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

Report of the Senate Bill 493 Implementation Committee Meeting held June 4, 2014

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

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

Meeting Minutes are provided as **Attachment 8** at the back of the committee report. Slide presentations made during the meeting and handouts are provided at the back of the minutes.

1. FOR INFORMATION: <u>Overview of SB 493 (Hernandez, Chapter 469, Statutes of 2013)</u>

Attachment 1

A summary of the major provisions in SB 493 is provided below (greater detail is provided in the meeting minutes):

SB 493 creates:

1. <u>For all licensed pharmacists</u>:

- Adds a determination that the Legislature declares pharmacists are health care providers who have the authority to provide health care services (section 4050)
- Allows a pharmacist to administer drugs and biological products that have been ordered by a prescriber (*section 4052)*
- 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 (section 4052.8)

Pharmacists that do such immunizations need to be certified to perform these functions.

- Pharmacists may furnish prescription medications not requiring a diagnosis recommended by the CDC for individuals traveling outside the US (travel medications)
  (CA B&P section 4052)
- Once a protocol is developed by the Board of Pharmacy and Medical Board of California:
  a. Allows a pharmacist to furnish nicotine replacement products in accordance with the state treatment protocol
     (*sections 4052 and 4052.9)*
  b. Pharmacists may furnish self-administered hormonal contraceptives in accordance with a state protocol developed by the Board and the Medical Board of California pursuant to the guidelines of the CDC.
     (CA B&P Section 4052, 4052.3)

2. <u>For pharmacists who become specially licensed as advanced practice pharmacists:</u>
   - Creates a new and additional license category of advanced practice pharmacist who may practice advanced practice pharmacy within or outside a pharmacy (section *4016.5)*
   - Allows an APP to possess controlled substances *(CA B&P 4060)*
   - Allows an APP to:
     - Perform patient assessments
     - Order and interpret drug therapy related tests
     - Refer patients to other health care providers
     - Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers
     - Initiate, adjust or discontinue drug therapy; must provide notification back to diagnosing prescriber or enter information into a patient record, shared with the prescriber
       (section 4052.6)
   - Requirements to become an APP:
     - Hold an active CA pharmacist license – in good standing
     - File an application with the board & pay fee ($300 max)
     - License will be good for 2 years linked to pharmacist license renewal
     - An additional 10 units of CE are required each renewal cycle in an area of practice relevant to the pharmacist's clinical practice
       (sections 4210, 4233)
   - Qualifications: possess 2 of the 3 below:
     a. Earn certification in a relevant area of practice (ambulatory care, critical care, geriatric, nuclear, nutrition support, oncology, pediatric, pharmacotherapy, psychiatric practice recognized by ACPE or another entity recognized by the board)

b. Complete postgraduate residency in accredited postgraduate institution where 50 percent of experience includes direct patient care 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, APP, a pharmacist practicing collaborative drug therapy management, or health system *CA B&P 4210*

For reference, provided in **Attachment 1** is a copy of SB 493 (Hernandez, Chapter 469, Statutes of 2013).

2. FOR DISCUSSION: <u>Use of "Advanced Practice Pharmacists" in Other States</u>

Attachment 2

The board is aware that at least three states have some experience with a version of advanced practice pharmacists in their states. These are New Mexico, North Carolina and Montana. General information about the scope of services authorized to these pharmacists is provided in **Attachment 2** and was a topic of discussion at the meeting. This attachment also contains some of the registration requirements for the program in each state.

The committee reviewed the materials. President Weisser noted that the programs in other states rely heavily on the oversight of the Medical Board, while in California, SB 493 gives the Board of Pharmacy far more autonomy. President Weisser stated that this autonomy illustrates how important it is for the committee to implement a program that meets the high standards that are envisioned in the legislation

<u>In New Mexico</u>
The Pharmacist Prescriptive Authority Act (Sections 61-11B-1 through 61-11B-3 NMSA 1978) allows pharmacists, registered with the NM Board of Pharmacy, the authority to administer, prescribe and monitor certain drugs when working under the supervision of a supervising physician registered with the NM Board of Medical Examiners. It is the supervising physician that needs to be specially registered.

The board received extensive information about a pharmacist clinical services program at the University of New Mexico Health Sciences Center, which is also available in the attachment.

<u>In North Carolina</u>
A Clinical Pharmacist Practitioner (CPP) is a licensed pharmacist approved to provide drug therapy management, including controlled substances, under the direction of, or under the supervision of a licensed physician. Only a pharmacist approved by the NC Pharmacy Board and the NC Medical Board may legally identify himself/herself as a CPP.

In Montana

A "Clinical Pharmacist Practitioner" is required to have five years of clinical practice experience or have completed a pharmacy residency and two years clinical practice experience and hold one of the following active certifications:

1. Board of Pharmacy Specialties certification
2. Nationally recognized certification in an area of practice approve by the MT Pharmacy Board and MT Board of Medical Examiners

Plus:

- Submission of a signed collaborative practice agreement.
- Must notify the board within 10 days of discontinuance of work under an approved collaborative drug therapy agreement.

During the committee meeting, there was little discussion about these programs and their relevance to California's requirements.

3. FOR DISCUSSION: Identification of Services Where Board Guidance is Envisioned

Attachment 3

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) Initiate and Administer Immunizations Pursuant to Recommended Immunization Schedules by the Federal Advisory Committee of Immunization Practices

(b) Prescription Medications not Requiring a Diagnosis that are Recommended by the CDC for Travel Outside the US

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

President Weisser noted that in the interest of patient safety, the board may wish to develop guidance or fact sheets to ensure all pharmacists who provide such services are fully aware of the requirements.

During inspections, the board will monitor to ensure those pharmacists who provide these services are appropriately qualified to do so.

During the meeting, the committee heard a number of comments on these services. The minutes detail the discussions held during the meeting. Below are items for research and future discussion based on comments made during the June 4, 2014 meeting.

1. Some of the APP qualification methods seem to overlap, particularly in regards to becoming certified in a certain area of practice and completing a certain number of

experience hours to becoming certified. Can an applicant use the same qualifying experience to qualify for licensure?

2. Can a year of residency also be counted towards a year of direct patient care experience? One attendee encouraged the board to look at how North Carolina interpreted this requirement.

3. The category of "travel medications" is very broad. The CDC's website has extensive materials regarding recommended medications travelers may need sorted by country. **Attachment 3** contains information from the CDC on travel medications. Does the legislation apply 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? Could a pharmacist write a prescription for a patient to have such a prescription filled in another pharmacy?

   Several attendees suggested that because furnishing travel medications is something that all pharmacists can now do (not just those with an APP license), the committee may want to consider creating extra protocols in this area. There was concern expressed that a protocol may help protect pharmacists from employers who would force pharmacists to provide these services even if beyond their knowledge, training and expertise. It was emphasized several times that anytime a pharmacist is asked to do something that is beyond the pharmacist's training or knowledge; it is the pharmacist's professional obligation to refuse. Acknowledgement was made that in some cases a pharmacist may need to find another employer. Dr. Gutierrez noted that this is a difficult position for pharmacists to be in if they want to keep their job. Ms. Veale commented that large chain pharmacies will likely be hesitant to force this type of service without proper training and protocols as they can face lawsuits if a patient is harmed.

4. Many pharmacists in California, particularly those in acute care settings, already perform many of the duties authorized in SB 493. The committee was asked if those pharmacists will now have to become licensed as APPs in order to keep performing the duties they have done for years. Ms. Herold responded that SB 493 did not change any of the existing provisions and that pharmacists can continue to work under these provisions without becoming licensed as APPs.

5. Senate Bill 493 was created to alleviate overburdened health care professionals (doctors and nurse practitioners). For example, a patient does not need to be diagnosed by a doctor to receive travel medications for a trip to Africa or to use nicotine cessation products to quit smoking.

   Are travel injections covered under the travel medication provisions? It was noted that as 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. The board will have its attorneys review this issue for guidance to the board.
Dr. Jeff Goad, Chapman University, reported that only around 5 percent of the traveling population sees a healthcare professional before traveling. 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. Dr. Goad noted that a board-produced protocol could be difficult to maintain relevancy because with travel medications, things can change overnight based on outbreaks and protocols would take time to modify. Training and education are recommended for pharmacists who provide travel medicine, given that there are requirements for smoking cessation and oral contraception, but not for travel medication. The CDC's recommendations for medication for international travelers are contained in a book commonly known as "the yellow-book." The yellow-book was identified as a good reference for pharmacists to determine what medications are recommended for international travel. The book is updated annually, but the CDC sends out notices of outbreak information so that practitioners can make adjustments based on current international situations.

There is a program for training pharmacists on travel medications through APHA.

5. Dr. Kathleen Hill-Besinque, from USC and CPHA, stated that she looked up the definition of "furnish" in the law book and it does not say that it must be a medication that the pharmacist has on a pharmacy's shelf. The definition says "by any means" so a pharmacist could write a prescription so the patient could go somewhere else to get the medication. The board will have its attorneys review this issue for guidance to the board.

6. The board was asked to consider accepting curriculum-based training for graduates of schools of pharmacy, rather than requiring containing education training classes. Ms. Herold asked how the board could ensure that the curriculum at each school was providing similar information to ensure that students are really graduating with adequate knowledge. Dr. Hill-Besinque commented that Hawaii allows for curriculum-equivalent training in contraception. Thus USC students becoming licensed in Hawaii, are recognized as having the contraception training after she writes a letter to the Hawaii board stating that the student had the training and how many hours they received. This training has been a part of USC's curriculum since 2000. The committee noted that they may need to consider graduation date when accepting curriculum based training. Ms. Herold commented that the board will need some way to verify that a student received the training.

7. The committee was encouraged to look outside of California to see what kinds of training universities elsewhere provide for travel medications, as they serve a population that frequently travels overseas.

One meeting attendee who had graduated from a school of pharmacy outside California stated that he did not receive any training travel medications. He strongly recommended protocols to ensure that pharmacists would be directed in how to care for patients in this area.

8. Robin Corelli, from the University of California, San Francisco, commented that since 2000 all California schools of pharmacy graduates receive an average of 6.5 hours of education on smoking cessation education as part of the core curriculum.

9. Sally Rafie, from the University of California, San Diego, commented that developing a very detailed protocol for travel medication may not be necessary as the CDC already has information that the board could leverage.

   She also expressed her support for curriculum based training for oral contraception and smoking cessation as opposed to a CE based training. Dr. Gutierrez asked if the schools provided any documentation for students when they complete the training. Dr. Rafie responded that UCSD currently provides a certificate to students. Dr. Gutierrez asked how long the schools feel that curriculum-based training should be valid before they need subsequent training. Dr. Hill-Besinque commented that legally there is not a time limit; however as a healthcare professional, they should update their knowledge if they are providing care.

10. Dr. Lisa Kroon, Department Chair for Clinical Pharmacy at the University of California, San Francisco, expressed her support for curriculum based training. She added that the schools should provide the board with information on the content of the training they provide in the curriculum. President Weisser asked how long after graduation would she recommend allowing curriculum-based training to be valid. Dr. Kroon commented that as long as the person is a practicing pharmacist who is maintaining their CE, the curriculum-based training should be valid for as far back as the school could provide documentation.

11. Jon Roth, CEO of CPHA, encouraged the board not to implement rigid protocols. The passage of SB 493 illustrated that both lawmakers and the medical profession feel that pharmacists possess the professional knowledge, skills and training to provide patient care. Mr. Roth added that the board would need to have documentation that the curriculum based training occurred so they could validate that the pharmacist was operating within the guidelines of the training.

    Mr. Roth stated that CPhA opposes dedicated CE requirements as CE should be the responsibility of the health care professional to determine what CE he or she needs to provide patient care. President Weisser commented that he is always surprised about how many pharmacists are discovered to have not completed the required CE when the board audits their renewals.

12. The committee discussed whether pharmacists should be required to complete ongoing CE in smoking cessation, hormonal contraception and travel medications, or if pharmacists would just have to provide documentation of initial training in the area and then use their professional judgment to complete CE as needed.

13. Michelle Tenerelli, Rite Aid pharmacist, commented that she would encourage the board not to create additional protocols. However, she would support training programs. She added that in California five Rite Aid locations provide travel medication services and the pharmacists all receive training and have resources available to them.

14. Dr. Hill-Besinque commented that in regards to hormonal contraception she feels that the board could create protocols as long as they were not too prescriptive and referenced the CDC guidelines. Referencing the CDC guidelines would allow for the protocols to remain current without having to go through a long process every time there was an update at the CDC. Dr. Hill-Besinque added that curriculum-based training provided better education than most continuing education courses. The board will examine whether the development of a protocol referencing a CDC protocol was possible.

15. Three Western University School of Pharmacy students provided the committee with their comments on the type of education they have received during pharmacy school. They all expressed that they would feel comfortable in providing patient care in smoking cessation, hormonal contraception and travel medicine based on the education they have received in school.

16. Ms. Tenerelli asked if pharmacists who attended school prior to the time when ACPE started endorsing schools of pharmacy would need to be re-trained. Ms. Herold stated most likely they would.

17. Regarding the ordering of tests, CSHP created a committee to develop guidelines for ordering and interpreting tests after the passage of SB 493. The committee created draft guidelines for the board to review. President Weisser thanked CSHP for their work and reminded the public and the committee that the responsibility for the implementation of SB 493 ultimately fell to the board. This document is provided as at the back of the meeting minutes in **Attachment 8**.

18. The committee and the audience were provided with copies of the entire guideline document at the meeting. This document can be found in the meeting minutes.

CSHP Draft Guidelines for Pharmacists Ordering and Managing Tests to Ensure Safe and Appropriate Medication Therapy

The purpose of the guideline is to identify the professional standards pharmacists should follow when ordering and interpreting tests for the purpose

of monitoring the efficacy and safety or drug therapy. Specific objectives are contained in the guidelines.

President Weisser asked about the meaning of "coordination" between a pharmacist and physician when ordering, reviewing and sharing lab tests. Mr. Deamer, who presented the material, responded that communication is key. The electronic system in place in many health care systems makes this communication between health care providers much easier.

Any pharmacist, not just an APP, can order and interpret tests. Mr. Deamer commented that physician groups were hesitant about pharmacists ordering and interpreting tests. The challenge was to show that pharmacists have the knowledge and skills needed, and especially in the case of drug therapy management, excel at interpreting results.

When there is no primary care provider, could a pharmacist still order tests? Mr. Deamer responded that the pharmacist could refer the patient to a physician within the health system or in the community. He added that the pharmacist may need to refuse to order a test until the patient is seen by a physician. Ms. Herold noted that the committee needs to consider that a patient may change physicians without telling their pharmacist and account for how to handle such situation.

Dr. Gutierrez expressed concern that the pharmacist may order tests that result in the need for a diagnosis, which would need to be handled by a physician, not the pharmacist.

Ms. Veale commented that she envisioned pharmacists ordering test that would determine the effectiveness of a drug therapy, not a new test used to diagnose. She added that if a test the pharmacist ordered did reveal a problem that needed diagnosis it would be the responsibility of the pharmacist to contact the physician and discuss it with him or her. Dr. Gutierrez stated that she is not as concerned about pharmacists who are practicing within a health system being able to contact the physician if a diagnosis is needed; rather pharmacists who are practicing independently. Ms. Veale responded that as a health care provider, the pharmacist should do what he or she needs to do to contact the physician.

Ms. Herold reported that for years pharmacists have been able to order tests to evaluate drug therapies, however SB 493 gives them autonomy previously not allowed. She concluded that the committee will need to address this new autonomy.

19. Jon Roth clarified that SB 493 allows all pharmacists to order and interpret tests *only* for efficacy and toxicity related to a drug therapy. An APP pharmacist is allowed to order and interpret tests related to drug therapy. Mr. Roth said the language sets two different requirements for regular pharmacists and APP pharmacists. President

Weisser asked if there is any concern with patients diagnosis shopping. Mr. Roth responded that at least in the near future, patients will have to pay out-of-pocket for these tests and he does not see much incentive.

20. Ryan Gates, clinical pharmacist, commented that historically pharmacists have not had access to critical information related to patient care. SB 493 is intended to give the pharmacist more information and make them part of the medical team. Dr. Gates noted that they were very careful to use language that required the pharmacist to coordinate testing with the primary care provider to eliminate redundant testing.

    A compounding pharmacist specializing in hormone replacement therapy, commented that ordering and interpreting tests for drug efficacy is already a common practice with compounding pharmacists. She described how collaboration between the patient, pharmacist and physician occurs in her practice.

    Dr. Robinson, Dean of Western University, commented he would estimate that about 70 percent of the curriculum in schools focuses on drug therapy management. Senate Bill 493 gives pharmacists access to lab testing to allow pharmacists to effectively monitor the drug therapy for patients.

21. John Simimi, acute care pharmacist, commented that he believes there should be a strong protocol in place regarding testing. Ms. Veale said she would prefer there not be a protocol for everything that a pharmacist does, as it could minimize the effectiveness of the bill.

22. Dr. Gray, CSHP, reminded the committee that SB 493 was created to address the health care shortage. He added that during the development of the bill, physicians asked that pharmacists be allowed to order tests to evaluate a drug therapy so that pharmacists can make clear recommendations about patient care based on objective results. The language was specific to say “testing” rather than “lab testing” so that pharmacists could order tests like X-rays to monitor for osteoporosis. He added that pharmacist will now be able to order tests to determine if a patient has opioids in their system. If the results show that there are no opioids in their system then it could point to the patient selling the drugs to others.

    Sarah McBane, University of California, San Diego, stated that protocols could potentially overly restrict the pharmacist and harm patient care.

23. Dr. Gates commented that if test results come back showing there are critical, potentially life-threatening problems, the pharmacist may not discontinue the drug therapy but should at least hold the prescription until the pharmacist can talk to the physician. He added that they may even send the patient to the emergency room for immediate treatment if the results are serious enough.

24. Andrew Lowe, clinical pharmacist, commented that he sees many patients who regularly switch primary care providers. To address this, they require asking a patient to confirm if he or she is still seeing the last physician on record as part of every consultation.

25. What criteria should the board use to evaluating and establishing certification programs for pharmacists to qualify for APP licensure.

26. All pharmacists can order tests for toxicity and efficacy of drug therapy, what are the implications of this for the duties of pharmacists? For example, will pharmacists be required to review test results prior to dispensing a particular medication. What impacts will this have on pharmacist's providing long-term medication if no tests are ever evaluation? Also, would this change their corresponding responsibility when dispensing opioids?

4. FOR DISCUSSION: <u>Requirements for Pharmacists who Furnish Self-Administered Hormonal Contraceptives and the Development of Draft Protocols with the Medical Board</u>

Attachment 4

During the meeting, the committee discussed the requirements for the development of a protocol for self-administered hormonal contraception. These requirements include:

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

Attachment 4 contains materials related to this topic. The USMEC Eligibility Criteria for Contraceptive Use is in detailed tabular form. There is also a draft protocol developed by CPhA/CSHP. There are a number of reference materials available on the CDC's and other websites.

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. This can be done either in stand-alone meetings or in conjunction with SB 493 committee meetings.

5. **FOR DISCUSSION: <u>Discussion on the Requirements for Pharmacists Who Furnish Nicotine Replacement Products and Development of Draft Protocols</u>**

Attachment 5

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.

Attachment 5 contains materials on this provision.

Staff recommends that the board establish at least two public meetings to develop the protocol with the Medical Board and with other interested parties. As with the hormonal contraception protocol, these meetings can be scheduled either as stand-alone meetings or as part of the SB 493 committee meetings.

6. **FOR DISCUSSION: <u>Application Requirements for APP Licensure</u>**

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

The specific provisions in SB 493 relating to this new licensure category are presented below. The focus of the discussion under this topic will be on section 4210.

4016.5.

"Advanced practice pharmacist" means a licensed pharmacist who has been recognized as an advanced practice pharmacist by the board, pursuant to Section 4210. A board-recognized advanced practice pharmacist is entitled to practice advanced practice pharmacy, as described in Section 4052.6, within or outside of a licensed pharmacy as authorized by this chapter.

4052.6.

(a) A pharmacist recognized by the board as an advanced practice pharmacist may do all of the following:
   (1) Perform patient assessments.
   (2) Order and interpret drug therapy-related tests.
   (3) Refer patients to other health care providers.
   (4) Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers.
   (5) Initiate, adjust, or discontinue drug therapy in the manner specified in paragraph (4) of subdivision (a) of Section 4052.2.

(b) A pharmacist who adjusts or discontinues drug therapy shall promptly transmit written notification to the patient's diagnosing prescriber or enter the appropriate information in a patient record system shared with the prescriber, as permitted by that prescriber. A pharmacist who initiates drug therapy shall promptly transmit written notification to, or enter the appropriate information into, a patient record system shared with the patient's primary care provider or diagnosing provider, as permitted by that provider.

(c) This section shall not interfere with a physician's order to dispense a prescription drug as written, or other order of similar meaning.

(d) Prior to initiating or adjusting a controlled substance therapy pursuant to this section, a pharmacist shall personally register with the federal Drug Enforcement Administration.

(e) A pharmacist who orders and interprets tests pursuant to paragraph (2) of subdivision (a) shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by that prescriber.

4210.

(a) A person who seeks recognition as an advanced practice pharmacist shall meet all of the following requirements:
   (1) Hold an active license to practice pharmacy issued pursuant to this chapter that is in good standing.

(2) 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.

(3) File an application with the board for recognition as an advanced practice pharmacist.

(4) Pay the applicable fee to the board.

(b) An advanced practice pharmacist recognition issued pursuant to this section shall be valid for two years, coterminous with the certificate holder's license to practice pharmacy.

(c) The board shall adopt regulations establishing the means of documenting completion of the requirements in this section.

(d) The board shall, by regulation, set the fee for the issuance and renewal of advanced practice pharmacist recognition at the reasonable cost of regulating advanced practice pharmacists pursuant to this chapter. The fee shall not exceed three hundred dollars ($300).

(a) FOR DISCUSSION: <u>Board of Pharmacy Specialties Certification Programs</u>

Attachment 6

At the February 2014 Licensing Committee Meeting, the board heard a lengthy presentation by the Board of Pharmacy Specialties on their certification programs. Minutes from this meeting are provided in **Attachment 6**, and provide an excellent framework for knowledge of the certification programs in place by the Board of Pharmacy Specialties.

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

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

In the area of pharmacy, BPS provides these eight certifications. The Commission in Geriatric Pharmacy provides one certification in geriatric pharmacy (a presentation by this organization was provided at this meeting under the next topic).

The requirements for BPS certification are high. For ambulatory care, the BPS requires:

1. Graduation from an ACPE approved school of pharmacy or equivalent outside the US
2. Current, active license practice as a pharmacist in the US or another jurisdiction
3. Completion of four years of experience where at least 50 percent of the time was spent in ambulatory care pharmacy activities (as defined by BPS content outline),

or

completion of a PGY1 residency plus one additional year of practice with at least 50 percent of time spent in ambulatory care pharmacy activities,

or

completion of a specialty (PGY2) residency in ambulatory care pharmacy.

4. Passing the Ambulatory Care Specialty Certification Examination

Recertification is required in seven years.

During the committee meeting, Ms. Veale briefly reviewed the presentation that Brian Lawson and Andrea Ianucci, from Board of Pharmacy Specialties (BPS), gave at the February 12, 2014 Licensing Committee meeting.

Megan Coder, consultant for BPS, described the qualification process for taking the BPS exam. Ms. Coder commented that the BPS program is not accredited by ACPE. However the continuing education that BPS offers is accredited by ACPE.

Ms. Coder reported that BPS recently added two specialties: Critical Care and Pediatrics. She added that any organizations that would like to see additional specialties added they could petition BPS. All of the BPS tests offered are psychometrically sound. Ms. Coder responded that all of the tests are psychometrically valid across the United States; this is ensured by an independent vendor/consultant.

Ms. Veale commented that while BPS is a great program, the committee hopes that there will be additional avenues available for licensees.

Dr. Gutierrez asked what the difference is between the BPS program and a certificate program. Ms. Coder and Dr. McBane explained that a certificate program is a one-time class that usually lasts about 15 hours and has no ongoing education once the class is completed. They added that programs like BPS require extensive continuing education.

(b) FOR DISCUSSION: <u>Other Certification Programs (i.e., Commission for Certification in Geriatric Pharmacy)</u>

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

Commission for Certification in Geriatric Pharmacy (CCGP)

<u>CCGP</u>

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

<u>Accreditation</u>

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

<u>CCGP Overview</u>

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

<u>Recognition</u>

- Australia – CGP credential recognized by Australian government as one of two pathways for pharmacists to qualify for payment for HMR and RMR
- North Carolina – CGP credential recognized as one of qualifications for Clinical Pharmacist Practitioner
- Missouri – CGP credential recognized as one of the eligibility criteria for pharmacists to qualify for "certificate of medication therapeutic authority from the Missouri State Board of Pharmacy to provide medication therapy services that include

initiating or implementing a modification of a patient's medication therapy or device usage."

Development

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

Administration

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

Eligibility

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

Recertification

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

Summary

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

There are about 200 geriatric certified pharmacists in California. About 77 percent recertify after five years. The CE required for recertification must be taken through the American Society of Consultant Pharmacists.

The cost of the certification test is $600. If an applicant passes the exam there, is a $250 administrative fee that covers the whole five years the certification is valid. He noted that there are payment plans available. The costs for continuing education are not included in the certification and recertification fees, and are paid directly to the course provider.

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

Issue Area 27: Dr. Robinson commented that the language in SB 493 states that the certification program must be recognized by ACPE or the Board of Pharmacy. However, ACPE does not recognize certification programs. Dr. Robinson concluded that the in the future they could look at a legislative change to the language. Another solution might be for the board to recognize NCCA as an appropriate accreditation body. This is another issue area the board will need to research.

(c) <u>Other Programs Envisioned or Under Development</u>

President Weisser asked the public if there was anyone who would like to discuss other programs. There were several programs discussed during the meeting, brought to the attention of the committee by members of the audience.

Eric Gupta, from Western University, brought the Clinical Lipid Specialist Exam to the committee's attention. He noted that while it is mostly taken by physicians, it is available to pharmacists.

Lisa Kroon, from UCSF, highlighted the Certified Diabetes Educator and the American Academy of HIV Medicine as two existing certification programs. Ms. Veale asked if they were both recognized by NCCA. Dr. Kroon responded that she thought they were, but she would need to confirm.

Ryan Gates, clinical pharmacist, commented that after the passage of SB 493 he expects to see more pharmacists becoming certified and feels that pharmacists will come from other states to practice in California. He encouraged the board to be sure that whatever certification program is approved ensures patient safety. Dr. Gates also noted that when the board is considering programs, they should compare the scope of the content of the exam and the scope of the duties and requirements for an APP pharmacist.

7. FOR DISCUSSION: <u>Development of Elements for Other Certification (or Certificate?) Programs</u>

Attachment 7

Ms. Veale commented that she does not want to have multiple programs petitioning the committee. The committee should create objective criteria that programs must meet to be considered.

Ms. Herold commented that programs should come before the committee similar to how BPS and CCGP have done.

Mr. Veale noted that even if an APP-licensed pharmacist does a one-time certificate course he or she will still be required to complete 10 additional continuing education hours in their specialty area before the pharmacist can renew their APP license.

Mary Staples, from the National Association of Chain Drug Stores, commented that NACDS supports multiple pathways for certification. She provided the committee with a list of certification programs, which can be found immediately following these meeting minutes.

Lisa Kroon commented that there is an online, 20-week program offered by the Canadian Pharmacists Association. The course is practice-based and focuses on patient care skills. The program has a class size of 13-14 pharmacists and has a coach who monitors the learning taking place.

President Weisser asked if the program was academically rigorous. Dr. Kroon responded that she found the program to be extremely high quality. Dr. Gutierrez asked if there is a test at the end of the program. Dr. Kroon responded that at the end of the program the student creates an action plan for a complicated sample patient and the plan is graded. President Weisser asked if someone could provide a presentation on the Canadian program.

Dr. Kroon also suggested that the committee consider the use of an Objective Structured Clinical Exam (OSCE). These exams are hands-on and are used in schools of pharmacy and in other medical professions. Dr. Gray commented that OSCE programs are not standardized and differ depending who administers the exam. Dr. Gray agreed that the committee should first develop program criteria before allowing numerous groups to come before the committee.

Issue area 28: Ms. Herold and Dr. Gutierrez agreed and asked legal counsel to look at the law to see what the board has the authority to require.

Ms. Herold commented that before organizations give presentations on their programs, criteria should be developed by the committee.

There is a requirement in California law that all licensure exams must be validated; this might be particularly difficult for OSCE-type exams. Dr. Gray commented that there are currently pharmacists who are doing APP-type work that could be observed to validate tests.

To aid the board in discussion of this element at the board, meeting, in **Attachment 7** is background information provided to the Licensing Committee in February from the Council on Credentialing in Pharmacy and its "Guiding Principles for Post-licensure Credentialing of Pharmacists." This document describes "credentials," "credentialing" and "privileging." This is a key document to review as the board directs the committee to begin to establish parameters for qualifications for advance practice pharmacists.

Also provided is "Credentialing and Privileging of Pharmacists," "Credentialing in Pharmacy: A Resource Paper" and "National Commission for Certifying Agencies, Standards for the Accreditation of Certification Programs."

8. FOR DISCUSSION: <u>Renewal Requirements of the Advanced Practice Pharmacist License</u>

License expiration of the advance practice pharmacist license will be linked to the renewal or the underlying California pharmacist license.

Renewal of the APP license will require an additional 10 unit of CE in one or more areas relevant to the pharmacist's specialty.

Currently, the board requires certification under penalty of perjury at time of renewal that the pharmacist has completed at least 30 hours during the prior two years on the renewal application for his or her license. The board does NOT require renewal applications to be accompanied by the CE completion certificates. Instead the board routinely audits some pharmacists every month. Typically about 20 percent of those pharmacists audited cannot provide proof that they have completed 30 units of CE. In such cases, the pharmacists are given citations and fines.

In the case of APPs, the board's staff plans to audit a high percent of APP renewals for full completion of both the 30 units and the additional 10 units.

Attachment 1

Senate Bill No. 493

CHAPTER 469

An act to amend Sections 733, 4040, 4050, 4051, 4052, 4052.3, 4060, 4076, 4111, and 4174 of, and to add Sections 4016.5, 4052.6, 4052.8, 4052.9, 4210, and 4233 to, the Business and Professions Code, relating to pharmacy.

[Approved by Governor October 1, 2013. Filed with Secretary of State October 1, 2013.]

LEGISLATIVE COUNSEL'S DIGEST

SB 493, Hernandez. Pharmacy practice.

The Pharmacy Law provides for the licensing and regulation of pharmacists by the California State Board of Pharmacy in the Department of Consumer Affairs. The law specifies the functions pharmacists are authorized to perform, including to administer, orally or topically, drugs and biologicals pursuant to a prescriber's order, and to administer immunizations pursuant to a protocol with a prescriber. Pharmacists may also furnish emergency contraception drug therapy pursuant to standardized procedures if they have completed a training program. A violation of the Pharmacy Law is a crime.

This bill, instead, would authorize a pharmacist to administer drugs and biological products that have been ordered by a prescriber. The bill would authorize pharmacists to perform other functions, including, among other things, to furnish self-administered hormonal contraceptives, nicotine replacement products, and prescription medications not requiring a diagnosis that are recommended for international travelers, as specified. Additionally, the bill would authorize pharmacists to order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies, and to independently initiate and administer routine vaccinations, as specified. This bill also would establish board recognition for an advanced practice pharmacist, as defined, would specify the criteria for that recognition, and would specify additional functions that may be performed by an advanced practice pharmacist, including, among other things, performing patient assessments, and certain other functions, as specified. The bill would authorize the board, by regulation, to set the fee for the issuance and renewal of advanced practice pharmacist recognition at the reasonable cost of regulating advanced practice pharmacists pursuant to these provisions, not to exceed $300.

Because a violation of these provisions would be a crime, the bill would impose a state-mandated local program.

The bill would make other conforming and technical changes.

This bill would incorporate additional changes in Section 4076 of the Business and Professions Code proposed by SB 205, that would become

operative only if SB 205 and this bill are both chaptered and become effective on or before January 1, 2014, and this bill is chaptered last.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. Section 733 of the Business and Professions Code is amended to read:

733. (a) A licentiate shall not obstruct a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient. A violation of this section constitutes unprofessional conduct by the licentiate and shall subject the licentiate to disciplinary or administrative action by his or her licensing agency.

(b) Notwithstanding any other law, a licentiate shall dispense drugs and devices, as described in subdivision (a) of Section 4024, pursuant to a lawful order or prescription unless one of the following circumstances exists:

(1) Based solely on the licentiate's professional training and judgment, dispensing pursuant to the order or the prescription is contrary to law, or the licentiate determines that the prescribed drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition.

(2) The prescription drug or device is not in stock. If an order, other than an order described in Section 4019, or prescription cannot be dispensed because the drug or device is not in stock, the licentiate shall take one of the following actions:

(A) Immediately notify the patient and arrange for the drug or device to be delivered to the site or directly to the patient in a timely manner.

(B) Promptly transfer the prescription to another pharmacy known to stock the prescription drug or device that is near enough to the site from which the prescription or order is transferred, to ensure the patient has timely access to the drug or device.

(C) Return the prescription to the patient and refer the patient. The licentiate shall make a reasonable effort to refer the patient to a pharmacy that stocks the prescription drug or device that is near enough to the referring site to ensure that the patient has timely access to the drug or device.

(3) The licentiate refuses on ethical, moral, or religious grounds to dispense a drug or device pursuant to an order or prescription. A licentiate may decline to dispense a prescription drug or device on this basis only if the licentiate has previously notified his or her employer, in writing, of the drug or class of drugs to which he or she objects, and the licentiate's employer can, without creating undue hardship, provide a reasonable accommodation of the licentiate's objection. The licentiate's employer shall

establish protocols that ensure that the patient has timely access to the prescribed drug or device despite the licentiate's refusal to dispense the prescription or order. For purposes of this section, "reasonable accommodation" and "undue hardship" shall have the same meaning as applied to those terms pursuant to subdivision (*l*) of Section 12940 of the Government Code.

(c) For the purposes of this section, "prescription drug or device" has the same meaning as the definition in Section 4022.

(d) This section applies to emergency contraception drug therapy and self-administered hormonal contraceptives described in Section 4052.3.

(e) This section imposes no duty on a licentiate to dispense a drug or device pursuant to a prescription or order without payment for the drug or device, including payment directly by the patient or through a third-party payer accepted by the licentiate or payment of any required copayment by the patient.

(f) The notice to consumers required by Section 4122 shall include a statement that describes patients' rights relative to the requirements of this section.

SEC. 2. Section 4016.5 is added to the Business and Professions Code, to read:

4016.5. "Advanced practice pharmacist" means a licensed pharmacist who has been recognized as an advanced practice pharmacist by the board, pursuant to Section 4210. A board-recognized advanced practice pharmacist is entitled to practice advanced practice pharmacy, as described in Section 4052.6, within or outside of a licensed pharmacy as authorized by this chapter.

SEC. 3. Section 4040 of the Business and Professions Code is amended to read:

4040. (a) "Prescription" means an oral, written, or electronic transmission order that is both of the following:

(1) Given individually for the person or persons for whom ordered that includes all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the condition or purpose for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor who issues a drug order pursuant to Section 2746.51, 2836.1, 3502.1, or 3640.5, respectively, or the pharmacist who issues a drug order pursuant to Section 4052.1, 4052.2, or 4052.6.

(2) Issued by a physician, dentist, optometrist, podiatrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7 or, if a drug order is issued pursuant to Section 2746.51, 2836.1, 3502.1, or 3460.5, by a certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor licensed in this state, or pursuant to Section 4052.1, 4052.2, or 4052.6 by a pharmacist licensed in this state.

(b) Notwithstanding subdivision (a), a written order of the prescriber for a dangerous drug, except for any Schedule II controlled substance, that contains at least the name and signature of the prescriber, the name and address of the patient in a manner consistent with paragraph (2) of subdivision (a) of Section 11164 of the Health and Safety Code, the name and quantity of the drug prescribed, directions for use, and the date of issue may be treated as a prescription by the dispensing pharmacist as long as any additional information required by subdivision (a) is readily retrievable in the pharmacy. In the event of a conflict between this subdivision and Section 11164 of the Health and Safety Code, Section 11164 of the Health and Safety Code shall prevail.

(c) "Electronic transmission prescription" includes both image and data prescriptions. "Electronic image transmission prescription" means any prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber. "Electronic data transmission prescription" means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy.

(d) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

(e) Nothing in the amendments made to this section (formerly Section 4036) at the 1969 Regular Session of the Legislature shall be construed as expanding or limiting the right that a chiropractor, while acting within the scope of his or her license, may have to prescribe a device.

SEC. 4. Section 4050 of the Business and Professions Code is amended to read:

4050. (a) In recognition of and consistent with the decisions of the appellate courts of this state, the Legislature hereby declares the practice of pharmacy to be a profession.

(b) Pharmacy practice is a dynamic, patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes. Pharmacy practice is continually evolving to include more sophisticated and comprehensive patient care activities.

(c) The Legislature further declares that pharmacists are health care providers who have the authority to provide health care services.

SEC. 5. Section 4051 of the Business and Professions Code is amended to read:

4051. (a) Except as otherwise provided in this chapter, it is unlawful for any person to manufacture, compound, furnish, sell, or dispense a

dangerous drug or dangerous device, or to dispense or compound a prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist under this chapter.

(b) Notwithstanding any other law, a pharmacist may authorize the initiation of a prescription, pursuant to Section 4052.1, 4052.2, 4052.3, or 4052.6, and otherwise provide clinical advice, services, information, or patient consultation, as set forth in this chapter, if all of the following conditions are met:

(1) The clinical advice, services, information, or patient consultation is provided to a health care professional or to a patient.

(2) The pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice.

(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

SEC. 6. Section 4052 of the Business and Professions Code is amended to read:

4052. (a) Notwithstanding any other law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) Administer drugs and biological products that have been ordered by a prescriber.

(4) Perform procedures or functions in a licensed health care facility as authorized by Section 4052.1.

(5) Perform procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, as authorized by Section 4052.2.

(6) Perform procedures or functions as authorized by Section 4052.6.

(7) Manufacture, measure, fit to the patient, or sell and repair dangerous devices, or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(8) Provide consultation, training, and education to patients about drug therapy, disease management, and disease prevention.

(9) Provide professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals, and participate in multidisciplinary review of patient progress, including appropriate access to medical records.

(10) Furnish the medications described in subparagraph (A) in accordance with subparagraph (B):

(A) (1) Emergency contraception drug therapy and self-administered hormonal contraceptives, as authorized by Section 4052.3.

(2) Nicotine replacement products, as authorized by Section 4052.9.

(3) 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.

(B) 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.

(11) Administer immunizations pursuant to a protocol with a prescriber.

(12) 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 prescriber, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by that prescriber.

(b) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.

(c) This section does not affect the applicable requirements of law relating to either of the following:

(1) Maintaining the confidentiality of medical records.

(2) The licensing of a health care facility.

SEC. 7. Section 4052.3 of the Business and Professions Code is amended to read:

4052.3. (a) (1) Notwithstanding any other law, a pharmacist may furnish self-administered hormonal contraceptives in accordance with standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association, and other appropriate entities. The standardized procedure or protocol shall require that the patient use a self-screening tool that will identify patient risk factors for use of self-administered hormonal contraceptives, based on the current United States Medical Eligibility Criteria (USMEC) for Contraceptive Use developed by the federal Centers for Disease Control and Prevention, and that the pharmacist refer the patient to the patient's primary care provider or, if the patient does not have a primary care provider, to nearby clinics, upon furnishing a self-administered hormonal contraceptive pursuant to this subdivision, or if it is determined that use of a self-administered hormonal contraceptive is not recommended.

