accrediting bodies depending on the focus of the program. A major accrediting body for many health care certification programs is the National Commission for Certifying Agencies.³ Certain accreditation processes of health care facilities provide standards for credentialing/privileging processes.

What are considerations when pharmacists are added to existing credentialing and privileging processes? A process will often need to be designed or modified to accommodate inclusion of pharmacists for credentialing and privileging. The previous section provides an overview of the general processes to be considered when designing a new process for pharmacists or modifying an existing process that can be applied to pharmacists. Some of the factors to consider that are important for pharmacists are pointed out here. At the local level, both individual pharmacists and employers should address these factors.

- ***Accredited education and training*** – Pharmacy degree programs and continuing education providers are accredited by the Accreditation Council for Pharmacy Education (www.acpe-accredit.org). Residency training programs are accredited by the American Society for Health-System Pharmacists (<http://www.ashp.org/menu/Accreditation/ResidencyAccreditation.aspx>).
- ***Employment setting*** – The setting affects how the credentialing and privileging processes work. While a large organization may have a dedicated department, a small pharmacy may prefer a contract service if the processes cannot be managed “in house” by available staff.
- ***Model of practice*** – Models of practice help define the structure and the scope of services individual pharmacists will provide.
- ***Scope of services*** – Scope of services allowable through the pharmacist’s employment site (following state laws and regulations) is a determinant of the actual patient services a pharmacist is allowed to provide under the employment arrangement.
- ***Role of peer review and process alignment*** – Peer review is the accepted approach in the health care industry for the establishment of performance competencies. When feasible, peer review should be incorporated into the process of establishing credentialing standards and assessing performance in the competency areas required for specific privileges, as well as in the reappraisal process. Pharmacists should be considered members of peer review panels when pharmacists are eligible for performance competency evaluation for credentialing and privileging.
- ***On-going assessment and renewal*** – An on-going mechanism for revising competencies expected, assessment of these competencies amongst those who have received privileges and subsequent renewal needs to be a core part of the credentialing and privileging program.
- ***Relevant Rules and Regulations of the State*** – External factors such as rules, regulations and statutes within each state or credential-granting body may have relevance to the process developed or adopted (McKnight, 2009).

³ The National Commission for Certifying Agencies (NCCA) was created in 1987 by the Institute for Credentialing Excellence (ICE) 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.

Examples of Pharmacist Credentialing and/or Privileging Programs

Selected examples of pharmacist credentialing and privileging processes that have been described in the literature are summarized below. They describe various settings, roles, scopes of practice, and methods of implementation. As these examples suggest, there are a range of acceptable processes that may be used to assure quality and competence in patient care delivery by pharmacists. While this listing is not exhaustive, it provides an overview of the various ways credentialing and privileging of pharmacists can be addressed. CCP does not provide the examples as a standard of practice, nor intends to represent them as best or expected practices.

Example of reorganization of clinical hospital pharmacists positions to be governed by the medical staff and associated program for credentialing

It is proposed that hospitals use the well-defined process for credentialing and evaluating health care providers that currently exists internally under the by-laws for medical staff members. A change in organizational structure to support clinical pharmacy services as a division of the medical staff would offer hospital several benefits.

Merrigan, D. (2002). Internal approach to competency-based credentialing for hospital clinical pharmacists. *American Journal of Health-System Pharmacy*, 59(6), 552-558.

Example of community pharmacists trained and privileged as immunizers and skin testers in a grocery store setting through continuing education

A grocery store pharmacy implemented a 9 hour continuing education course and training to prepare their pharmacists to immunize patients with the complete hepatitis B vaccination series, demonstrate proper purified protein derivative (PPD) administration and interpretation, and be current in cardiopulmonary resuscitation.

Hecox, N. (2008). Tuberculin skin testing by pharmacists in a grocery store setting. *Journal of the American Pharmacists Association*. 48:86-61.