(2) The board and the Medical Board of California are both authorized to ensure compliance with this subdivision, and each board is specifically charged with the enforcement of this subdivision with respect to its respective

licensees. This subdivision does not expand the authority of a pharmacist to prescribe any prescription medication.

(b) (1) Notwithstanding any other law, a pharmacist may furnish emergency contraception drug therapy in accordance with either of the following:

(A) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.

(B) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association, and other appropriate entities. The board and the Medical Board of California are both authorized to ensure compliance with this clause, and each board is specifically charged with the enforcement of this provision with respect to its respective licensees. This subdivision does not expand the authority of a pharmacist to prescribe any prescription medication.

(2) Prior to performing a procedure authorized under this subdivision, a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.

(3) A pharmacist, pharmacist's employer, or pharmacist's agent shall not directly charge a patient a separate consultation fee for emergency contraception drug therapy services initiated pursuant to this subdivision, but may charge an administrative fee not to exceed ten dollars ($10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this paragraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. This paragraph shall become inoperative for dedicated emergency contraception drugs if these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.

(4) A pharmacist shall not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this subdivision.

(c) For each emergency contraception drug therapy or self-administered hormonal contraception initiated pursuant to this section, the pharmacist shall provide the recipient of the drug with a standardized factsheet that

includes, but is not limited to, the indications and contraindications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Public Health, the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. This section does not preclude the use of existing publications developed by nationally recognized medical organizations.

SEC. 8. Section 4052.6 is added to the Business and Professions Code, to read:

4052.6. (a) A pharmacist recognized by the board as an advanced practice pharmacist may do all of the following:

(1) Perform patient assessments.

(2) Order and interpret drug therapy-related tests.

(3) Refer patients to other health care providers.

(4) Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers.

(5) Initiate, adjust, or discontinue drug therapy in the manner specified in paragraph (4) of subdivision (a) of Section 4052.2.

(b) A pharmacist who adjusts or discontinues drug therapy shall promptly transmit written notification to the patient's diagnosing prescriber or enter the appropriate information in a patient record system shared with the prescriber, as permitted by that prescriber. A pharmacist who initiates drug therapy shall promptly transmit written notification to, or enter the appropriate information into, a patient record system shared with the patient's primary care provider or diagnosing provider, as permitted by that provider.

(c) This section shall not interfere with a physician's order to dispense a prescription drug as written, or other order of similar meaning.

(d) Prior to initiating or adjusting a controlled substance therapy pursuant to this section, a pharmacist shall personally register with the federal Drug Enforcement Administration.

(e) A pharmacist who orders and interprets tests pursuant to paragraph (2) of subdivision (a) shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by that prescriber.

SEC. 9. Section 4052.8 is added to the Business and Professions Code, to read:

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.

(b) In order to initiate and administer an immunization described in subdivision (a), a pharmacist shall do all of the following:

(1) Complete an immunization training program endorsed by the CDC or the Accreditation Council for Pharmacy Education 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.

(2) Be certified in basic life support.

(3) Comply with all state and federal recordkeeping and reporting requirements, including providing documentation to the patient's primary care provider and entering information in the appropriate immunization registry designated by the immunization branch of the State Department of Public Health.

(c) A pharmacist administering immunizations pursuant to this section, or paragraph (11) of subdivision (a) of Section 4052, may also initiate and administer epinephrine or diphenhydramine by injection for the treatment of a severe allergic reaction.

SEC. 10. Section 4052.9 is added to the Business and Professions Code, to read:

4052.9. (a) A pharmacist may furnish nicotine replacement products approved by the federal Food and Drug Administration for use by prescription only in accordance with standardized procedures and protocols developed and approved by both the board and the Medical Board of California in consultation with other appropriate entities and provide smoking cessation services if all of the following conditions are met:

(1) The pharmacist maintains records of all prescription drugs and devices furnished for a period of at least three years for purposes of notifying other health care providers and monitoring the patient.

(2) The pharmacist notifies the patient's primary care provider of any drugs or devices furnished to the patient, or enters 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 provides the patient with a written record of the drugs or devices furnished and advises the patient to consult a physician of the patient's choice.

(3) The pharmacist is certified in smoking cessation therapy by an organization recognized by the board.

(4) The pharmacist completes one hour of continuing education focused on smoking cessation therapy biennially.

(b) The board and the Medical Board of California are both authorized to ensure compliance with this section, and each board is specifically charged with the enforcement of this section with respect to their respective licensees. Nothing in this section shall be construed to expand the authority of a pharmacist to prescribe any other prescription medication.

SEC. 11. Section 4060 of the Business and Professions Code is amended to read:

4060. A person shall not possess any controlled substance, except that furnished to a person upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or furnished pursuant to a drug order issued by a certified nurse-midwife pursuant to Section 2746.51, a nurse practitioner pursuant to Section 2836.1, a physician assistant pursuant to Section 3502.1, a naturopathic doctor pursuant to Section 3640.5, or a pharmacist pursuant to Section 4052.1, 4052.2, or 4052.6. This section does not apply to the possession of any controlled substance by a manufacturer, wholesaler, pharmacy, pharmacist, physician, podiatrist, dentist, optometrist, veterinarian, naturopathic doctor, certified nurse-midwife, nurse practitioner, or physician assistant, if in stock in containers correctly labeled with the name and address of the supplier or producer.

This section does not authorize a certified nurse-midwife, a nurse practitioner, a physician assistant, or a naturopathic doctor, to order his or her own stock of dangerous drugs and devices.

SEC. 12. Section 4076 of the Business and Professions Code is amended to read:

4076. (a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except when the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

(11) (A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6.

(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5

(commencing with Section 2840)), who is acting within his or her scope of practice.

SEC. 12.5. Section 4076 of the Business and Professions Code is amended to read:

4076. (a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except when the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

(11) (A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

(c) If a pharmacist dispenses a dangerous drug or device in a health facility, as defined in Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6.

(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within his or her scope of practice.

(e) This section shall remain in effect only until January 1, 2016, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2016, deletes or extends that date.

SEC. 12.7. Section 4076 is added to the Business and Professions Code, to read:

4076. (a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except when the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor

who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

(11) (A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

(b) The information required by paragraphs (1), (2), (3), (7), and (10) of subdivision (a) shall be printed in at least a 12-point typeface.

(c) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in

a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

(d) If a pharmacist dispenses a dangerous drug or device in a health facility, as defined in Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6.

(e) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within his or her scope of practice.

(f) This section shall become operative on January 1, 2016.

SEC. 13. Section 4111 of the Business and Professions Code is amended to read:

4111. (a) Except as otherwise provided in subdivision (b), (d), or (e), the board shall not issue or renew a license to conduct a pharmacy to any of the following:

(1) A person or persons authorized to prescribe or write a prescription, as specified in Section 4040, in the State of California.

(2) A person or persons with whom a person or persons specified in paragraph (1) shares a community or other financial interest in the permit sought.

(3) Any corporation that is controlled by, or in which 10 percent or more of the stock is owned by a person or persons prohibited from pharmacy ownership by paragraph (1) or (2).

(b) Subdivision (a) shall not preclude the issuance of a permit for an inpatient hospital pharmacy to the owner of the hospital in which it is located.

(c) The board may require any information the board deems is reasonably necessary for the enforcement of this section.

(d) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy to be owned or owned and operated by a person licensed on or before August 1, 1981, under the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code) and qualified on or before August

1, 1981, under subsection (d) of Section 1310 of Title XIII of the federal Public Health Service Act, as amended, whose ownership includes persons defined pursuant to paragraphs (1) and (2) of subdivision (a).

(e) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy to be owned or owned and operated by a pharmacist authorized to issue a drug order pursuant to Section 4052.1, 4052.2, or 4052.6.

SEC. 14. Section 4174 of the Business and Professions Code is amended to read:

4174. Notwithstanding any other law, a pharmacist may dispense drugs or devices upon the drug order of a nurse practitioner functioning pursuant to Section 2836.1 or a certified nurse-midwife functioning pursuant to Section 2746.51, a drug order of a physician assistant functioning pursuant to Section 3502.1 or a naturopathic doctor functioning pursuant to Section 3640.5, or the order of a pharmacist acting under Section 4052.1, 4052.2, 4052.3, or 4052.6.

SEC. 15. Section 4210 is added to the Business and Professions Code, to read:

4210. (a) A person who seeks recognition as an advanced practice pharmacist shall meet all of the following requirements:

(1) Hold an active license to practice pharmacy issued pursuant to this chapter that is in good standing.

(2) 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.

(3) File an application with the board for recognition as an advanced practice pharmacist.

(4) Pay the applicable fee to the board.

(b) An advanced practice pharmacist recognition issued pursuant to this section shall be valid for two years, coterminous with the certificate holder's license to practice pharmacy.

(c) The board shall adopt regulations establishing the means of documenting completion of the requirements in this section.

(d) The board shall, by regulation, set the fee for the issuance and renewal of advanced practice pharmacist recognition at the reasonable cost of

regulating advanced practice pharmacists pursuant to this chapter. The fee shall not exceed three hundred dollars ($300).

SEC. 16. Section 4233 is added to the Business and Professions Code, to read:

4233. A pharmacist who is recognized as an advanced practice pharmacist shall complete 10 hours of continuing education each renewal cycle in addition to the requirements of Section 4231. The subject matter shall be in one or more areas of practice relevant to the pharmacist's clinical practice.

SEC. 17. Sections 12.5 and 12.7 of this bill incorporate amendments to Section 4076 of the Business and Professions Code proposed by both this bill and Senate Bill 205. They shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2014, (2) each bill amends Section 4076 of the Business and Professions Code, and (3) this bill is enacted after Senate Bill 205, in which case Section 12 of this bill shall not become operative.

SEC. 18. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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Attachment 2

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Advanced-practice Pharmacists

Practice Characteristics and Reimbursement of Pharmacists Certified for Collaborative Clinical Practice in New Mexico and North Carolina

Matthew Murawski, Kristin R. Villa, Ernest J. Dole, Timothy J. Ives, Dale Tinker, Vincent J. Colucci, Jeffrey Perdiew |
Am J Health Syst Pharm. 2011;68(24):2341-2350.

Abstract and Introduction

Abstract

Purpose The results of a survey assessing the practice settings, clinical activities, and reimbursement experiences of pharmacists with advanced-practice designations are reported.

Methods A questionnaire was sent to all certified Pharmacist Clinicians in New Mexico and all Clinical Pharmacist Practitioners in North Carolina (a total of 189 pharmacists at the time of the survey in late 2008) to elicit information on practice settings, billing and reimbursement methods, collaborative drug therapy management (CDTM) protocols, and other issues.

Results Of the 189 targeted pharmacists, 64 (34%) responded to the survey. On average, the reported interval from pharmacist licensure to certification as an advanced practitioner was 11 years. The majority of survey participants were practicing in community or institutional settings, most often hospital clinics or physician offices. About two thirds of the respondents indicated that their employer handled the billing of their services using standard evaluation and management codes, with estimated total monthly billings averaging $6500. At the time of the survey, about 80% of the respondents were engaged in a CDTM protocol. The survey results suggest that pharmacists with advanced-practice designations are perceived favorably by patients and physicians and their services are in high demand, but more than one third of respondents indicated a need to justify their advanced-practice positions to administrators.

Conclusion Pharmacists with advanced-practice designations are providing clinical services in various settings under collaborative practice arrangements that include prescribing privileges. Despite growing patient and physician acceptance, reimbursement challenges continue to be a barrier to wider use of CDTM programs.

Introduction

Collaborative drug therapy management (CDTM) entails an agreement between a physician and a pharmacist wherein a pharmacist may initiate, modify, and continue medication regimens, order related laboratory tests, and perform patient assessments under a defined protocol.[1] Such physician and pharmacist collaboration was first introduced by the Indian Health Service in the 1960s. Originally limited to federal facilities, CDTM now occurs in many settings, including private hospitals, clinics, and physician offices;[1,2] state legislation and attendant regulations authorizing pharmacists to engage in some form of CDTM have facilitated that expansion. Washington, in 1979, was the first state to allow pharmacists to prescribe under a protocol agreement.[2] In 2002, when the American College of Clinical Pharmacy created its position statement on CDTM, 38 states permitted pharmacists some form of CDTM authority within their scope of practice.[1] In most states, the privileges granted to pharmacists under the governing pharmacy practice acts were and continue to be distinctly limited. However, in two states, New Mexico and North Carolina, legislators extended much broader privileges to pharmacists.

In 1993, the New Mexico legislature passed the Pharmacist Prescriptive Authority Act (PPAA), allowing pharmacists to enter into collaborative practice agreements with physicians.[3] A new designation, Pharmacist Clinician, was created to describe licensed pharmacists who had completed additional training requirements, including training in diagnosis and physical assessment equivalent to that of physician assistants.[2,4] Under the PPAA, certified

Pharmacist Clinicians may register for a personal Drug Enforcement Administration (DEA) number and apply for prescriptive authority under the supervision of a physician according to a collaborative practice protocol.[5,6]

In 2000, North Carolina extended similar prescriptive authority to pharmacists via the enactment of the Clinical Pharmacist Practitioner Act (CPPA), under which a licensed pharmacist approved by the state's board of pharmacy and board of medicine may enter into a CDTM agreement with a physician under a written agreement. As in New Mexico, pharmacists in North Carolina who hold the Clinical Pharmacist Practitioner designation have prescriptive authority and may register for a DEA number.[2,7] More recently, in 2010, Montana enacted legislation modeled after the legislation enacted in New Mexico and North Carolina. In addition, five other states (California, Massachusetts, Minnesota, North Dakota, and Washington) allow pharmacists to obtain a DEA number.[2]

Similar initiatives have occurred outside the United States. In 2003, the United Kingdom expanded pharmacist-prescribing powers. Pharmacists may obtain prescribing privileges after the completion of a training program recognized by the National Health Service (NHS) and are designated as Pharmacist Supplementary Prescribers.[8] As of 2005, less than 2% of the 44,951 registered U.K. pharmacists had obtained prescriber status.[9] In a study published in 2010, Baqir and Smith[10] found that Pharmacist Supplementary Prescribers lacked a defined prescribing role, were unable to independently prescribe controlled medications, and had difficulty showing financial benefits to their organizations. In a related study, Baqir et al.[11] noted that the skill set of pharmacist prescribers was not being used to the fullest degree despite the fact that they are legally recognized as "midlevel" providers throughout NHS and receive reimbursement as such.[8,9]

Unfortunately, while U.S. pharmacists with advanced-practice designations have more prescriptive privileges than "traditional" pharmacists (i.e., those without such designations), they do not enjoy the official provider status extended to their counterparts in the United Kingdom. Moreover, in both countries, advanced-practice pharmacists often find that obtaining reimbursement for their nondispensing services is every bit as difficult as it is for traditional pharmacists.

In the United States, the reality is that pharmacists of any level of training are still not recognized as midlevel providers (for most services) by the majority of insurance companies and federal programs, including Medicare Part B.[12] In 2004, a congressional bill (H.R. 4724) that would have implemented payments for clinical pharmacy services provided by Pharmacist Clinicians or Clinical Pharmacist Practitioners was introduced;[13] the bill was reintroduced in 2008 as H.R. 5780.[14] In 2010, another bill (H.R. 5389) that proposed a framework for pharmacists to receive payments for clinically oriented services was introduced;[12,15] if enacted, the Medicare Clinical Pharmacist Practitioner Services Coverage Act of 2010 would have permitted pharmacists with advanced-practice designations to bill Medicare Part B as midlevel providers at 85% of the physician reimbursement rate in a manner similar to the mechanism for payment of Pharmacist Supplementary Prescribers in the United Kingdom. All three bills were introduced in Congress and referred to the House Ways and Means Subcommittee on Health, but all versions failed to progress and died in committee.[13–15]

Currently there is a small population of pharmacy practitioners who have pursued the appropriate training, obtained the Pharmacist Clinician or Clinical Pharmacist Practitioner designation, and enjoy prescribing privileges comparable to those held by U.K. pharmacist prescribers—but they have not been granted status as providers as a mechanism of reimbursement. The purposes of the study described here were to investigate the practice characteristics and reimbursement methods of pharmacists certified as Pharmacist Clinicians or Clinical Pharmacist Practitioners, their opinions regarding the benefits of those designations, and the barriers to wider implementation of the advanced-practice model; and to explore their knowledge and opinions of the potential impact of H.R. 5780, the bill under consideration at the time the study was completed.

Methods

Description of Questionnaire

A questionnaire was created in order to gather information on the practice environment of Clinical Pharmacist Practitioners and Pharmacist Clinicians. The questionnaire consisted of 61 items (27 multiple-choice items and 34 free-response items). Free-response items were used extensively in an attempt to avoid constraining responses.

The multiple-choice items addressed four major categories: site characteristics, practitioner characteristics, practitioner perceptions, and knowledge of H.R. 5780. Questionnaire items about pharmacists' practice sites elicited information on the duration of current collaborative practice protocols, disease states managed, billing procedures, and site responsibilities. The practitioner characteristics assessed included the dates of licensure and advanced-practice certification, education and training, and type of practice site. The evaluated practitioner perceptions included the respondents' views on the requirements for justification of their advanced-practice position, the satisfaction of clinicians and administrators with the care and services provided, the benefits of their services to patients and organizations, and the demand for their services and the need for additional advanced-practice clinicians in their area. Finally, participants were asked if they were aware of H.R. 5780, if they would write their representative in support of it, and how the bill might affect them if passed.

The free-response items addressed similar issues and concerns but allowed respondents to elaborate, therefore eliciting more information than the multiple-choice items. For example, the respondents could estimate how much money they helped a patient save in one month, the approximate revenue generated through reimbursement of their services, specific information on collaborative practice protocols, the costs of obtaining and maintaining an advanced-practice designation, and the effectiveness and acceptance of their services. Free-response questions elicited information on barriers to implementation of their services, as well as advice regarding pitfalls to avoid when implementing advanced-practice programs and ways to make such programs effective.

Respondent and Data Collection

In September and October 2008, the New Mexico and North Carolina boards of pharmacy were contacted and asked to provide the names and addresses of all certified advanced practitioners; 189 names and addresses were obtained.

The questionnaire was administered via direct mail using a modified Dillman method.[16] In November 2008, the 189 prospective respondents were notified by postcard that they would soon receive a survey. A few weeks later the questionnaire was sent via first-class mail to the targeted pharmacists along with a hand-signed cover letter explaining the purpose of the study and a pre-addressed, postage-paid envelope to use in returning the completed questionnaire. Four weeks after the initial mailing, nonresponders were sent a reminder mailing.

Data Analysis

Information collected through the survey was entered into Microsoft Excel (Microsoft Corporation, Redmond, WA), with quantitative responses numerically coded and free-text responses transcribed. Descriptive statistics for each quantitative item were calculated using Stata version 11 (StataCorp LP, College Station, TX). For quantitative questions with an "other" response option, all responses were reviewed by the investigators in order to ensure the response was conceptually unique. Responses regarding practice settings and disease state management were consolidated on a functional basis. For instance, with regard to practice sites, the responses "family medicine clinic" and "ambulatory care clinic" were consolidated because those types of practice site were considered to be functionally equivalent despite differences in funding. A similar approach was taken in grouping responses to questionnaire items about practice activities; for example, a response of "medication management" was considered to be functionally equivalent to a response of "helping patients secure medication assistance and benefits."

Thematic content analysis of free-text responses was performed. For example, one survey item asked, "In what ways do you see yourself as being different from a registered (non-Pharmacist Clinician/Clinical Pharmacist Practitioner) pharmacist?"; responses such as "more direct patient care," "more respect from nonpharmacy colleagues," and "more up to date on areas of practice" were dually categorized under the theme of direct patient

care and the theme of functional confidence and competence. Thus, individual responses could include more than one theme. The study investigators reviewed all responses and themes for agreement, and any discrepancies were resolved via discussion. The response count for each theme was then used to determine which ideas were the most prevalent among all the responses.

Results

Respondent Characteristics

Surveys were mailed to 122 practitioners in New Mexico and 67 practitioners in North Carolina. There were 64 respondents, a response rate of 34%; by state, the response rate was 23.8% (n = 29) in New Mexico and 52.2% (n = 35) in North Carolina. The respondents' year of licensure ranged from 1971 to 2008, and the year in which they earned an advanced-practice designation ranged from 1994 to 2008 (one response indicating 1978 was not included in the data analysis, as neither state recognized such a designation at that time). On average, the responding practitioners received a pharmacy license 11 years before obtaining an advanced-practitioner designation.

Of the 64 respondents, 13 (20.3%) had obtained only a bachelor of science degree in pharmacy, 20 (31.3%) had obtained only a doctor of pharmacy (Pharm.D.) degree, and 31 (48.4%) had obtained both degrees (). Twenty-three respondents (35.9%) reported the completion of a one-year residency, while 2 respondents indicated another form of postgraduate education (respectively, a master of science degree in pharmacy and a fellowship). When asked about the initial education and training requirements needed to obtain an advanced-practice designation in their state, only 15 respondents (23.4%) gave answers in keeping with the requirements listed in the North Carolina or New Mexico pharmacy regulations (appendix).[17,18] Responses that were not fully consistent with the applicable pharmacy board requirements often did not give details of how the required number of preceptorship hours were obtained or stated that such training was included in the Pharm.D. curriculum completed. When asked about the number of continuing-education (CE) hours per year needed to maintain their status as advanced practitioners, 34 respondents (37.5%) gave responses consistent with applicable state requirements (35 CE hours in North Carolina and 10 CE hours in New Mexico, in addition to the CE hours required for pharmacist licensure). Responses that were not consistent with known current requirements often contained errors regarding the hours required for pharmacy licensure and for earning an advanced-practice designation.

Table 1. Education, Postgraduate Training, and Certifications of Survey Respondents (n = 64)[a]

Education or Designation	No. (%)
Doctor of pharmacy degree	51 (79.7)
Bachelor of science degree in pharmacy	44 (68.8)
Residency	23 (35.9)
Board certification	15 (23.4)
Certified Diabetes Educator	14 (21.9)
Certified Geriatric Pharmacist	2 (3.1)
Board-Certified Pharmacotherapy Specialist	2 (3.1)
Certified Anticoagulation Care Provider	2 (3.1)
National Clinical Pharmacy Specialist (IHS training)	2 (3.1)
Master of science degree in pharmacy	1 (1.6)
Fellowship	1 (1.6)

[a] IHS = Indian Health Service.

Practice Sites

When asked to select a practice-site category, 21 respondents (32.8%) indicated community practice, 23 (35.9%) indicated institutional practice, and 19 (29.7%) indicated that their practice site fell outside of the traditional community or institutional practice. "Other" sites included ambulatory care clinic (n = 8, 12.5%), outpatient clinic (n = 5, 7.8%), government clinic (n = 3, 4.7%), "mixed" community and institutional practice (n = 1, 1.6%), and health plan (n = 1, 1.6%); one respondent indicated "other" but did not specify a practice site. When asked to classify their practice sites more specifically (more than one choice was allowed), the responding pharmacists most often indicated practicing in hospital clinics (n = 15, 23.4%) and physician offices (n = 15, 23.4%), followed by freestanding clinics (n = 9, 14.1%), "other" (n = 8, 12.5%), hospitals (n = 7, 10.9%), "community" (n = 5, 7.8%), Veterans Affairs hospitals (n = 3, 4.7%), and managed care organizations (n = 2, 3.1%); "other" responses included federal facilities (n = 2, 3.1%) and health centers (n = 2, 3.1%).

Practice Activities

As part of the survey, respondents were given a list of activities commonly performed by advanced practitioners and asked to estimate the percentage of time (from 0% to 100%) they spent engaged in those activities during a typical workday. On average, respondents indicated spending 35.0% of their time in patient consultation, 16.4% in teaching, 14.2% in administration or management, 14.2% in medication review, 10.0% in note dictation, 9.6% in diagnosis, 9.0% in laboratory testing activities, 8.4% in chart review, 7.8% in research, 6.6% in providing drug information, 4.1% in pharmacy and therapeutics committee duties, and 3.1% in activities pertaining to prior authorization.

Reimbursement Methods

Sixty-four percent (n = 41) of the respondents indicated that their organization bills for the services they provide; when asked to indicated which entities were billed for their services, "insurance companies" was the most common response (n = 34), followed by Medicare (n = 24), self-pay patients (n = 24), Medicaid (n = 22), internal billing departments (n = 16), and state health plans (n = 1). The most commonly reported method of billing for procedures was the use of Common Procedural Terminology evaluation and management (E&M) codes 99211, 99212, 99213, and 99214 (n = 37); other reported methods were billing for "incident-to" fees (n = 13), immunization fees (n = 6), facility fees (n = 4), pharmacy consultation fees (n = 1), fees for patient visits based on time and effort (n = 1), and fees relating to medication therapy management E&M codes 99605, 99606, and 99607 (n = 1). Sixteen respondents estimated the total amount of money billed for their services each month; their estimates ranged from $120 to $24,000, with an average of $6,500 per month.

Six respondents estimated the amount of money billed to Medicaid each month, and the estimates ranged from $74 to $6,700, with an average of $2,712 per month. Forty-three respondents indicated that they or someone else within their organization tracked the revenue generated from their services. Seven respondents estimated the amount of revenue generated from their services; their estimates ranged from $1,500 to $18,400 per month, with an average of $7,379 per month.

Protocol Characteristics

Fifty-one respondents (79.7%) indicated that their organization had a program in place that made use of their status as an advanced practitioner. Respondents indicated that one or more protocols allowing collaborative practice had been in place at their practice site for periods ranging from 6 to 204 months (average, 60 months). When asked about specific aspects of protocols, 21 respondents (32.8%) indicated that they had prescribing authority, 14 (23.3%) indicated that the supervising physician was required to review a percentage of their charts and meet with them on a regular basis, and 8 (12.5%) indicated that countersigning of their notes and prescriptions by the supervising physician was required. Eight respondents (12.5%) indicated that they could order laboratory tests and

other procedures to help manage patients, 8 (12.5%) indicated that they were required to involve the physician in complicated cases and cases outside their scope, 4 (6.3%) indicated that the governing protocol was specific to a particular disease state, 3 (5.5%) indicated that protocol-specified guidelines followed the North Carolina Board of Pharmacy guidelines (the respondents did not provide specific details), and 1 (1.6%) indicated that the protocol required the documentation of all patient encounters.

The survey respondents reported involvement in managing a wide variety of disease states: diabetes (*n* = 37, 57.8%), coagulation or lipid disorders (*n* = 35, 54.7%), hypertension (*n* = 30, 46.9%), asthma or chronic obstructive pulmonary disease (COPD) (*n* = 15, 23.4%), pain (*n* = 13, 20.3%), and heart failure (*n* = 11, 17.2%). Eighteen respondents (28.1%) indicated involvement in smoking cessation, and a number of respondents indicated involvement in managing "other" disease states and clinical situations. Respondents reported a total of 21 disease states or clinical situations that they managed in their practice ().

Table 2. "Other" Disease States and Clinical Situations Managed by Survey Respondents

Disease State or Clinical Situation	No. (%)
Polypharmacy	4 (6.3)
Medication assistance (including benefits)	4 (6.3)
All diseases (open protocol)	3 (4.7)
Family practice–primary care	3 (4.7)
Migraine	2 (3.1)
Mental health	2 (3.1)
Oncology	2 (3.1)
Immunizations	2 (3.1)
Hematology–anemia	2 (3.1)
Thyroid	2 (3.1)
Obesity–wellness	2 (3.1)
Intensive care unit	1 (1.6)
Inpatient	1 (1.6)
Osteoporosis	1 (1.6)
Metabolic syndrome	1 (1.6)
Aminoglycosides	1 (1.6)
Internal medicine	1 (1.6)
Cardiology	1 (1.6)
Upper respiratory infections	1 (1.6)
Urinary tract infections	1 (1.6)
Hospice	1 (1.6)

Patient and Physician Perceptions

Respondents were asked to rate the extent to which patients and the physicians they worked with might view pharmacists with an advanced-practice designation as different from traditional pharmacists on a five-point scale

(not at all, a little, not sure, somewhat, a great deal). With regard to patient perceptions, 23.4% (n = 15) of respondents indicated their view that patients see them as somewhat different from traditional pharmacists, while 59.4% (n = 38) indicated that patients see a great deal of difference. When rating the perceptions of physicians, 20.3% (n = 13) of respondents were of the opinion that physicians see them as somewhat different from traditional pharmacists, and 70.3% (n = 45) indicated that physicians see a great deal of difference.

The survey respondents were also asked about their own perceptions of differences between advanced-practice and traditional pharmacists, and their responses were consolidated into seven thematic categories. The pharmacists indicated their view that there were differences in autonomy (n = 33, 51.6%), direct patient care (n = 14, 21.9%), functional competence and confidence (n = 13, 20.3%), lack of medication dispensing (n = 6, 9.4%), collaborative practice (n = 5, 7.8%), certifications and licensure (n = 4, 6.3%), and documentation requirements (n = 2, 3.1%). Two respondents indicated that they saw no differences between their practice and that of a traditional pharmacist.

The survey also included a question about how respondents believed their relationships with physicians might differ from those of traditional pharmacists. The response categories, and the number and proportion of respondents indicating agreement, were as follows: pharmacist viewed as colleague (n = 18, 28.1%), physician confidence in abilities (n = 11, 17.2%), physician recognition of additional training (n = 9, 14.1%), use for knowledge other than drug information and medication management (n = 6, 9.4%), more face-to-face interaction with physician (n = 4, 6.3%), skills used more frequently to resolve patient-care issues (n = 3, 4.7%), physician willingness to collaborate (n = 2, 3.1%), and pharmacists viewed as problem solvers (n = 2, 3.1%). Six respondents indicated that there was no difference between their own relationships with physicians and those of a traditional pharmacist.

Asked to rate the level of satisfaction with their services among different groups, 90.6% (n = 58) of respondents indicated that patients were "a great deal" satisfied with services provided by advanced-practice pharmacists and 84.4% (n = 54) indicated that physicians were "a great deal" satisfied with their services. Half of the respondents (n = 32) were of the opinion that their organization's administration was "a great deal" satisfied with their services, and 28.1% (n =18) felt their organization's administration was "somewhat" satisfied.

Impact on Costs and Outcomes

When asked about their views on the benefits of the services they provided, 53 respondents (82.8%) indicated that their services were saving money for patients, and 59 respondents (92.2%) indicated that their services were decreasing costs for the U.S. health care system. Twenty-four respondents (37.5%) estimated how much money they saved patients in a typical month. Approximately half estimated a total of $1,189 for all patients seen in a month; the remaining respondents indicated that they saved approximately $249 per patient seen during the month but did not give an estimate of the number of patients seen.

Ten respondents estimated the monthly cost-saving impact of their activities for the U.S. health care system, with an average estimate of $37,200. Although few respondents gave an exact estimate of the amount of money saved to the health care system, 61 respondents answered if they felt it was less than, about equal, or greater than their salary with 7, 12, and 42 agreements, respectively. Respondents also estimated that their services, if provided by a physician, would cost on average 69% more than when provided by an advanced-practitioner pharmacists (range, 0 –500%). When asked if their functions improve patient outcomes, 85.9% (n = 55) of respondents felt their services were improving outcomes "a great deal."

Demand for Services

Respondents were asked to rate the demand for their services on the previously mentioned five-point scale; 54.7% (n = 35) felt there was "a great deal" of demand; 25% (n = 16) felt their services were "somewhat" in demand, 4.7% (n = 3) indicated they were "unsure," 3.1% (n = 2) indicated there was "a little" demand, and 9.4% (n = 6) felt there was no demand. In response to a related question, respondents indicated that the demand for advanced-practice pharmacists' services in their area required additional advanced practitioners. Thirty-seven respondents (57.8%) felt

the need for more was great, 13 (20.3%) felt the current number was just right, and 11 (17.2%) felt there was no need for more advanced practitioners in their area.

Program Justification

Despite the generally expressed view that the services of advanced-practice pharmacists are cost-effective, improve patient outcomes, and are in demand, some respondents (n = 24, 37.5%) indicated a need to justify their position in order to continue their collaborative practice activities. Methods of justification cited by survey respondents included reporting cash-flow metrics (n = 11, 45.8%), providing cost-avoidance estimates (n = 17, 70.8%), and the use of other metrics (n = 4, 16.7%) such as clinical outcomes and benefits to the organization in the areas of research and administration. When asked to rank the importance of a number of factors, or "arguments," for the continuation of advanced-practice activities, the improvement of patient outcomes was ranked first by the majority of responding survey participants (n = 15, 62.5%), followed by clinical impact (n = 8, 33.3%), revenue generation (n = 6, 25.0%), and cost avoidance (n = 5, 20.8%).

Program Discontinuation

The survey participants were asked if their institution formerly had a program in place to capitalize on their status as an advanced practitioner that had been discontinued; 10 respondents answered in the affirmative. When the pharmacists were asked about the reasons for program discontinuation, their responses were in four main thematic categories: inadequate promotion of the clinic's services (n = 2), financial reasons (n = 4), personal issues (n = 2), and organizational downsizing (n = 3); one respondent cited multiple factors. Eight respondents indicated that they had not made full use of their advanced-practice designation for periods ranging from 1 to 108 months, generally due to "personal preference" or "employer reasons."

Challenges and Barriers

The survey included questions regarding challenges in the implementation of programs structured around the capabilities of advanced-practice pharmacists, as well as factors in successful program implementation, at their institutions. Regarding implementation barriers, the respondents cited a wide range of factors, which were grouped into nine thematic categories: issues with acceptance (n = 15, 23.4%), reimbursement challenges (n = 12, 18.8%), administrative issues (n = 6, 9.4%), patient acceptance and awareness (n = 3, 4.7%), lack of previous program experience (n = 2, 3.1%), legislation or regulations (n = 2, 3.1%), cost issues (n = 2, 3.1%), space issues (n = 1, 1.6%), and time constraints (n = 1, 1.6%).

In response to a question regarding problems they had encountered in the development or implementation of new clinically oriented programs, the surveyed pharmacists cited various pitfalls to avoid in eight broad categories: inadequate planning (n = 10, 15.6%), poorly chosen disease concentration (n = 5, 7.8%), "turf disputes" (n = 5, 7.8%), improper billing methods (n = 3, 4.7%), performance of extra duties as a part of normal pharmacy practice (n = 3, 4.7%), supervisors' lack of clinical experience (n = 3, 4.7%), financial problems (n = 1, 1.6%), and failure to use the facility's electronic medical record (n = 1, 1.6%).

Key factors in program success cited by survey participants included provider support and "buy-in" (n = 26, 40.6%), the reporting of health outcomes data (n = 11, 17.2%), the reporting of financial metrics (n = 9, 14.1%), patient acceptance and buy-in (n = 9, 14.1%), administrative support (n = 6, 9.4%), proper workload balance (n = 4, 6.3%), a demonstrated need for services (n = 4, 6.3%), the personal drive of the pharmacist (n = 4, 6.3%), cost neutrality for the institution (n = 2, 3.1%), training and certification (n = 2, 3.1%), a manageable number of targeted disease states (n = 2, 3.1%), and a balanced patient caseload (n = 1, 1.6%).

Program Recommendations

Respondents were also asked to offer ideas on setting up a program that would help make it as effective as possible. Recommendations offered by survey participants (grouped into 11 thematic categories) included adequate

financial planning and revenue generation (n = 10, 15.6%); relationship building with physicians, administrators, and other health care professionals (n = 10, 15.6%); proper planning for implementation (n = 9, 14.1%); monitoring of program outcomes (n = 5, 7.8%); proper documentation (n = 3, 4.7%); staff training (n = 3, 4.7%); marketing and promotion of services (n = 2, 3.1%); judicious selection of chronic disease states to treat (n = 1, 1.6%); continuous quality improvement (n = 1, 1.6%); involvement in the education of pharmacy school students (n = 1, 1.6%); and the pharmacist's communication skills (n = 1, 1.6%).

Knowledge of Legislation

Asked if they were aware of H.R. 5780, which was under congressional consideration at the time of the survey, 75% (n = 48) of the respondents indicated awareness of the bill. When asked if they would have advised their legislators to vote for the bill if they had been prompted to do so before the bill died in committee, 93.8% (n = 60) of the respondents indicated that they would have urged their lawmakers to support the bill. Respondents were also asked to predict the likely impact of possible future passage of such a bill on their practice using a 13-point scale, with scores ranging from −6 (strong negative impact) to +6 (strong positive impact); 46.9% (n = 30) of the respondents predicted a strong positive impact (+6) on their practice. None of the respondents felt the bill would have no impact on their practice, and 1 respondent felt it would have a strong negative impact.

Discussion

The overall response rate for this survey was 34%, but there was a substantial difference in the response rates of pharmacists in New Mexico (23.8%) and pharmacists in North Carolina (52.2%). One possible explanation for the widely divergent response rates relates to the manner in which the survey participants earned an advanced-practice designation. Pharmacists in North Carolina who hold the Clinical Pharmacist Practitioner designation have, in effect, elected to obtain additional training to become advanced practitioners. In contrast, at the time the survey was conducted, all new graduates of the sole college of pharmacy in New Mexico could obtain the training required for the Pharmacist Clinician designation by completing their Pharm.D. coursework; consequently, there may be a large number of pharmacists in the state who possess but do not actively use their advanced-practice designation to engage in collaborative practice arrangements, and such pharmacists might have been less likely to participate in the survey. Another possible factor underlying the relatively low survey response rate among New Mexico pharmacists might have been the inability of some Pharmacist Clinicians to arrange a collaboration enabling them to use their advanced-practice skills.

Currently, the number of New Mexico Pharmacist Clinicians with protocols in place is less than 75 (New Mexico Pharmacists Association, personal communication, 2011 Aug 15). It may be that, in the absence of provider status, some as yet unknown factor is limiting the number of collaborative practice sites available in each state; thus, the lower survey response rate among New Mexico pharmacists might have reflected a large number of advanced-practice pharmacists pursuing a small number of physicians willing to engage in collaborations. That there are roughly twice as many advanced-practice pharmacists in New Mexico as there are in North Carolina even though New Mexico's population is only about one fifth of North Carolina's population would support that hypothesis.

In the survey described here, the reported year of pharmacist licensure ranged from 1971 to 2008, and advanced-practice designations were obtained from 1994 to 2008. Assuming a traditional graduation age of 23–24 years, it is clear that many pharmacists obtained an advanced-practice designation years after becoming licensed. The age distribution of the surveyed pharmacists suggested that those designations attract a certain type rather than a certain generation of pharmacist. The survey results indicated that the average interval between licensure and obtaining an advanced-practice designation was 11 years, which suggests that many of the pharmacists obtaining the designations are seasoned practitioners who have evaluated the pharmacy practice environment and have made an educated choice to obtain the designations based on a desire to further their practices. Additionally, based on information supplied by respondents, less than 40% chose to complete some form of postgraduate education;

this illustrates that a residency or other postgraduate training is not a necessity for obtaining an advanced-practice designation and furthering a pharmacy practice through that designation.

The examination of pharmacist-provided estimates of time spent performing certain functions led to one common finding: that the primary practice function of the survey participants involved direct patient contact.

The unexpected distribution of practice-setting classifications may also be attributed to pharmacists gravitating toward settings that increase the differentiation between themselves and traditional pharmacists, as well as settings in which they are more likely to experience increased patient and physician satisfaction with their services. The majority of respondents clearly expressed the view that physicians and patients perceived them as fulfilling a different role than that of traditional pharmacists; furthermore, they perceived themselves as relating to physicians at a more collegial level and as having different training and considerably more autonomy than traditional pharmacists.

The respondents also indicated that their services were in high demand and that patients and physicians were generally satisfied with the services they provided. However, the perceived level of satisfaction of institutional or organizational administrators was substantially lower. This discrepancy may relate to the issue of billable status, arguably a matter of far larger concern to administrators than to advanced-practice pharmacists' other constituencies.

Judging by the survey results, most advanced-practice pharmacists (79.7%) were operating under protocol, with the degree of autonomy ranging from full prescribing authority to a requirement that the pharmacist's notes and orders be cosigned by the attending physician. Overall, approximately one half of all respondents indicated that they had considerable prescribing authority. Disease states covered by CDTM protocols ranged broadly but included common disorders (e.g., diabetes, hyperlipidemia, hypertension, COPD) that involve "high-intensity" patient populations requiring substantial interaction time and relatively low levels of billable claims. It can be inferred from the survey results that advanced-practice pharmacists may be allowing physicians to reduce the amount of time allocated to such high-input, low-billing populations, thereby reducing overall costs to the health care system while enabling physicians to spend more time on more intensive patient cases.

Though survey participants indicated that the disease states covered by CDTM protocols generally offered limited billing opportunities, the majority of respondents (64%) were attempting to generate revenue for their organizations by billing for the services they provided, typically by using E&M codes or by billing "incident-to" fees; however, it is clear that organizations were using a variety of reimbursement mechanisms. Respondents estimated that, on average, they were billing for fees of $6500 per month for their services. This mean billing amount was less than the average monthly salary of a pharmacist, suggesting that the advanced-practice pharmacists were operating at a loss. The implication is that these pharmacists add value to the organization outside of revenue.

The survey findings indicated a strong sense among advanced-practice pharmacists that their activities save money for patients and the health care system. According to the estimates given by respondents, the activities of advanced-practice pharmacists save the health care system an amount of money two to three times greater than their annual salary, in part because their services were estimated (by some survey respondents) to cost the health care system or patient an average of 69% less when provided by a pharmacist rather than a physician. However, more than one third of respondents indicated a need to justify their position in order to continue in that position. The majority of those who indicated a need to justify their position reported doing so using cash-flow or cost-avoidance metrics; this suggested that the continuation of pharmacists' advanced-practice activities may often be a fiscal issue and not an issue of clinical impact or demand. Some respondents expressed the view that a larger number of advanced-practice pharmacists are needed in their community or organization.

Despite evidence of improved patient outcomes and demand for their services, several respondents indicated that programs structured around pharmacists' advanced-practice capabilities had been discontinued, and approximately 10% of the respondents indicated that they were not using their advanced-practice designation to advance their

practice at the time of the survey. Not surprisingly, the barriers to program success most often cited by the survey participants were acceptance, administrative, and reimbursement issues.

The survey respondents acknowledged both benefits of and barriers to their advanced-practice activities. The cited benefits included increased autonomy and increased interaction with providers and patients; cited barriers related to lack of acceptance by other providers and the inability to bill for services and receive adequate reimbursement. In addition, billing methods were found to be different across organizations, with varying levels of reimbursement success. Difficulties with billing and the respondents' desire for more uniform billing procedures were apparent in their knowledge of H.R. 5780, which called for implementation of a uniform billing procedure under Medicare Part B. Respondents were both highly aware of and highly in favor of H.R. 5780, which proposed the creation of a federal mechanism by which advanced practitioners would be recognized as midlevel providers and thus be positioned to develop a dependable new revenue stream.

Overall, the most important issue identified in the survey results was reimbursement for services. The respondents indicated that they were primarily involved in managing disease states associated with limited billing opportunities; therefore, it follows that any opportunity to bill for pharmacist-provided services is important to the continuation of their advanced-practice collaboration. Respondents indicated there were numerous methods for billing, which led to a wide variation in estimates of amounts billed for services and the reported revenue generated. Many of the advanced-practice pharmacists apparently were not generating revenue sufficient to cover their own salary and were therefore operating at a loss. Respondents indicated that the inability to bill and receive adequate reimbursement for their services was a major issue and should be considered before the initiation of advanced-practice protocols.

Among several important limitations of this project, the survey response rate was only 34%; while that is comparable to the response rates in other surveys of pharmacists, it is questionable whether the results can be viewed as representative of the characteristics and experiences of the entire population of advanced-practice pharmacists. In addition, the wide variation in the response rates of New Mexico and North Carolina pharmacists may have introduced sampling bias.

Another limitation of this project was that the survey participants often added additional (i.e., unrequested) information to responses in order to help explain their answer or to promote their practice. While this added insight into the respondents' practice characteristics, it often necessitated the creation of additional categories of responses and complicated the in-depth interpretation of the results.

We found that Clinical Pharmacist Practitioners and Pharmacist Clinicians were well regarded, in high demand, and providing important services; this suggests that under certain circumstances, they can provide patient care comparable to that of physicians and at a lower cost to the health care system. Unfortunately, the survey results suggest that these practitioners were often struggling to generate a revenue stream adequate to justify their employment. Unless some form of reimbursement through governmental channels is enacted, the model of advanced-practice pharmacy is not likely to succeed; this echoes the circumstances faced by practitioners in the United Kingdom.[19–21] Nevertheless, creating a new designation for U.S. pharmacists who want to practice under a collaborative protocol is a growing legislative trend in the states.[22] In our opinion, the best chance for further development of the advanced-practice model will arise if and when a state decides to use its administrative control to enact, for the purposes of the state's Medicaid program, legislation that recognizes pharmacists with advanced-practice designations as midlevel providers eligible for reimbursement at some fraction of the current physician rate. This scenario will provide the opportunity to demonstrate the large-scale fiscal impact of this model of practice, which may then lead to widespread adoption of the model in other states and, eventually, across the country at the federal level.

Conclusion

Pharmacists with advanced-practice designations are providing clinical services in various settings under collaborative practice arrangements that include prescribing privileges. Despite growing patient and physician acceptance, reimbursement challenges continue to be a barrier to wider use of CDTM programs.

Appendix Requirements for Obtaining Advanced-practice Designation, By State17,18

New Mexico

1. Completion of a 60-hour physical assessment course
2. 150-hour, 300-patient-contact preceptor-ship supervised by a physician or other practitioner with prescriptive authority, with hours counted only during direct patient interactions
    - log of patient encounters submitted with application
    - patient encounters completed within two years of application

North Carolina

1. Has a certification from the Board of Pharmaceutical Specialties, is a Certified Geriatric Pharmacist, or has completed an American Society of Health-System Pharmacists (ASHP) accredited residency program.
2. Has a Doctor of Pharmacy degree, has three years of clinical experience, and has completed a certificate program in the area(s) covered by the protocol
3. Has a Bachelor of Science in Pharmacy, has five years of clinical experience, and has completed two certificate programs with at least one program in the area(s) covered by the protocol

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NEW MEXICO'S REQUIRMENTS

TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING
CHAPTER 10 MEDICINE AND SURGERY PRACTITIONERS
PART 11 PHYSICIANS SUPERVISING PHARMACIST CLINICIANS

16.10.11.1 ISSUING AGENCY: New Mexico Medical Board, hereafter called the board.
[4/5/97, 4/27/2000; 16.10.11.1 NMAC - Rn & A, 16 NMAC 10.11.1, 1/10/07]

16.10.11.2 SCOPE: This applies to physicians who supervise pharmacist clinicians.
[4/5/97, 4/27/2000; 16.10.11.2 NMAC - Rn, 16 NMAC 10.11.2, 1/10/07]

16.10.11.3 STATUTORY AUTHORITY: These rules of practice and procedure govern the practice of medicine in New Mexico and are promulgated pursuant to and in accordance with the Medical Practice Act, sections 61-6-1 through 61-6-35 NMSA 1978, the Uniform Licensing Act, section 61-1-1 through 61-1-33 NMSA 1978, and the Impaired Physician Act, section 61-7-1 through 61-7-12 NMSA 1978.
[4/5/97; 16.10.11.3 NMAC - Rn, 16 NMAC 10.11.3, 1/10/07]

16.10.11.4 DURATION: Permanent
[4/5/97; 16.10.11.4 NMAC - Rn, 16 NMAC 10.11.4, 1/10/07]

16.10.11.5 EFFECTIVE DATE: June 15, 1995, unless a later date is cited at the end of a section.
[4/5/97; 16.10.11.5 NMAC - Rn & A, 16 NMAC 10.11.5, 1/10/07]

16.10.11.6 OBJECTIVE: These rules and regulations are adopted to carry out the boards' responsibilities set forth in Sections 61-11B to 61-11B-3, NMSA 1978, the "Pharmacist Prescriptive Authority Act."
[4/5/97; 16.10.11.6 NMAC - Rn & A, 16 NMAC 10.11.6, 1/10/07]

16.10.11.7 DEFINITIONS:

A. "**Consultation**" means in person, telephonically, by two-way radio, by e-mail or by other electronic means.

B. "**Alternate supervising physician**" means a physician who holds a current unrestricted license, is a cosignatory on the notification of supervision, and agrees to act as the supervising physician in the supervising physician's absence with no change to the scope of practice or protocol of the pharmacist clinician. The alternate supervising physician must be approved by the board.

C. "**Scope of practice**" means duties and limitations of duties placed upon a pharmacist clinician by their supervising physician and/or the alternate supervising physician(s) and the board; includes the limitations implied by the field of practice of the supervising physician and/or the alternate supervising physician(s) and the board.
[4/5/97, 4/27/2000; 16.10.11.7 NMAC - Rn & A, 16 NMAC 10.11.7, 1/10/07]

16.10.11.8 INTRODUCTION: These rules and regulations are adopted to carry out the boards' responsibilities set forth in Sections 61-11B to 61-11B-3, NMSA 1978, the "Pharmacist Prescriptive Authority Act."
[4/5/97; 16.10.11.8 NMAC - Rn & A, 16 NMAC 10.11.8, 1/10/07]

16.10.11.9 APPROVAL OF SUPERVISING PHYSICIANS: A physician shall only be approved as a pharmacist clinician supervisor after the pharmacist clinician registers with the board by submitting an application for authority to practice under the supervision of a licensed physician. The application shall include:

A. the name, address, phone number of the applicant and his/her proof of current certification as a pharmacist clinician by the board of pharmacy;

B. the name, address, and phone number of the supervising physician;

C. a written protocol agreed to and signed by the pharmacist clinician and the supervising physician that shall include:

(1) a statement identifying the physician authorized to prescribe dangerous drugs and the pharmacist clinician who is a party to the guidelines or protocol;

(2) a statement of the types of prescriptive authority that the pharmacist clinician is authorized to make within his scope of practice which may include:

(a) a statement of the types of diseases, dangerous drugs or dangerous drug categories involved and the type of prescriptive authority authorized in each case; and

(b) a general statement of the procedures, decision criteria or plan the pharmacist clinician is to follow when exercising prescriptive authority;

(c) a statement of the activities the pharmacist clinician is to follow in the course of exercising prescriptive authority, including documentation of decisions made and a plan for communication to and consultation with the supervising physician concerning specific decisions made; documentation may occur on the prescriptive record, patient profile, patient medical chart or in a separate log book; and

(d) a statement that describes appropriate mechanisms for reporting to the physician the pharmacist clinician's activities in monitoring the patients; and

(e) a statement that describes provisions for immediate communication or consultation between the pharmacist clinician and the supervising physician or alternate supervising physician.

D. The pharmacist clinician may be authorized in the protocol to monitor dangerous drug therapy as follows:

(1) collecting and reviewing patient dangerous drug histories;

(2) measuring and reviewing routine patient vital signs including pulse, temperature, blood pressure and respiration; and

(3) ordering and evaluating the results of laboratory tests relating to dangerous drug therapy, including blood chemistries and cell counts, controlled substance therapy levels, blood, urine, tissue or other body fluids, culture and sensitivity tests when performed in accordance with guidelines or protocols applicable to the practice setting.

E. A pharmacist clinician may only prescribe controlled substances if he/she:

(1) has obtained a New Mexico controlled substances registration and a drug enforcement agency registration, and

(2) prescribes controlled substances within the parameters of written guidelines or protocols established under theses regulations and Section 3, A. of the Pharmacist Prescriptive Authority Act.

F. The protocol for each pharmacist clinician shall be reviewed by the board as least every two years.

G. A pharmacist clinician shall perform only those services that are set forth in the protocol.

H. Pharmacist clinicians may prescribe only those drugs described in a board approved protocol.

I. A physician may supervise as many pharmacist clinicians as the physician can effectively supervise and communicate with in the circumstances of their particular practice setting.

J. Within thirty days after an employer terminates the employment of a pharmacist clinician, the supervising physician and/or the pharmacist clinician shall submit a written notice to the board providing the date of termination and reason for termination. The pharmacist clinician shall not work as a pharmacist clinician until the board approves another supervising physician.

[4/5/97, 4/27/2000; 16.10.11.9 NMAC - Rn & A, 16 NMAC 10.11.9, 1/10/07; A, 1/2/08]

16.10.11.10 THE PHYSICIAN'S REQUIREMENTS OF SUPERVISION:

A. Supervising physicians must provide direction to pharmacist clinicians to specify the pharmacotherapeutic services to be provided under the circumstances in each case. This may be done by written protocol or by oral consultation. It is the responsibility of the supervising physician to assure that the appropriate directions are given and understood.

B. Supervising physicians must establish a quality assurance program for review of medical services provided by the pharmacist clinician.

C. If the supervising physician is of the opinion that circumstances warrant exceptions to the requirements set forth in Subsections A or B above, the supervising physician must specify the circumstances in writing and deliver the same to the board. The board will review, grant or deny requests for exceptions or waivers, at the board's discretion.

D. Documentation of the supervising physician reviews must be retained by the pharmacist clinician and be available for board inspection for a period of not less than five (5) years from the date of such reviews.

E. The pharmacist clinician must have prompt access to the physician by telephone or other electronic means for advice and direction.

F. If the supervising physician plans to be or is absent from his or her practice for any reason, the supervising physician cannot designate a pharmacist clinician to take over those duties or cover the practice during such absence. The supervising physician may designate an alternate supervising physician, approved by the board, to cover the practice and perform the duties of supervising physician. The alternate supervising physician will then supervise the pharmacist clinician and will be responsible for the pharmacist clinician's actions or omissions in exercising prescriptive authority or other duties as a pharmacist clinician.

G. In order to change a supervising physician between biennial renewals of registration, without a change to the pharmacist clinician's scope of practice or protocol, a pharmacist clinician shall submit to the board a change of supervising physician form and the required fee, as specified in 16.10.9.11 NMAC. The new supervising physician may only act after the application is approved by the board.

[4/5/97, 4/27/2000; 16.10.11.10 NMAC - Rn & A, 16 NMAC 10.11.10, 1/10/07]

16.10.11.11 REPORT AND COMMITTEE: The chair of the board shall appoint two (2) members of the board, or a member and an agent of the board to an oversight committee that shall also include two members appointed by the board of pharmacy. The oversight committee will make a report that may include non-binding recommendations to both the board of pharmacy and the medical board regarding disciplinary action. Each board can accept or reject the recommendations.

[4/5/97; 16.10.11.11 NMAC - Rn & A, 16 NMAC 10.11.11, 1/10/07]

HISTORY OF 16.10.11 NMAC:

Pre-NMAC History: The material in this part was derived from that previously filed with State Records Center and Archives under:

Rule 25, Physicians Supervising Pharmacist Clinicians, filed 6/15/95.

History of Repealed Material: [RESERVED]

Pharmacist Clinician Practice Guidelines
Prescriptive Authority Protocol
Dr.
&
PhC

Introduction

These guidelines establish the relationship between **PhC** and his designated supervising practitioner and alternates. This protocol serves as a mechanism by which the pharmacist clinician may perform drug therapy management for designated patients. They also serve as the standing delegation order by the supervising physician for the pharmacist clinician to perform all necessary activities related to drug therapy management according to the laws and regulations of the State of New Mexico, the State of New Mexico Board of Medical Examiners and the State of New Mexico Board of Pharmacy.

The ultimate responsibility lies with the supervising physician. The pharmacist clinician may manage drug therapy for disease states listed in these guidelines. All new diagnosis will require direct consultation with the supervising physician. The pharmacist clinician is authorized to identify and treat adverse drug reactions. Direct consultation with the supervising physician will take place. These guidelines take into consideration the qualifications, education and experience of the pharmacist clinician to treat the clinical situation presented.

Monitoring Dangerous Drug Therapy

The pharmacist clinician is authorized to perform medical histories, drug histories, physical assessments and mental status assessments as indicated to monitor the safety and efficacy of any aspect of the patient drug therapy.

The pharmacist clinician is authorized to order diagnostic testing necessary to monitor the safety and efficacy of any aspect of drug therapy, as well as evaluate disease status.
The pharmacist clinician is authorized to order mental health, physical therapy, occupational therapy, speech language and dietary consults as indicated to facilitate positive drug therapy outcomes.

Types of Prescriptive Authority Permitted

The pharmacist clinician is authorized to exercise prescriptive authority for the disease states listed in these guidelines. This includes initiating orders for new medications, adjusting dosages, and discontinuing medications as clinically indicated. Evidence Based Medicine, as it emerges in published reviews, expert consensus guidelines and clinical practice guidelines will serve as the general guideline for the treatment of these disease states. These practices will be continuously updated as dictated by emerging literature and respected medical consensus. The therapeutic class of these drugs will be per appropriate clinical guidelines.

Types of Disease states for which Prescriptive Authority is Permitted

The pharmacist clinician may treat the disease categories listed below utilizing appropriate guidelines per current standards of practice. Maintaining a practice with updated Guideline review is considered part of the personal development and continuing education plan of the listed practitioners.

Lipidemia /cholesterol- National Cholesterol Education Program, Adult Treatment Panel III guidelines and update

Diabetes- American Diabetes Association's Standards of Care (2010)

Hypertension-US Dept. of Health and Human Services Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure

DOCUMENTATION OF PHARMACIST CLINICIAN ACTIVITIES

The pharmacist clinician will document patient-care activities in the patient medical record. This may include, but is not limited to, documentation in the treatment plan, progress notes, physician orders, prescriptive record, and drug regimen review. A pharmaceutical plan of care will be maintained.

Pharmacist Clinician Scope of Practice

The scope of practice of **PhC(name)** as a Pharmacist Clinician will be primarily post-diagnostic, drug therapy related general medicine as outlined in the disease management protocols of this document. His role as a pharmacist clinician is multidimensional, with boundaries for accountability that interface with other members of the health care team.

Quality Improvement/Quality Assurance Peer Review

A supervising physician will review orders monthly. All conflicting findings discovered by a supervising physician will be resolved with the clinician in conference.
Charts will be randomly selected for Quality Assurance of patient care where PhC(name)is associated in their care. .

Position Statement of Supervising Physician

The pharmacist clinician and the supervising physician will meet regularly, at least monthly, to discuss and review patient care issues.

All assessment and plans of care are to be documented in the patient chart.
The supervising physician will review the pharmacist clinician's documentation as necessary.

The pharmacist clinician will notify the supervising physician of any new finding, a finding he is uncomfortable with, or is not covered in the protocol. The supervising physician will assess all.

_____ Date:_____

Dr.

PhC(name)

References etc.

University of New Mexico Health Sciences Center
University of New Mexico Hospitals
Pharmacist Clinician Protocol
Cardiovascular Pharmacotherapy

Pharmacist Clinician: Joe R. Anderson, PharmD, PhC, BCPS

Supervising Physician: Bart Cox, MD, Associate Professor UNM School of Medicine, Attending Physician Department of Cardiology, University of New Mexico Health Sciences Center

Alternate Supervising Physicians:

Abinash Achrekar, MD, Assistant Professor, UNM School of Medicine, Attending Physician Department of Cardiology, University of New Mexico Health Sciences Center

Bina Ahmed, MD, Assistant Professor, UNM School of Medicine, Attending Physician Department of Cardiology, University of New Mexico Health Sciences Center

PURPOSE:

1. To provide pharmaceutical care to University of New Mexico Hospital patients with at risk for and/or with cardiovascular (CV) disease. These will include patients with: coronary artery disease (CAD), risk for CV disease, heart failure, mechanical heart valves, dysrhythmia, angina, or other CV disorders not otherwise specified.
2. To provide medication therapy management and review a comprehensive patient medical profile, assuring that patient care is compliant with current treatment guidelines and University Hospital prescribing practices. These practices will be continuously updated as dictated by emerging literature.
3. To provide appropriate therapeutic monitoring.
4. To provide the most effective drug regime, in a cost-effective fashion.
5. To obtain pertinent medical and medication histories.
6. To conduct research in the therapy of cardiovascular disease.
7. To provide clinical pharmacy services for CV research studies.
8. Serve as an educational site for pharmacy students, pharmacy practice residents, pharmacy specialty residents and fellows, medical students, medical residents and fellows and nursing students.

DEFINITIONS:

Pharmacist Clinician (PhC): a pharmacist with additional training required by regulations adopted by the New Mexico Board of Pharmacy in consultation with the New Mexico Board of Medical Examiners and the New Mexico Academy of Physician Assistants, who exercises prescriptive authority in accordance with guidelines or protocol. {16 NMAC 19.4.23.2.7}

Pharmaceutical Care: is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life.

POLICY:

1. Measuring/reviewing vital signs: Vital signs will be taken by the nurse aide or medical assistant prior to the appointment for the pharmacist clinician. Measurements outside of the following will be called to the supervising physician and/or the alternate supervising physician:
   - Blood pressure: SBP > than 200 mmHg or DBP > 110 mmHg; SBP < 80 mmHg and/or DBP < 50 mmHg or any blood pressure that results in symptoms of hypotension.
   - Heart rate < 50 bpm or symptomatic bradycardia. Heart rate > 120 bpm or symptomatic tachycardia.
   - Temperature greater than 98.6 °F.
   - Blood glucose < 60mg/dL (If unable to correct with food items on-hand in clinic.)
   - Fasting > 400 mg/dL, or random blood glucose > 500mg/dL
   - Suspected diabetic ketoacidosis
   - Chest pain consistent with unstable angina
   - Shortness of breath at rest (New York Heart Association Functional Class IV) that is either of new onset or refractory to treatment.

2. A Pharmacist Clinician, post-Pharm. D Resident, or pharmacy student will assess patient risk factors, medication risk factors, and need for healthcare maintenance, and provide recommendations for the initiation and/or modification of therapeutic lifestyle changes (TLC) and/or medication therapy where appropriate.

3. The Pharmacist Clinician, post-Pharm. D Resident, or pharmacy student will assess and monitor patient response to therapy (lifestyle and/or pharmacotherapeutic) and maintain a comprehensive patient medication profile to include therapeutic goals to promote a rational, safe, and effective therapeutic regimen.

4. Patients will be provided education and counseling concerning their risk factors, therapeutic lifestyle change recommendations, medication regimens, and monitoring parameters.

5. A Pharmacist Clinician, post-Pharm. D Resident, or pharmacy student will provide other health care professionals with medication information.

6. The Pharmacist Clinician in charge will supervise pharmacy students and residents.

PROCEDURE:

Responsible staff: Pharmacist Clinicians, post-Pharm. D Residents, and pharmacy students. The Pharmacist Clinician in charge has final responsibility.

Procedural Steps:

1. Referral from provider: Providers may refer patients to the PhC or specialty clinic in which the PhC practices for assessment, evaluation, recommendations and/or management of cardiovascular and/or cardiovascular-related conditions included in this protocol. Therapeutic recommendations and/or changes will be communicated to the

referring provider and patient's primary care provider if they are not also the referring provider.

2. Physical assessment of the patient will be conducted and laboratory and diagnostic tests ordered as clinically necessary.

3. A SOAP note will be written and/or dictated to address some or all of the following:

   - Assessment of the cardiovascular and/or cardiovascular-related condition.
   - Medication history including drug allergies, intolerances, and adherence problems.
   - Medication dosing, anticipated duration, potential adverse effects, drug interactions, and treatment goals as per current clinical guidelines.
   - Use of most cost-effective medications.
   - Appropriate communication to the referring provider and primary care provider if they are not the referring provider.
   - Patient education regarding medication self-administration and disease state monitoring.
   - Referrals to cardiac rehabilitation, smoking cessation, diabetic education classes, or other patient education programs as deemed clinically necessary.
   - Upon consultation with the supervising physician and/or the primary care provider, referral to other specialty provider services as clinically appropriate.

4. The treatment of CV disease can be complicated by many other co-morbid conditions; therefore, treatment of the patient with CV disease is not restricted to the treatment of the CV system alone. Other factors that can potentially worsen CV disease include but is not limited to the following:
   - CV factors:
     - Ischemia or infarction
     - Uncontrolled hypertension
     - Valvular disease
     - New onset or uncontrolled dysrhythmia (eg. atrial fibrillation)
   - Systemic factors:
     - Inappropriate medications
     - Infection
     - Anemia
     - Uncontrolled diabetes
     - Thyroid dysfunction
     - Acute/Chronic pain
     - Mental illness (eg. Anxiety, depression)
     - Electrolyte disorders
     - BPH
     - Diet and/or dietary deficiencies
     - Gastrointestinal disorders (eg. GERD, peptic ulcer disease)
     - Pulmonary disease (eg. Asthma, COPD)
     - Pregnancy
   - Patient related factors:
     - Medication non-compliance
     - Dietary indiscretions
   - Alcohol, tobacco, or other substance abuse

- Hormone replacement therapy (HRT): Conjugated estrogens, progesterones, estrogen/progesterone combinations, and estradiol. HRT may be continued for menopause symptom control or may need to be refilled in order to taper the patient off of the medications. A risk/benefit assessment will be performed for every patient receiving or requesting HRT therapy. The Recommendations for estrogen and progestogen use in peri- and postmenopausal women: 2012 position statement of The North American Menopause Society or the most recent evidence-based literature will be used as guidance to treat and monitor patients with HRT.[22] The patients will be referred to their primary care provider for routine cancer screenings.

- Gastrointestinal medications: H_2 blockers, metoclopramide, sucralfate, antacids, and proton pump inhibitors (PPIs) for the treatment of gastroesophageal reflux (GERD.) Often times in patients with chronic heart failure, it may be difficult to ascertain whether pain has a cardiac or non-cardiac etiology. Based on information from the patient (i.e.: temporal relationship of pain with meals or symptoms in relationship to foods known to exacerbate GERD), an empiric trial of H_2 blockers or PPIs may be attempted to rule out worsening cardiac disease. Patients with documented esophageal dysfunction or gastroparesis secondary to diabetes mellitus may also present with non-cardiac related chest pain or discomfort. H_2 blockers and PPIs may also be used for GI protection in patients using anti-inflammatory/antiplatelet drugs.[23-27]

- Chronic and acute pain management: Non-controlled substances including anti-inflammatories (NSAIDS, COX-2 inhibitors, and salicylates), acetaminophen, anticonvulsants, and antidepressants.[27-29] If a patient needs a controlled substance for pain management they will be referred to the primary care provider. All new disease state findings will be discussed with supervising physician or primary care provider.

- Pulmonary Medications: All classes of pulmonary medications including but not limited to the following: beta-agonists, corticosteroids (inhaled and/or oral), anticholinergics, and leukotriene modifiers. In the form of oral medications, metered dose inhalers, dry powder inhalers, and nebulizers for the treatment of COPD/asthma. Additionally peak flow monitors, pulse oximetry, and pulmonary function tests may be ordered. All new disease state findings will be discussed with supervising physician and/or primary care provider.[30, 31]

- Electrolyte replacement/dietary supplements. This would include agents used in the treatment of drug-induced electrolyte abnormalities (i.e., potassium and magnesium,), anemia (i.e., vitamin B12, folic acid, iron, or multivitamins) and vitamin deficiencies (i.e., vitamin B12, vitamin D).

- Antidepressants: Serotonin reuptake inhibitors, tricyclic antidepressants (TCA's), and other antidepressants as indicated. Due to the high prevalence of cardiac and diabetes related depression, patients will be assessed and monitored for depression as clinically indicated using a validated tool such as the Geriatric Depression Scale or the Becks Depression Inventory.[32-34]

- Smoking cessation: Nicotine gum, patches, lozenges, inhalers, or nasal sprays, buproprion, or varenicline as deemed clinically appropriate per patient or referral to a smoking cessation program. Choice of product will consider each patient's needs.

5. The following medications may be ordered, adjusted, or administered with appropriate communication to the referring provider and/or primary care provider (PCP) as part of the CV PhC consult. Therapeutic management will be based on both professional guidelines and the most recent evidence-based research for each of the following areas:

   - Antihyperlipidemic medications: All classes of antihyperlipidemic agents not limited to the following: HMG Co-A reductase inhibitors (statins), bile acid sequestrants, fibric acid derivatives, niacin and nicotinic acid, cholesterol uptake inhibitors, fish oil (including omega 3 ethyl esters), as well as plant stanols and other OTC products where appropriate. Treatment will be in accordance with current NCEP guidelines.[1,2]

   - Antihypertensive agents: All classes of antihypertensive agents not limited to the following: diuretics, beta-blockers, calcium channel blockers, ace inhibitors, alpha blockers, angiotensin II antagonists, renin inhibitors, vasodilators, and centrally acting alpha adrenergic agonists where appropriate. Treatment will be in accordance with current Joint National Committee (JNC) on Prevention, Detection, Evaluation, and Treatment of high blood pressure guidelines.[3,4]

   - Antiplatelets/Anticoagulants: Antiplatelet drugs (both Rx and OTC), coumadin, low molecular weight heparins (LMWH), unfractionated heparin (UFH), anti-Xa medications, direct thrombin inhibitors (DTIs), in accordance with ACC/AHA and American College of Chest Physicians (ACCP) guidelines for the management of patients with cardiovascular disease.[5-18] Patient requiring long term warfarin, LMWH, UFH, DTIs, or anti-Xa medications will be referred to the UNMH Anticoagulation Clinic.

   - Antidiabetic medications: All classes of antidiabetic medications not limited to the following: sulfonylureas, α- glucosidase inhibitors, meglitinides, metformin, thiazolidinediones (TZD), glucagon-like peptide 1 agonists (GLP-1 agonists), dipeptidyl peptidase 4 inhibitors (DPP-4 inhibitors), amylin agonists (pramlintide), glucagon, and insulin (including syringes) where appropriate. This would also include self-monitoring blood glucose (SMBG) supplies including monitors, test strips, and lancets/lancet devices. Treatment will be in accordance with current American Diabetes Association Standards of Care.[19-20]

   - Vaccinations: Vaccines will be ordered by the pharmacist clinician and given by the pharmacist clinician or another authorized healthcare provider in the clinic in accordance with the Centers for Disease Control Guidelines (available at: http://www.cdc.gov/vaccines/recs/default.htm) and as listed in the New Mexico Board of Pharmacy prescriptive authority protocol.

   - Thyroid medications: T3 and T4. Hypothyroidism has been linked to elevated LDL and triglyceride values, both of which are risk factors for cardiovascular disease. TSH levels should be drawn at baseline and then 4-6 weeks after the initiation of therapy or dosage adjustment. Treatment will be in accordance with the American Association of Clinical Endocrinologists (AACE) guidelines for the treatment of hypothyroidism.[21] Elderly patients and those with CHF or CAD will be started at low doses and monitored closely.

PhC's will follow the recommendations based on the U.S. Department of Health and Human Services Clinical Practice Guidelines and as listed in the New Mexico Board of Pharmacy prescriptive authority protocol.[35]

- Weight loss: Gastrointestinal lipase inhibitors (i.e. orlistat). Obesity is a risk factor for cardiac disease. Therapeutic life style modifications are the first line treatment (i.e.: diet and exercise) for weight loss, however not all patients are able to obtain their goal body weight (within 10% of their ideal body weight). Diet and exercise counseling will be provided during consultations. Should it be deemed necessary for a patient to receive a prescription, it would only be done in conjunction with referral for additional nutritional counseling and consultation with the supervising physician and/or the patient's PCP.[36]

- Anti-arrhythmics: Class I and III anti-arrhythmics, digoxin, beta-blockers, or calcium channel blockers (for refill and dosage modification purposes only). All new disease state findings will be discussed with supervising physician.[8,37]

- Anti-anginals: Beta-blockers, calcium channel blockers, ranolazine, and nitrates as indicated. Treatment will be in accordance with recent AHA/ACC guidelines for the management of patients with stable chronic angina.[5]

- Congestive Heart Failure: For Stages A – D Heart Failure (HF) with preserved or reduced ejection fraction, therapeutic lifestyle modifications and medications will be managed according to the AHA/ACC Guidelines for heart failure.[38]

- Diuretics: Thiazides, loop diuretics, aldosterone inhibitors, potassium sparing diuretics, and vasopressin antagonists. These medications will be used in combination as clinically necessary to treat HF and its associated symptoms of volume overload. Choice of medications and dose regimen will be individualized to each patient as clinically tolerated. The supervising physician will be notified should the patient become unresponsive to the prescribed diuretic regimen. Treatment will be in accordance with the ACC/AHA guidelines for the treatment of heart failure.[38]

- Antibiotics: Amoxicillin, cephalexin, clindamycin, azithromycin, or clarithromycin for endocarditis or bacteremia in joint replacement prophylaxis prior to dental procedures or other procedures as per ACC/AHA guidelines for the management of patients with valvular disease.[14]

- Benign prostatic hyperplasia/Urinary incontinence: α_1-adrenergic antagonists, 5α-reductase inhibitors, anticholinergics for urinary incontinence/urge symptoms, and mirabegron. Treatment will be in accordance with the American Urologic Association guidelines or more recent data, including use of screening tools for monitoring.[39,40]

- Medication Review: All patients' medications will be routinely reviewed for appropriateness of therapy. The review may include identification of drug-drug interactions, inappropriate dose and duration, drug-disease interactions, no necessity of the drug based on medical conditions, and therapeutic duplication. As a result of this review, medications may be adjusted, discontinued or tapered off. Refills of any non-controlled substances prescriptions may be made during this review or during

ongoing management of other chronic diseases to ensure adherence with maintenance therapy.

- Medications deemed appropriate per consultation with PCP or attending physician, or changes based on patient-specific formulary or patient assistance program.

6. Laboratory and diagnostic tests to be ordered where appropriate (including, but not limited to):
   - Liver function tests—sequential testing will be performed at specified intervals to monitor for potential toxicity.
   - Fasting complete lipoprotein profiles (Total cholesterol, LDL, HDL and triglycerides), or individual lipoprotein elements where appropriate.
   - Thyroid function tests.
   - Complete blood count (CBC) with or without differential or Hemoglobin/Hematocrit
   - Glycosylated hemoglobin (HbA1c), blood glucose, C-peptide, and OGTT
   - Renal function tests.
   - Electrolytes
   - hs-C-reactive protein (hs-CRP)
   - B-type natriuretic peptide (BNP)
   - Coagulation panel (including evaluation for hypercoagulability)
   - Iron studies, B12, folate, vitamin D
   - Homocysteine
   - Therapeutic drug monitoring
   - Drug toxicology screening
   - Urinalysis
   - Metanephrines (urinary and/or plasma), aldosterone, plasma renin activity
   - Labs and/or diagnostics deemed appropriate for assessment and evaluation by the supervising physician and/or PCP
   - ECG
   - Transthoracic echocardiogram
   - Transesophageal echocardiogram (after consultation with supervising physician)
   - Exercise treadmill and pharmacologic stress tests (with and without nuclear perfusion), cardiac catheterization upon consultation with the supervising physician
   - Coronary artery calcium scoring (Computerized Tomography)
   - Pulmonary function tests (PFT's)
   - Sleep study
   - Chest X-ray
   - Oximetry
   - Ankle-brachial index
   - 24-hour ambulatory blood pressure monitoring
   - Renal ultrasound
   - Carotid ultrasound
   - Lower extremity Doppler ultrasound
   - D-dimer
   -

7. Clinical pharmacy services for cardiovascular research studies will be those services required by the clinical research protocol to be provided by either the principal investigator or co-investigator.

- Performing required physical examination procedures.
- Ordering and interpretation of required diagnostics, such as laboratory tests, electrocardiograms, chest radiographs, echocardiograms, etc.
- Initiating and titrating study medication per research protocol and writing medical orders for research studies.
- Initiating and adjusting concomitant medication as necessary per research protocol.
- Providing patient education regarding the research protocol.
- Administration of research-related medications.
- Submission of consult requests for other medical services when appropriate.

8. All clinic notes will be scanned, typed and/or dictated into the patient's electronic medical record at UNMH.

9. Quality assurance: The supervising physician will review at least 10% of the PhC charts. The PhC will meet with the supervising physician as needed to review cases.

10. Patients will be referred back to their PCP or urgent care for any new symptoms reported by the patient regardless of etiology for appropriate assessment. If the new symptoms are deemed urgent, the PCP and/or supervising physician will be immediately consulted for further instructions.

Pharmacist Clinician Name (printed): _____

Pharmacist Clinician (signature): _____ Date: _____
Joe R. Anderson, PharmD, RPh, PhC, BCPS

Supervising Physician:

Physician Name (printed): _____

Physician (signature): _____ Date: _____
Bart Cox, MD, Internal Medicine/Cardiology

Alternate Supervising Physicians:

Physician Name (printed): _____

Physician (signature): _____ Date:_____
Abinash Achrekar, MD, Internal Medicine/Cardiology

Physician Name (printed): _____

Physician (signature): _____ Date:_____
Bina Ahmed, MD, Internal Medicine/Cardiology

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UNM COLLEGE of PHARMACY

PHYSICAL ASSESSMENT FOR PHARMACISTS

At the completion of the course, the student will demonstrate the ability to assess physical abnormalities and monitor drug therapy by satisfactorily performing a physical examination on a simulated patient.

BASIC PRINCIPLES OF COMMUNICATION; BASIC PATIENT INTERVIEWING

The pharmacist shall be able to:

1. Use open-ended questions to gather unbiased, patient-centered information from patients.
2. Use closed-ended questions to clarify and/or confirm information.
3. Demonstrate active-listening skills.
4. Properly introduce self to patient and provide comfortable setting that promotes respect, empathy, and confidentiality in interviewing.
5. Use proper dress, professional mannerism, voice tone, language, "body language," and recording techniques to promote patient communication.
6. Screen systems quickly and redirect interview using directed and closed-ended questions.
7. Demonstrate sensitivity in dealing with sensitive topics such as: death & dying, sexual activity & history, domestic violence, psychiatric illness, alcohol and/or drug abuse.
8. List techniques for dealing with patients with special needs (e.g. geriatrics, pediatrics, inebriated patients, adolescents, hostile patients, schizophrenics, attractive or seductive patients, AIDS patients, patients of different cultures, blind patients).

THE HEALTH HISTORY; MEDICATION HISTORY

The pharmacist shall be able to:

1. Describe the components, content and organization of the health history (e.g. chief complaint, history of present illness, past medical history, etc.).
2. Obtain complete, descriptive data of the history of present illness by use of the "Basic Seven."
3. Perform and record a health history, up to the Review of Systems, on a real or simulated patient.
4. Perform a medication history including a) appropriate medication history documentation, b) drug allergies, c) use of OTC products or herbal therapies, d) an assessment of the patient's compliance with treatment, e) response to therapy, f) presence or lack of adverse reactions, and g) a plan for any indicated interventions or other corrective action, if indicated.

Review of Systems; Approach to Symptoms

The pharmacist shall be able to:

1. List appropriate questions to screen for abnormalities of the various body systems.
2. Obtain and record a Review of Systems on a real or simulated patient, using open-ended questions for screening, and directed, closed-ended questions to clarify problems.
3. Obtain complete, descriptive data by use of the "Basic Seven."
4. Interpret patient symptoms and describe in medical terminology that facilitates a differential diagnosis or presentation to a physician for a differential diagnosis.
5. Apply the information obtained from a health history, complete with review of systems, to monitor a real or simulated patient's response to a given drug for a general condition (e.g. pain) and identification of any adverse drug reactions.

Documentation & SOAP/SOAR Format

The pharmacist shall be able to:

1. Classify all findings as subjective or objective.
2. Given a patient interview, history, physical findings and laboratory data, decide which findings are most appropriate to include in your note.
3. Write assessments and plans that are accurate, clear, and concise.