Example of internally developed process for credentialing advanced practice critical care pharmacists

A multi-source evaluation was proposed, using portfolio, specialty-base assessment and multiple source peer review. Each candidate was considered individually by the credentialing panel using this evidence and mapped against the Advanced and Consultant Level Framework (ACLF; <http://www.codeg.org/fileadmin/codeg/pdf/ACLF.pdf>) and the Critical Care Curriculum Framework (CCF; <http://www.aacn.nche.edu/cn/curricfrmwrk.pdf>).

McKenzie, C., & Borthwick, M. (2011). Developing a process for credentialing advanced level practice in the pharmacy profession using a multi-source evaluation tool. *The Pharmaceutical Journal*, 286, 1-5.

Example of credentialing pharmacists as certified diabetes educators or advanced diabetes managers – an area where other professions are credentialed

Pharmacists who wish to become a certified diabetes educator (CDE) must have at least 1000 hours of experience in a diabetes educator role over a 2 year period of time and pass a comprehensive exam.

Pharmacists are also eligible for the Advanced Diabetes Management (BC-ADM) credential through the American Nurses Credentialing Center.

Haines, S. (2003). Diabetes education and management: Credentialing and reimbursement issues. *ASHP Midyear Clinical Meeting*, 38 (abstract).

Example for credentialing and privileging of ambulatory care pharmacists

The objective of this project was to design and implement a credentialing model for three ambulatory specialty pharmacy services within the Metro region of Aurora Health Care. The credentialing process for nursing and medical staff and for pharmacists and other institutions was reviewed and adapted to fit the department's needs. By creating a credentialing and privileging model similar to models used in the medical and nursing professions, the profession of pharmacy has the potential to gain credibility in the interdisciplinary setting.

Claxton, K. L., & Wojtal, P. (2006). Design and implementation of a credentialing and privileging model for ambulatory care pharmacists. *American Journal of Health-System Pharmacy*, 63(17), 1627-1632.

Examples for voluntary privileging of hospital pharmacists

Privileging is the method by which a healthcare organization authorizes a practitioner to perform a scope of patient care services according to the facility's standard of care. To better recognize pharmacists as providers within the organization, document clinical competencies, and be consistent with other healthcare providers, a voluntary pharmacist privileging program was created and implemented at a university medical center.

Fortier, C., Blair, M., & Mazur, J. (2006). Implementing a pharmacist privileging process at a university medical center. *ASHP Midyear Clinical Meeting*, 41(abstract).

A community teaching hospital established a process to assure five clinical pharmacists maintained shared competencies in a 7 day a week, on call, weekend and holiday coverage therapeutics consultation service. Shared competencies governed through collaborative agreements were established and privileged in the areas of nutrition, pain management, palliative care, pharmacokinetics and inpatient anticoagulation.

Grimone, A.J., Pascale, P. (2007). Implementation of a privileging program for clinical pharmacists in a community teaching hospital. *ASHP Midyear Clinical Meeting*, 42 (abstract).

Examples of privileging and credentialing programs for pharmacists in various settings

This article answers the basic questions that pharmacists may have about the privileging and credentialing processes and explains the purposes, terminology, rationale, and processes of clinical privileging. The differences between privileging and credentialing are explained, and background information about the privileging of other health professions is also provided. Four different case descriptions of pharmacist privileging and credentialing programs are provided.

Galt, K. A. (2004). Credentialing and privileging for pharmacists. *American Journal of Health-System Pharmacy*, 61(7), 661-670.