Physical Assessment Techniques, Vital Signs

The pharmacist shall be able to:

1. Describe room environment and positioning of the patient during the physical exam.
2. Demonstrate appropriate technique for measuring vital signs in adult patients.
3. List the normal ranges of vital signs in adult patients.

Examination of the Head, Eyes, Ears, Nose, Throat and Skin

The pharmacist shall be able to:

1. Name the structures of the head, eye, ears, nose and throat.
2. Examine the head and neck, describing the possible abnormalities using the correct terminology.
3. Know how to palpate the lymph nodes and be familiar with reasons attributable to enlarged lymph nodes.
4. Discuss expected facial/neck findings in inadequately treated hypo- or hyperthyroidism.
5. Demonstrate how to test for visual acuity, visual fields, the external eye structures, and ocular movements, describing normal and possible abnormal findings.

6. Examine extraocular movements, and name the eye muscles and cranial nerves involved in each direction tested.
7. Describe the different parts and appropriate use of the opthalmoscope and otoscope.
8. Examine papillary response, accommodation, the iris, lacrimal apparatus, and the anterior chamber, explaining possible abnormalities.
9. List drugs that have adverse ocular effects and the techniques for assessing such effects.
10. Perform a funduscopic exam, describing structures examined.
11. Describe funduscopic monitoring for glaucoma, increased intraocular pressure, or adverse ocular effects caused by poorly controlled hypertension or diabetes.
12. Examine the ear, describing the structures of the external and inner ear and discuss findings one might find in otitis externa and/or otitis media.
13. Describe how the performance of an ear exam on a child is different from that of an adult.
14. Test hearing, lateralization, and auditory air and bone condition.
15. Examine the nose and mouth, describing structures. Discuss potential abnormalities.
16. List objective terms used to describe the qualities of the hair, skin, and nails.
17. Use appropriate terms to describe the color, shape, size, structure, and distribution of abnormal dermatological lesions.
18. Use appropriate documentation to document the physical findings of the head, eyes, ears, nose, throat, and skin.

EXAMINATION OF THE NERVOUS SYSTEM AND THE MENTAL STATUS EXAM

The pharmacist shall be able to:

1. List the 12 cranial nerves and explain the function of each.
2. Examine the 12 cranial nerves and document findings.
3. Explain the motor and sensory pathways of the nervous system, examine each, and document findings.
4. Identify the dermatomes used in pain assessment.
5. Examine and grade the reflexes and document findings.
6. Examine and grade muscle strength and document findings.
7. Demonstrate techniques for evaluating and reporting level of consciousness, appearance, behavior, orientation, and affect in a patient.
8. Demonstrate techniques for evaluating and reporting speech and language that may be abnormal in a patient with a developmental, neurological, mental or emotional condition.
9. Asks appropriate questions to determine a patient's mood, affect, and attitude as a tool to determine a patient's probability of compliance with treatment, response to antidepressants, and identification of depressive adverse effects to medication (e.g., antihypertensives).

10. Determine a patient's orientation, memory, and higher cognitive functions using appropriate questioning and assessment tools (e.g., proverbs, serial 7 subtraction).
11. Perform a complete mental status exam on a real or simulated patient, and discuss drugs or drug classes, which are monitored by use of elements in the mental status exam.
12. Be able to incorporate your mental status findings into a SOAP format chart note.

EXAMINATION OF THE CARDIOVASCULAR SYSTEM

The student shall be able to:

1. Identify the point of maximal impulse by inspection and palpation.
2. Identify auscultation locations for the 4 heart valves.
3. Using proper auscultation techniques, identify SB_{1B} and SB_{2B} heart sounds as well as common "extra" heart sounds.
4. Describe the grading and attributes of murmurs.
5. Identify the valve and abnormality (stenosis or insufficiency) most likely associated with different murmurs based on location and timing of the murmur.
6. Measure the jugular venous pressure and discuss the significance of elevated pressure.
7. Palpate the following pulses: carotid, radial, ulnar, brachial, dorsalis pedis, posterior tibial, popliteal, and femoral.
8. Examine the lower extremities for edema.
9. Accurately measure blood pressure using a sphygmomanometer.
10. Appropriately document physical findings on a patient record.
11. Using proper interviewing technique, effectively obtain information from a patient regarding his or her disease (history, symptomatology, etc.) and drug history.
12. For a given patient with a given cardiovascular disease, utilize appropriate physical assessment techniques to assess disease severity, monitor drug efficacy and adverse effects.

EXAMINATION OF THE THORAX AND LUNGS

The pharmacist shall be able to:

1. Identify intercostals spaces, structures of the chest and back, and location of the lungs.
2. Inspect the thorax and describe retractions, and abnormalities found in COPD.
3. Percuss the lungs and excursion of the diaphragm in the correct locations.
4. Palpate the lungs and describe fremitus.
5. Auscultate the lungs and describe possible adventitious sounds and associate pathology.
6. Describe abnormal patterns of breathing and their significance.
7. Demonstrate appropriate documentation of pulmonary findings.

Examination of the Musculoskeletal Systems, Abdomen, Rectum, Anus, Breast, and Prostate

The pharmacist shall be able to:

1. Assess significant joints for range of motion, crepitus, inflammation, and deformities.
2. Examine, grade and report muscle strength.
3. Use appropriate documentation to document physical findings of the musculoskeletal system examination.
4. List the proper sequence of examination techniques for the abdomen.
5. Indicate where the internal organs are located with respect to the abdomen.
6. Auscultate the abdomen for bowel sounds and bruits (aorta, renal, iliac and femoral)
7. Perform light and deep palpation of the abdomen to examine for tenderness, landmarks of the liver or spleen, fluid, and masses.
8. Be able to determine liver size through percussion.
9. Be able to percuss for spleenomegaly, and for costovertebral angle tenderness.
10. Describe possible findings in appendicitis and/or acute cholecystitis.
11. On lab model or through description, examine the anus, rectum, breast, and prostate.

Examination of the Infant, Child and Adolescent

The pharmacist shall be able to:

1. Describe the normal vital signs for an infant and child.
2. Demonstrate special procedures for examining an infant or child.
3. Discuss special considerations in examining or counseling an adolescent.

NORTH CAROLINA'S REQUIREMENTS

North Carolina

CLINICAL PHARMACIST PRACTITIONER PROTOCOL

Supervising physician: Thomas O'Connell, MD

Clinical Pharmacist Practitioner: Caron Misita, PharmD, BCPS

The following protocol summarizes medication and laboratory prescribing privileges granted to Caron Misita, PharmD, BCPS by Thomas O'Connell, MD for patients of the UNC Hospitals Highgate Specialty Center in Durham, NC.

Patients seen at the UNC Hospitals Highgate Specialty Center and evaluated by Thomas O'Connell, MD, or another physician, may be referred to the Clinical Pharmacist Practitioner for drug therapy management of the following medical conditions.

Diagnosis	ICD-9 code
Diabetes	250.0-250.8
Hyperlipidemia	272.0, 272.1, 272.4
Hypertension	401.1, 401.9
Hypothyroidism	243, 244.0, 244.1, 244.8, 244.9
Osteoporosis	733.00
Thyroid hormone overproduction	242.8
Tobacco use disorder	305.1

Medication Therapy

The following medication classes are authorized by Thomas O'Connell, MD for written, electronic or telephone prescription order by Caron Misita, PharmD, BCPS. Medications listed below are grouped by therapeutic category.

Insulins
Sulfonylureas
Thiazolidinediones
Biguanides
Alpha-Glucosidase Inhibitors
Meglitinides
Dipeptidyl Peptidase IV (DPP-IV) Inhibitors
Amylin Mimetics
Incretin Mimetics
SGLT2 inhibitors
Tricyclic antidepressants (neuropathy therapy)
Gabapentin (neuropathy therapy)
Duloxetine (neuropathy therapy)

Diuretics
Beta Blockers
Alpha Blockers
ACE Inhibitors/Angiotensin Receptor Blockers
Calcium Channel Blockers
Alpha 2 Adrenergic Agonist
Vasodilators

HMG-CoA Reductase Inhibitors
Fibric Acid Derivatives
Bile Acid Sequestrants
Niacin
Omega-3 Fatty Acids

Levothyroxine
Liothyronine
Thyroid, dessicated
Antithyroid agents (methimazole, PTU)

Bisphosphonates
Calcitonin
Calcitriol
Raloxifene
Parathyroid Hormone Analog (teriparatide)

Nicotine Replacement Therapy
Partial Nicotine Agonist (varenicline)
Bupropion (as smoking cessation aid)

Supervising MD initials_____

Medication dosage forms include oral, transdermal, inhaled, intranasal and subcutaneous therapies. Dose and schedule will be determined according to standard medical, pharmacy, and drug information references (e.g. *Lexi Comp Drug Information Handbook*) as well as primary literature sources, including consensus guidelines such as those of the American Diabetes Association. The *Lexi Comp Drug Information Handbook* is updated monthly via electronic device by the Clinical Pharmacist Practitioner and will be maintained on site during clinic times.

Substitution of chemically dissimilar products is not permitted without written physician authorization.

Laboratory Tests and Monitoring

The following laboratory tests are authorized by Thomas O'Connell, MD for ordering by Caron Misita, PharmD, BCPS. Laboratory evaluation will be used as a means of appropriately dosing and monitoring efficacy and safety of medication therapy.

Laboratory Test	Medication Therapy
Blood glucose	diabetes medications
Hemoglobin A1C	diabetes medications
Liver enzymes	thiazolidinediones, hyperlipidemia medications
Serum electrolytes/creatinine	diabetes medications, diuretics, ACE inhibitors/ARBs
Complete blood count	Biguanides, antithyroid agents
B12	Biguanides
Folate	Biguanides
Urine microalbumin / creatinine	diabetes medications, ACE inhibitors/ARBs
Urinalysis	diabetes / hypertension medications
Lipid panel	hyperlipidemia medications
Creatine phosphokinase	hyperlipidemia medications
Apolipoprotein B	hyperlipidemia medications
Thyroid stimulating hormone	thyroid medications
Free or total triiodothyronine (T3)	thyroid medications
Free or total thyroxine (T4)	thyroid medications
Alkaline phosphatase	osteoporosis medications
Serum/urine calcium	osteoporosis medications
Serum phosphorus	osteoporosis medications
Uric acid	osteoporosis medications
Urine/serum N- or C-telopeptide	osteoporosis medications
Serum osteocalcin	osteoporosis medications
Serum PINP / PICP	osteoporosis medications
Bone mineral density (DXA)	osteoporosis medications

Emergency Plan

Medical emergencies will be handled following UNC Hospitals Highgate Specialty Center procedures for such situations. In the event of a cardiopulmonary arrest, cardiopulmonary resuscitation will be initiated while office staff calls 911.

Supervising MD initials_____

Consultation and Supervision
Physician consultation will be sought by the Clinical Pharmacist Practitioner for all of the following situations as well as any other deemed appropriate.

- Any situation that extends beyond the intent of the protocols, scope of practice, or experience level of the Clinical Pharmacist Practitioner
- A patient's condition fails to respond to the management plan in an appropriate time frame
- Any uncommon, unfamiliar, or unstable patient condition is encountered
- Any condition which does not fit the commonly accepted diagnostic pattern for a disease/condition
- All emergency situations (after initial stabilizing care has been started)

Notation of the physician consultation, including the physician's name, will be made in the clinic visit note included in the patient's medical record.

Quality Control, Review and Countersignature
The Clinical Pharmacist Practitioner and supervising physician will meet weekly in a face-to-face conference for the purpose of quality control and review. The supervising physician (or referring attending physician) will countersign all clinic notes made by the Clinical Pharmacist Practitioner within seven days of the visit.

Patient Notification
Patients will be notified of their referral to the Clinical Pharmacist Practitioner at the time of scheduling the appointment. The practice agreement will be explained to the patient at the beginning of the first visit with the Clinical Pharmacist Practitioner.

Termination Provision
The practice agreement will be terminated if either the Clinical Pharmacist Practitioner or the supervising physician resigns from the agreement.

Approved: _____ _____
Supervising Physician Date

_____ _____
Clinical Pharmacist Practitioner Date

North Carolina

Certificate Program Requirements

According to 21 NCAC 46.3101(2) b, all certificate programs must contain a core curriculum including at a minimum the following components:

1. communicating with healthcare professionals and patients regarding drug therapy, wellness, and health promotion,

2. designing, implementing, monitoring, evaluating, and modifying or recommending modifications in drug therapy to insure effective, safe, and economical patient care,

3. identifying, assessing, and solving medication-related problems and providing a clinical judgment as to the continuing effectiveness of individualized therapeutic plans and intended therapeutic outcomes,

4. conducting physical assessment, evaluating patient problems, ordering and monitoring medications and/or laboratory tests in accordance with established standard of practice,

5. referring patients to other health professionals as appropriate,

6. administering medications,

7. monitoring patients and patient populations regarding the purposes, uses, and effects and pharmacoeconomics of their medication and related therapy,

8. counseling patients regarding the purposes, uses, and effects of their medication and related therapy,

9. integrating relevant diet, nutritional and non-drug therapy with pharmaceutical care,

10. recommending, counseling, and monitoring patient use of non-prescription drugs, herbal remedies, and alternative medicine practices,

11. devices, and durable medical equipment,

12. providing emergency first care,

13. retrieving, evaluating, utilizing, and managing data and professional resources,

14. using clinical data to optimize therapeutic drug regimens,

15. collaborating with other health professionals,

16. documenting interventions and evaluating pharmaceutical care outcomes,

17. integrating pharmacy practice within healthcare environments,

18. integrating national standards for the quality of healthcare, and

19. conducting outcomes and other research.

Print Form

North Carolina Board of Pharmacy and North Carolina Medical Board

Clinical Pharmacist Practitioner Application for Approval Form Instructions

Clinical Pharmacist Practitioner Approval to Practice Process
[See Rule 21 NCAC 32T.0101 or 21 NCAC 46.3101]

APPLICATIONS ARE CONFIDENTIAL AND MAY BE DISCUSSED ONLY WITH THE CLINICAL PHARMACIST PRACTITIONER APPLICANT OR SUPERVISING PHYSICIAN

MEETING DATES AND DEADLINES

Completed application forms WITH ALL REQUIRED ATTACHMENTS must be received in the office of the Board of Pharmacy by the first day of the month. The Board of Pharmacy will then submit these applications to the North Carolina Medical Board after approval at the Pharmacy Board meeting. The applicant is responsible for insuring that the application is completed when submitted. Board of Pharmacy meeting dates are listed on its website (www.ncbop.org). Keep a current check on the Pharmacy Board's website for any revised meeting dates.

To become a CPP, as defined, in 21 NCAC 46.3101, you must be a licensed pharmacist and have an agreement with a physician, as defined in 21 NCAC 46.3101 (6). In addition, you must have either: (1) have completed a Board of Pharmaceutical Specialties (BPS) Certification or Geriatric Certification, or the American Society of Health-Systems Pharmacists (ASHP) accredited residency program and have 2 years clinical experience **OR** (2) you must have earned a PharmD degree, have 3 years experience, and have completed a Certificate Program **OR** (3) you must have earned a BS degree, have 5 years experience, and have completed two certificate programs.

ONLY original signatures are acceptable on the application returned to the Boards. Facsimiles or copies are not acceptable and will be returned.

Submit all material to: Attn: Deborah Stump, Director of Licensing
NC Board of Pharmacy
6015 Farrington Road, Suite 201
Chapel Hill, NC 27517

Revised April 2013

I. *APPLICATION FOR APPROVAL TO PRACTICE AS A CLINICAL PHARMACIST PRACTITIONER IN NORTH CAROLINA*

Applications must be reviewed and approved by the NC Board of Pharmacy and the NC Medical Board. Written notification of the *FINAL* action will be mailed to the CPP's home address or preferred address approximately 7 to 10 days after approval by the NC Medical Board. **Final action on an application cannot be given by phone.**

- Completed application forms must be typewritten or neatly printed.
- Please list your protocols on the Template for Clinical Pharmacist Practitioner Protocol and have the supervising physician initial the form. If additional pages are required, please have the supervising physician initial all pages. ***This needs to be submitted with the application and it should be kept on site at all times.***
- Please include the name of the practice, practice address, name of the supervising physician and attach the appropriate application fee ($100) made payable to the **NC Medical Board,** to the application form. This fee is non-refundable.

DEA Numbers
If you are going to prescribe or order controlled substances, you must obtain a DEA number. Contact: Drug Enforcement Administration, Registration Unit, 75 Spring Street, SW, Room 740; Atlanta, GA 30303 (888-219-8689) or www.deadiversion.usdoj.gov - Direct Registration - Form 224.

Submit all material to: Attn: Deborah Stump, Director of Licensing
NC Board of Pharmacy
6015 Farrington Road, Suite 201
Chapel Hill, NC 27517

II. *CLINICAL PHARMACIST PRACTITIONER CHANGE OF STATUS FORM*
[All pages must be initialed by supervising physician.]

Change of status form is needed for:
* Addition of practice sites
* Addition/Change of supervisor at previously approved site

Requests for addition of practice sites and supervising physicians may be processed administratively by the NC Medical Board in a timely manner. Administrative approval is not automatic.

A. Mail to: NC Medical Board, PO Box 20007, Raleigh, NC 27619-0007
B. Completed change of status forms must be typewritten or printed legibly. **Incomplete forms will be returned.**

III. Registration/Annual Renewal: You will be required to renew your approval(s) to practice with the Medical Board within 30 days of your birth date each year [See Rule 21 NCAC 32T.0101(c)]. You will be notified by mail when it is time for you to renew.

Only original signatures are acceptable on the application returned to the Boards. Facsimiles or copies are not acceptable and will be returned.

APPLICATION FOR CLINICAL PHARMACIST PRACTITIONER

Print Form

North Carolina Board of Pharmacy
6015 Farrington Road, Suite 201
Chapel Hill, NC 27517

Application for approval to practice as a CPP is effective for a period of **1 YEAR** from the date your signed application is notarized.

North Carolina General Statute 90-691 (a) (1) states an application may be denied or revoked if the applicant gives false information or withholds material information from the Committee in procuring or attempting to procure a license.

I hereby make application for approval to practice as a CPP in the State of North Carolina and submit the following statement concerning my age, moral character, medical education, and practice.

First Name: _____ Middle Name: _____ Last Name: _____ Suffix: _____

Other names you have been known by: _____
(Provide copies of official documents showing name change, i.e., a marriage certificate)

Home Address: _____

Practice Address: _____

Preferred Mailing Address (choose one): ◯ Practice ◯ Home

Place of Birth: _____ Date of Birth (Month): _____ (Day): _____ (Year): _____

Email Address: _____

Current Home Phone Number: _____
(Enter 10-digit phone number only, with no dashes, spaces or parentheses)

Current Business Phone Number: _____

Current Fax Number: _____

Print Form

DESCRIPTION OF PRACTICE STRUCTURE

A. Please describe, in detail, the structure of your practice and relationship with your supervising physician. Examples may include whether you and your supervising physician are employed within the same practice, whether you accept referrals from other physicians within or outside your practice and your supervising physician is a clinic or program director, or whether you have your own freestanding practice and accept referrals from outside supervising physicians.

B. Describe/Check all that apply:

- ☐ CPP and Supervising Physician, same practice
- ☐ CPP accepts referrals from other physicians (within or outside of CPP's practice) and is supervised by clinic, program, or medical director
- ☐ University/Academic setting
- ☐ Hospital setting
- ☐ CPP freestanding practice receiving referrals from outside physicians

C. Description of Details:

REQUIREMENTS FOR CPP APPLICANTS

To become a CPP, as defined in 21 NCAC 46.3101, you must be a licensed pharmacist and have an agreement with a physician, as defined in 21 NCAC 46.3101 (6). In addition, you must have either: (1) have completed a Board of Pharmaceutical Specialties (BPS) Certification or Geriatric Certification, or the American Society of Health-Systems Pharmacists (ASHP) accredited residency program and have 2 years clinical experience **OR** (2) you must have earned a PharmD degree, have 3 years experience, and have completed a Certificate Program **OR** (3) you must have earned a BS degree, have 5 years experience, and have completed two certificate programs.

Academic Degree: _____ University Attended: _____
(BS or Doctorate in Pharmacy)

Date Degree Awarded: _____

Pharmacist License: _____ Year Original License Issued: _____
(NC License Number)

BPS or Geriatric Certification: _____ Date Completed: _____ Certificate Number: _____
(Specialty Certification)

ASHP Residency: _____ Date Started: _____ Date Completed: _____
(Location)

Print Form

CERTIFICATE PROGRAMS

The Certificate Program completed must be a North Carolina Center for Pharmaceutical Care (NCCPC) or American Council on Pharmaceutical Education (ACPE) approved certificate program in the area of practice covered by the CPP agreement. Two Certificate Programs are required for BS degree recipients, and one is required for PharmD recipients.

(Certificate Completed)	(Identifier)	(Date Completed)
(Certificate Completed)	(Identifier)	(Date Completed)

EXPERIENCE

Five years of clinical experience is required for BS degree recipients, and 3 years is required for PharmD recipients. Different locations should be listed separately below.

Position Held	(Date Started)	(Date Completed)

Describe clinical experience: _____

Position Held	(Date Started)	(Date Completed)

Describe clinical experience: _____

Position Held	(Date Started)	(Date Completed)

Describe clinical experience: _____

Position Held	(Date Started)	(Date Completed)

Describe clinical experience: _____

Position Held	(Date Started)	(Date Completed)

Describe clinical experience: _____

Print Form

PHYSICIAN INFORMATION

****If you will have multiple supervising physicians at the same practice site, please provide the following information for each supervising physician. Also, please have each physician sign and date this form. Attach additional sheets if necessary.**

Physician's Name: _____ NC License Number: _____

Type of Practice: _____

Practice Address: _____

Practice Phone Number: _____ Practice Fax Number: _____

Physician's Name: _____ NC License Number: _____

Type of Practice: _____

Practice Address: _____

Practice Phone Number: _____ Practice Fax Number: _____

Physician's Name: _____ NC License Number: _____

Type of Practice: _____

Practice Address: _____

Practice Phone Number: _____ Practice Fax Number: _____

CLICK "PRINT FORM" (TOP RIGHT CORNER), HAVE THE APPROPRIATE PERSON(S) SIGN & DATE BELOW, AND SUBMIT TO THE NC BOARD OF PHARMACY

Pharmacist Signature: _____ Date: _____

Physician Signature: _____ Date: _____

Physician Signature: _____ Date: _____

Physician Signature: _____ Date: _____

Approved by:

_____ _____

President of the NC Board of Pharmacy Date:

_____ _____

Executive Director of the NC Board of Pharmacy Date:

Once approved by the NC Board of Pharmacy, the application will be forwarded to the NC Medical Board. A fee of $100.00 for the initial application will be due to the NC Medical Board with the application.

CLAIMS INFORMATION

The Clinical Pharmacist Practitioner applicant must complete this form for **each** liability or malpractice claim. **Please print or make as many photocopies of this form as needed.** Complete one form for each claim or suit. Original signature of the clinical pharmacist practitioner applicant is required on each completed form.

1. Briefly describe the details of the allegations against you. Include the patient's name, a brief history, comments regarding the care surrounding the allegations. If suits are pending, a very brief summary of the allegations or charges must be included regardless of the litigation state. Simply stating that the charges were dismissed is inadequate. If charges were dismissed, please provide official documentation regarding the dismissal.

2. Date of the claim: _____

3. If an insurance carrier was involved, list the name, address and telephone number:

4. Is the claim pending? *(yes or no)*: _____

5. Was there a judgment or settlement? *(yes or no)*: _____

6. What was the amount and date of the judgment **OR** settlement?

   Amount: _____

   Date: _____

7. Comments:

I certify that the information which I have given is correct to the best of my knowledge.

_____ _____

Signature of Clinical Pharmacist Practitioner Applicant Date

(ORIGINAL SIGNATURE)

AUTHORIZATION FOR RELEASE OF MALPRACTICE INSURANCE INFORMATION

To Whom It May Concern:

I, _____, hereby consent and request that the North Carolina Board of Pharmacy and its employees and/or agents be permitted to examine and obtain copies of all records relating to my file with _____ related to claims, settlements, payments and dismissals and/or any other documents maintained by this malpractice insurance carrier. I understand that by signing this document, the North Carolina Board of Pharmacy may review the information contained in these files in conjunction with the review process for my application for approval as a Clinical Pharmacist Practitioner.

I am willing that a photostat of this Authorization be accepted with the same authority as the original.

Date: _____

_____
Signature

_____
(Print Name)

_____
(Street Address)

_____
(City, State, Zip Code)

_____
(Phone Number) *enter 10 digits with no spaces, hyphens, etc.*

CLINICAL PHARMACIST PRACTITIONER APPLICANT BACKGROUND

Please answer the following questions (yes or no). **Provide a detailed description for any "YES" answers.**

YES / NO

1. Have you ever been convicted of a misdemeanor/felony (other than minor traffic violation) or do you have any charges pending whatsoever? Charges or convictions of DWI's should be reported.

2. Have you ever had, or do you now have any pending actions against a pharmacist license issued to you by another state? This includes consent order or agreement, revocation, suspension, restriction, probation, reprimand, censure, participation in an alternative chemical dependency program in lieu of disciplinary action, or any other disciplinary proceedings?

3. Have you ever had action involving you taken by any other governmental agency or professional licensing board?

4. Have you ever voluntarily or otherwise surrendered any license?

5. Have you been told you are impaired as a result of your use of alcohol or other substances within the past five (5) years?

6. *Have you ever been named as a defendant in a legal action involving professional liability malpractice?

7. *Have you had a professional liability claim paid on your behalf, or paid such a claim on yourself?

8. Are you aware of any reports made about you to the National Practitioner's Data Bank or the Healthcare Integrity and Protection Data Bank (HIPDB)?

(Questions continue on next page)

CLINICAL PHARMACIST PRACTITIONER APPLICANT BACKGROUND

(Continued)

YES / NO

9. *Have you ever been warned, censured, disciplined, had admissions monitored, had privileges limited, had privileges suspended, been put on probation, or been requested to withdraw from or failed to re-apply for privileges, or been denied staff membership by a licensed hospital, clinic, managed care organization or other health care facility with an organized medical staff, in which you have trained, been a staff member or held hospital privileges?

10. Have you ever been warned by the Drug Enforcement Administration (U.S. or State), or has any portion of your controlled substance registration certificate voluntarily or otherwise, been limited, denied, revoked, suspended or surrendered? If yes, enclose explanation.

***If you answer "YES" to question #6, #7, or #9, complete the enclosed form entitled Claims Information. Also, please sign the Authorization to Release Information form if you complete the Claims Information form so we can obtain the detailed information.**

APPLICANT'S OATH

I hereby certify that I am the individual named in this Clinical Pharmacist Practitioner (CPP) registration application that all statements I have made herein are true, and that I am the original and lawful possessor of the various forms and credentials furnished to this Board as part of my application. I hereby acknowledge that falsification on any of these documents and/or making of false statements may be cause for disciplinary action against my registration after proper notice and hearing.

I further state that by filing this application for CPP registration in the State of North Carolina, I hereby authorize and consent to an investigation of my professional reputation and fitness for CPP registration. I agree to provide any additional information which may be requested.

I hereby release, discharge, and exonerate the NC Board of Pharmacy, its agents or representatives and any person so furnishing information, from any and all liability of every nature and kind arising out of the furnishing or inspection of such information or the investigation made by the NC Board of Pharmacy. I authorize the NC Board of Pharmacy to release information, materials, documents, orders or the like relating to me, or to this application, to any other agency of the State of North Carolina or other governmental entity licensing or regulating CPPs in any other state or territory of the United States or province of Canada.

Signature of Clinical Practitioner Applicant
(ORIGINAL SIGNATURE)

Date

WHILE THIS APPLICATION IS PENDING, ANY CHANGE OF INFORMATION MUST BE REPORTED TO THE BOARD OF PHARMACY IMMEDIATELY.

TEMPLATE FOR CLINICAL PHARMACIST PRACTITIONER PROTOCOLS

Disease State	Drug Product/Therapies	Dosage Form, Schedule, and Tests

*Add additional entries on a separate sheet if necessary. If additional sheets are required, please have the supervising physician initial each page.

Additional Protocols

Doctor of Pharmacy (PharmD) licensed by the North Carolina Board of Pharmacy and approved by the North Carolina Medical Board as a Clinical Pharmacist Practitioner is approved to perform the following functions in collaboration and under the supervision of the following physician(s):

1. Patients with the following disease states will be eligible for referral to the Clinical Pharmacist Practitioner: **[list those disease states described in the chart above].**

2. The Clinical Pharmacist Practitioner will practice as per statute N.C. Gen. Stat. § 90-18.4(b) and regulation 21 NCAC 32T.

3. Emergency Plan **[provide details]**. An example may read as follows:

In the event of a cardiopulmonary arrest, cardiopulmonary resuscitation will be initiated while office staff calls 911. In the event of an emergent event, the office staff will call 911 and the client will be transferred to the emergency department.

4. Consultation and Supervision **[provide details].** An example may read as follows:

In general, the medical director or physician consultation will be sought for all of the following situations as well as any other deemed appropriate. Whenever a physician is consulted, a notation to that effect including the physician's name must be in the patient's chart.

-- When situations arise that go beyond the intent of the protocols or scope of practice, or experience level of the CPP.

-- Whenever a client's condition fails to respond to the management plan in an appropriate time frame.

-- Any uncommon, unfamiliar, or unstable client condition is encountered.

-- Any condition which does not fit the commonly accepted diagnostic pattern for a disease/condition.

-- Whenever a client requests consultation.

-- All emergency situations after initial stabilizing care has been started.

5. Countersignature. The supervising physician will countersign all medical record notes made by the Clinical Pharmacist Practitioner within **seven (7) days** of the date of the visit.

6. Other Protocols/Instructions - **[provide details]**

Approved: _____

Name of Supervising Physician

_____

Clinical Pharmacist Practitioner

Date: _____

MONTANA'S REQUIREMENTS

Linda McCulloch
MONTANA SECRETARY OF STATE

HOME SEARCH ABOUT US CONTACT US HELP

Rule: 24.174.526

Prev Up Next

Rule Title: REQUIREMENTS TO BECOME A CLINICAL PHARMACIST PRACTITIONER

Department: LABOR AND INDUSTRY
Chapter: BOARD OF PHARMACY
Subchapter: Licensing

Add to Favorites

Latest version of the adopted rule presented in Administrative Rules of Montana (ARM):

Printer Friendly Version

24.174.526 REQUIREMENTS TO BECOME A CLINICAL PHARMACIST PRACTITIONER

(1) An applicant for a clinical pharmacist practitioner registration shall:

(a) submit an application on a form prescribed by the board;

(b) pay a registration fee as prescribed by the board;

(c) hold an active, unrestricted Montana pharmacist license;

(d) have completed five years of clinical practice experience or have completed a pharmacy residency and two years clinical practice experience and hold one of the following active certifications:

(i) BPS certification; or

(ii) nationally recognized certification in an area of practice as approved by the board and Board of Medical Examiners (BME).

(e) submit a signed collaborative practice agreement to the board that includes a description of the type of supervision the collaborating physician will exercise over the clinical pharmacist practitioner;

(f) following approval of the board, submit the application and collaborative practice agreement to the BME for approval; and

(g) appear before the board and/or BME if requested.

(2) Within ten days of discontinuing work under an approved collaborative drug therapy agreement, the pharmacist shall notify the board and the clinical pharmacist practitioner's registration shall be inactive, until such time as a new application is approved.

History: 37-7-201, MCA; IMP, 37-7-201, 37-7-306, MCA; NEW, 2010 MAR p. 2968, Eff. 12/24/10.

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For questions regarding the content, interpretation, or application of a specific rule, please contact the agency that issued the rule. A directory of state agencies is available online at http://www.mt.gov/govt/agencylisting.asp.

For questions about the organization of the ARM or this web site, contact sosarm@mt.gov.

MONTANA BOARD OF PHARMACY
P. O. Box 200513
(301 S PARK, 4TH FLOOR HELENA MT 59601- Delivery)
Helena, Montana 59620-0513
PHONE (406) 841-2356 FAX (406) 841-2344
E-MAIL: dlibsdpha@mt.gov WEBSITE: www.pharmacy.mt.gov

ILLEGIBLE AND INCOMPLETE APPLICATIONS WILL BE RETURNED.

APPROVAL REQUIREMENTS:

- Hold an active, unrestricted Montana pharmacist license.
- Proof of completion of five years of clinical practice experience or have completed a pharmacy residency and two years clinical practice experience and submit a copy of an active certificate from one of the following:
  - BPS certification; **or**
  - Nationally recognized certification in an area of practice as approved by the Board and the Board of Medical Examiners (BME)
- Submit a signed collaborative practice agreement to the Board of Pharmacy that includes a description of the type of supervision the collaborating physician will exercise over the clinical pharmacist practitioner
- Following approval by the Board of Pharmacy, submit the application and collaborative practice agreement to the BME for approval; and
- Appear before the Board of Pharmacy and/or BME if requested.

FEE: $25.00 (Non-Refundable) - Application Fee

ADDITIONAL RULES AND STATUTES

24.174.525 DEFINITIONS (1) "Board of Pharmaceutical Specialties" (BPS) means an independent nongovernmental certification body that provides recognition of persons involved in the advanced
practice of pharmacy specialties through development and administration, a certification process that is consistent with public policy regarding the credentialing of healthcare professionals.
(2) "Clinical practice experience" means working in a pharmacy practice setting which includes at least 50 percent of time spent in:
(a) communication with healthcare professionals and patients regarding drug therapy, wellness, and health promotion;
(b) designing, implementing, monitoring, evaluating, and modifying or recommending modifications in drug therapy to optimize patient care;
c) identifying, assessing, and solving medication-related problems and providing a clinical judgment as to the continuing effectiveness of the therapeutic plan;
(d) conducting physical assessment applicable to the area of practice, evaluating patient problems, ordering and monitoring medications, and/or laboratory tests in accordance with established standards of practice;
(e) referring patients to other healthcare professionals as appropriate;
(f) integrating relevant diet, exercise, and other non-drug therapy with pharmaceutical care;
(g) retrieving, evaluating, utilizing, and managing data and professional resources;
(h) documenting interventions and evaluating outcomes; and
(i) integrating national standards for the quality of healthcare.
(3) "Collaborative practice agreement" is defined as set forth in ARM

APPLICATION PROCEDURES

- When the application file is complete, it will be processed and considered by Board staff for licensure. The applicant may be notified if additional information is required or if required to appear before the Board for an interview.
- If the application is considered a non-routine application, there may be a delay in processing of the application. You may be requested to provide additional information, or make a personal appearance before the Board during a regularly scheduled Board meeting and/or the application may require Board consideration. Non-routine applications may take up to 120 days to process.

PROCESSING PROCEDURES

- Once a routine application is complete, the application takes up to 30 days to process from the time it is received in the Board office.
- The applicant will be notified in writing of any deficient or missing items from the application file.

For information with regard to the processing of this application or other concerns please contact the Board of Pharmacy staff at (406) 841-2356 or 841-2355 or email us at: dlibsdpha@mt.gov **or review the laws and rules at:** www.pharmacy.mt.gov

MONTANA BOARD OF PHARMACY
P. O. Box 200513
(301 S PARK, 4TH FLOOR HELENA MT 59601- Delivery)
Helena, Montana 59620-0513
PHONE (406) 841-2356 FAX (406) 841-2344
E-MAIL: dlibsdpha@mt.gov WEBSITE: www.pharmacy.mt.gov

ILLEGIBLE AND INCOMPLETE APPLICATIONS WILL BE RETURNED.

NAME _____

ADDRESS _____

CITY/STATE/ZIP _____

PHONE _____ FAX _____

LICENSE # _____

EMAIL ADDRESS _____

Have you ever had an application for a professional or occupational license refused or denied? If yes, please attach a detailed explanation and provide supporting documentation from the source. ☐ Yes ☐ No

Have you ever withdrawn an application for licensure prior to the licensing agency's decision regarding your application? If yes, please attach a detailed explanation and provide supporting documentation from the source. ☐ Yes ☐ No

Has a licensing agency initiated or completed disciplinary action against any professional or occupational license you have held? If yes, please provide agency documents including the complaint, initiating documents, orders, final orders, stipulations and consent and/or settlement agreements directly from the source. ☐ Yes ☐ No

Have you ever voluntarily surrendered, cancelled, forfeited, failed to renew a professional or occupation license in anticipation of or during an investigation or disciplinary proceedings or action? If yes, please attach a detailed explanation and provide supporting documentation from the source. ☐ Yes ☐ No

Has a complaint ever been made against you with a professional or occupational licensing agency? If yes, please attach a detailed explanation and provide supporting documentation from the source. ☐ Yes ☐ No

Have any civil legal proceedings been filed against you by a (patient/client), (former patient/client) or employer/employee? If yes, attach a detailed explanation and documentation from the source including initiating document(s) and documentation of final disposition. ☐ Yes ☐ No

Have you ever been convicted of a misdemeanor or felony crime or do you have a pending criminal charge? "Convicted" for the purposes of this question includes a conviction under appeal, guilty plea, no contest plea, and/or forfeiture of bond. "A pending criminal charge" for the purposes of this question includes a deferred imposition of sentence and/or deferred prosecution. If you answer yes, you must submit a detailed explanation of the events AND the charging documents and final judgments or orders of dismissal. You must report but may omit documentation for: (1) misdemeanor traffic violations older than 10 years ago and that resulted in fines of less than $200; and (2) convictions prior to your 18th birthday unless you were tried as an adult. ☐ Yes ☐ No

Have you ever been diagnosed with chemical dependency or another addiction, or have you participated in a chemical dependency or other addiction treatment program? If yes, please attach a detailed explanation and provide documentation regarding evaluations, diagnosis, treatment recommendations and monitoring from the source. ☐ Yes ☐ No

Have you ever been diagnosed with a physical condition or mental health disorder involving potential health risk to the public? If yes, please provide a detailed explanation. ☐ Yes ☐ No

Have you ever been courts martial or discharged other than honorably from any branch of the armed service? If yes, attach a detailed explanation and documentation from the source. ☐ Yes ☐ No

Have you ever been denied the privilege of taking an examination required for any professional or occupational license? If yes, please attach a detailed explanation and provide supporting documentation from the source. ☐ Yes ☐ No

Have you ever withdrawn or been suspended, placed on probation, expelled or requested to resign from any postsecondary educational program? If yes, please attach a detailed explanation and provide supporting documentation from the source. ☐ Yes ☐ No

Have you ever requested temporary or permanent leave of absence, been placed on probation, restricted, suspended, revoked, allowed to resign, or otherwise acted against by any professional or occupational education program (i.e., residency, internship, apprenticeship, etc)? If yes, please attach a detailed explanation and provide supporting documentation from the source. ☐ Yes ☐ No

Have you ever been the subject of any sanction or action, denial, suspension, revocation, restriction or termination regarding hospital, facility or staff privileges; health maintenance organization participation, third party provider or Medicare/Medicaid participation; or any other privileges? If yes, please attach a detailed explanation and provide supporting documentation from the source. ☐ Yes ☐ No

Have you ever been censured, expelled, denied membership or asked to resign from a professional organization related to your profession or occupation? If yes, please attach a detailed explanation and provide documentation from the source. ☐ Yes ☐ No

Have you ever been the subject of any sanction or action, denial, suspension, revocation, restriction or termination regarding your ability to prescribe, dispense or administer drugs including controlled substances? If yes, please attach a detailed explanation and provide documentation from the source. ☐ Yes ☐ No

Do you have any initiated or completed action against you by any state, federal, tribal, or foreign licensing jurisdiction? (For example: Drug Enforcement Agency; Alcohol, Tobacco and Firearms; Homeland Security; Indian Health Service, etc) If yes, please attach a detailed explanation and provide documentation from the source. ☐ Yes ☐ No

_____
Applicant's Printed Name

_____ _____
Applicant's Signature Date

Attachment 3

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives. Protecting People.™

Destinations

For Travelers

Where are you going?

Afghanistan

What kind of traveler are you?
(optional)

- ☐ Traveling with Children
- ☐ Chronic Disease
- ☐ Cruise Ship
- ☐ Extended Stay/Study Abroad
- ☐ Immune-Compromised Travelers
- ☐ Pregnant Women
- ☐ Mission/Disaster Relief
- ☐ Visiting Friends or Family

Go

For Clinicians

Destination

Afghanistan

Special population(s)
(optional)

- ☐ Traveling with Children

- ☐ Chronic Disease
- ☐ Cruise Ship
- ☐ Extended Stay/Study Abroad
- ☐ Immune-Compromised Travelers
- ☐ Pregnant Women
- ☐ Mission/Disaster Relief
- ☐ Visiting Friends or Family

Go

Complete List of Destinations

A (#group-a) B (#group-b) C (#group-c) D (#group-d) E (#group-e) F (#group-f) G (#group-g) H (#group-h) I (#group-i) J (#group-j) K (#group-k) L (#group-l) M (#group-m) N (#group-n) O (#group-o) P (#group-p) Q (#group-q) R (#group-r) S (#group-s) T (#group-t) U (#group-u) V (#group-v) W (#group-w) Y (#group-y) Z (#group-z)

A

- Afghanistan (/travel/destinations/traveler/none/afghanistan)
- Albania (/travel/destinations/traveler/none/albania)
- Algeria (/travel/destinations/traveler/none/algeria)
- American Samoa (/travel/destinations/traveler/none/american-samoa)
- Andorra (/travel/destinations/traveler/none/andorra)
- Anegada (see Virgin Islands, British (/travel/destinations/traveler/none/british-virgin-islands))
- Angola (/travel/destinations/traveler/none/angola)
- Anguilla (U.K.) (/travel/destinations/traveler/none/anguilla)
- Antarctica (/travel/destinations/traveler/none/antarctica)
- Antigua and Barbuda (/travel/destinations/traveler/none/antigua-and-barbuda)
- Argentina (/travel/destinations/traveler/none/argentina)
- Armenia (/travel/destinations/traveler/none/armenia)
- Aruba (/travel/destinations/traveler/none/aruba)
- Austral Islands (see French Polynesia (France) (/travel/destinations/traveler/none/french-polynesia))
- Australia (/travel/destinations/traveler/none/australia)
- Austria (/travel/destinations/traveler/none/austria)
- Azerbaijan (/travel/destinations/traveler/none/azerbaijan)
- Azores (/travel/destinations/traveler/none/azores)

B

- Bahamas, The (/travel/destinations/traveler/none/the-bahamas)
- Bahrain (/travel/destinations/traveler/none/bahrain)
- Bangladesh (/travel/destinations/traveler/none/bangladesh)
- Barbados (/travel/destinations/traveler/none/barbados)
- Barbuda (see Antigua and Barbuda (/travel/destinations/traveler/none/antigua-and-barbuda))
- Belarus (/travel/destinations/traveler/none/belarus)

- Belgium (/travel/destinations/traveler/none/belgium)
- Belize (/travel/destinations/traveler/none/belize)
- Benin (/travel/destinations/traveler/none/benin)
- Bermuda (U.K.) (/travel/destinations/traveler/none/bermuda)
- Bhutan (/travel/destinations/traveler/none/bhutan)
- Bolivia (/travel/destinations/traveler/none/bolivia)
- Bonaire (/travel/destinations/traveler/none/bonaire)
- Bora-Bora (see French Polynesia (France) (/travel/destinations/traveler/none/french-polynesia))
- Bosnia and Herzegovina (/travel/destinations/traveler/none/bosnia-and-herzegovina)
- Botswana (/travel/destinations/traveler/none/botswana)
- Brazil (/travel/destinations/traveler/none/brazil)
- British Indian Ocean Territory (U.K.) (/travel/destinations/traveler/none/british-indian-ocean-territory)
- Brunei (/travel/destinations/traveler/none/brunei)
- Bulgaria (/travel/destinations/traveler/none/bulgaria)
- Burkina Faso (/travel/destinations/traveler/none/burkina-faso)
- Burma (Myanmar) (/travel/destinations/traveler/none/burma)
- Burundi (/travel/destinations/traveler/none/burundi)

C

- Caicos Islands (see Turks and Caicos Islands (U.K.) (/travel/destinations/traveler/none/turks-and-caicos))
- Cambodia (/travel/destinations/traveler/none/cambodia)
- Cameroon (/travel/destinations/traveler/none/cameroon)
- Canada (/travel/destinations/traveler/none/canada)
- Canary Islands (Spain) (/travel/destinations/traveler/none/canary-islands)
- Cape Verde (/travel/destinations/traveler/none/cape-verde)
- Cayman Islands (U.K.) (/travel/destinations/traveler/none/cayman-islands)
- Central African Republic (/travel/destinations/traveler/none/central-african-republic)
- Chad (/travel/destinations/traveler/none/chad)
- Chile (/travel/destinations/traveler/none/chile)
- China (/travel/destinations/traveler/none/china)
- Christmas Island (Australia) (/travel/destinations/traveler/none/christmas-island)
- Cocos (Keeling) Islands (Australia) (/travel/destinations/traveler/none/cocos-islands)
- Colombia (/travel/destinations/traveler/none/colombia)
- Comoros (/travel/destinations/traveler/none/comoros)
- Congo, Republic of the (/travel/destinations/traveler/none/congo)
- Cook Islands (New Zealand) (/travel/destinations/traveler/none/cook-islands)
- Costa Rica (/travel/destinations/traveler/none/costa-rica)
- Croatia (/travel/destinations/traveler/none/croatia)
- Cuba (/travel/destinations/traveler/none/cuba)
- Curaçao (/travel/destinations/traveler/none/curacao)
- Cyprus (/travel/destinations/traveler/none/cyprus)
- Czech Republic (/travel/destinations/traveler/none/czech-republic)
- Côte d'Ivoire (/travel/destinations/traveler/none/ivory-coast)

D

- Democratic Republic of the Congo (/travel/destinations/traveler/none/democratic-republic-of-congo)
- Denmark (/travel/destinations/traveler/none/denmark)
- Djibouti (/travel/destinations/traveler/none/djibouti)
- Dominica (/travel/destinations/traveler/none/dominica)
- Dominican Republic (/travel/destinations/traveler/none/dominican-republic)
- Dubai (see United Arab Emirates (/travel/destinations/traveler/none/united-arab-emirates))

E

- Easter Island (Chile) (/travel/destinations/traveler/none/easter-island)
- Ecuador (/travel/destinations/traveler/none/ecuador)
- Egypt (/travel/destinations/traveler/none/egypt)
- El Salvador (/travel/destinations/traveler/none/el-salvador)
- England (see United Kingdom (/travel/destinations/traveler/none/united-kingdom))
- Equatorial Guinea (/travel/destinations/traveler/none/equatorial-guinea)
- Eritrea (/travel/destinations/traveler/none/eritrea)
- Estonia (/travel/destinations/traveler/none/estonia)
- Ethiopia (/travel/destinations/traveler/none/ethiopia)

F

- Falkland Islands (Islas Malvinas) (/travel/destinations/traveler/none/falkland-islands)
- Faroe Islands (Denmark) (/travel/destinations/traveler/none/faroe-island)
- Fiji (/travel/destinations/traveler/none/fiji)
- Finland (/travel/destinations/traveler/none/finland)
- France (/travel/destinations/traveler/none/france)
- French Guiana (France) (/travel/destinations/traveler/none/french-guiana)
- French Polynesia (France) (/travel/destinations/traveler/none/french-polynesia)

G

- Gabon (/travel/destinations/traveler/none/gabon)
- Galápagos Islands (see Ecuador (/travel/destinations/traveler/none/ecuador))
- Gambia, The (/travel/destinations/traveler/none/the-gambia)
- Georgia (/travel/destinations/traveler/none/georgia)
- Germany (/travel/destinations/traveler/none/germany)
- Ghana (/travel/destinations/traveler/none/ghana)
- Gibraltar (U.K.) (/travel/destinations/traveler/none/gibraltar)
- Greece (/travel/destinations/traveler/none/greece)
- Greenland (Denmark) (/travel/destinations/traveler/none/greenland)
- Grenada (/travel/destinations/traveler/none/grenada)
- Grenadines (see Saint Vincent and the Grenadines (/travel/destinations/traveler/none/saint-vincent-and-the-grenadines)
- Guadeloupe (/travel/destinations/traveler/none/guadeloupe)
- Guam (U.S.) (/travel/destinations/traveler/none/guam)
- Guatemala (/travel/destinations/traveler/none/guatemala)
- Guernsey (see United Kingdom (/travel/destinations/traveler/none/united-kingdom))
- Guinea (/travel/destinations/traveler/none/guinea)
- Guinea-Bissau (/travel/destinations/traveler/none/guinea-bissau)

- Guyana (/travel/destinations/traveler/none/guyana)

H

- Haiti (/travel/destinations/traveler/none/haiti)
- Holy See (see Italy (/travel/destinations/traveler/none/italy))
- Honduras (/travel/destinations/traveler/none/honduras)
- Hong Kong SAR (China) (/travel/destinations/traveler/none/hong-kong-sar)
- Hungary (/travel/destinations/traveler/none/hungary)

I

- Iceland (/travel/destinations/traveler/none/iceland)
- India (/travel/destinations/traveler/none/india)
- Indonesia (/travel/destinations/traveler/none/indonesia)
- Iran (/travel/destinations/traveler/none/iran)
- Iraq (/travel/destinations/traveler/none/iraq)
- Ireland (/travel/destinations/traveler/none/ireland)
- Isle of Man (see United Kingdom (/travel/destinations/traveler/none/united-kingdom))
- Israel, including the West Bank and Gaza (/travel/destinations/traveler/none/israel)
- Italy (/travel/destinations/traveler/none/italy)
- Ivory Coast (see Côte d'Ivoire (/travel/destinations/traveler/none/ivory-coast))

J

- Jamaica (/travel/destinations/traveler/none/jamaica)
- Japan (/travel/destinations/traveler/none/japan)
- Jersey (see United Kingdom (/travel/destinations/traveler/none/united-kingdom))
- Jordan (/travel/destinations/traveler/none/jordan)
- Jost Van Dyke (see Virgin Islands, British (/travel/destinations/traveler/none/british-virgin-islands))

K

- Kazakhstan (/travel/destinations/traveler/none/kazakhstan)
- Kenya (/travel/destinations/traveler/none/kenya)
- Kiribati (/travel/destinations/traveler/none/kiribati)
- Kosovo (/travel/destinations/traveler/none/kosovo)
- Kuwait (/travel/destinations/traveler/none/kuwait)
- Kyrgyzstan (/travel/destinations/traveler/none/kyrgyzstan)

L

- Laos (/travel/destinations/traveler/none/laos)
- Latvia (/travel/destinations/traveler/none/latvia)
- Lebanon (/travel/destinations/traveler/none/lebanon)
- Lesotho (/travel/destinations/traveler/none/lesotho)
- Liberia (/travel/destinations/traveler/none/liberia)
- Libya (/travel/destinations/traveler/none/libya)
- Liechtenstein (/travel/destinations/traveler/none/liechtenstein)
- Lithuania (/travel/destinations/traveler/none/lithuania)

- Luxembourg (/travel/destinations/traveler/none/luxembourg)

M

- Macau SAR (China) (/travel/destinations/traveler/none/macau-sar)
- Macedonia (/travel/destinations/traveler/none/macedonia)
- Madagascar (/travel/destinations/traveler/none/madagascar)
- Madeira Islands (Portugal) (/travel/destinations/traveler/none/maderia-islands)
- Malawi (/travel/destinations/traveler/none/malawi)
- Malaysia (/travel/destinations/traveler/none/malaysia)
- Maldives (/travel/destinations/traveler/none/maldives)
- Mali (/travel/destinations/traveler/none/mali)
- Malta (/travel/destinations/traveler/none/malta)
- Marquesas Islands (see French Polynesia (France) (/travel/destinations/traveler/none/french-polynesia))
- Marshall Islands (/travel/destinations/traveler/none/marshall-islands)
- Martinique (France) (/travel/destinations/traveler/none/martinique)
- Mauritania (/travel/destinations/traveler/none/mauritania)
- Mauritius (/travel/destinations/traveler/none/mauritius)
- Mayotte (France) (/travel/destinations/traveler/none/mayotte)
- Mexico (/travel/destinations/traveler/none/mexico)
- Micronesia, Federated States of (/travel/destinations/traveler/none/micronesia)
- Moldova (/travel/destinations/traveler/none/moldova)
- Monaco (/travel/destinations/traveler/none/monaco)
- Mongolia (/travel/destinations/traveler/none/mongolia)
- Montenegro (/travel/destinations/traveler/none/montenegro)
- Montserrat (U.K.) (/travel/destinations/traveler/none/montserrat)
- Moorea (see French Polynesia (France) (/travel/destinations/traveler/none/french-polynesia))
- Morocco (/travel/destinations/traveler/none/morocco)
- Mozambique (/travel/destinations/traveler/none/mozambique)

N

- Namibia (/travel/destinations/traveler/none/namibia)
- Nauru (/travel/destinations/traveler/none/nauru)
- Nepal (/travel/destinations/traveler/none/nepal)
- Netherlands, The (/travel/destinations/traveler/none/netherlands)
- New Caledonia (France) (/travel/destinations/traveler/none/new-caledonia)
- New Zealand (/travel/destinations/traveler/none/new-zealand)
- Nicaragua (/travel/destinations/traveler/none/nicaragua)
- Niger (/travel/destinations/traveler/none/niger)
- Nigeria (/travel/destinations/traveler/none/nigeria)
- Niue (New Zealand) (/travel/destinations/traveler/none/niue)
- Norfolk Island (Australia) (/travel/destinations/traveler/none/norfolk-island)
- North Korea (/travel/destinations/traveler/none/north-korea)
- Northern Ireland (see United Kingdom (/travel/destinations/traveler/none/united-kingdom))
- Northern Mariana Islands (U.S.) (/travel/destinations/traveler/none/northern-mariana-islands)
- Norway (/travel/destinations/traveler/none/norway)

O

- Oman (/travel/destinations/traveler/none/oman)

P

- Pakistan (/travel/destinations/traveler/none/pakistan)
- Palau (/travel/destinations/traveler/none/palau)
- Panama (/travel/destinations/traveler/none/panama)
- Papua New Guinea (/travel/destinations/traveler/none/papua-new-guinea)
- Paraguay (/travel/destinations/traveler/none/paraguay)
- Peru (/travel/destinations/traveler/none/peru)
- Philippines (/travel/destinations/traveler/none/philippines)
- Pitcairn Islands (U.K.) (/travel/destinations/traveler/none/pitcairn-islands)
- Poland (/travel/destinations/traveler/none/poland)
- Portugal (/travel/destinations/traveler/none/portugal)
- Puerto Rico (U.S.) (/travel/destinations/traveler/none/puerto-rico)

Q

- Qatar (/travel/destinations/traveler/none/qatar)

R

- Romania (/travel/destinations/traveler/none/romania)
- Rota (see Northern Mariana Islands (U.S.) (/travel/destinations/traveler/none/northern-mariana-islands)
- Rurutu (see French Polynesia (France) (/travel/destinations/traveler/none/french-polynesia))
- Russia (/travel/destinations/traveler/none/russia)
- Rwanda (/travel/destinations/traveler/none/rwanda)
- Réunion (France) (/travel/destinations/traveler/none/reunion)

S

- Saba (/travel/destinations/traveler/none/saba)
- Saint Barthelemy (/travel/destinations/traveler/none/saint-barthelemy)
- Saint Croix (see Virgin Islands, U.S. (/travel/destinations/traveler/none/usvirgin-islands))
- Saint Helena (U.K.) (/travel/destinations/traveler/none/saint-helena)
- Saint John (see Virgin Islands, U.S. (/travel/destinations/traveler/none/usvirgin-islands))
- Saint Kitts and Nevis (/travel/destinations/traveler/none/st-kitts-and-nevis)
- Saint Lucia (/travel/destinations/traveler/none/saint-lucia)
- Saint Martin (/travel/destinations/traveler/none/saint-martin)
- Saint Pierre and Miquelon (France) (/travel/destinations/traveler/none/saint-pierre-and-miquelon)
- Saint Thomas (see Virgin Islands, U.S. (/travel/destinations/traveler/none/usvirgin-islands))
- Saint Vincent and the Grenadines (/travel/destinations/traveler/none/saint-vincent-and-the-grenadines)
- Saipan (see Northern Mariana Islands (U.S.) (/travel/destinations/traveler/none/northern-mariana-islands)
- Samoa (/travel/destinations/traveler/none/samoa)
- San Marino (/travel/destinations/traveler/none/san-marino)
- Saudi Arabia (/travel/destinations/traveler/none/saudi-arabia)

- Scotland (see United Kingdom (/travel/destinations/traveler/none/united-kingdom))
- Senegal (/travel/destinations/traveler/none/senegal)
- Serbia (/travel/destinations/traveler/none/serbia)
- Seychelles (/travel/destinations/traveler/none/seychelles)
- Sierra Leone (/travel/destinations/traveler/none/sierra-leone)
- Singapore (/travel/destinations/traveler/none/singapore)
- Sint Eustatius (/travel/destinations/traveler/none/sint-eustatius)
- Sint Maarten (/travel/destinations/traveler/none/sint-maarten)
- Slovakia (/travel/destinations/traveler/none/slovakia)
- Slovenia (/travel/destinations/traveler/none/slovenia)
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- Solomon Islands (/travel/destinations/traveler/none/solomon-islands)
- Somalia (/travel/destinations/traveler/none/somalia)
- South Africa (/travel/destinations/traveler/none/south-africa)
- South Georgia and the South Sandwich Islands (U.K.) (/travel/destinations/traveler/none/south-georgia-south-sandwich-islands)
- South Korea (/travel/destinations/traveler/none/south-korea)
- South Sandwich Islands (see South Georgia and the South Sandwich Islands (U.K.) (/travel/destinations/traveler/none/south-georgia-south-sandwich-islands)
- South Sudan (/travel/destinations/traveler/none/south-sudan)
- Spain (/travel/destinations/traveler/none/spain)
- Sri Lanka (/travel/destinations/traveler/none/sri-lanka)
- Sudan (/travel/destinations/traveler/none/sudan)
- Suriname (/travel/destinations/traveler/none/suriname)
- Swaziland (/travel/destinations/traveler/none/swaziland)
- Sweden (/travel/destinations/traveler/none/sweden)
- Switzerland (/travel/destinations/traveler/none/switzerland)
- Syria (/travel/destinations/traveler/none/syria)
- São Tomé and Príncipe (/travel/destinations/traveler/none/sao-tome-and-principe)

T

- Tahiti (see French Polynesia (France) (/travel/destinations/traveler/none/french-polynesia))
- Taiwan (/travel/destinations/traveler/none/taiwan)
- Tajikistan (/travel/destinations/traveler/none/tajikistan)
- Tanzania (/travel/destinations/traveler/none/tanzania)
- Thailand (/travel/destinations/traveler/none/thailand)
- Timor-Leste (East Timor) (/travel/destinations/traveler/none/east-timor)
- Tinian (see Northern Mariana Islands (U.S.) (/travel/destinations/traveler/none/northern-mariana-islands)
- Tobago (see Trinidad and Tobago (/travel/destinations/traveler/none/trinidad-and-tobago))
- Togo (/travel/destinations/traveler/none/togo)
- Tokelau (New Zealand) (/travel/destinations/traveler/none/tokelau)
- Tonga (/travel/destinations/traveler/none/tonga)
- Tortola (see Virgin Islands, British (/travel/destinations/traveler/none/british-virgin-islands))
- Trinidad and Tobago (/travel/destinations/traveler/none/trinidad-and-tobago)
- Tubuai (see French Polynesia (France) (/travel/destinations/traveler/none/french-polynesia))
- Tunisia (/travel/destinations/traveler/none/tunisia)

- Turkey (/travel/destinations/traveler/none/turkey)
- Turkmenistan (/travel/destinations/traveler/none/turkmenistan)
- Turks and Caicos Islands (U.K.) (/travel/destinations/traveler/none/turks-and-caicos)
- Tuvalu (/travel/destinations/traveler/none/tuvalu)

U

- Uganda (/travel/destinations/traveler/none/uganda)
- Ukraine (/travel/destinations/traveler/none/ukraine)
- United Arab Emirates (/travel/destinations/traveler/none/united-arab-emirates)
- United Kingdom (/travel/destinations/traveler/none/united-kingdom)
- United States (/travel/destinations/traveler/none/united-states)
- Uruguay (/travel/destinations/traveler/none/uruguay)
- Uzbekistan (/travel/destinations/traveler/none/uzbekistan)

V

- Vanuatu (/travel/destinations/traveler/none/vanuatu)
- Vatican City (see Italy (/travel/destinations/traveler/none/italy))
- Venezuela (/travel/destinations/traveler/none/venezuela)
- Vietnam (/travel/destinations/traveler/none/vietnam)
- Virgin Gorda (see Virgin Islands, British (/travel/destinations/traveler/none/british-virgin-islands))
- Virgin Islands, British (/travel/destinations/traveler/none/british-virgin-islands)
- Virgin Islands, U.S. (/travel/destinations/traveler/none/usvirgin-islands)

W

- Wake Island (/travel/destinations/traveler/none/wake-island)
- Wales (see United Kingdom (/travel/destinations/traveler/none/united-kingdom))
- Western Sahara (/travel/destinations/traveler/none/western-sahara)

Y

- Yemen (/travel/destinations/traveler/none/yemen)

Z

- Zambia (/travel/destinations/traveler/none/zambia)
- Zanzibar (see Tanzania (/travel/destinations/traveler/none/tanzania))
- Zimbabwe (/travel/destinations/traveler/none/zimbabwe)

Content source: Centers for Disease Control and Prevention
National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)
Division of Global Migration and Quarantine (DGMQ)

Centers for Disease Control and Prevention 1600 Clifton Rd. Atlanta, GA 30333, USA
800-CDC-INFO (800-232-4636) TTY: (888) 232-6348 - Contact CDC–INFO

USA.gov Government Made Easy

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives. Protecting People.™

Destinations

For Travelers

Where are you going?

Afghanistan

What kind of traveler are you?
(optional)

- ☐ Traveling with Children
- ☐ Chronic Disease
- ☐ Cruise Ship
- ☐ Extended Stay/Study Abroad
- ☐ Immune-Compromised Travelers
- ☐ Pregnant Women
- ☐ Mission/Disaster Relief
- ☐ Visiting Friends or Family

Go

For Clinicians

Destination

Tahiti

Special population(s)
(optional)

- ☐ Traveling with Children

- ☐ Chronic Disease
- ☐ Cruise Ship
- ☐ Extended Stay/Study Abroad
- ☐ Immune-Compromised Travelers
- ☐ Pregnant Women
- ☐ Mission/Disaster Relief
- ☑ Visiting Friends or Family

Go

Complete List of Destinations

A (#group-a) B (#group-b) C (#group-c) D (#group-d) E (#group-e) F (#group-f) G (#group-g) H (#group-h) I (#group-i) J (#group-j) K (#group-k) L (#group-l) M (#group-m) N (#group-n) O (#group-o) P (#group-p) Q (#group-q) R (#group-r) S (#group-s) T (#group-t) U (#group-u) V (#group-v) W (#group-w) Y (#group-y) Z (#group-z)

A

- Afghanistan (/travel/destinations/traveler/none/afghanistan)
- Albania (/travel/destinations/traveler/none/albania)
- Algeria (/travel/destinations/traveler/none/algeria)
- American Samoa (/travel/destinations/traveler/none/american-samoa)
- Andorra (/travel/destinations/traveler/none/andorra)
- Anegada (see Virgin Islands, British (/travel/destinations/traveler/none/british-virgin-islands))
- Angola (/travel/destinations/traveler/none/angola)
- Anguilla (U.K.) (/travel/destinations/traveler/none/anguilla)
- Antarctica (/travel/destinations/traveler/none/antarctica)
- Antigua and Barbuda (/travel/destinations/traveler/none/antigua-and-barbuda)
- Argentina (/travel/destinations/traveler/none/argentina)
- Armenia (/travel/destinations/traveler/none/armenia)
- Aruba (/travel/destinations/traveler/none/aruba)
- Austral Islands (see French Polynesia (France) (/travel/destinations/traveler/none/french-polynesia))
- Australia (/travel/destinations/traveler/none/australia)
- Austria (/travel/destinations/traveler/none/austria)
- Azerbaijan (/travel/destinations/traveler/none/azerbaijan)
- Azores (/travel/destinations/traveler/none/azores)

B

- Bahamas, The (/travel/destinations/traveler/none/the-bahamas)
- Bahrain (/travel/destinations/traveler/none/bahrain)
- Bangladesh (/travel/destinations/traveler/none/bangladesh)
- Barbados (/travel/destinations/traveler/none/barbados)
- Barbuda (see Antigua and Barbuda (/travel/destinations/traveler/none/antigua-and-barbuda))
- Belarus (/travel/destinations/traveler/none/belarus)

- Belgium (/travel/destinations/traveler/none/belgium)
- Belize (/travel/destinations/traveler/none/belize)
- Benin (/travel/destinations/traveler/none/benin)
- Bermuda (U.K.) (/travel/destinations/traveler/none/bermuda)
- Bhutan (/travel/destinations/traveler/none/bhutan)
- Bolivia (/travel/destinations/traveler/none/bolivia)
- Bonaire (/travel/destinations/traveler/none/bonaire)
- Bora-Bora (see French Polynesia (France) (/travel/destinations/traveler/none/french-polynesia))
- Bosnia and Herzegovina (/travel/destinations/traveler/none/bosnia-and-herzegovina)
- Botswana (/travel/destinations/traveler/none/botswana)
- Brazil (/travel/destinations/traveler/none/brazil)
- British Indian Ocean Territory (U.K.) (/travel/destinations/traveler/none/british-indian-ocean-territory)
- Brunei (/travel/destinations/traveler/none/brunei)
- Bulgaria (/travel/destinations/traveler/none/bulgaria)
- Burkina Faso (/travel/destinations/traveler/none/burkina-faso)
- Burma (Myanmar) (/travel/destinations/traveler/none/burma)
- Burundi (/travel/destinations/traveler/none/burundi)

C

- Caicos Islands (see Turks and Caicos Islands (U.K.) (/travel/destinations/traveler/none/turks-and-caicos))
- Cambodia (/travel/destinations/traveler/none/cambodia)
- Cameroon (/travel/destinations/traveler/none/cameroon)
- Canada (/travel/destinations/traveler/none/canada)
- Canary Islands (Spain) (/travel/destinations/traveler/none/canary-islands)
- Cape Verde (/travel/destinations/traveler/none/cape-verde)
- Cayman Islands (U.K.) (/travel/destinations/traveler/none/cayman-islands)
- Central African Republic (/travel/destinations/traveler/none/central-african-republic)
- Chad (/travel/destinations/traveler/none/chad)
- Chile (/travel/destinations/traveler/none/chile)
- China (/travel/destinations/traveler/none/china)
- Christmas Island (Australia) (/travel/destinations/traveler/none/christmas-island)
- Cocos (Keeling) Islands (Australia) (/travel/destinations/traveler/none/cocos-islands)
- Colombia (/travel/destinations/traveler/none/colombia)
- Comoros (/travel/destinations/traveler/none/comoros)
- Congo, Republic of the (/travel/destinations/traveler/none/congo)
- Cook Islands (New Zealand) (/travel/destinations/traveler/none/cook-islands)
- Costa Rica (/travel/destinations/traveler/none/costa-rica)
- Croatia (/travel/destinations/traveler/none/croatia)
- Cuba (/travel/destinations/traveler/none/cuba)
- Curaçao (/travel/destinations/traveler/none/curacao)
- Cyprus (/travel/destinations/traveler/none/cyprus)
- Czech Republic (/travel/destinations/traveler/none/czech-republic)
- Côte d'Ivoire (/travel/destinations/traveler/none/ivory-coast)

D

- Democratic Republic of the Congo (/travel/destinations/traveler/none/democratic-republic-of-congo)
- Denmark (/travel/destinations/traveler/none/denmark)
- Djibouti (/travel/destinations/traveler/none/djibouti)
- Dominica (/travel/destinations/traveler/none/dominica)
- Dominican Republic (/travel/destinations/traveler/none/dominican-republic)
- Dubai (see United Arab Emirates (/travel/destinations/traveler/none/united-arab-emirates))

E

- Easter Island (Chile) (/travel/destinations/traveler/none/easter-island)
- Ecuador (/travel/destinations/traveler/none/ecuador)
- Egypt (/travel/destinations/traveler/none/egypt)
- El Salvador (/travel/destinations/traveler/none/el-salvador)
- England (see United Kingdom (/travel/destinations/traveler/none/united-kingdom))
- Equatorial Guinea (/travel/destinations/traveler/none/equatorial-guinea)
- Eritrea (/travel/destinations/traveler/none/eritrea)
- Estonia (/travel/destinations/traveler/none/estonia)
- Ethiopia (/travel/destinations/traveler/none/ethiopia)

F

- Falkland Islands (Islas Malvinas) (/travel/destinations/traveler/none/falkland-islands)
- Faroe Islands (Denmark) (/travel/destinations/traveler/none/faroe-island)
- Fiji (/travel/destinations/traveler/none/fiji)
- Finland (/travel/destinations/traveler/none/finland)
- France (/travel/destinations/traveler/none/france)
- French Guiana (France) (/travel/destinations/traveler/none/french-guiana)
- French Polynesia (France) (/travel/destinations/traveler/none/french-polynesia)

G

- Gabon (/travel/destinations/traveler/none/gabon)
- Galápagos Islands (see Ecuador (/travel/destinations/traveler/none/ecuador))
- Gambia, The (/travel/destinations/traveler/none/the-gambia)
- Georgia (/travel/destinations/traveler/none/georgia)
- Germany (/travel/destinations/traveler/none/germany)
- Ghana (/travel/destinations/traveler/none/ghana)
- Gibraltar (U.K.) (/travel/destinations/traveler/none/gibraltar)
- Greece (/travel/destinations/traveler/none/greece)
- Greenland (Denmark) (/travel/destinations/traveler/none/greenland)
- Grenada (/travel/destinations/traveler/none/grenada)
- Grenadines (see Saint Vincent and the Grenadines (/travel/destinations/traveler/none/saint-vincent-and-the-grenadines)
- Guadeloupe (/travel/destinations/traveler/none/guadeloupe)
- Guam (U.S.) (/travel/destinations/traveler/none/guam)
- Guatemala (/travel/destinations/traveler/none/guatemala)
- Guernsey (see United Kingdom (/travel/destinations/traveler/none/united-kingdom))
- Guinea (/travel/destinations/traveler/none/guinea)
- Guinea-Bissau (/travel/destinations/traveler/none/guinea-bissau)

- Guyana (/travel/destinations/traveler/none/guyana)

H

- Haiti (/travel/destinations/traveler/none/haiti)
- Holy See (see Italy (/travel/destinations/traveler/none/italy))
- Honduras (/travel/destinations/traveler/none/honduras)
- Hong Kong SAR (China) (/travel/destinations/traveler/none/hong-kong-sar)
- Hungary (/travel/destinations/traveler/none/hungary)

I

- Iceland (/travel/destinations/traveler/none/iceland)
- India (/travel/destinations/traveler/none/india)
- Indonesia (/travel/destinations/traveler/none/indonesia)
- Iran (/travel/destinations/traveler/none/iran)
- Iraq (/travel/destinations/traveler/none/iraq)
- Ireland (/travel/destinations/traveler/none/ireland)
- Isle of Man (see United Kingdom (/travel/destinations/traveler/none/united-kingdom))
- Israel, including the West Bank and Gaza (/travel/destinations/traveler/none/israel)
- Italy (/travel/destinations/traveler/none/italy)
- Ivory Coast (see Côte d'Ivoire (/travel/destinations/traveler/none/ivory-coast))

J

- Jamaica (/travel/destinations/traveler/none/jamaica)
- Japan (/travel/destinations/traveler/none/japan)
- Jersey (see United Kingdom (/travel/destinations/traveler/none/united-kingdom))
- Jordan (/travel/destinations/traveler/none/jordan)
- Jost Van Dyke (see Virgin Islands, British (/travel/destinations/traveler/none/british-virgin-islands))

K

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- Kiribati (/travel/destinations/traveler/none/kiribati)
- Kosovo (/travel/destinations/traveler/none/kosovo)
- Kuwait (/travel/destinations/traveler/none/kuwait)
- Kyrgyzstan (/travel/destinations/traveler/none/kyrgyzstan)

L

- Laos (/travel/destinations/traveler/none/laos)
- Latvia (/travel/destinations/traveler/none/latvia)
- Lebanon (/travel/destinations/traveler/none/lebanon)
- Lesotho (/travel/destinations/traveler/none/lesotho)
- Liberia (/travel/destinations/traveler/none/liberia)
- Libya (/travel/destinations/traveler/none/libya)
- Liechtenstein (/travel/destinations/traveler/none/liechtenstein)
- Lithuania (/travel/destinations/traveler/none/lithuania)

- Luxembourg (/travel/destinations/traveler/none/luxembourg)

M

- Macau SAR (China) (/travel/destinations/traveler/none/macau-sar)
- Macedonia (/travel/destinations/traveler/none/macedonia)
- Madagascar (/travel/destinations/traveler/none/madagascar)
- Madeira Islands (Portugal) (/travel/destinations/traveler/none/maderia-islands)
- Malawi (/travel/destinations/traveler/none/malawi)
- Malaysia (/travel/destinations/traveler/none/malaysia)
- Maldives (/travel/destinations/traveler/none/maldives)
- Mali (/travel/destinations/traveler/none/mali)
- Malta (/travel/destinations/traveler/none/malta)
- Marquesas Islands (see French Polynesia (France) (/travel/destinations/traveler/none/french-polynesia))
- Marshall Islands (/travel/destinations/traveler/none/marshall-islands)
- Martinique (France) (/travel/destinations/traveler/none/martinique)
- Mauritania (/travel/destinations/traveler/none/mauritania)
- Mauritius (/travel/destinations/traveler/none/mauritius)
- Mayotte (France) (/travel/destinations/traveler/none/mayotte)
- Mexico (/travel/destinations/traveler/none/mexico)
- Micronesia, Federated States of (/travel/destinations/traveler/none/micronesia)
- Moldova (/travel/destinations/traveler/none/moldova)
- Monaco (/travel/destinations/traveler/none/monaco)
- Mongolia (/travel/destinations/traveler/none/mongolia)
- Montenegro (/travel/destinations/traveler/none/montenegro)
- Montserrat (U.K.) (/travel/destinations/traveler/none/montserrat)
- Moorea (see French Polynesia (France) (/travel/destinations/traveler/none/french-polynesia))
- Morocco (/travel/destinations/traveler/none/morocco)
- Mozambique (/travel/destinations/traveler/none/mozambique)

N

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- New Zealand (/travel/destinations/traveler/none/new-zealand)
- Nicaragua (/travel/destinations/traveler/none/nicaragua)
- Niger (/travel/destinations/traveler/none/niger)
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- Niue (New Zealand) (/travel/destinations/traveler/none/niue)
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- North Korea (/travel/destinations/traveler/none/north-korea)
- Northern Ireland (see United Kingdom (/travel/destinations/traveler/none/united-kingdom))
- Northern Mariana Islands (U.S.) (/travel/destinations/traveler/none/northern-mariana-islands)
- Norway (/travel/destinations/traveler/none/norway)

O

- Oman (/travel/destinations/traveler/none/oman)

P

- Pakistan (/travel/destinations/traveler/none/pakistan)
- Palau (/travel/destinations/traveler/none/palau)
- Panama (/travel/destinations/traveler/none/panama)
- Papua New Guinea (/travel/destinations/traveler/none/papua-new-guinea)
- Paraguay (/travel/destinations/traveler/none/paraguay)
- Peru (/travel/destinations/traveler/none/peru)
- Philippines (/travel/destinations/traveler/none/philippines)
- Pitcairn Islands (U.K.) (/travel/destinations/traveler/none/pitcairn-islands)
- Poland (/travel/destinations/traveler/none/poland)
- Portugal (/travel/destinations/traveler/none/portugal)
- Puerto Rico (U.S.) (/travel/destinations/traveler/none/puerto-rico)

Q

- Qatar (/travel/destinations/traveler/none/qatar)

R

- Romania (/travel/destinations/traveler/none/romania)
- Rota (see Northern Mariana Islands (U.S.) (/travel/destinations/traveler/none/northern-mariana-islands)
- Rurutu (see French Polynesia (France) (/travel/destinations/traveler/none/french-polynesia))
- Russia (/travel/destinations/traveler/none/russia)
- Rwanda (/travel/destinations/traveler/none/rwanda)
- Réunion (France) (/travel/destinations/traveler/none/reunion)

S

- Saba (/travel/destinations/traveler/none/saba)
- Saint Barthelemy (/travel/destinations/traveler/none/saint-barthelemy)
- Saint Croix (see Virgin Islands, U.S. (/travel/destinations/traveler/none/usvirgin-islands))
- Saint Helena (U.K.) (/travel/destinations/traveler/none/saint-helena)
- Saint John (see Virgin Islands, U.S. (/travel/destinations/traveler/none/usvirgin-islands))
- Saint Kitts and Nevis (/travel/destinations/traveler/none/st-kitts-and-nevis)
- Saint Lucia (/travel/destinations/traveler/none/saint-lucia)
- Saint Martin (/travel/destinations/traveler/none/saint-martin)
- Saint Pierre and Miquelon (France) (/travel/destinations/traveler/none/saint-pierre-and-miquelon)
- Saint Thomas (see Virgin Islands, U.S. (/travel/destinations/traveler/none/usvirgin-islands))
- Saint Vincent and the Grenadines (/travel/destinations/traveler/none/saint-vincent-and-the-grenadines)
- Saipan (see Northern Mariana Islands (U.S.) (/travel/destinations/traveler/none/northern-mariana-islands)
- Samoa (/travel/destinations/traveler/none/samoa)
- San Marino (/travel/destinations/traveler/none/san-marino)
- Saudi Arabia (/travel/destinations/traveler/none/saudi-arabia)

- Scotland (see United Kingdom (/travel/destinations/traveler/none/united-kingdom))
- Senegal (/travel/destinations/traveler/none/senegal)
- Serbia (/travel/destinations/traveler/none/serbia)
- Seychelles (/travel/destinations/traveler/none/seychelles)
- Sierra Leone (/travel/destinations/traveler/none/sierra-leone)
- Singapore (/travel/destinations/traveler/none/singapore)
- Sint Eustatius (/travel/destinations/traveler/none/sint-eustatius)
- Sint Maarten (/travel/destinations/traveler/none/sint-maarten)
- Slovakia (/travel/destinations/traveler/none/slovakia)
- Slovenia (/travel/destinations/traveler/none/slovenia)
- Society Islands (see French Polynesia (France) (/travel/destinations/traveler/none/french-polynesia))
- Solomon Islands (/travel/destinations/traveler/none/solomon-islands)
- Somalia (/travel/destinations/traveler/none/somalia)
- South Africa (/travel/destinations/traveler/none/south-africa)
- South Georgia and the South Sandwich Islands (U.K.) (/travel/destinations/traveler/none/south-georgia-south-sandwich-islands)
- South Korea (/travel/destinations/traveler/none/south-korea)
- South Sandwich Islands (see South Georgia and the South Sandwich Islands (U.K.) (/travel/destinations/traveler/none/south-georgia-south-sandwich-islands)
- South Sudan (/travel/destinations/traveler/none/south-sudan)
- Spain (/travel/destinations/traveler/none/spain)
- Sri Lanka (/travel/destinations/traveler/none/sri-lanka)
- Sudan (/travel/destinations/traveler/none/sudan)
- Suriname (/travel/destinations/traveler/none/suriname)
- Swaziland (/travel/destinations/traveler/none/swaziland)
- Sweden (/travel/destinations/traveler/none/sweden)
- Switzerland (/travel/destinations/traveler/none/switzerland)
- Syria (/travel/destinations/traveler/none/syria)
- São Tomé and Príncipe (/travel/destinations/traveler/none/sao-tome-and-principe)

T

- Tahiti (see French Polynesia (France) (/travel/destinations/traveler/none/french-polynesia))
- Taiwan (/travel/destinations/traveler/none/taiwan)
- Tajikistan (/travel/destinations/traveler/none/tajikistan)
- Tanzania (/travel/destinations/traveler/none/tanzania)
- Thailand (/travel/destinations/traveler/none/thailand)
- Timor-Leste (East Timor) (/travel/destinations/traveler/none/east-timor)
- Tinian (see Northern Mariana Islands (U.S.) (/travel/destinations/traveler/none/northern-mariana-islands)
- Tobago (see Trinidad and Tobago (/travel/destinations/traveler/none/trinidad-and-tobago))
- Togo (/travel/destinations/traveler/none/togo)
- Tokelau (New Zealand) (/travel/destinations/traveler/none/tokelau)
- Tonga (/travel/destinations/traveler/none/tonga)
- Tortola (see Virgin Islands, British (/travel/destinations/traveler/none/british-virgin-islands))
- Trinidad and Tobago (/travel/destinations/traveler/none/trinidad-and-tobago)
- Tubuai (see French Polynesia (France) (/travel/destinations/traveler/none/french-polynesia))
- Tunisia (/travel/destinations/traveler/none/tunisia)

- Turkey (/travel/destinations/traveler/none/turkey)
- Turkmenistan (/travel/destinations/traveler/none/turkmenistan)
- Turks and Caicos Islands (U.K.) (/travel/destinations/traveler/none/turks-and-caicos)
- Tuvalu (/travel/destinations/traveler/none/tuvalu)

U

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- Ukraine (/travel/destinations/traveler/none/ukraine)
- United Arab Emirates (/travel/destinations/traveler/none/united-arab-emirates)
- United Kingdom (/travel/destinations/traveler/none/united-kingdom)
- United States (/travel/destinations/traveler/none/united-states)
- Uruguay (/travel/destinations/traveler/none/uruguay)
- Uzbekistan (/travel/destinations/traveler/none/uzbekistan)

V

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- Vatican City (see Italy (/travel/destinations/traveler/none/italy))
- Venezuela (/travel/destinations/traveler/none/venezuela)
- Vietnam (/travel/destinations/traveler/none/vietnam)
- Virgin Gorda (see Virgin Islands, British (/travel/destinations/traveler/none/british-virgin-islands))
- Virgin Islands, British (/travel/destinations/traveler/none/british-virgin-islands)
- Virgin Islands, U.S. (/travel/destinations/traveler/none/usvirgin-islands)

W

- Wake Island (/travel/destinations/traveler/none/wake-island)
- Wales (see United Kingdom (/travel/destinations/traveler/none/united-kingdom))
- Western Sahara (/travel/destinations/traveler/none/western-sahara)

Y

- Yemen (/travel/destinations/traveler/none/yemen)

Z

- Zambia (/travel/destinations/traveler/none/zambia)
- Zanzibar (see Tanzania (/travel/destinations/traveler/none/tanzania))
- Zimbabwe (/travel/destinations/traveler/none/zimbabwe)

Content source: Centers for Disease Control and Prevention
National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)
Division of Global Migration and Quarantine (DGMQ)

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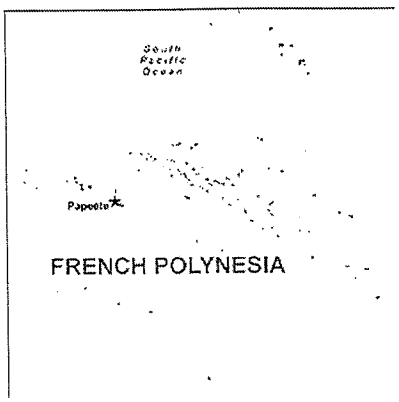
Health Information for Travelers to French Polynesia, including the island groups of Society Islands (Tahiti, Moorea, and Bora-Bora), Marquesas Islands (Hiva Oa and Ua Huka), and Austral Islands (Tubuai and Rurutu)

Clinician View



Traveler View
(/travel/destinations/traveler/vfr/french-polynesia)

Vaccines and Medicines

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Prepare travelers to French Polynesia with recommendations for vaccines and medications.