Additional Resources

Resource documents already available from CCP's website www.pharmacycredentialing.org include:

- List of Certification Programs for Pharmacists (October 2012)
- Guiding Principles for Post-Licensure Credentialing of Pharmacists (Feb 2011)
- Credentialing in Pharmacy (Nov 2010)
- Pharmacy Technician Credentialing Framework (Aug 2009)
- Scope of Contemporary Pharmacy Practice (Feb 2009)
- Guiding Principles for Accreditation of Organizations, Sites or Programs in Pharmacy (Jan 2006)
- Guiding Principles for Certification of Individuals in Pharmacy (Jan 2006)
- Continuing Professional Development in Pharmacy: Resource Document (2004)
- Continuing Professional Development in Pharmacy (2004)⁴
- Continuing Professional Development in Pharmacy Commentary (2004)⁵
- White Paper on Pharmacy Technicians: Needed Changes Can No Longer Wait (2002)

Other resource documents to assist in developing or participating in the credentialing and privileging process are shown below. Several of these provide examples of standards, applications, forms and guidelines for use in credentialing and privileging:

- Joint Commission Resources (2010). *Credentialing and Privileging Your Medical Staff – Examples for Improving Compliance*, 2nd ed. Oakbrook Terrace, Illinois. May be purchased at: <http://www.jcrinc.com/>.
- Department of Veterans Affairs VHA Handbook, Washington, DC 20420. Accessible through <http://www.va.gov/vhapublications>.
- Roberts, A. (2013). *The Essential Guide to Medical Staff Reappointment*, 2nd Ed., HCPro, Inc.; Marblehead, Massachusetts.
- Deutsch, S. & Mobley, C.S. (1999). *The Credentialing Handbook*. Jones and Bartlett Learning; Burlington, Massachusetts.
- Gassiot, C.A., Searcy, V.L., & Giles, C.W. (2011). *The Medical Staff Services Handbook Fundamentals and Beyond*. Jones and Bartlett Publishers, Sudbury Massachusetts.
- Watkins, A.E. (2005). *Negligent Credentialing Lawsuits: Strategies to Protect your Organization*. HCPro, Inc.; Marblehead, Massachusetts.
- Youngberg, B.J. (1996). *Managing the Risks of Managed Care*. Aspen Publishers, Inc.; Gaithersburg, Maryland.
- Blair, M.M., Carmichael, J., Young, E., & Thrasher, K. (2007). Pharmacist privileging in a health system: Report of the qualified provider model ad hoc committee. *American Journal of Health-System Pharmacy*, 64(22), 2373-2381.

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⁴ Originally published in *Am J Health-Syst Pharm*. 2004; 61 :2069-76. ©2004, American Society of Health-System Pharmacists, Inc. All rights reserved. Reprinted with permission.

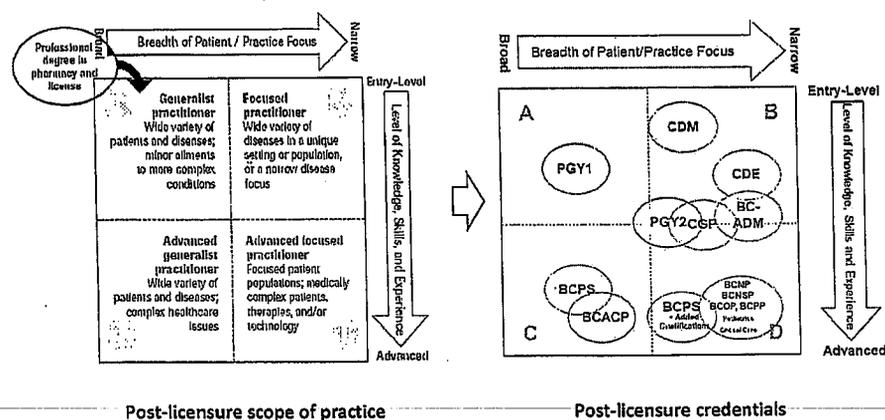
⁵ Originally published in *J Am Pharm Assoc*. 2004; 44:517–520. ©2004, American Pharmacists Association (APhA). Reprinted by permission of APhA.

Appendix A

CREDENTIALING AND PRIVILEGING ARE WAYS TO ASSURE PHARMACISTS' COMPETENCY TO PROVIDE SERVICES

Post-licensure education, training and certification are ways that pharmacists establish their competence to provide patient care services within a defined scope. Pharmacists enter pharmacy practice with a professional degree in pharmacy and a license. Beyond this entry point, pharmacists may gain education and training to retain and enhance generalist competencies, but add a focus area, or attain advanced practice competencies as a generalist or focused expert.

The document entitled, *Scope of Contemporary Pharmacy Practice: Roles, Responsibilities, and Functions of Pharmacists and Pharmacy Technicians - A Resource Paper of the Council on Credentialing in Pharmacy*, has provided a model framework to guide pharmacists and other stakeholders about the forms of education, training and certification that pharmacists are presently engaged in to establish competence in direct patient care services provision.⁶ Figure 2 displays how the education, training and certification components of this framework relate to how pharmacists' scopes of practice exist. This model organizes pharmacists' scopes of practice into four possible quadrants (A through D).



LEGEND: PGY1 = Post Graduate Year One (Residency), PGY2 = Post Graduate Year Two (Residency), BCACP = Board Certified Ambulatory Care Pharmacist, BCADM = Board Certified-Advanced Diabetes Management, BCNP = Board Certified Nuclear Pharmacist, BCNSP = Board Certified Nutrition Support Pharmacist, BCOP = Board Certified Oncology Pharmacist, BCPP = Board Certified Psychiatric Pharmacist, BCPS = Board Certified Pharmacotherapy Specialist, CDE = Certified Diabetes Educator, CDM = Certified Disease Manager, CGP = Certified Geriatric Pharmacist

Figure 2. How post-licensure scope of practice for pharmacists relates to education, training and post-licensure credentials

⁶ *Scope of Contemporary Pharmacy Practice: Roles, Responsibilities, and Functions of Pharmacists and Pharmacy Technicians - A Resource Paper of the Council on Credentialing in Pharmacy*. Approved for distribution by CCP Board of Directors on February 25, 2009, ©2009, Council on Credentialing in Pharmacy.

Post licensure education and training provide the necessary skills and knowledge to perform specific services within defined scopes of practice. The range of post-licensure education and training activities pharmacists engage in to maintain their professional competencies and to support their continuing professional development include: (1) continuing education (CE) activities which, in the majority of cases, are offered by ACPE-accredited providers of continuing pharmacy education, (2) certificate programs, which focus on the development of professional skills and their application in practice, and (3) traineeships. Post-Graduate Year One (PGY1) pharmacy residencies provide training for generalists in hospitals, health systems, managed care, or community settings, and Post-Graduate Year Two (PGY2) residencies, provide advanced training in a focused area of patient care. Residencies are typically one to two years in length and a PGY1 residency must be completed before going on to a PGY2 residency. Guidance on how to assess skill equivalency of pharmacists to a PGY1 pharmacy residency program has been published (American College of Clinical Pharmacy, 2009).

Post-licensure certification is another form of credential for several areas for pharmacists who have advanced generalist and/or advanced focused areas of practice. Pharmacists may obtain one or more of the certifications shown in Figure 2. These certifications are intended to assure that the pharmacist desiring to have a scope of practice at the advanced level has the competencies mastered to provide care services safely and effectively. In many settings, criteria are set to define the equivalency in work experience and performance skills to recognize a pharmacist as competent to perform advanced focused areas of practice who has not completed a formal certification in an area.