	Recommendations	Transmission	Guidance
Routine vaccines	Recommended for all travelers	varied	Immunization schedules (http://www.cdc.gov/vaccines/schedules/hcp/index.html)
Hepatitis A (/travel/yellowbook/2012/chapter-3-infectious-diseases-related-to-travel/hepatitis-a)	Recommended for most travelers, including those with "standard" itineraries and accommodations	Fecal-oral route (contaminated food and water) Person-to-person contact	Hepatitis A (http://wwwnc.cdc.gov/travel/yellowbook/2012/chapter-3-infectious-diseases-related-to-travel/hepatitis-a.htm) (Yellow Book) Dosing info (http://wwwnc.cdc.gov/travel/yellowbook/2012/chapter-3-infectious-diseases-related-to-travel/hepatitis-a.htm#1933)
Hepatitis B (/travel/yellowbook/2012/chapter-3-infectious-diseases-related-to-travel/hepatitis-b)	Consider for most travelers; recommended for those who might be exposed to blood or other body fluids, have sexual contact with the local population, or be exposed through medical treatment (e.g., for an accident).	Contact with blood and other body fluids: • Unprotected sex • Injection drug use • Contaminated transfusions • Exposure to human blood • Contaminated tattoo and piercing equipment	Hepatitis B (http://wwwnc.cdc.gov/travel/yellowbook/2012/chapter-3-infectious-diseases-related-to-travel/hepatitis-b.htm) (Yellow Book) Dosing info (Twinrix) (/travel/yellowbook/2012/chapter-3-infectious-diseases-related-to-travel/hepatitis-a#1935)
Typhoid (/travel/yellowbook/2012/chapter-3-infectious-diseases-related-to-travel/typhoid-and-paratyphoid-fever)	Recommended for most travelers, especially those who are staying with friends or relatives; visiting smaller cities,	Fecal-oral route (contaminated food and water)	Typhoid (http://wwwnc.cdc.gov/travel/yellowbook/2012/chapter-3-infectious-diseases-related-to-travel/typhoid-and-paratyphoid-fever.htm) (Yellow Book) Dosing info (http://wwwnc.cdc.gov/travel/yellowbook/2012/chapter-

Recommendations	Transmission	Guidance
villages, or rural areas where exposure might occur through food or water; or prone to "adventurous eating"		3-infectious-diseases-related-to-travel/typhoid-and-paratyphoid-fever.htm#1947) (Yellow Book)

Non-Vaccine-Preventable Diseases

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The following diseases are possible risks your patients may face when traveling in French Polynesia. This list is based on our best available surveillance data and risk assessment information at the time of posting. It is not a complete list of diseases that may be present in a destination. Risks may vary within different areas of a destination.

	Guidance	Patient Eduction	Notes
		Vectorborne	
Dengue	• Dengue (/travel/yellowbook/2012/chapter-3-infectious-diseases-related-to-travel/dengue-fever-and-dengue-hemorrhagic-fever.htm) (CDC Yellow Book) • Dengue (http://www.cdc.gov/Dengue/) • Western Hemisphere Map (/travel/yellowbook/2012/chapter-3-infectious-diseases-related-to-travel/dengue-fever-and-dengue-hemorrhagic-fever.htm#2332) • Eastern Hemisphere Map (/travel/yellowbook/2012/chapter-3-infectious-diseases-related-to-travel/dengue-fever-and-dengue-hemorrhagic-fever.htm#2333) • DengueMap (http://www.healthmap.org/dengue/index.php) (http://www.cdc.gov/Other/disclaimer.html) (interactive map)	• Dengue (/travel/diseases/dengue-fever) • Avoid Bug Bites (/travel/page/avoid-bug-bites)	• More risk in urban and residential areas than for other vectorborne diseases • Leading cause of febrile illness among travelers returning from the Caribbean, South America, and South and Southeast Asia

Patient Counseling

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Counsel your patients on actions they can take on their trip to stay healthy and safe.

Eat and drink safely

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Prevent bug bites

Show (javascript:void(0);)

Stay safe outdoors

Show (javascript:void(0);)

Keep away from animals

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Reduce your exposure to germs

Show (javascript:void(0);)

Avoid sharing body fluids

Show (javascript:void(0);)

Know how to get medical care while traveling

Show (javascript:void(0);)

Select safe transportation

Show (javascript:void(0);)

Maintain personal security

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Healthy Travel Packing List

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Remind your patients to pack health and safety items. Use the Healthy Travel Packing List for French Polynesia (France) (/travel/destinations/french-polynesia/traveler/packing-list) for a list of health-related items they should consider packing.

Travel Health Notices

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Stay aware of current health issues in French Polynesia in order to advise your patients on additional steps they may need to take to protect themselves.

Watch Level 1, Practice Usual Precautions

- **Zika Fever in French Polynesia (Tahiti) (/travel/notices/watch/zika-fever-french-polynesia-tahiti)**
  Updated February 13, 2014
  The French Polynesia Department of Health has confirmed an outbreak of Zika fever in the islands of Tahiti, Moorea, Raiatea, Tahaa, Bora Bora, Huahine, Nuku Hiva, Hiva Oa, Ua Pou, Hao, Rangiroa, Fakarava, Tikehau, Takaroa Ahe and Arutua. Read More >> (/travel/notices/watch/zika-fever-french-polynesia-tahiti)

Advising Returning Travelers

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Although some illnesses may begin during travel, others may occur weeks, months, or even years after return. A history of travel, particularly within the previous 6 months, should be part of the routine medical history for every ill patient. A newly returned, ill international traveler should be preferentially evaluated by a physician versed in travel-related illness.

Here are two professional medical organizations that provide directories of travel clinics throughout the United States:

- American Society of Tropical Medicine and Hygiene (ASTMH) (http://www.astmh.org/source/ClinicalDirectory/) (http://www.cdc.gov/Other/disclaimer.html)
- International Society of Travel Medicine (ISTM) (http://www.istm.org/WebForms/SearchClinics/Default.aspx?SearchType=Advanced) (http://www.cdc.gov/Other/disclaimer.html)

For more information on advising patients after international travel, see Yellow Book Chapter 5: Post-Travel Evaluation (/travel/yellowbook/2012/table-of-contents.htm#26).

***Map Disclaimer** - The boundaries and names shown and the designations used on maps do not imply the expression of any opinion whatsoever on the part of the Centers for Disease Control and Prevention concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Approximate border lines for which there may not yet be full agreement are generally marked.*

Page last updated: June 19, 2013
Content source: Centers for Disease Control and Prevention
National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)
Division of Global Migration and Quarantine (DGMO)

Centers for Disease Control and Prevention 1600 Clifton Rd. Atlanta, GA 30333, USA
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Attachment 4

United States Medical Eligibility Criteria (US MEC) for Contraceptive Use, 2010

The *United States Medical Eligibility Criteria for Contraceptive Use, 2010 (US MEC) (http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5904a1.htm?s_cid=rr5904a1_e)* is intended to assist health care providers when counseling women, men, and couples about contraceptive method choice. The US MEC provides guidance on the safety of contraceptive method use for women with specific characteristics and medical conditions. This document is not intended to be a substitute for professional medical advice; persons should seek advice from their health care providers when determining family planning options.

CDC went through a formal adaptation process to create the US MEC. In 1996, the World Health Organization (WHO) published the first edition of the *Medical Eligibility Criteria for Contraceptive Use*. WHO has always intended for its global guidance to be used by policy makers, family planning program managers, and the scientific community as a reference when developing family planning guidance at the country or program level.

The US MEC has a companion document, U.S. Selected Practice Recommendations for Contraceptive Use, 2013 (US SPR), which addresses how to use contraceptive methods. While the US MEC provides guidance on who can use various methods of contraception, the US SPR provides guidance on how contraceptive methods can be used and how to remove unnecessary barriers for patients in accessing and successfully using contraceptive methods.

US MEC Resources

- *Update to CDC's U.S. Medical Eligibility Criteria for Contraceptive Use, 2010: Revised Recommendations for the Use of Hormonal Contraception Among Women at High Risk for HIV or infected with HIV. (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6124a4.htm?s_cid=mm6124a4_e%0d%0a)* Source: *MMWR* 2012;61(24);449–452. CDC has updated the recommendations for hormonal contraceptive use among women at high risk for HIV or infected with HIV, based on new scientific evidence.
- *Update to CDC's U.S. Medical Eligibility Criteria for Contraceptive Use, 2010*: Revised Recommendations for the Use of Contraceptive Methods During the Postpartum Period. (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6026a3.htm?s_cid=mm6026a3_w) Source: *MMWR*. 2011;60(26):878–883. CDC has updated the recommendations for combined hormonal contraceptive use among postpartum women, on the basis of new scientific evidence.

Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use

Key:
1 No restriction (method can be used)
2 Advantages generally outweigh theoretical or proven risks
3 Theoretical or proven risks usually outweigh the advantages
4 Unacceptable health risk (method not to be used)

Updated June 2012. This summary sheet only contains a subset of the recommendations from the US MEC. For complete guidance, see: http://www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm

Most contraceptive methods do not protect against sexually transmitted infections (STIs). Consistent and correct use of the male latex condom reduces the risk of STIs and HIV.

Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Injection		Implant		LNG-IUD		Copper-IUD	
		I	C	I	C	I	C	I	C	I	C	I	C
Age		Menarche to <40=1		Menarche to <18=1		Menarche to <18=2		Menarche to <18=1		Menarche to <20=2		Menarche to <20=2	
		>40=2		18-45=1		18-45=1		18-45=1		>20=1		>20=1	
				>45=1		>45=2		>45=1					
Anatomic abnormalities	a) Distorted uterine cavity									4		4	
	b) Other abnormalities									2		2	
Anemias	a) Thalassemia	1		1		1		1		1		2	
	b) Sickle cell disease‡	2		1		1		1		1		2	
	c) Iron-deficiency anemia	1		1		1		1		1		2	
Benign ovarian tumors	(including cysts)	1		1		1		1		1		1	
Breast disease	a) Undiagnosed mass	2*		2*		2*		2*		2		1	
	b) Benign breast disease	1		1		1		1		1		1	
	c) Family history of cancer	1		1		1		1		1		1	
	d) Breast cancer‡												
	i) current	4		4		4		4		4		1	
	ii) past and no evidence of current disease for 5 years	3		3		3		3		3		1	
Breastfeeding (see also Postpartum)	a) < 1 month postpartum	3*		2*		2*		2*					
	b) 1 month or more postpartum	2*		1*		1*		1*					
Cervical cancer	Awaiting treatment	2		1		2		2		4	2	4	2
Cervical ectropion		1		1		1		1		1		1	
Cervical intraepithelial neoplasia		2		1		2		2		2		1	
Cirrhosis	a) Mild (compensated)	1		1		1		1		1		1	
	b) Severe‡ (decompensated)	4		3		3		3		3		1	
Deep venous thrombosis (DVT) /Pulmonary embolism (PE)	a) History of DVT/PE, not on anticoagulant therapy												
	i) higher risk for recurrent DVT/PE	4		2		2		2		2		1	
	ii) lower risk for recurrent DVT/PE	3		2		2		2		2		1	
	b) Acute DVT/PE	4		2		2		2		2		2	
	c) DVT/PE and established on anticoagulant therapy for at least 3 months												
	i) higher risk for recurrent DVT/PE	4		2		2		2		2		2	
	ii) lower risk for recurrent DVT/PE	3*		2		2		2		2		2	
	d) Family history (first-degree relatives)	2		1		1		1		1		1	
	e) Major surgery												
	(i) with prolonged immobilization	4		2		2		2		2		1	
	(ii) without prolonged immobilization	2		1		1		1		1		1	
	f) Minor surgery without immobilization	1		1		1		1		1		1	
Depressive disorders		1*		1*		1*		1*		1*		1*	
Diabetes mellitus (DM)	a) History of gestational DM only	1		1		1		1		1		1	
	b) Non-vascular disease												
Diabetes mellitus (cont.)	(i) non-insulin dependent	2		2		2		2		2		1	
	(ii) insulin dependent‡	2		2		2		2		2		1	
	c) Nephropathy/ retinopathy/ neuropathy‡	3/4*		2		3		2		2		1	
	d) Other vascular disease or diabetes of >20 years' duration‡	3/4*		2		3		2		2		1	
Endometrial cancer‡		1		1		1		1		4	2	1	2
Endometrial hyperplasia		1		1		1		1		1		1	
Endometriosis		1		1		1		1		1		2	
Epilepsy‡	(see also Drug Interactions)	1*		1*		1*		1*		1*		1*	
Gallbladder disease	a) Symptomatic												
	(i) treated by cholecystectomy	2		2		2		2		2		1	
	(ii) medically treated	3		2		2		2		2		1	
	(iii) current	3		2		2		2		2		1	
	b) Asymptomatic	2		2		2		2		2		1	
Gestational trophoblastic disease	a) Decreasing or undetectable ß-hCG levels	1*		1		1		1		3		3	
	b) Persistently elevated ß-hCG levels or malignant disease‡	1		1		1		1		4		4	
Headaches	a) Non-migrainous	1*	2*	1*	1*	1*	1*	1*	1*	1*	1*	1*	
	b) Migraine												
	i) without aura, age <35	2*	3*	1*	2*	2*	2*	2*	2*	2*	2*	1*	
	ii) without aura, age ≥35	3*	4*	1*	2*	2*	2*	2*	2*	2*	2*	1*	
	iii) with aura, any age	3*	4*	2*	3*	2*	3*	2*	3*	2*	3*	1*	
History of bariatric surgery‡	a) Restrictive procedures	1		1		1		1		1		1	
	b) Malabsorptive procedures	COCs: 3 P/R: 1		3		1		1		1		1	
History of cholestasis	a) Pregnancy-related	2		1		1		1		1		1	
	b) Past COC-related	3		2		2		2		2		1	
History of high blood pressure during pregnancy		2		1		1		1		1		1	
History of pelvic surgery		1		1		1		1		1		1	
HIV	High risk	1*		1*		1*		1*		2	2	2	2
	HIV infected (see also Drug Interactions)‡	1*		1*		1*		1*		2	2	2	2
	AIDS (see also Drug Interactions) ‡	1*		1*		1*		1*		3	2*	3	2*
	Clinically well on therapy	If on treatment, see Drug Interactions								2	2	2	2
Hyperlipidemias		2/3*		2*		2*		2*		2*		1	
Hypertension	a) Adequately controlled hypertension	3*		1*		2*		1*		1*		1	
	b) Elevated blood pressure levels (properly taken measurements)												
	(i) systolic 140-159 or diastolic 90-99	3		1		2		1		1		1	
	(ii) systolic ≥160 or diastolic ≥100‡	4		2		3		2		2		1	
	c) Vascular disease	4		2		3		2		2		1	

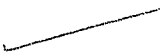
Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Injection		Implant		LNG--IUD		Copper-IUD	
		I	C	I	C	I	C	I	C	I	C	I	C
Inflammatory bowel disease	(Ulcerative colitis, Crohn's disease)	2/3*		2		2		1		1		1	
Ischemic heart disease‡	Current and history of	4		2	3	3		2	3	2	3	1	
Liver tumors	a) Benign												
	i) Focal nodular hyperplasia	2		2		2		2		2		1	
	ii) Hepatocellular adenoma‡	4		3		3		3		3		1	
	b) Malignant‡	4		3		3		3		3		1	
Malaria		1		1		1		1		1		1	
Multiple risk factors for arterial cardiovascular disease	(such as older age, smoking, diabetes and hypertension)	3/4*		2*		3*		2*		2		1	
Obesity	a) ≥30 kg/m² body mass index (BMI)	2		1		1		1		1		1	
	b) Menarche to < 18 years and ≥ 30 kg/m² BMI	2		1		2		1		1		1	
Ovarian cancer‡		1		1		1		1		1		1	
Parity	a) Nulliparous	1		1		1		1		2		2	
	b) Parous	1		1		1		1		1		1	
Past ectopic pregnancy		1		2		1		1		1		1	
Pelvic inflammatory disease	a) Past, (assuming no current risk factors of STIs)												
	(i) with subsequent pregnancy	1		1		1		1		1	1	1	1
	(ii) without subsequent pregnancy	1		1		1		1		2	2	2	2
	b) Current	1		1		1		1		4	2*	4	2*
Peripartum cardiomyopathy‡	a) Normal or mildly impaired cardiac function												
	(i) < 6 months	4		1		1		1		2		2	
	(ii) ≥ 6 months	3		1		1		1		2		2	
	b) Moderately or severely impaired cardiac function	4		2		2		2		2		2	
Postabortion	a) First trimester	1		1		1		1		1		1	
	b) Second trimester	1		1		1		1		2		2	
	c) Immediately post-septic abortion	1*		1*		1*		1*		4		4	
Postpartum (see also Breastfeeding)	a) < 21 days	3		1		1		1					
	b) 21 days to 42 days												
	(i) with other risk factors for VTE	3*		1		1		1					
	(ii) without other risk factors for VTE	2		1		1		1					
	c) > 42 days	1		1		1		1					
Postpartum (in breastfeeding or non-breastfeeding women, including post-cesarean section)	a) < 10 minutes after delivery of the placenta									2		1	
	b) 10 minutes after delivery of the placenta to < 4 weeks									2		2	
	c) ≥ 4 weeks									1		1	
	d) Puerperal sepsis									4		4	
Pregnancy		NA*		NA*		NA*		NA*		4*		4*	
Rheumatoid arthritis	a) On immunosuppressive therapy	2		1		2/3*		1		2	1	2	1
	b) Not on immunosuppressive therapy	2		1		2		1		1		1	
Schistosomiasis	a) Uncomplicated	1		1		1		1		1		1	
	b) Fibrosis of the liver‡	1		1		1		1		1		1	
Severe dysmenorrhea		1		1		1		1		1		2	
Sexually transmitted infections (STIs)	a) Current purulent cervicitis or chlamydial infection or gonorrhea	1		1		1		1		4	2*	4	2*
	b) Other STIs (excluding HIV and hepatitis)	1		1		1		1		2	2	2	2

Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Injection		Implant		LNG--IUD		Copper-IUD	
		I	C	I	C	I	C	I	C	I	C	I	C
Sexually transmitted infections (cont.)	c) Vaginitis (including trichomonas vaginalis and bacterial vaginosis)	1		1		1		1		2	2	2	2
	d) Increased risk of STIs	1		1		1		1		2/3*	2	2/3*	2
Smoking	a) Age < 35	2		1		1		1		1		1	
	b) Age ≥ 35, < 15 cigarettes/day	3		1		1		1		1		1	
	c) Age ≥ 35, ≥15 cigarettes/day	4		1		1		1		1		1	
Solid organ transplantation‡	a) Complicated	4		2		2		2		3	2	3	2
	b) Uncomplicated	2*		2		2		2		2		2	
Stroke‡	History of cerebrovascular accident	4		2	3	3		2	3	2		1	
Superficial venous thrombosis	a) Varicose veins	1		1		1		1		1		1	
	b) Superficial thrombophlebitis	2		1		1		1		1		1	
Systemic lupus erythematosus‡	a) Positive (or unknown) antiphospholipid antibodies	4		3		3	3	3		3		1	1
	b) Severe thrombocytopenia	2		2		3	2	2		2*		3*	2*
	c) Immunosuppressive treatment	2		2		2	2	2		2		2	1
	d) None of the above	2		2		2	2	2		2		1	1
Thrombogenic mutations‡		4*		2*		2*		2*		2*		1*	
Thyroid disorders	Simple goiter/ hyperthyroid/hypothyroid	1		1		1		1		1		1	
Tuberculosis‡ (see also Drug Interactions)	a) Non-pelvic	1*		1*		1*		1*		1		1	
	b) Pelvic	1*		1*		1*		1*		4	3	4	3
Unexplained vaginal bleeding	(suspicious for serious condition) before evaluation	2*		2*		3*		3*		4*	2*	2*	2*
Uterine fibroids		1		1		1		1		2		2	
Valvular heart disease	a) Uncomplicated	2		1		1		1		1		1	
	b) Complicated‡	4		1		1		1		1		1	
Vaginal bleeding patterns	a) Irregular pattern without heavy bleeding	1		2		2		2		1	1	1	
	b) Heavy or prolonged bleeding	1*		2*		2*		2*		1*	2*	2*	
Viral hepatitis	a) Acute or flare	3/4*	2	1		1		1		1		1	
	b) Carrier/Chronic	1	1	1		1		1		1		1	
Drug Interactions													
Antiretroviral therapy	a) Nucleoside reverse transcriptase inhibitors	1*		1		1		1		2/3*	2*	2/3*	2*
	b) Non-nucleoside reverse transcriptase inhibitors	2*		2*		1		2*		2/3*	2*	2/3*	2*
	c) Ritonavir-boosted protease inhibitors	3*		3*		1		2*		2/3*	2*	2/3*	2*
Anticonvulsant therapy	a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	3*		3*		1		2*		1		1	
	b) Lamotrigine	3*		1		1		1		1		1	
Antimicrobial therapy	a) Broad spectrum antibiotics	1		1		1		1		1		1	
	b) Antifungals	1		1		1		1		1		1	
	c) Antiparasitics	1		1		1		1		1		1	
	d) Rifampicin or rifabutin therapy	3*		3*		1		2*		1		1	

I = initiation of contraceptive method; C = continuation of contraceptive method; NA = Not applicable

* Please see the complete guidance for a clarification to this classification: www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm

‡ Condition that exposes a woman to increased risk as a result of unintended pregnancy.

Switching from:	Switching to: Pill	Patch	Ring	Progestin shot ("Depo")	Progestin implant	Hormone IUD	Copper IUD
Pill	**No gap:** take 1st pill of new pack the day after taking any pill in old pack	Start patch **1 day before** stopping pill	**No gap:** insert ring the day after taking any pill in pack	First shot **7 days before** stopping pill	Insert implant **4 days before** stopping pill	Insert hormone IUD **7 days before** stopping pill	Can insert copper IUD up to 5 days *after* stopping pill
Patch	Start pill **1 day before** stopping patch		**No gap:** insert ring and remove patch on the same day	First shot **7 days before** stopping patch	Insert implant **4 days before** stopping patch	Insert hormone IUD **7 days before** stopping patch	Can insert copper IUD up to 5 days *after* stopping patch
Ring	Start pill **1 day before** stopping ring	Start patch **2 days before** stopping ring		First shot **7 days before** stopping ring	Insert implant **4 days before** stopping ring	Insert hormone IUD **7 days before** stopping ring	Can insert copper IUD up to 5 days *after* stopping ring
Progestin shot ("Depo")	Can take 1st pill up to 15 weeks *after* the last shot	Can start patch up to 15 weeks *after* the last shot	Can insert ring up to 15 weeks *after* the last shot		Can insert implant up to 15 weeks *after* the last shot	Can insert hormone IUD up to 15 weeks *after* the last shot	Can insert copper IUD up to 16 weeks *after* the last shot
Progestin implant 	Start pill **7 days before** implant is removed	Start patch **7 days** before implant is removed	Start ring **7 days before** implant is removed	First shot **7 days before** implant is removed		Insert hormone IUD **7 days before** implant is removed	Can insert copper IUD up to 5 days *after* implant is removed
Hormone IUD	Start pill **7 days before** IUD is removed	Start patch **7 days before** IUD is removed	Start ring **7 days before** IUD is removed	First shot **7 days before** IUD is removed	Insert implant **4 days before** IUD is removed		Can insert copper IUD right *after* hormone IUD is removed
Copper IUD	Start pill **7 days before** IUD is removed	Start patch **7 days before** IUD is removed	Start ring **7 days before** IUD is removed	First shot **7 days before** IUD is removed	Insert implant **4 days before** IUD is removed	Insert hormone IUD right after copper IUD is removed and use back-up method for **7 days**	

SELF-ASSESSMENT QUESTIONS	
Are you a smoker? If yes: how many cigarettes per day_____	☐ Yes ☐ No
Have you ever taken birth control pills or used a birth control patch or ring?	☐ Yes ☐ No
Did you ever experience a bad reaction to using birth control?	☐ Yes ☐ No
Are you currently using birth control pills or a patch or a ring?	☐ Yes ☐ No
Have you ever been told not to take hormones?	☐ Yes ☐ No
Do you think you might be pregnant now?	☐ Yes ☐ No
Have you given birth within the past 6 weeks?	☐ Yes ☐ No
Have you had bariatric surgery or stomach reduction surgery?	☐ Yes ☐ No
Do you have high blood pressure or high cholesterol?	☐ Yes ☐ No
Have you had a blood clot in your lung or leg (NOT varicose veins) or take medicine to prevent a blood clot?	☐ Yes ☐ No
Have you had a heart attack or stroke or been told you had heart disease?	☐ Yes ☐ No
Have you had breast cancer?	☐ Yes ☐ No
Do you have migraine headaches?	☐ Yes ☐ No
Do you have diabetes?	☐ Yes ☐ No
Do you take any regular prescription medications?	☐ Yes ☐ No
Do you take medication for seizures, tuberculosis (TB), or human immunodeficiency virus (HIV)?	☐ Yes ☐ No
Have you ever had hepatitis, liver disease, gall bladder disease or liver cancer?	☐ Yes ☐ No
Do you have lupus, rheumatoid arthritis, or any blood disorders?	☐ Yes ☐ No
Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	☐ Yes ☐ No
Do you have any other medical problems?	☐ Yes ☐ No

From CDC website

WHO/RHR/08.17

SELECTED PRACTICE RECOMMENDATIONS FOR CONTRACEPTIVE USE

2008 update

EXECUTIVE SUMMARY

The *Selected practice recommendations for contraceptive use* – one of the four cornerstones of the World Health Organization's (WHO) evidence-based family planning guidance – provides evidence-based recommendations on how to safely and effectively use contraceptive methods once they are deemed medically appropriate for an individual. This guideline is intended for use by policy-makers, programme managers, and the scientific community in the preparation of national family planning/sexual and reproductive health programmes for delivery of contraceptives. The first edition of the *Selected practice recommendations for contraceptive use* was published in 2002, and the second edition in 2004.

On 1–4 April 2008, WHO convened an expert Working Group in Geneva, Switzerland, to revise the second edition in response to newly published evidence and requests for clarification of specific recommendations from users of the guideline. The meeting brought together 43 participants from 23 countries, including nine agency representatives. The expert Working Group was comprised of: international family planning experts, including clinicians, epidemiologists, policy-makers, programme managers; experts in evidence identification and synthesis; experts in pharmacology; and users of the guideline. All members of the expert Working Group were asked to declare any conflict of interest; three of the experts declared a conflict of interest relevant to the subject matter of the meeting. They were not asked to withdraw from recommendation formulation.

METHOD OF WORK

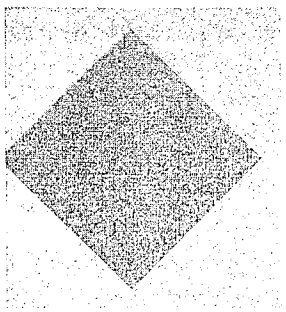
Using a system that identifies new evidence on an ongoing basis (the Continuous Identification of Research Evidence, or CIRE system, www.infoforhealth.org/cire/cire_pub.pl),[1] WHO identified five recommendations from the second edition for which new evidence had become available. Systematic reviews were then conducted to appraise the complete body of evidence for those recommendations. To conduct the systematic reviews, studies were identified using the CIRE system as well as through searches of PubMed and *The Cochrane Library* from 1966 to January 2008. The search also included reviews of reference lists in articles identified by the literature search and contact with experts in the field. The systematic reviews were provided to the expert Working Group prior to the meeting and served as the basis for the Group's deliberations during the meeting. The Group arrived at its recommendations through consensus.

[1] Mohllajee AP, Curtis KM, Flanagan RG, Rinehart W, Gaffield ML, Peterson HB. Keeping up with evidence: a new system for WHO's evidence-based family planning guidance. *American Journal of Preventive Medicine*, 2005; 28:483–490.

World Health Organization

Department of Reproductive Health

A WHO FAMILY PLANNING CORNERSTONE



HOW TO USE THIS SUMMARY

This document summarizes the changes made to recommendations related to questions 6, 9, 11, 18 and 22 in the second edition of the *Selected practice recommendations for contraceptive use*. The revised recommendations will appear in the 3rd edition of the guideline when it is published. In addition, this document includes a clarification of the recommendation related to question 17.

Only recommendations that have changed are included here. The changes are highlighted in **bold** lettering. For the complete text of each of the questions refer to the 2nd edition of the guideline (available at http://www.who.int/reproductive-health/publications/spr/index.htm).

It is expected that the recommendations in the 3rd edition of the *Selected practice recommendations for contraceptive use* will remain valid until 2011. The Department of Reproductive Health and Research at WHO Headquarters in Geneva will be responsible for initiating a review of the guideline at that time.

Grace period for a repeat injection of DMPA extended to 4 weeks

The following changes were made to address situations where a woman comes late for her repeat DMPA injection.

Question 6. When can a woman have repeat progestogen-only injectables (POIs) – depot-medroxyprogesterone acetate (DMPA) or norethisterone enantate (NET-EN)?

Late for an injection

- The repeat injection of **DMPA can be given up to 4 weeks late** without requiring additional contraceptive protection. For NET-EN, the repeat injection can be given up to 2 weeks late without requiring additional contraceptive protection.
- If she is more than **4 weeks late for a DMPA repeat injection,** or more than 2 weeks late for a NET-EN repeat injection, she can have the injection if it is reasonably certain that she is not pregnant. She will need to abstain from sex or use additional contraceptive protection for the next 7 days. She may wish to consider the use of emergency contraception if appropriate.

Comments

The expert Working Group considered the risk of ovulation to be minimal within **4 weeks** following the time for a repeat injection for DMPA (3 months) and 2 weeks following the time for a repeat injection for NET-EN (2 months).

DMPA injections should be administered every 3 months. While the repeat DMPA injection can be given up to 4 weeks late without requiring additional contraceptive protection, this does not mean that the regular DMPA injection interval can be extended by 4 weeks.

Postpartum IUD insertion timing clarified

Guidance for postpartum IUD insertion was revised in the *Medical eligibility criteria for contraceptive use* (4th edition, in press). The recommendations below reflect those changes.

Question 9. When can a woman have a copper-bearing IUD inserted?

Postpartum and breastfeeding or non-breastfeeding (including after caesarean delivery)

- **She can have a copper-bearing IUD inserted up to 48 hours after delivery, including immediately after delivery of the placenta.**
- **If the delivery is by caesarean section, a copper-bearing IUD can be placed after delivery of the placenta, before closing the uterus.**

Question 11. When can a woman have a levonorgestrel-releasing IUD (LNG-IUD) inserted?

Postpartum and non-breastfeeding (including after caesarean delivery)

- **She can have an LNG-IUD inserted up to 48 hours after delivery, including immediately after delivery of the placenta.**
- **If the delivery is by caesarean section, the LNG-IUD can be placed after delivery of the placenta, before closing the uterus.**

Clarification of recommendations related to question 17 on missed combined oral contraceptive pills

Question 17. What can a woman do if she misses combined oral contraceptives (COCs)?

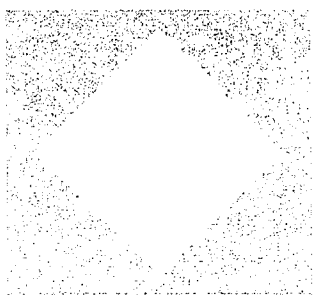
The expert Working Group addressed this issue in response to requests from the field to clarify the language of the recommendations related to missed pills. The clarification is not based on any new data, rather it relates to the wording of the recommendations. In the recommendations for Question 17, each time the text refers to missing active pills, the text now states that the pills are missed on **consecutive days, i.e. 1 or 2 days in a row, or 3 or more days in a row.**

Comments on 75 µg desogestrel-containing pills added to the recommendation on missed progestogen-only pills

Question 18. What can a woman do if she misses progestogen-only pills (POPs)?

Comments

Existing guidance is provided for situations when a user misses one or more pills by more than 3 hours. For women taking the 75 µg desogestrel-containing pill, the existing guidance for both women having menstrual cycles and those breastfeeding and amenorrhoeic applies when one or more pills have been missed by more than 12 hours.



Expanded treatment options for women with bleeding or spotting while using progestogen-only injectables

Two nonsteroidal anti-inflammatory drugs, mefenamic acid and valdecoxib, were added to the currently available recommendations for women experiencing either spotting or light bleeding, or heavy or prolonged bleeding related to the use of progestogen-only injectables.

Question 22. What can be done if a woman has menstrual abnormalities when using progestogen-only injectables (POIs) – depot medroxyprogesterone acetate (DMPA) or norethisterone enantate (NET-EN)?

Spotting or light bleeding

- **If no gynaecologic problems are found and she finds the bleeding unacceptable, short-term treatment with nonsteroidal anti-inflammatory drugs may be helpful.** If she decides to discontinue the injectable, help her choose another method.

Heavy or prolonged bleeding (more than 8 days or twice as much as her usual menstrual period)

- If the bleeding becomes a threat to the health of the woman or it is not acceptable to her, discontinue the injectable. Help her choose another method. **In the interim, short-term treatment with either ethinylestradiol or nonsteroidal anti-inflammatory drugs may be helpful.**

Comments

The expert Working Group reviewed the limited available data on treatment options for light or heavy bleeding and determined that the following drugs may be helpful for short-term treatment (i.e. 5–7 days):

Spotting or light bleeding

- **Nonsteroidal anti-inflammatory drugs**
  - **Mefenamic acid**
  - **Valdecoxib**

Heavy or prolonged bleeding

- **Nonsteroidal anti-inflammatory drugs**
  - **Mefenamic acid**
  - **Valdecoxib**
- **Hormonal drugs**
  - **Ethinylestradiol**

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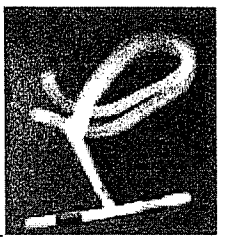
For further information contact:

Department of Reproductive Health and Research,
World Health Organization
Avenue Appia 20, CH-1211 Geneva 27, Switzerland
Email: reproductivehealth@who.int

cDC

Contraception

Reversible Methods of Birth Control

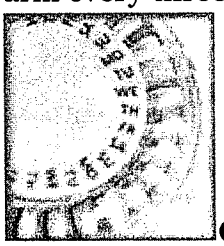


Intrauterine Contraception

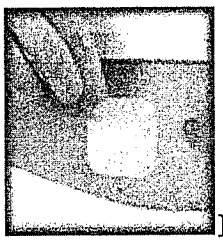
- **Copper T intrauterine device (IUD)** —This IUD is a small device that is shaped in the form of a "T." Your doctor places it inside the uterus to prevent pregnancy. It can stay in your uterus for up to 10 years. Typical use failure rate: 0.8%.
- **Levonorgestrel intrauterine system (LNG IUD)**—The LNG IUD is a small T-shaped device like the Copper T IUD. It is placed inside the uterus by a doctor. It releases a small amount of progestin each day to keep you from getting pregnant. The LNG IUD stays in your uterus for up to 5 years. Typical use failure rate: 0.2%.

Hormonal Methods

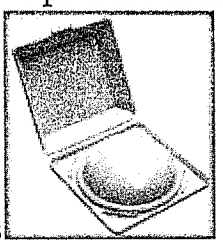
- **Implant**—The implant is a single, thin rod that is inserted under the skin of a women's upper arm. The rod contains a progestin that is released into the body over 3 years. Typical use failure rate: 0.05%.
- **Injection or "shot"**—Women get shots of the hormone progestin in the buttocks or arm every three months from their doctor. Typical use failure rate: 6%.