Post-licensure credentials provide evidence for the credentialing process. These forms of post-licensure credentials provide some of the evidence needed for credentialing of pharmacists for purposes of practicing as a paid employee of an organization, or in some situations to receive payment or compensation for service provision. Pharmacists either *may* obtain or *must* obtain specific credentials, dependent upon the circumstances the pharmacist is in. For example, pharmacists may desire to have effective and comprehensive skills in providing asthma education services to patients. While a pharmacist could provide these patient care services as part of the scope of practice recognized through being licensed and therefore not required to obtain the credential, the pharmacist could also choose to obtain a credential through completion of the requirements to become a Certified Asthma Educator (AEC). Doing so provides the pharmacist with a nationally recognized credential that may give patients and other stakeholders increased confidence in the quality of the pharmacist's services. In another example, a pharmacist may seek employment to provide direct patient care as a specialist in oncology services in a specialty oncology hospital. The employer may require that the pharmacist hold the credential of Board Certified Oncology Specialist in order to be employable in this role (American College of Clinical Pharmacy, 2011). The employer may have a credentialing process that requires the pharmacist to produce evidence of this credential to be eligible for employment. Further, the employer may also have a privileging process once the pharmacist is hired, that requires the pharmacist to produce evidence of competency for specific tasks the pharmacist is to perform in direct patient care. Tasks such as prescribing specific therapies per protocol in supportive care for oncology patients, or demonstrating specific physical assessment skills required to assess the patient's health status, may be examples of this. A detailed resource document describing different certification programs that pharmacists are eligible to participate in is available through CCP to assist pharmacists and other stakeholders to consider some of the options for attaining education and training that result in a credential.⁷

⁷ <http://www.pharmacycredentialing.org/ccp/Files/CertificationPrograms-comprehensivelist08-10Final.pdf>

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Comment [EW1]: Revise reference list based on content changes; decision on current Appendix A, etc.

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National Commission for Certifying Agencies

Standards for the Accreditation of Certification Programs



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Preamble

INTRODUCTION

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

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

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

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

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

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

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

STRUCTURE AND DEVELOPMENT OF THE STANDARDS

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

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

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

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

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

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

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

Standards

PURPOSE, GOVERNANCE, and RESOURCES

Standard 1

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

Essential Element:

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

Commentary:

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

Standard 2

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

Essential Elements:

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

Commentary:

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

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

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

Standard 3

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

Essential Elements:

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

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

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

Commentary:

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

The public member should not be:

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

The public member should not have:

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

Standard 4

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

Essential Element:

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

Commentary:

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

Standard 5

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

Essential Elements:

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

Commentary:

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

RESPONSIBILITIES to STAKEHOLDERS

Standard 6

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

Essential Elements:

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

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

Commentary:

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

Standard 7

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

Essential Element:

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

Commentary:

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

Standard 8

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

Essential Elements:

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

Commentary:

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

Standard 9

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

Essential Element:

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

Commentary:

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

ASSESSMENT INSTRUMENTS

Standard 10

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

Essential Elements:

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

Commentary:

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

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

Standard 11

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

Essential Elements:

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

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

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

Commentary:

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

Standard 12

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

Essential Elements:

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

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

Commentary:

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

Standard 13

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

Essential Elements:

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

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

Commentary:

- A. Certification programs are responsible for establishing quality control procedures that regularly monitor the precision of calculations used to compute assessment scores and their conversion to standardized, equated, or scaled scores, if performed.
- B. The certification program should publish an explanation of the appropriate uses and misuses of reported score information.
- C. Suggested evidence to document that the Standard has been met may include descriptions of scoring procedures, training documents, quality control procedures, and sample score reports for passing and failing candidates.
- D. Evidence in support of essential element D should include documentation of aggregate assessment data to the various stakeholder groups on interest. For example, details of the aggregate assessment data might be 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

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

Essential Element:

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

Commentary:

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

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

Standard 15

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

Essential Elements:

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

Commentary:

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

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

- G. Certification programs should, whenever possible, conduct pilot studies prior to implementation of the adapted version of the assessment instruments. Field study research should be part of a program of ongoing maintenance and improvement. Tryout and field studies should be part of a larger research program to ensure comparability and quality of cross-cultural information on the assessment instruments.
- H. Suggested evidence to document that the Standard has been met may include:
- A description of the methods used to determine that different forms of an assessment instrument measure equivalent content and ensure that candidates are not disadvantaged for taking a form of the assessment instrument that varies in difficulty from another form
 - An equating and scaling report

Standard 16

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

Essential Element:

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

Commentary:

- A. Non-standardized administration procedures may adversely influence scores as well as the inferences drawn from these scores. When administration procedures deviate from the expected, such irregularities must be thoroughly documented.
- B. Chief examiners and proctors should be thoroughly trained in proper administration of the assessment instruments in an effort to minimize the influence of test administration on scores. Similarly, all candidates should have equal access to preparatory materials and instructions available from the sponsor.
- C. Certification programs are responsible for protecting the integrity of assessment information. This responsibility requires a security program that restricts access to assessment information to authorized personnel.
- D. Administration sites should offer similar conditions, such as adequate lighting, comfortable seating, and an environment free from noise and other distraction.
- E. Suggested evidence to document that the Standard has been met may include:
- Candidate handbook or similar document
 - Chief examiner and/or proctor manual
 - Quality control policy and procedures documents
 - Security procedures manual

Standard 17

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

Essential Element:

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

Commentary:

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

Standard 18

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

Essential Element:

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

Commentary:

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

RECERTIFICATION

Standard 19

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

Essential Elements:

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

Commentary:

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

Standard 20

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

Essential Element:

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

Commentary:

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

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

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

MAINTAINING ACCREDITATION

Standard 21

The certification program must demonstrate continued compliance to maintain accreditation.

Essential Elements:

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

Glossary

Accommodation—

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

Accountability—

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

Accreditation—

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

Administrative Independence—

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

Applicant—

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

Assessment Instruments—

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

Autonomy—

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

Bias—

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

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

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

Candidate—

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

Certificant—

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

Certification—

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

Certification Agency—

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

Certification Board—

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

Certification Committee—

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

Certification Program—

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

Commentary—

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

Content Domains—

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

Consumer—

See also "Public Member"

Continuing Competence—

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

Continuing Education—

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

Cut Score—

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

Discipline—

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

Eligibility Requirements—

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

Equating—

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

Essential Element—

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

Fairness—

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

Grandfathering—

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

Governing Committee—

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

Incorporation Status—

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

Item—

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

Item Bank—

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

Item Type or Format—

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

Job/Practice Analysis/Role Delineation Study—

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

Parent Organization—

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

Performance Domains—

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

Public Member—

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

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

Publish—

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

Recertification—

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

Reliability—

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

Role—

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

Self-Assessment—

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

Stakeholders—

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

Standard—

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

Standardization—

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

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

Technical Report—

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

Undue influence—

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

Validity—

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

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Roy Swift, Ph.D., OTR, FAOTA, Swift Consulting

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

Ted Twardowski, Safety and Occupational Health, OSHA - US Department of Labor

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

Project Manager, Larue D. Coats, Ph.D., Coats Knudsen & Associates

Task Force on Purpose, Governance, Resources

Chair, Nadine Davis, MA, Liaison Council on Certification for the Surgical Technologist

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

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

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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

Task Force on Responsibilities to Stakeholders

Chair, Valarie French, National Board for Professional Teaching Standards

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

Dennis Whitney, CMA, CFM, Institute of Certified Management Accountants

Task Force on Assessment Instruments

Chair, Roy Swift, PhD. OTR, FAOTA, Swift Consulting

Rose Mary Ammons, Ed.D., Professional Development Technologies Incorporated

William C. Anderson, PE, DEE, Council of Engineering and Scientific Specialty Boards

John Ford, Ph.D., Personnel Resources and Development Center, US Office of Personnel Management

Steven Halsey, Halsey, Rains, and Associates

William G. Harris, Ph.D., Association of Test Publishers

Stephen Koffler, Ed.D., The Chauncey Group International

I. Leon Smith, Ph.D., Professional Examination Service

Task Force on Recertification

Chair, Steve Permison, MD, Division of Quality Assurance, Bureau of Health Professions, US Department of Health and Human Services

James Hogan, Ph.D., Carl Vinson Institute of Government, The University of Georgia

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

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