- **Combined oral contraceptives**—Also called "the pill," combined oral contraceptives contain the hormones estrogen and progestin. It is prescribed by a doctor. A pill is taken at the same time each day. If you are older than 35 years and smoke, have a history of blood clots or breast cancer, your doctor may advise you not to take the pill. Typical use failure rate: 9%.
- **Progestin only pill**—Unlike the combined pill, the progestin-only pill (sometimes called the mini-pill) only has one hormone, progestin, instead of both estrogen and progestin. It is prescribed by a doctor. It is taken at the same time each day. It may be a good option for women who can't take estrogen. Typical use failure rate: 9%.



- **Patch**—This skin patch is worn on the lower abdomen, buttocks, or upper body (but not on the breasts). This method is prescribed by a doctor. It releases hormones progestin and estrogen into the bloodstream. You put on a new patch once a week for three weeks. During the fourth week, you do not wear a patch, so you can have a menstrual period. Typical use failure rate: 9%, but may be higher in women who weigh more than 198 pounds.
- **Hormonal vaginal contraceptive ring**—The ring releases the hormones progestin and estrogen. You place the ring inside your vagina. You wear the ring for three weeks, take it out for the week you have your period, and then put in a new ring. Typical use failure rate: 9%.
- **Emergency contraception**—Emergency contraception is NOT a regular method of birth control. Emergency contraception can be used after no birth control was used during sex, or if the birth control method failed, such as if a condom broke.
  - Women can have the Copper T IUD inserted within five days of unprotected sex.
  - Women can take emergency contraceptive pills up to 5 days after unprotected sex, but the sooner the pills are taken, the better they will work. There are three different types of emergency contraceptive pills available in the United States. Some emergency contraceptive pills are available over the counter.



Barrier Methods

- **Diaphragm or cervical cap**—Each of these barrier methods are placed inside the vagina to cover the cervix to block sperm. The diaphragm is shaped like a shallow cup. The cervical cap is a thimble-shaped cup. Before sexual intercourse, you insert them with spermicide to block or kill sperm. Visit your doctor for a proper fitting because diaphragms and cervical caps come in different sizes. Typical use failure rate: 12%.
- **Spermicides**—These products work by killing sperm and come in several forms—foam, gel, cream, film, suppository, or tablet. They are placed in the vagina no more than one hour before intercourse. You leave them in place at least six to eight hours after intercourse. You can use a spermicide in addition to a male condom, diaphragm, or cervical cap. They can be purchased at drug stores.

The American College of
Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

COMMITTEE OPINION

Number 577 • November 2013

Committee on Gynecologic Practice

This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed.

Understanding and Using the U.S. Selected Practice Recommendations for Contraceptive Use, 2013

ABSTRACT: The *U.S. Selected Practice Recommendations for Contraceptive Use, 2013* (U.S. SPR), issued by the Centers for Disease Control and Prevention is a companion piece to the Centers for Disease Control and Prevention's *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010*. The *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010*, provides guidance for which contraceptive methods are safe for women with selected characteristics and medical conditions, whereas the U.S. SPR offers guidance on how to use these methods most effectively. The American College of Obstetricians and Gynecologists endorses the U.S. SPR and encourages its use by Fellows; providers should always consider the specific clinical situation when applying these guidelines to individual clinical care.

In June 2013, the Centers for Disease Control and Prevention (CDC) released the *U.S. Selected Practice Recommendations for Contraceptive Use, 2013* (U.S. SPR) (1). This guidance is a companion document to the CDC's previously released *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010* (U.S. MEC) (2, 3). The U.S. MEC provides guidance for which contraceptive methods are safe for women with selected characteristics and medical conditions, whereas the U.S. SPR offers guidance on how to use these methods most effectively. Simply stated, the U.S. MEC summarizes the "who" and the U.S. SPR focuses on the "how." Like the U.S. MEC, the U.S. SPR was adapted from global guidance published by the World Health Organization (4, 5). The American College of Obstetricians and Gynecologists endorses the U.S. SPR and encourages its use by Fellows; providers should always consider the specific clinical situation when applying these guidelines to individual clinical care. The full guidance can be found at www.cdc.gov/mmwr/pdf/rr/rr6205.pdf. Updates can be found at www.cdc.gov/reproductivehealth/UnintendedPregnancy/USSPR.htm.

The U.S. SPR provides evidence-based guidance that addresses common but sometimes complicated issues in contraceptive management. The U.S. SPR is arranged by contraceptive method and includes recommendations for intrauterine devices (IUDs), implants, injections, combined hormonal contraceptives, progestin-only pills, standard days method of natural family planning, emergency contraception, and female and male sterilization. For most reversible methods of contraception, the U.S. SPR provides recommendations on the following:

- What clinical information is needed before method initiation
- What routine follow-up is recommended
- How to manage common problems, including regimen nonadherence (eg, late injections or missed pills) and side effects.

The U.S. SPR addresses management of bleeding abnormalities with IUDs, progestin-only pills, and extended use of combined hormonal contraceptives. Additionally, the U.S. SPR provides guidance for how to be reasonably certain a woman is not pregnant before initiating contraception, for the initiation of contraception following emergency contraception, and for when a woman can stop contraception.

The U.S. SPR aims to reduce some of the barriers women may face to initiating contraception and using it effectively. For example, the U.S. SPR clarifies that all methods may be initiated at any time in the menstrual cycle ("quick start") if the provider is reasonably certain that the woman is not pregnant. Missing pills is a major reason for oral contraceptive failure leading to unin-

tended pregnancies; the U.S. SPR provides clear algorithms for what to do if women miss pills, as well as recommendations for provision of a 1-year supply of pill packs.

Overall, the U.S. SPR provides guidance for contraceptive management that has the potential to improve contraceptive initiation and consistent and correct use, thus helping to decrease the high rate of unplanned pregnancies in the United States. The American College of Obstetricians and Gynecologists continues to support making oral contraceptives available over-the-counter as a potential way to improve contraceptive access and use, and possibly decrease unintended pregnancy rates (6).

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pill use. Participants who did not understand a question on the medical checklist left it blank, and these responses were treated as missing values. Overall, self-screening or clinician-screening data were missing for three participants. Participants for whom data were missing were excluded from analyses requiring those responses.

Agreement between the respondent's self-screen and the clinician screen was 98% or higher for each of the individual contraindications except for two. In the case of hypertension, 9% of the respondents were found to be hypertensive (systolic blood pressure ≥ 140 mm Hg or diastolic blood pressure ≥ 90 mm Hg) and did not know this to be the case. With regard to migraine headaches, 6% of the respondents believed their condition made them ineligible to use the pill, but the nurse practitioner did not assess their migraine as one involving aura, which is the true contraindication.

We used logistic regression models to assess the association between selected demographic characteristics (including age, education, language spoken at home, recruitment site, parity and contraceptive use) and respondents' incorrect self-assessment of one or more contraindications to pill use. The coefficients in these models indicate that women age 35 and older had significantly higher odds of incorrectly self-reporting that they were eligible for pill use compared to younger women ($p<0.05$). Participants reporting Spanish as their primary language had lower odds of incorrectly reporting that they were eligible for pill use compared to English-speaking women ($p<0.05$). In addition, women who had completed at least some college education had lower odds of incorrectly reporting that they were contraindicated to oral contraceptive use compared to those with less education ($p<0.05$). Neither parity nor contraceptive use were significantly associated with the odds of either incorrectly reporting contraindications or incorrectly reporting pill eligibility. (Regression models not shown but available upon request).

DISCUSSION

In the population studied here, we found that 39.3% of women were contraindicated to oral contraceptives, a prevalence that seems surprisingly high. Shortridge and Miller examined the prevalence of contraindications to combined oral contraceptives in the US general population using data from the National Health and Nutrition Examination Survey (NHANES) and found that 16% of fecund women aged 10 to 51 were contraindicated to oral contraceptives.[11] Only nine contraindicated diseases were recorded in the NHANES dataset, and several prevalent conditions such as migraine with aura were not identifiable. The study from Washington found that among women presenting to a family planning clinic, 4.6% were contraindicated to hormonal contraceptive use.[7] While it is certainly surprising that the prevalence of contraindications is ten-fold larger in our sample, there are important differences between our study and the report from Washington. Eighty-eight percent of the women in the Washington study were seeking hormonal contraception, and 90% were between the ages of 15 to 30.[7] Our population was older, which increases the likelihood of being contraindicated to oral contraceptives, and a smaller proportion was using hormonal contraception, suggesting they were less likely to have been previously screened for contraindications. The prevalence of contraindications reported here is closer to that reported using data from a national health survey in Mexico,[6] although, like the report based on the NHANES data, that study was not able to include migraine with aura as a contraindication.

A simple question asking a woman if she thought the pill was medically safe for her served as a poor screening test for being contraindicated to oral contraceptive use. Using a medical checklist of contraindications, women were more accurate in their self-assessments. One way to evaluate screening tests, known as Youden's J, involves adding the positive predictive and negative predictive values and subtracting one.[12] This value for the initial self-screening

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Agreement between women's and providers' assessment of hormonal contraceptive risk factors

Solmaz Shotorbani[a], Leslie Miller[b], David K. Blough[a], Jacqueline Gardner[a,*]

[a]*Department of Pharmacy, The University of Washington, Box 357630, Seattle, WA 98195, USA*

[b]*Department of Obstetrics and Gynecology, The University of Washington, Seattle, WA 98195, USA*

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Abstract

Objective: To measure agreement between women's self-administered risk factor questionnaire and their providers' evaluation of their medical eligibility for hormonal contraceptive use.

Methods: This was an anonymous cross-sectional study. Participants were women 15–45 years old who completed a 20-item self-administered questionnaire. Women were recruited from six public health family planning clinics in the Seattle Metropolitan area. A matching medical evaluation questionnaire was completed concurrently by each participant's health care provider. Using provider evaluation as the "gold standard" against which we compared self-reported medical history, we calculated participant–provider agreement with point estimates and 95% confidence interval (CI).

Results: Of 399 participant and provider pairs, participant–provider agreement was obtained for 392 participant pairs. The majority of the participants (90.3%) were 15–30 years old and 77.7% had used a hormonal contraceptive method for more than 1 year. The estimated proportion of the overall agreement was 96% (95% CI, 0.92–0.98). Women were more likely to report severe headaches (12.4% vs. 3.3%), possible pregnancy (7.3% vs. 3.5%) and smoking (6.2% vs. 2.1%) than providers, but less likely to report smoking more than 15 cigarettes per day (2.6% vs. 9.2%) and irregular menses (6.5% vs. 9.9%).

Conclusion: Overall, a high proportion of the women in this study completed our medical history questionnaire in concordance with their health care providers' same-day medical evaluation. Agreement on critical medical eligibility criteria such as hypertension was well above 90%. For criteria on which there was disagreement, women were more likely to identify contraindications than were their providers.

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Keywords: Hormonal contraception; Self-screening; Risk assessment; Self-administered questionnaire

1. Introduction

Contraception plays a vital role in decreasing the number of unintended pregnancies. Despite the safety and widespread use of hormonal contraceptives, present prescriptive practices in the United States often require a physical examination prior to the prescription or renewal of hormonal contraceptives. This practice can pose a barrier to the timely acquisition of highly effective methods. Moreover, breast and pelvic examinations are no longer deemed necessary for the initial prescription and safe use of combined hormonal contraceptives for asymptomatic women of reproductive age [1–6].

Nevertheless, accurate medical history and blood pressure assessments are needed for the safe provision of hormonal contraceptives [2,7]. In 2004, the World Health Organization convened its third consortium of a scientific Working Group to review and update the medical eligibility criteria for contraceptive use [2]. These criteria are classified into four categories based on conditions affecting eligibility for the use of each contraceptive method, ranging from Category 1, which indicates no restrictions for the use of the contraceptive method to Category 4, which indicates a condition that represents an unacceptable health risk if the contraceptive is used. Based on these criteria, Family Health International developed contraceptive eligibility checklists for the provision of combined oral contraceptives and depot-medroxyprogesterone acetate (DMPA) in community-based programs

* Corresponding author. Tel.: +1 206 685 4128; fax: +1 206 543 3835.
E-mail address: jsgardne@u.washington.edu (J. Gardner).

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[6,8]. These checklists were validated for use by community-based workers and implemented internationally.

We adapted the provider checklist for the initiation of combined contraceptives [6,8] and revised it for self-administration for women seeking a prescription for hormonal contraceptives from community pharmacists in a feasibility study [9]. The resultant 20-item medical history checklist incorporated Category 1 classification of the World Health Organization's medical eligibility criteria [2].

The purpose of this study was to validate this checklist among a comparable population of women and providers at the local family planning clinics. Specifically, we measured agreement between women's self-administered risk factor questionnaire and their providers' evaluation of their medical eligibility for hormonal contraceptive use.

2. Materials and methods

We pilot-tested the medical eligibility checklist with 20 women at two public health family planning clinics and refined it for readability. Subsequently, we transformed this checklist (Table 1) into a questionnaire for validation and appended to it additional queries regarding demographic information such as age, education, family income and pregnancy history; a query of contraceptive history; and a question regarding the desired contraceptive method. The study protocol was reviewed and approved by the University of Washington Institutional Review Board and the Public Health Seattle King County Family Planning Program.

Women of reproductive age (15–45 years), menstruating or at risk for pregnancy, and proficient in English who attended one of six public health family planning clinics within the study period were given information sheets describing the study. The women were not necessarily seeking contraceptive-related services at the time of the recruiting visit. Clinic staff kept a daily log of the total number of clients seen, the number of women declining to participate and the number of women ineligible to participate. Following the women's verbal consent to participate in the study, a medical assistant or nurse instructed participants to complete a one-page anonymous questionnaire, seal it in an attached envelope and place it in a locked box prior to seeing their providers. The women were given $5 gift coupons for completing the questionnaire.

Each participant's medical provider completed a matching medical evaluation questionnaire immediately after the woman's clinic visit. The medical provider evaluation questionnaire mirrored that of the participant, with language modified slightly to incorporate medical terminology. For example, the phrase "high blood pressure" was replaced with "hypertension," and "blood clot" with "DVT," respectively, in the provider questionnaire. The only question that was notably stated differently in the provider questionnaire was the question regarding participant's history of migraines. Whereas we provided a specific definition for the type of migraine on which we were querying the participants (Table 1), we asked the providers whether their participants had "chronic headaches or atypical migraines" with the assumption that the providers had the training and background to decipher the difference between migraines and an occasional headache. Providers were asked to respond to the 20 corresponding medical history questions and to determine whether the women could safely use progestin-only or combination methods. Medical providers completed the evaluation questionnaire for each participant after the clinic visit and prior to seeing their next patient, sealed it into an envelope and deposited it into the locked box provided for each site.

Each clinic received between 65 and 70 preassembled questionnaire packets. No identifiers were collected from either the participants or the providers. A matching number on the participant and provider questionnaires linked the two forms. We provided in-service training to providers and clinic staff on the purpose of the study, data collection methods, and both participant and provider questionnaires at

Table 1
Participant 20-item medical history questionnaire

Medical history questions	Participant	Responses
1. Do you have or have you ever had breast cancer?	Y__	N__
2. Do you have a liver disease or jaundice (yellow skin or eyes)?	Y__	N__
3. Do you take pills every day for tuberculosis, fungal infections or seizures?	Y__	N__
4. Do you smoke cigarettes? (If "no" go to Question 7)	Y__	N__
5. Do you smoke more than 15 cigarettes a day?	Y__	N__
6. If you smoke, are you 35 years of age or older?	Y__	N__
7. Do you get bad headaches that make you feel sick to your stomach or involve numbness, or make you lose the ability to see, or make it hard to be in light?	Y__	N__
8. Are you breast-feeding a baby right now who is under 6 months of age?	Y__	N__
9. Do you have high blood pressure?	Y__	N__
10. Do you have diabetes (sugar in your blood)?	Y__	N__
11. Do you have gallbladder disease?	Y__	N__
12. Have you ever had a stroke, blood clot in your legs or lungs, heart attack or any heart disease?	Y__	N__
13. Has your father, mother, sister, or brother ever had blood clots?	Y__	N__
14. Do you weigh more than 200 pounds?	Y__	N__
15. Are you in a wheelchair?	Y__	N__
16. Are you planning to have surgery in the next 4 weeks?	Y__	N__
17. Has a doctor or nurse ever told you not to take hormones?	Y__	N__
18. Do you have any other medical problem or take regular medication that could prevent you from using hormonal birth control?	Y__	N__
19. Do you think you could be pregnant now?	Y__	N__
20. Do you usually get your period every month?	Y__	N__

all sites prior to data collection. No incentives were provided for the health care providers. All questionnaires and study logs were retrieved from each site at the completion of data collection.

Questionnaire data were entered into a Microsoft® Access (Seattle, WA, 2000) database and analyzed using SAS 9.1 (SAS 9.1, SAS Institute, Inc, Cary, NC). Generalized estimating equations (GEE) were used to account for intraclass correlations. In order to account for within-provider correlations while simultaneously adhering to the anonymous nature of the study, providers were asked to choose an alias and to use it consistently on all of the evaluation questionnaires they completed. Univariate descriptive statistics were generated to characterize the study participants and to describe the overall distribution of responses. We used the point-estimate and 95% confidence interval (CI) to measure participant–provider agreement. The criteria used to define agreement included either "yes/yes" or "no/no" participant–provider responses to each question.

Logistic regression was used to model the outcome variable of interest (participant–provider agreement) and to estimate agreement among subgroups defined by age, income, education and prior hormonal contraceptive use. In order to minimize the time required to complete the questionnaires and to restrict them to one page in length, we were unable to include the range of ethnic classifications used by the United States' Census Bureau to classify individuals into racial/ethnic categories and thus did not query the women on ethnicity.

We expected that participant–provider agreement would reach 90% and that women's higher age, education, income and prior contraceptive use would be associated with higher participant–provider agreement. When constructing the confidence interval for agreement, the robust GEE standard error was used. The sample size was calculated to estimate participant–provider agreement with a 95% CI, ±5%. The within-provider correlation coefficient was specified at .10, the within-clinic correlation was specified at 0, and we assumed a cluster size of 30 participants per provider. Based on these assumptions, our target sample size was determined to be 400 participant–provider pairs. A p value of .05 or less was considered statistically significant.

3. Results

Questionnaires were completed within a 4-week period at all six study sites, between August and November 2004. Of the clients seen in the clinics during the study period, 356 were judged to be ineligible (84 males, 253 non-English-speaking women, 19 women outside of the age range). Of the women invited to participate, 212 declined and 399 agreed. Of the 399 participant–provider pairs, completed questionnaires were returned for 395 pairs. Three women to whom questionnaires had been administered were outside the protocol age range (15–45 years) and were excluded from analysis. The following results are based on the analyses of 392 participant–provider questionnaires. Eighteen Advanced Registered Nurse Practitioners completed the corresponding questionnaires, and on average, each provider completed 21 questionnaires, with actual completion rates ranging from 3 to 52 questionnaires per provider.

Participant demographic characteristics are presented in Table 2. The estimated proportion of the overall participant–provider agreement on the 20 medical eligibility questions was 96% (95% CI, 0.92–0.98). The overall percentage of agreement in response to screening questions was compared in subgroups of age (p=.12), income (p=.30), education (p=.22) and prior contraceptive use (p=.47). Among these comparisons, none was statistically significant, although a slight trend of higher agreement was apparent among women who had used hormonal contraceptives for longer than 1 year (data not shown).

Participant–provider agreement was at or above 90% for 17 of the 20 medical eligibility criteria with the lowest agreement for the question "Do you usually get your period

Table 2
Demographic characteristics of participants

	All women (N = 392), n (%)
Age (y)	
15–20	185 (47.6)
21–30	166 (42.7)
31–40	34 (8.7)
41–45	4 (1.0)
English as first language	341 (88.6)
Formal education	
≤8th grade–11th grade	92 (23.6)
High school/GED–2 years of college	270 (69.4)
4 years college–graduate training (≥2 years)	27 (7.0)
Family income	
0–$15,000	189 (54.9)
$15,001–$25,000	67 (19.5)
$25,001–$35,000	36 (10.5)
$≥35,001	53 (15.1)
Gravidity	
Nulligravida	210 (55.0)
Gravida 1 or more	172 (45.0)
Parity	
Nulliparous	267 (71.0)
Para 1 or more	109 (29.0)
Lifetime hormonal method use[a]	
Oral contraceptive pills	277 (70.7)
Injection (DMPA)	184 (46.9)
Injection (combination)	12 (3.1)
Transdermal patch	99 (25.3)
Vaginal ring	29 (7.4)
Levonorgestrel implant	5 (1.3)
Levonorgestrel IUD	13 (3.3)
Emergency contraceptive	106 (27.0)
Length of method use	
Never	20 (5.2)
<1 year	66 (17.1)
>1 year	299 (77.7)

GED, general equivalency diploma.
[a] Includes multiple responses.

every month" at 83.6% (Table 3). The direction of disagreement for selected criteria is shown in Table 4. Women were more likely to report severe headaches (12.4% vs. 3.3%), possible pregnancy (7.3% vs. 3.5%) and smoking (6.2% vs. 2.1%) than were providers, but less likely to report smoking more than 15 cigarettes per day (2.6% vs. 9.2%) and irregular menses (6.5% vs. 9.9%).

Respondents were asked which method of birth control they would like to use. Three hundred forty participants (87.8%) selected a hormonal method of birth control, 22 (5.6%) were undecided, 13 (3.3%) selected a nonhormonal method and 13 (3.3%) did not want to use birth control (data not shown). Of those selecting a hormonal method, 37 (10.9%) marked more than one method, including 16 of the 19 participants who had marked "emergency contraceptive pills." We also wanted to assess whether women would or could differentiate between progestin-only and combination methods, so we provided a secondary scale of questions for women selecting pills as their desired method. One hundred fifty-seven women (46.2%) selected pills, whereas 58 women and 14 women selected "pills with estrogen" and "pills with progestin only," respectively.

Table 3
Unadjusted participant–provider medical history agreement

	"Yes" participant responses	Agreement[a]	Number of pairs[b]
	n (%)	*n* (%)	
1. Jaundice/liver disease	1 (0.3)	390 (100)	390
2. Breast-feeding	2 (0.5)	389 (100)	389
3. Diabetes	1 (0.3)	391 (100)	391
4. In a wheelchair	0 (0)	390 (100)	390
5. Breast cancer	1 (0.3)	391 (99.7)	392
6. Gallbladder disease	3 (0.8)	389 (99.5)	391
7. Stroke/blood clots	4 (1)	388 (99.5)	390
8. High blood pressure	4 (1)	388 (99.5)	390
9. ≥35 years old and smoking[c]	7 (3)	258 (99.6)	259
10. Daily meds	2 (0.5)	386 (99.0)	390
11. Told not to take hormones	4 (1)	384 (98.9)	388
12. Planning surgery	6 (2)	383 (98.7)	388
13. >200 lb.	43 (11)	379 (97.2)	390
14. Other medical problems	7 (2)	373 (96.6)	386
15. History of blood clots with a first degree relative	23 (6)	370 (95.6)	387
16. Smokes >15 cigarettes[c]	25 (10)	237 (92.9)	255
17. Smoke cigarettes	143 (37)	355 (91.7)	387
18. Possible pregnancy	49 (13)	341 (89.2)	383
19. Severe headaches	67 (17)	327 (84.3)	388
20. Irregular menses[d]	95 (24)	321 (83.6)	384

[a] Agreement on these questions is based on "yes/yes" or "no/no" provider–participant responses, except for the conditional questions regarding smoking.

[b] Total number with response by both provider and participant.

[c] Participants and providers were instructed to skip these questions if participants were nonsmokers. Agreement for these questions is based on "yes/yes," "no/no" or when both participants and providers left the questions blank. Missing responses — defined by missing responses from either participants or providers — were excluded from analysis.

[d] For purpose of presenting the results on this table, we have reversed the response order to be consistent with the direction of all other responses and to reflect presence of irregular menses.

Table 4
The direction of unadjusted participant–provider medical history agreement for selected variables

	Participant marked "yes"; provider marked "no"	Participant marked "no"; provider marked "yes"	Agreement *n* (%)
Smokes >15 cigarettes[a]	4 (2.6)	14 (9.2)	237 (92.9)
Smoke cigarettes	24 (6.2)	8 (2.1)	355 (91.7)
Has severe headaches	48 (12.4)	13 (3.3)	327 (84.3)
Possible pregnancy	28 (7.3)	14 (3.5)	341 (89.2)
Irregular menses[b]	25 (6.5)	38 (9.9)	321 (83.6)

[a] Participants and providers were instructed to skip these questions if nonsmoker.

[b] For purpose of presenting the results on this table, we have reversed the response order to be consistent with the direction of all other responses and to reflect presence of irregular menses.

Medical providers were asked to evaluate their participants' ability to safely use progestin-only or combination methods. According to this evaluation, 381 (96.9%) of the participants could safely use a progestin-only method and 374 (95.4%) could safely use a combination method. Altogether, 40 reasons (with multiple reasons for some participants) were given for women not currently seeking or having used hormonal contraceptives in the past 6 months. The most common reasons reported by providers included "pregnancy, possible pregnancy or seeking pregnancy," "seeking nonhormonal methods (condom or abstinence)" or "other" such as "partner with vasectomy," "IUD copper" or "refuses hormonal method." None of the reasons provided included a medical condition that was outside of the 20-item medical history questionnaire.

4. Discussion

Overall, a high proportion of the women in this study completed our medical history questionnaire in concordance with their health care providers' same-day medical evaluation. Participant–provider agreement on critical medical eligibility criteria such as hypertension, history of stroke, blood clots and breast cancer was well above 90%. For criteria on which there was disagreement, women were more likely to identify contraindications than were their providers.

Questions that in general generate discrete responses, for example, the presence or absence of gallbladder disease, yielded the highest agreement, albeit these conditions were rare among this population. Conversely, questions regarding more subjective queries such as menstruation patterns or smoking habits generated greater disagreement. Other

studies have found similar areas of discordance [10–14]. In this study, the query regarding women's menstrual cycle produced the highest disagreement. This is most likely due to the high rate of DMPA use, the frequency of irregular menses and possible pregnancy among this young population.

Participants were more likely to respond in the affirmative to our query of severe headaches than were providers to check the presence of the medical diagnoses of "chronic headaches or atypical migraines" as stated on the provider questionnaire. The difference in the wording of this question between the two questionnaires may account for some of this discordance. Specifically, the explicit wording of this question as posed to the participants (Table 1) may have elicited a higher positive response from the women than from the providers. Conversely, providers may not seek or assign these diagnoses as frequently as they may be present, despite the high prevalence of migraines present among young women [15–17]. Nonetheless, this question warrants a closer examination in future research to ensure both an unnecessary exclusion from effective contraceptive methods and a proper diagnosis of the condition, if present.

Women were more likely to report a possible pregnancy than were providers. Participants completed their questionnaires prior to receiving the results of a pregnancy test, whereas providers completed their evaluation questionnaires after seeing their patients. Thus, the difference in the timing of the two questionnaires may have resulted in some of this disagreement. However, the direction of disagreement indicates that women would be more likely to exclude themselves from initiating a hormonal method on the assumption that they may be pregnant. Therefore, in order to ensure a timely start and to prevent a gap in contraception, prescribers may wish to request or advise a pregnancy test concurrently with prescribing a hormonal method.

Our study population was primarily composed of young, low-income women of various educational backgrounds. Furthermore, the public health family planning clinics from which we collected data provided access to women of diverse ethnic backgrounds representative of the King County population [18]. Similar to national estimates of contraceptive use [19], the majority (94%) of our study participants had ever used some form of hormonal contraceptives. Very few participants were first-time contraceptive users (5.2%), although 17% had used hormonal contraceptives for less than 1 year. While this study sample includes many experienced contraceptive users, it is nonetheless an important population to study as there can be issues related to safety of ongoing use and eligibility for refills can change over time. This study was also not solely limited to women seeking hormonal contraceptives. We examined the overall agreement among the small subset of women who had never used hormonal contraceptives and found no statistically significant difference in agreement. However, we did find a slight trend of higher agreement among women who had used hormonal contraceptives for longer than 1 year.

A limitation of this study is that participants are already integrated into the health care system and many are veteran hormonal contraceptive users. Because of this survivorship bias, many are also healthy women without the presence of the range of medical risks that may be found in the general population. Therefore, more disagreement may occur in populations where chronic diseases are more prevalent. Unfortunately, we were unable to collect the reasons for which women declined to participate in this study, as that subset of women would have provided some insight into any selection bias that may be present. Moreover, our study excluded non-English-speaking women who may have had a different understanding of the questions presented.

In an effort to increase access to contraceptive methods or prescriptions, family planning experts have recommended either a switch from prescription-only to over-the-counter access or an increase in the number and expansion of the types of prescribers of hormonal contraceptives [20–22]. The expansion of prescriptive authority to non-physician health and social service professionals such as pharmacists, public health nurses or social workers could provide an additional avenue for women to obtain their birth control methods and expedite or facilitate contraceptive service delivery while providing an opportunity for counseling. Counseling is of particular importance for certain populations who may need more information and reassurance regarding method side effects and safety concerns [23]. Women who purchase hormonal contraceptives through the Internet [24] could also benefit from the implementation of a more accurate and validated screening process, thus increasing safety of method use.

In conclusion, self-reported medical history is a valuable epidemiologic and diagnostic tool of increasing importance as health care efficiencies are being sought in various clinical settings [13,25–28]. Our self-screening questionnaire assesses a woman's risk for hormonal birth control use, which highly corresponds with providers' assessments for medical eligibility of hormonal contraceptive use. We recommend the next research step to include an "actual use study" to assess whether women at various risk levels — those living with chronic disease, non-English-speaking women, new start users, among others — who self-screen for medical eligibility for hormonal contraceptives actually select, start and use their contraceptive method safely and effectively.

Acknowledgments

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CPhA/CSHP

Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraceptives

Authority: Section 4052.3 of the California Business and Professions Code authorizes a pharmacist to furnish self-administered hormonal contraceptives pursuant to a protocol approved by the Board of Pharmacy and the Medical Board of California. Use of the following protocol satisfies that requirement.

Purpose: To provide access to self-administered hormonal contraceptives and ensure that women receive adequate information to successfully comply with therapy.

Definition of Self-Administered: Pursuant to Business and Professions Code Section 4052.3, this protocol covers self-administered hormonal contraceptives. Products with the following routes of administration are considered self-administered:

- Oral
- Transdermal patch
- Vaginal ring
- Intramuscular or subcutaneous injection

Procedure: When a woman (female of any age) requests a hormonal contraceptive, the pharmacist will complete the following steps:

- Have the woman complete a self-assessment questionnaire
- Review the questionnaire and clarify responses if needed
- Measure and record the woman's seated blood pressure
- Measure and record the woman's weight

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-assessment questionnaire and the weight and blood pressure as measured by the pharmacist.

Self-Assessment Questionnaire: The self-assessment questionnaire used by the pharmacist shall ask about conditions from the woman's medical history that may present an increased risk or a contraindication to the use of hormonal contraceptives.

Referral to primary care: The pharmacist will refer each woman requesting a hormonal contraceptive to a health care provider for appropriate follow-up care as indicated. When a hormonal contraceptive is furnished to a woman, she will be advised of the importance of receiving recommended preventative health screenings and referred to see a physician or other appropriate health care provider. If a woman is not a candidate for a self-administered hormonal contraceptive (USMEC Category 3 or 4), she will be advised of the potential risk and referred to see a physician or other appropriate health care provider for further evaluation.

Patient Counseling: The pharmacist will provide each woman to whom a hormonal contraceptive is furnished with appropriate counseling and information on the product furnished, including the FDA required patient product information leaflet.

Documentation: The pharmacist will document each hormonal contraceptive furnished pursuant to this protocol in a patient profile as required by law. A copy of the completed self-assessment questionnaire will be securely stored within the pharmacy.

Policies and Procedures: The pharmacy shall have policies and procedures to ensure that patient confidentiality and privacy are maintained.

Training: Prior to furnishing a hormonal contraceptive pursuant to this protocol, a pharmacist shall have completed a continuing education program specific to hormonal contraceptives and application of the USMEC, or an equivalent curriculum-based training program.

1. Do you have or have you ever had breast cancer? Y__N__

13. Have you had breast cancer?

2. Do you have a liver disease or jaundice(yellow skin or eyes)? Y__N__

11. Do you have liver disease or have you had liver cancer?

3. Do you take pills everyday for tuberculosis, fungal infections or seizures? Y__N__

15. Do you take medicine for seizures or tuberculosis (TB)?

4. Do you smoke cigarettes? (If no go to Question7) Y__N__

5. Do you smoke more than 15 cigarettes a day? Y__N__

6. If you smoke, are you 35 years of age or older? Y__N__

1. Are you a smoker age 35 or older?

7. Do you get bad headaches that make you feel sick to your stomach or involve numbness, or make you lose the ability to see, or make it hard to be in light? Y__N__

10. Do you have migraine headaches?

8. Are you breastfeeding a baby right now who is under 6 months of age? Y__N__

4. Are you currently breastfeeding and your baby is less than 6 months old?

9. Do you have high blood pressure? Y__N__

5. Do you have high blood pressure?

10. Do you have diabetes (sugar in your blood)? Y__N__

9. Do you have diabetes?

11. Do you have gallbladder disease? Y__N__

12. Do you have gall bladder disease?

12. Have you ever had a stroke, blood clot in your legs or lungs, heart attack or any heart disease? Y__N__

6. Have you had a heart attack or stroke?

7. Do you have heart disease?

8. Have you had a blood clot (thrombosis) in your lung or in your leg (NOT just varicose veins)?

13. Has your father, mother, sister, or brother ever had blood clots? Y__N__

14. Do you weigh more than 200 pounds? Y__N__

15. Are you in a wheelchair? Y__N__

16. Are you planning to have surgery in the next 4 weeks? Y__N__

17. Has a doctor or nurse ever told you not to take hormones? Y__N__

18. Do you have any other medical problem or take regular medication that could prevent you from using hormonal birth control? Y__N__

14. Do you take medicine for high cholesterol?

19. Do you think you could be pregnant now? Y__N__

2. Do you think you might be pregnant?

3. Have you had a baby in the past 3 weeks?

20. Do you usually get your period every month? Y__N__

Attachment 5

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Quitting Smoking

Overview
(/tobacco/data_statistics/fact_sheets/cessation/quitting/index.htm#overview)

Nicotine Dependence
(/tobacco/data_statistics/fact_sheets/cessation/quitting/index.htm#dependence)

Health Benefits of Quitting
(/tobacco/data_statistics/fact_sheets/cessation/quitting/index.htm#benefits)

Smokers' Attempts to Quit
(/tobacco/data_statistics/fact_sheets/cessation/quitting/index.htm#quitting)

Methods to Quit Smoking
(/tobacco/data_statistics/fact_sheets/cessation/c

Helpful Resources
(/tobacco/data_statistics/fact_sheets/cessation/c

References
(/tobacco/data_statistics/fact_sheets/cessation/c

For Further Information
(/tobacco/data_statistics/fact_sheets/cessation/c

Overview

Tobacco use can lead to tobacco/nicotine dependence and serious health problems. Quitting smoking greatly reduces the risk of developing smoking-related diseases.

Tobacco/nicotine dependence is a condition that often requires repeated treatments, but effective treatments and helpful resources exist. Smokers can and do quit smoking. In fact, today there are more former smokers than current smokers.[1]

Nicotine Dependence

- Nicotine is the drug in tobacco products that produces dependence.[2,3,4,5] Most smokers are dependent on nicotine.[2,3]
- Nicotine dependence is the most common form of chemical dependence in the United States.[6] Research suggests that nicotine may be as addictive as heroin, cocaine, or alcohol.[1,3,5]
- Quitting smoking is difficult and may require several attempts.[3,4] Users often return to smoking because of withdrawal symptoms, stress, and weight gain.[2,3,4]
- Nicotine withdrawal symptoms may include irritability, anxiety, difficulty concentrating, cravings for a cigarette, and increased appetite.[2,3]

Health Benefits of Quitting

Tobacco smoke contains a deadly mix of more than 7,000 chemicals; hundreds are toxic, and about 70 can cause cancer.[1,3,7] Tobacco smoking increases the risk for serious health problems, numerous diseases, and death.[1,3]

People who stop smoking greatly reduce their risk for disease and premature death. Although the health benefits are greater for people who stop at earlier ages, quitting is beneficial at all ages.[1,3,8,9]

Stopping smoking is associated with the following health benefits:[1,3,8,9]

- Lowered risk for lung cancer and many other types of cancer.
- Reduced risk for coronary heart disease, stroke, and peripheral vascular disease.
- Reduced coronary heart disease risk within 1 to 2 years of quitting.
- Reduced respiratory symptoms, such as coughing, wheezing, and shortness of breath. The rate of decline in lung function is slower among people who quit smoking than among those who continue to smoke.
- Reduced risk of developing chronic obstructive pulmonary disease (COPD), one of the leading causes of death in the United States.
- Reduced risk for infertility in women of reproductive age. Women who stop smoking during pregnancy also reduce their risk of having a low birth weight baby.

Smokers' Attempts to Quit

Among current U.S. adult cigarette smokers, 68.8% report that they want to quit completely.[10] Starting in 2002, the number of former smokers has exceeded the number of current smokers.[10]

Percentage of adult daily cigarette smokers who stopped smoking for more than 1 day in 2010 because they were trying to quit:

- 42.7% of all **adult** smokers[10]
- 48.5% of smokers aged **18–24** years[10]
- 46.8% of smokers aged **25–44** years[10]

- 38.8% of smokers aged **45–64** years[10]
- 34.6% of smokers aged **65** years or older[10]

Percentage of high school cigarette smokers who ever tried to stop smoking in the past 12 months:

- 50.8% of all high school students who smoke[11]

Methods to Quit Smoking

The majority of cigarette smokers quit without using evidence-based treatments.[10] However, the following treatments are proven to be effective for smokers who want help to quit:

- Brief clinical interventions (i.e., when a doctor takes 10 minutes or less to deliver advice and assistance about quitting)[2]
- Individual, group, or telephone counseling[2]
- Behavioral therapies (e.g., training in problem solving)[2]
- Treatments with more person-to-person contact and intensity (e.g., more or longer counseling sessions)[2]
- Programs to deliver treatments using mobile phones[12]

Medications for quitting that have been found to be effective include the following:

- Nicotine replacement products[2]
  - Over-the-counter (nicotine patch [which is also available by prescription], gum, lozenge)
  - Prescription (nicotine patch, inhaler, nasal spray)
- Prescription non-nicotine medications: bupropion SR (Zyban®)[2], varenicline tartrate (Chantix®).[2,13]

Counseling and medication are both effective for treating tobacco dependence, and **using them together is more effective than using either one alone.**[2]

Helpful Resources

Quitline Services

1-800-QUIT-NOW (http://smokefree.gov/) (http://www.cdc.gov/Other/disclaimer.html) (1-800-784-8669) is a **free** telephone support service that can help individuals who want to stop smoking or using tobacco. Callers are routed to their state quitlines, where they have access to several types of quit information and services, including:

- Free support, advice, and counseling from experienced quitline coaches

- A personalized quit plan
- Practical information on how to quit, including coping strategies
- The latest information about medications
- Free or discounted medications (available for at least some callers in most U.S. states)
- Referrals to other resources
- Mailed self-help materials

For information on quitting, go to the Quit Smoking Resources (http://www.cdc.gov/tobacco/quit_smoking/how_to_quit/resources/index.htm) page on CDC's Smoking & Tobacco Use Web site.

Publications

Visit CDC's Online Publications Catalog (http://apps.nccd.cdc.gov/osh_pub_catalog/PublicationList.aspx) to order free copies of materials about quitting as well as other helpful resources pertaining to tobacco control and prevention.

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For Further Information

Centers for Disease Control and Prevention

National Center for Chronic Disease Prevention and Health Promotion

Office on Smoking and Health

E-mail: tobaccoinfo@cdc.gov (mailto:tobaccoinfo@cdc.gov)

Phone: 1-800-CDC-INFO

Media Inquiries: Contact CDC's Office on Smoking and Health press line at 770-488-5493.

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USA.gov Government Made Easy

Medications for Smoking Cessation

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

	Nicotine Replacement Therapy (NRT) Formulations Used as Monotherapy					Combination NRT
	Gum	Lozenge	Patch	Nasal Spray	Inhaler	
Adverse Effects	▪ Mouth/jaw soreness ▪ Hiccups ▪ Dyspepsia ▪ Hypersalivation ▪ Effects associated with incorrect chewing technique: – Lightheadedness – Nausea/vomiting – Throat and mouth irritation	▪ Nausea ▪ Hiccups ▪ Cough ▪ Heartburn ▪ Headache ▪ Flatulence ▪ Insomnia	▪ Local skin reactions (erythema, pruritus, burning) ▪ Headache ▪ Sleep disturbances (insomnia, abnormal/vivid dreams); associated with nocturnal nicotine absorption	▪ Nasal and/or throat irritation (hot, peppery, or burning sensation) ▪ Rhinitis ▪ Tearing ▪ Sneezing ▪ Cough ▪ Headache	▪ Mouth and/or throat irritation ▪ Cough ▪ Headache ▪ Rhinitis ▪ Dyspepsia ▪ Hiccups	▪ See adverse effects listed for individual agents
Advantages	▪ Might satisfy oral cravings ▪ Might delay weight gain ▪ Patients can titrate therapy to manage withdrawal symptoms ▪ Variety of flavors are available	▪ 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	▪ 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	▪ Patients can titrate therapy to rapidly manage withdrawal symptoms	▪ Patients can titrate therapy to manage withdrawal symptoms ▪ Mimics hand-to-mouth ritual of smoking (could also be perceived as a disadvantage)	▪ Provides consistent nicotine levels over 24 hours and patients can titrate therapy to manage withdrawal symptoms and situational urges for tobacco ▪ Research studies suggest combination therapy provides a small, but meaningful increase in success rates compared to NRT monotherapy ▪ Attractive option for patients who have previously failed treatment with NRT monotherapy ▪ See advantages listed for individual agents
Disadvantages	▪ 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	▪ Need for frequent dosing can compromise compliance ▪ Gastrointestinal side effects (nausea, hiccups, heartburn) might be bothersome	▪ 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	▪ 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	▪ 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	▪ Increased cost of therapy ▪ See disadvantages listed for individual agents

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

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

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

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Pharmacy Interventions in Smoking Cessation

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Smoking cessation ~~management of nicotine~~ addiction

CDC website

Pharmacologic Interventions

At first look, nicotine replacement therapy appears to be the treatment of a disease with its cause. The rationale, however, is well established. Observations on the beneficial effects of nicotine replacement in abstinent smokers were first made in 1967 (Lucchesi et al. 1967), and the process has its medical precedent in the use of methadone for opiate dependence. Nicotine use, in the form of 10 or more cigarettes a day, provides continuous neuroexposure (Benowitz 1993). The resulting tolerance and physical dependence produce classic withdrawal symptoms (USDHHS 1988). As Benowitz (1993) has summarized, "Nicotine replacement therapy serves primarily to break the daily addiction cycle by relieving withdrawal symptoms, thereby facilitating behavioural modification that is necessary for permanent smoking cessation" (p. 158). However, as will be discussed later in this chapter, recent data suggest that nicotine replacement may be effective without behavioral support or counseling. A number of candidate delivery systems have now been extensively evaluated with clear and consistent results. In addition, nonnicotine pharmacotherapies for treatment of tobacco use are now available.

Nicotine Polacrilex

Nicotine polacrilex (nicotine gum) was approved by the Food and Drug Administration (FDA) for use as an aid to smoking cessation in a 2-mg dose in 1984 and in a 4-mg dose in 1994. The nicotine in the gum is bound to an ion-exchange resin. Chewing the gum liberates the nicotine, which is absorbed through the buccal mucosa. Currently, both doses of nicotine polacrilex are approved for use as over-the-counter preparations by adults. The package insert instructs patients to use the gum as needed with the constraint that they not exceed a daily dose of 20 pieces of 4-mg gum or 30 pieces of 2-mg gum.

Efficacy

With more than 50 studies on its efficacy, nicotine gum is the most extensively investigated pharmacologic treatment for smoking cessation. This body of research has been summarized by several major meta-analyses (Lam et al. 1987; Cepeda-Benito 1993; Silagy et al. 1994; Tang et al. 1994). The most recent meta-analysis (Fiore et al. 2000) is summarized in Table

4.3. All meta-analyses found the gum to be effective in helping smokers quit.

Lam and colleagues (1987) performed a metaanalysis of nine randomized, controlled trials of the 2-mg nicotine gum. These authors performed separate analyses on the trials conducted in specialized smoking cessation clinics and on those conducted in general medical settings. In the specialized clinics, cessation success was greater with nicotine gum than with placebo gum. In general medical practice settings, however, nicotine gum was no more successful than placebo gum; both types of gum were more successful than usual care. The authors suggested that participants at the specialized cessation clinics had greater success because such participants may have been more motivated to quit and may have received more intensive adjuvant behavioral support than those at the generalized settings. The authors also speculated that patients who seek treatment in specialized clinics may be more physically dependent on nicotine and thus more likely to benefit from nicotine replacement than the average patient seen in a general medical clinic.

Cepeda-Benito (1993) performed a meta-analysis of 33 trials of the 2-mg gum. As in the review by Lam and colleagues (1987), the trials were categorized according to whether the adjuvant behavioral support was intensive or brief and according to whether the control group used placebo gum or no gum. Pooled estimates of efficacy were derived for short-term (0–8 weeks after treatment) and long-term (12 ± 2 months) outcome measures within each category. Effect sizes were not systematically related to the

type of control treatment used but were related to the intensity of behavioral support provided. When used in intensive interventions, the gum was associated with greater abstinence success than the control treatments at both long-term and short-term follow-up. When used in brief behavioral interventions, however, the gum outperformed the control interventions only at short-term follow-up. The author concluded that nicotine gum is an effective aid to smoking cessation but questioned its long-term value in the absence of adjuvant psychosocial support.

In the context of a larger review of available nicotine replacement therapies, Tang and colleagues (1994) performed a meta-analysis of 28 randomized, controlled trials of the 2-mg gum and 6 randomized, controlled trials of the 4-mg gum. The authors found that among participants recruited through advertisements to attend specialized cessation clinics, the 2-mg gum was associated with an 11-percent increase in success over control treatments. However, among

smokers who were directly invited to participate in a general smoking cessation trial conducted by a nonspecialist physician, the 2-mg gum increased abstinence success by only 3 percentage points over control conditions. Consistent with the analysis by Lam and colleagues (1987), the authors suggested that these findings reflect (1) the greater motivation of the smokers who referred themselves (i.e., responded to advertisements instead of being directly invited), (2) the greater degree of nicotine dependence in the self-referred group, and (3) the more extensive encouragement and more detailed instructions provided by therapists in the specialized settings in which the self-referred smokers were treated.

Six of the 28 trials of the 2-mg gum (Fagerström 1982, 1984; Jarvik and Schneider 1984; Areechon and Punnotock 1988; Hughes et al. 1989b; Jensen et al. 1990) reported abstinence success as a function of nicotine dependence as assessed by the Fagerström Tolerance Questionnaire (described later in this chapter). The authors aggregated these data and found that the 2-mg gum improved cessation success by 16 percentage points among smokers scoring high (indicating considerable nicotine dependence) on the Table 4.3. Meta-analyses of efficacy (estimated odds ratio and abstinence rates) for seven pharmacotherapies used in tobacco dependence treatment

Pharmacotherapy	Number of study groups	Estimated odds ratio (95% CI*)	Estimated abstinence rate (95% CI)
Bupropion SR† (n = 2‡)			
Placebo	2	1.0	17.3
Bupropion SR	4	2.1 (1.5, 3.0)	30.5 (23.2, 37.8)
Nicotine gum, 2 mg (n = 13)			
Placebo	16	1.0	17.1
Nicotine gum	18	1.5 (1.3, 1.8)	23.7 (20.6, 26.7)
Nicotine inhaler (n = 4)			

Placebo	4	1.0	10.5
Nicotine inhaler	4	2.5 (1.7, 3.6)	22.8 (16.4, 29.2)
Nicotine nasal spray (n = 3)			
Placebo	3	1.0	13.9
Nicotine spray	3	2.7 (1.8, 4.1)	30.5 (21.8, 39.2)
Transdermal nicotine			
(the nicotine patch) (n = 27)			
Placebo	28	1.0	10.0
Transdermal nicotine	32	1.9 (1.7, 2.2)	17.7 (16.0, 19.5)
Clonidine (n = 5)			
Placebo	6	1.0	13.9
Clonidine	8	2.1 (1.4, 3.2)	25.6 (17.7, 33.6)
Nortriptyline (n = 2)			
Placebo	3	1.0	11.7
Nortriptyline	3	3.2 (1.8, 5.7)	30.1 (18.1, 41.6)

*Confidence interval.

†SR = sustained release.

‡Number of studies.

Source: Fiore et al. 2000.

Key Facts about Nicotine Replacement Therapy

What is Nicotine Replacement Therapy?

Nicotine replacement therapy works by providing nicotine in lower amounts that a person usually gets from smoking cigarettes. Nicotine replacement therapy is used to help prevent withdrawal symptoms that many people experience after quitting smoking. Using nicotine replacement therapy with behavioral counseling can increase your chances of success.

Types of Nicotine Replacement Therapy

There are many different types of nicotine replacement therapy. Your pharmacist can help to select the best one for you.

- Patches
- Gum
- Lozenge
- Inhaler
- Nasal spray

How to Use Nicotine Replacement Therapy

It is important to use any form of nicotine replacement therapy as recommended by your pharmacist. Most nicotine replacement therapies should be used on a regularly scheduled basis, not as needed, especially during the first 6-8 weeks of use.

Follow Up While Using Nicotine Replacement Therapy

Be sure to let your primary care provider know that you are using nicotine replacement therapy.

Other Resources

1 800 NO BUTTS - The California Smokers' Helpline is a free statewide service.

Smokefree.gov - A website created by the US Department of Health and Human Resources that provides free information.

CPhA/CSHP

Pharmacists Protocol for Dispensing Nicotine Replacement Products

Senate bill 493 (chapter 469, statutes of 2013) permits pharmacists to furnish nicotine replacement products approved by the Food and Drug Administration for use by prescription only in accordance with standardized procedures and protocols based on a statewide protocol adopted by the California state board of pharmacy and the medical board of California. On the following page is the approved protocol. Pharmacists may use this protocol after they have completed 1 hour of continuing education credit in Tobacco Cessation (a requirement of the new law). The protocol was prepared to comply with the statutory requirements established by senate bill 493.

The statutory provisions for pharmacists furnishing Nicotine Replacement Products is California Business and Professions Code section 4052.9.

Protocol for Pharmacists Furnishing Nicotine Replacement Products

Authority: Section 4052 of the California Business and Professions Code authorizes a pharmacist to furnish nicotine replacement products pursuant to a protocol approved by the Board of Pharmacy and the Medical Board of California. Use of the following protocol satisfies that requirement.

Purpose: To provide access to nicotine replacement products within required limits and ensure that the patient receives adequate information to successfully use the products to stop tobacco use.

Procedure: When a patient requests nicotine replacement products the pharmacist will provide brief counseling based on the 5A's (Ask, Advise, Assess, Assist, and Arrange) and address the following:

- If you have previously tried nicotine replacement products, did you experience any adverse effects?
- Are you over 18 years of age?
- 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.)

The pharmacist will furnish nicotine replacement products from the list of products specified in this protocol (see Table "Medications for Smoking Cessation").

The pharmacist shall provide the "Key Facts about Nicotine Replacement Therapy" fact sheet, and review any questions the patient may have regarding nicotine replacement products

Fact Sheet: The pharmacist will provide the patient with a copy of the current Nicotine Replacement Products fact sheet approved by the Board of Pharmacy.

Referrals and Supplies: If tobacco cessation services or nicotine replacement products are not immediately available at the pharmacy or the the pharmacist will refer the patient to another nicotine replacement product pharmacist and/or the California Smokers' Helpline.

Documentation: Each prescription authorized by a pharmacist will be documented in a patient profile as required by law.

Training: Prior to furnishing nicotine replacement products, pharmacists who participate in this protocol must have completed a minimum of one hour of continuing education specific to Tobacco Cessation.

Situations for referral:

- Women who are pregnant or are planning to be pregnant
- Patients with significant cardiac concerns (e.g. myocardial infarction within the previous 2 weeks, serious underlying arrhythmias, serious or worsening angina pectoris)
- Patients with uncontrolled mental health conditions

COMMENTARY

Brief intervention protocol for assisting patients with tobacco cessation

FRANK VITALE

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In recent years, educational efforts have been directed toward providing health care professionals with the necessary knowledge and skills to effectively counsel patients about tobacco cessation. By and large, these training programs have positioned the clinician as the sole provider of tobacco-cessation assistance. However, in almost all practice venues, practitioners do not have the time to provide such intensive counseling. As a result, most health care professionals do nothing in terms of helping patients quit tobacco products.

To address this issue within the pharmacy profession, the Smoking Cessation Leadership Center, a division of the Robert Wood Johnson Foundation, recently formed the Pharmacy Partnership for Tobacco Cessation.[1] This project, housed at the national headquarters of the American Society of Health-System Pharmacists, focuses on providing all pharmacists with the training needed to conduct basic tobacco-cessation interventions—in fewer than five minutes—with all patients who use tobacco. Interested readers may contact the corresponding author for information on specific training programs. This initiative intends to reposition the pharmacist from the sole provider of cessation services to the initiator of the cessation process. Pharmacists are in an ideal position to motivate patients to consider quitting by educating them on key topics. Pharmacists should then refer patients for more intensive, long-term counseling during which the actual cessation program will be created and monitored.

Motivate–educate–refer. Although pharmacists do not typically conduct intensive tobacco-cessation interventions from start to finish (e.g., including follow-up counseling), they can play a vital role by beginning the process. Because of the long-term, trusting relationship that many pharmacists have with patients, any particular pharmacist might be just the person to whom a particular patient will respond. Therefore, the message to quit the use of tobacco should become a standard part of all interactions with patients who use tobacco.

Initiating the cessation process requires only a few minutes during the course of a patient interaction. During this short period of time, a pharmacist can screen for tobacco use and then motivate the patient to consider quitting by connecting smoking with potential health complications. The pharmacist can then educate the patient by reviewing past quit attempts to identify prior successes and challenges. In doing so, the pharmacist can promote the benefits of receiving professional advice or counseling and discuss the importance of proper medication use. Finally, in the absence of time or expertise for more in-depth counseling, the pharmacist can refer those patients who are ready to quit to a formal tobacco-cessation program. Brief interventions can be accomplished quickly and are effective for increasing the odds of cessation.[2]

Motivate. Many things can motivate an individual to quit smoking. Pharmacists can help patients identify strong, clear, internal reasons to stop smoking. Because patients are visiting a pharmacy to receive medications to treat a specific illness, this visit provides a key "window of opportunity" for pharmacists to help patients find a compelling reason to quit. The conversation to explore this topic can be initiated by asking the patient to explain his or her current illness and then clearly connecting the illness with smoking from the perspective of "smoking is responsible for this illness," "smoking aggravates this illness," or "smoking reduces your ability to recover from this illness." It is important to be specific. For most patients, general statements like "smoking is bad for you" or "smoking will kill you" are less effective and may come across as nagging.

Educate. The vast majority of smokers have attempted to quit sev-

FRANK VITALE, M.A., is Senior Lecturer, Pharmaceutical Sciences, and National Director, Pharmacy Partnership for Tobacco Cessation, School of Pharmacy, University of Pittsburgh, 729 Salk Hall, Pittsburgh, PA 15261 (vitalef@pitt.edu).

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eral times.[3] These past quit attempts can be gold mines of information about why an individual continues to smoke or is hesitant to quit. However, very few individuals use these attempts in a positive way. Instead of viewing past relapses as learning experiences, smokers often view them as justification for not being able to quit. Therefore, the educational component of this protocol focuses on reviewing patients' past quit attempts and examining 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 of choice? If the patient did not make any behavior changes or use a medication, why not?

Pharmacists should encourage smokers to learn from their past quit attempts and not to use those relapses as excuses to never try again. If some patients quit for just a few days, it is likely that they can do it again if they understand what worked and what did not during that attempt. Pharmacists should educate all patients who use tobacco about the importance of behavior changes and the appropriate use of medications with labeling approved by the Food and Drug Administration (FDA) for smoking cessation.

Behavior change. Behavior change is an essential component of any successful quit attempt. However, most smokers actually do very little in terms of behavior change when they attempt to quit. Many simply think that if they "will" themselves to do it, they can somehow "make" themselves quit.

Quitting involves many of the same elements inherent in learning any new behavior. A concrete plan is needed to teach the patient to cope with the urges, desires, and triggers for a cigarette without having one. These coping techniques are crucial to any successful quit attempt. Informing patients of the importance of coping and then providing referrals to a behavior-change program will significantly increase their likelihood of success.

Appropriate medication use. Pharmacists can also significantly increase the odds that a patient will successfully quit by reviewing past tobacco-cessation medication use and ensuring proper current use. Many individuals have negative attitudes about the cessation products or claim they do not work, based on past experience with a product. It is likely that these negative experiences are at least partly attributable to the fact that few patients actually use the products correctly.[4]

Years of research and dozens of studies have shown that the use of medications with FDA-approved labeling for tobacco cessation approximately double chances of success.[5,6] Therefore, pharmacists are encouraged to take a few minutes to review the instructions for use with every patient using a smoking-cessation medication. Simply doing this and nothing else could be the difference between success and failure for a specific patient.

Refer. A multitude of referral sources are available to tobacco users nationwide. Every smoking-cessation medication with FDA-approved labeling is associated with a free behavior-change program that is available to consumers. In addition, many hospitals offer cessation programs to the general public, and the American Cancer Society and the American Lung Association operate group cessation programs at various locations.

Perhaps the most accessible resource is the national telephone quit line, 1-800-QUIT-NOW. This number automatically links a caller to an existing state quit line and serves as the counseling center for those states that do not have a quit line of their own. Callers receive expert advice from specially trained tobacco-cessation counselors through a series of proactive calls. The counselors are also available to answer questions and deal with problems that arise outside of the regularly scheduled telephone contacts. In all cases, these programs create and conduct the formal cessation plan for each enrollee. Despite their proven efficacy,[7-9] quit lines are underutilized by smokers. Pharmacists can profoundly increase the success of smokers desiring to quit by informing them about the available resources and strongly encouraging patients to seek additional assistance.

If the motivate–educate–refer protocol suggestions appear to be impractical in light of the demands of your particular practice site, please consider adopting an even briefer strategy:

- Ask every patient about tobacco use,
- Advise tobacco users to quit, and
- Refer tobacco users to the toll-free national quit line, 1-800-QUIT-NOW.

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Attachment 6

Licensing Committee Meeting Minutes Excerpt

February 12, 2014

Also provided in meeting materials is background information on the Council on Credentialing in Pharmacy and its "Guiding Principles for Post-licensure Credentialing of Pharmacists." This document describes "credentials," "credentialing" and "privileging." This is a key document to review as the committee begins to establish parameters for qualifications for advance practice pharmacists. Additional background documents include: "Credentialing and Privileging of Pharmacists," "Credentialing in Pharmacy: A Resource Paper" and "National Commission for Certifying Agencies, Standards for the Accreditation of Certification Programs."

Discussion

Chair Veale stated section 4016.5 indicates what the Advanced Practice Pharmacist (APP) can do as an APP while section 4210 is the section the committee will be discussing how this APP implemented.

Chair Veale asked for comments from the committee and the public. There were no comments from the board or public.

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

Background

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

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

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

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

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

Presentation

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

a criteria referenced based scoring but she was unsure if NABP used criteria referenced based scoring for the NAPLEX. The board conducts a job analysis every five years and adjusts the content outline based on the frequency and importance of the skill. Ms. Herold stated any examination selected by the board will have to meet the requirements of a job related examination.

Dr. Lawson continued in 2011, BPS conducted a group of stakeholders to determine the next steps in moving forward. BPS developed their strategic plan and white paper focusing on the growth of current specialties; the addition of new specialties; marketing the value of specialties; and assessing the model for recertification. BPS continues to meet with stakeholders to look at the landscape of what other health care professions do in terms of assessing, certifying specialties, and re-certifying specialties. BPS will continue to have this discussion as the environment continues to change.

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

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

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

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

Chair Veale inquired if there were any other states that have similar APP laws. Dr. Lawson indicated he believed North Carolina and New Mexico had similar requirements and Iowa was in the development stages. Chair Veale inquired if the other states embraced BPS certification.

Dr. Lawson indicated BPS certification was not required in statute but BPS remains open to discuss.

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

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

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

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

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

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

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

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

Chair Veale asked if there were questions from the public.

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

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

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

3. FOR DISCUSSION: <u>Development of Other Certification Programs or Qualifying Methods for Licensure as Advanced Practice Pharmacists</u>

<u>Background</u>
The committee must discuss what elements it seeks to establish as components for advanced practice pharmacists. Specifically to qualify for licensure as contained in section 4210(a):

> (2) 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

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

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CREDENTIALING IN PHARMACY: A RESOURCE PAPER

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The Council on Credentialing in Pharmacy
Washington, DC, November 2010[1]

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.

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- **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

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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 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,

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

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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, pharmaceutics, 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.asp?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

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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.

- **Fellowships**[4]
  - 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 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

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.

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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 confidentially 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

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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

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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.

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

Education	Entry into Practice	Practice
Pharmacists		
Doctor of pharmacy (Pharm.D.) degree (ACPE)	Licensure (R.Ph.) (state boards of pharmacy)	License renewal (state boards of pharmacy) State-specific criteria, including mandatory continuing education (ACPE)
		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)
		Certification (optional) Specialty (BPS) Non-specialty (CCGP) Multidisciplinary (various)
Pharmacy technicians[c]		
Education/Training: Certificate of completion or associate's degree in some states (ASHP/state boards of pharmacy)	Registration/licensure in some states (boards of pharmacy)	Certification (PTCB, ICPT)

[a]Oversight bodies are described in text.
[b]Effective January 2008, certificate programs are referred to as practice-based CPE activities in ACPE standards.
[c]State differences exist; refer to the main text.

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Appendix A: Glossary[5]

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.

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.

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.

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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

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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.napb.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.rxptec.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.ccgp.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

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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]	
Heath 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 Pharmacorherapy 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)

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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)

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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.

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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 organizations[1], 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.

- 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.

CREDENTIALING AND PRIVILEGING OF PHARMACISTS

A Resource Paper from the 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.pharmacycredentialing.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.

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.

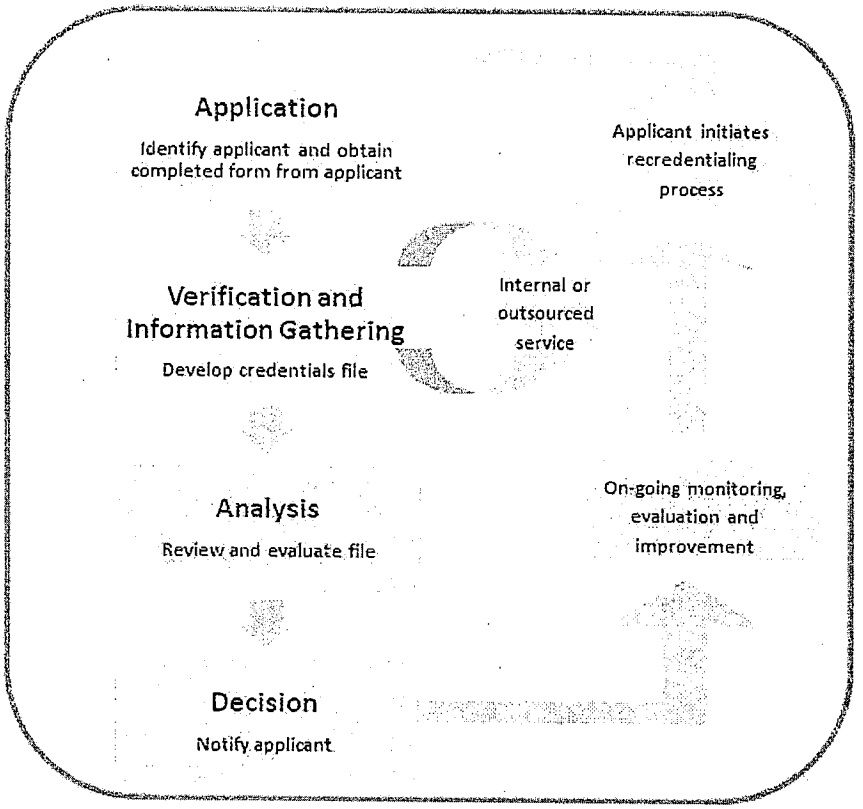

Figure 1. The Basic Credentialing Process Followed by Organizations

Application The credentialing process is commonly initiated using an application checklist. The individual pharmacist applies for employment or subsequently for recredentialing. 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 (Gassiott, 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

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[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/cnl/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.
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- 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.

This publication is owned by the Commission on Credentialing in Pharmacy. The recommended citation for this document is: Council on Credentialing in Pharmacy (2014). Credentialing and Privileging of Pharmacists: Council on Credentialing in Pharmacy National Resource Guide. The document may be retrieved from http://www.pharmacycredentialing.org.

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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.

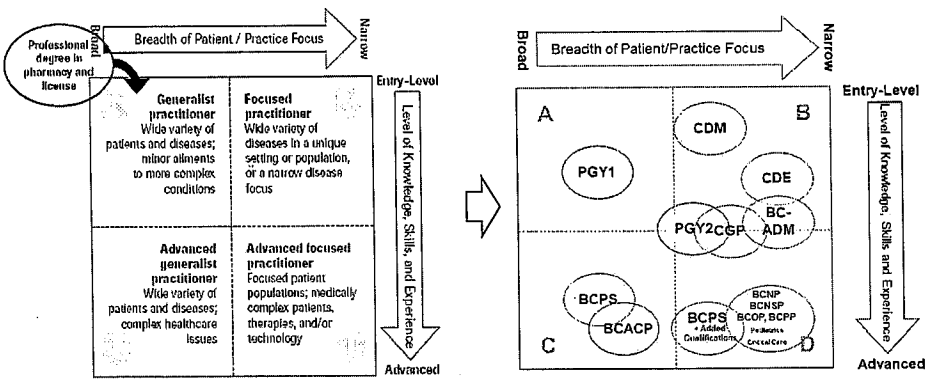
[5] Originally published in *J Am Pharm Assoc*. 2004; 44:517--520. ©2004, American Pharmacists Association (APhA). Reprinted by permission of APhA.

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).



Post-licensure scope of practice **Post-licensure credentials**

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 Contemparary 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 (AE-C). 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.

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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.

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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.

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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.

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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

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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.

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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:

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- 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).

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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.

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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.

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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.

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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.

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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.

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C. Candidates must be provided meaningful information on their performance on assessment instruments. Such information must enable failing candidates to benefit from the information and, if psychometrically defensible, understand their strengths and weaknesses as measured by the assessment instruments.

D. Reports of aggregate assessment data in summarized form must be made available to stakeholders without violating confidentiality obligations.

Commentary:

A. Certification programs are responsible for establishing quality control procedures that regularly monitor the precision of calculations used to compute assessment scores and their conversion to standardized, equated, or scaled scores, if performed.

B. The certification program should publish an explanation of the appropriate uses and misuses of reported score information.

C. Suggested evidence to document that the Standard has been met may include descriptions of scoring procedures, training documents, quality control procedures, and sample score reports for passing and failing candidates.

D. Evidence in support of essential element D should include documentation of aggregate assessment data to the various stakeholder groups on interest. For example, details of the aggregate assessment data might be appropriate reported to representatives of the program sponsor (e.g. a board or committee) and documented in the NCCA Accreditation application. In addition, however, some aggregate data must be available to the public and the certificant population, at a minimum addressing the number of candidates and the number of individuals attaining the certification credential during a specified period of time.

Standard 14

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

Essential Element:

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

Commentary:

A. The level of reliability required for an assessment instrument depends on the type of assessment device and the purpose for which scores will be used.

B. Different types of assessment instruments require different methods of estimating reliability. Reliability should be estimated using methods that are appropriate for characteristics of the assessment instruments and the intended uses of the scores.

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

- Methods used to assess reliability of scores (including subscores), and the rationale for using them
- Characteristics of the population involved (e.g., demographic information, employment status)

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- 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

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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

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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.

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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

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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.

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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.

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

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

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

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

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

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

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

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

Consumer—
See also "Public Member"

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

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

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

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

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.

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

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

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

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

Public Member—
A representative of the consumers of services provided by a defined certificant population, serving as a voting member on the governing body of a certification program, with all rights and privileges, including holding office and serving on committees. The public member should bring a perspective to the decision and policy making of the organization that is different from that of the certificants, and helps to balance the organization's role in protecting the public while advancing the interests of the profession.
(remove "consumer" from the glossary, as it has no definition)

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

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

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

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

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

Stakeholders—

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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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General Counsel
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Stephen Permison, MD, Division of Quality Assurance, Bureau of Health Professions, US Department of Health and Human Services

Gary Smith, National Board for Respiratory Care

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

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

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

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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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Attachment 8

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

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

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

DATE: June 4, 2014

LOCATION: Rancho Los Amigos Rehabilitation Center
7601 E. Imperial Highway
Downey, CA 90242

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

COMMITTEE MEMBERS NOT PRESENT: Victor Law, RPh

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

Call to Order

President Weisser called the meeting to order at 9:08 a.m.

President Weisser opened the meeting with a brief statement: The purpose of the committee is to allow board members to give their undivided attention to the implementation of SB 493. He said it is critical that as the board goes forward with implementation that it is done right the first time so the board does not have to make major changes down the road. President Weisser noted that he took his time picking the committee members and considered the expertise that each member will bring to the process. He added that he purposefully kept the committee small so that it could remain agile. Since the passage of SB 493, many groups have been working on the implementation, the committee looks forward to their input; however, it is important to remember that the responsibility for implementation is soley the board's. President Weisser concluded that he expects the committee to meet more often than other

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board committees and he hopes that the committee can make a final recommendation to the full board by the end of 2014.

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

1. Overview of Elements of SB 493 (Hernandez, Chapter 469, Statutes of 2013)

President Weisser asked Executive Officer Virginia Herold to give an overview of SB 493.

Ms. Herold provided an overview of SB 493 as follows:

<u>For pharmacists who become specially licensed as advanced practice pharmacists:</u>

- Creates a new license category of advanced practice pharmacist who may practice advanced practice pharmacy within or outside a pharmacy.
- Allows an APP to possess controlled substances
- Allows an APP to:
    - Perform patient assessments
    - Order and interpret drug therapy related tests
    - Refer patients to other health care providers
    - Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers
    - Initiate, adjust or discontinue drug therapy; must provide notification back to diagnosing prescriber or enter information into a patient record, shared with the prescriber
        -- require registration with DEA for prescribing APP
        -- tests ordered by APP in coordination with and notification to patient's diagnosing physician
- Requirements to become an APP:
    - Hold an active CA pharmacist license – in good standing
    - File an application with the board and pay a fee. The board did a cost analysis and determined that a $300 fee would cover the board's costs.
    - License will be good for 2 years linked to pharmacist license renewal
    - An additional 10 units of CE are required each renewal cycle in an area of practice relevant to the pharmacist's clinical practice
- Qualifications: possess 2 of the 3 below:
    1. Earn certification in a relevant area of practice (ambulatory care, critical care, geriatric, nuclear, nutrition support, oncology, pediatric, pharmacotherapy, psychiatric practice recognized by ACPE or another entity recognized by the board)

2. Complete postgraduate residency in accredited postgraduate institution where 50 percent of experience includes direct patient care with interdisciplinary teams
3. Have provided clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, APP, a pharmacist practicing collaborative drug therapy management or health system.

For all licensed pharmacists:

- Adds a determination that the Legislature declares pharmacists are health care providers who have the authority to provide health care services.
- Allows a pharmacist to administer drugs and biological products that have been ordered by a prescriber.
- 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.

  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.

  Note: pharmacists that do such immunizations need to be certified to perform these functions.
- Pharmacists may furnish prescription medications not requiring a diagnosis recommended by the CDC for individuals traveling outside the US (travel medications)
- Once a protocol is developed by the Board of Pharmacy and Medical Board of California:
  1. Allows a pharmacist to furnish nicotine replacement products in accordance with a state treatment protocol, provided:
     - Records are retained of drugs and devices furnished for at least 3 years so as to notify health providers or permit monitoring of the patient
     - The pharmacist notifies the patient's primary care provider of drugs and devices furnished or into a patient record
     - the pharmacist must complete 1 hour of CE on smoking cessation therapy biennially
  2. Pharmacists may furnish self-administered hormonal contraceptives in accordance with a state protocol developed by the Board and the Medical Board of California pursuant to the guidelines of the CDC.

Public Comment

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

2. Use of "Advanced Practice Pharmacists" in Other States

President Weisser reported that at least three states have some experience with a version of advanced practice pharmacists. They are New Mexico, North Carolina and Montana. General information about the scope of services authorized to these pharmacists was provided in the meeting materials.

President Weisser noted that the programs in other states rely heavily on the oversight of the Medical Board; while in California, SB 493 gave the Board of Pharmacy autonomy. President Weisser stated that this autonomy illustrates how important it is for the committee to implement a program that meets the high standard that has been set.

Public Comments
There were no comments from the public or from the committee members.

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

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

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

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

President Weisser stated that the meeting materials contained a wealth of information on this agenda item. President Weisser asked the committee members if there was a section (a, b or c) that they would like to discuss. The committee did not comment so President Weisser opened the floor to the public.

Public Comment
Felix Pham, clinical pharmacist, noted that some of the APP qualification methods seemed to overlap, particularly in regards to becoming certified in a certain area of practice and completing a certain number of experience hours. Ms. Herold responded that the overlap of the qualification methods is something that this committee will have to discuss; however, the board has to work within the guidelines of the legislation as it was passed.

Dr. Steve Gray, representing CSHP and Kaiser, commented that there are currently 47 stated that have some sort of collaborative drug therapy management where pharmacists can prescribe and order tests - including California. Dr. Gray commented that the board should look at other states to learn what problems could be avoided. Dr. Gray concluded that SB 493 was created to give better access to healthcare, and Kaiser as well as other organizations are willing to help the board in any way needed. The committee noted that the board will have to find a balance that creates a high standard for APPs, but is not so limiting that it defeats the intended purpose of SB 493.

Dr. Dan Robertson, dean of Western University, commented that what he likes most about SB 493 is the independence that it gives pharmacists in that they were given provider status. He added that SB 493 allows pharmacist to practice at the full scope of their knowledge and experience and increases their involvement in direct patient care. Ms. Veale and President Weisser agreed that gaining provider status was an important piece of SB 493 as it potentially will allow pharmacists to be reimbursed by insurance companies for their services. Ms. Herold noted that the board cannot secure or advocate for reimbursement; that will be up to pharmacists.

Dr. Robertson asked to clarify if a year of residency can also count towards a year of direct patient care experience. He noted that perhaps the committee could look at how North Carolina interpreted this requirement. President Weisser responded that this would be an important point for the committee to discuss.

Larry Lovett, from Long Beach Memorial Hospital, noted that "travel medications" is very broad and asked if the legislature had intended it only for the use of travel immunizations or if it went beyond that scope. Ms. Herold responded that the way the bill is written it includes both immunization and other medications you may need while traveling such as antibiotics or anti-nausea medications. Ms. Herold noted that the CDC has extensive resources available.

Mr. Lovett stated that as furnishing travel medications is something that all pharmacists can now do (not just those with an APP license) the committee may want to consider creating extra protocols in this area. A registered pharmacist agreed that additional protocols should be in place as pharmacists are not doctors and employers may force pharmacists to provide these services without proper support or training. Ms. Herold responded that anytime a pharmacist is asked to do something that is beyond their training or knowledge it is there professional obligation to refuse. She added that this may mean a pharmacists needs to find another employer. Dr. Gutierrez added that it is a difficult position for pharmacists to be in if they want to keep their job. Ms. Veale commented that large chain pharmacies will likely be hesitant to force this type of service without proper training and protocols as they can face lawsuits if a patient is harmed.

Mr. Lovett commented that many pharmacists in California, particularly those in acute care settings, already perform many of the duties described in SB 493. He asked if those pharmacists will now have to become licensed as an APP in order to keep working as they have done for years. Ms. Herold responded that SB 493 did not change any of the existing provisions and they can continue to work under these provisions without becoming licensed as an APP.

Dr. Gray, representing CSHP, commented that SB 493 was created to alleviate overburdened health care professionals (doctors and nurse practitioners). For example, a patient does not need to be diagnosed by a doctor to receive travel medications for a trip to Africa or to use nicotine cessation products to quit smoking. Dr. Gray noted that it is important to remember that there is a difference between furnishing and prescribing.

President Weisser asked the public if there was anyone who could give the committee additional information on the injectable portion of travel medications. Jeff Goad, from Chapman University, reported that the way SB 493 was written; independently initiated travel vaccines were not technically included. However, as the protocol provision was left untouched, a pharmacist can still provide ACIP routinely recommended travel vaccines, as long as they do so under protocol, which still requires physician involvement. Ms. Herold commented that the committee will take a look at the language and determine if they agree with that interpretation.

Dr. Goad reported that only around 5 percent of the traveling population sees a healthcare professional before traveling. 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. Dr. Goad noted that he would be opposed to creating a protocol for travel medications as things can change overnight based on outbreaks and protocols would considerably slow the process. Dr. Goad commented that he does recommend training and education for travel medicine. He added that he was surprised to see that there are requirements for smoking cessation and oral contraception, but not for travel medication.

Dr. Goad reported that the law does specifically mention the CDC's recommendation for international travelers, otherwise known as "the yellow-book." The yellow-book is a good reference for pharmacists to determine what medications are recommended for international travel. Ms. Veale asked how often this book is updated. Dr. Goad responded that the book is updated once a year, however, the CDC sends out notices of outbreak information so that practitioners can make adjustments based on current international situations.

President Weisser asked if there are existing programs that could provide training for pharmacists. Dr. Goad responded that APHA does have a program and other universities may also be creating programs.

Dr. Kathleen Hill-Besinque, from USC and CPHA, commented that she looked up the definition of "furnish" in the law book and it does not say that it must be a medication that the pharmacist has on the shelf. The definition says "by any means" so a pharmacist could write a prescription so the patient could go somewhere else to get the medication.

Dr. Hill-Besinque, asked the board to consider curriculum-based training, rather than requiring containing education training classes. Ms. Herold asked how the board could ensure that the curriculum at each school was providing similar information to ensure that students are really graduating with adequate knowledge. Dr. Hill-Besinque commented that Hawaii allows for curriculum equivalent training in contraception, so she writes a letter to the Hawaii board stating that the student had the training and how many hours they received. Dr. Gutierrez asked how long this training has been a part of USC's curriculum. Dr. Hill-Besinque responded since 2000. The committee noted that they may need to consider graduation date when accepting curriculum based training. Ms. Herold commented that the board will need some way to verify that a student received the training.

Dr. Gray, commented that the committee should also look outside of California to see what kinds of training universities on the East Coast provide for travel medications, as they serve a population that frequently travels overseas.

Robin Corelli, from the University of California, San Francisco, commented that since 2000 all California schools of pharmacy graduates receive an average of 6.5 hours of education on smoking cessation education as part of the core curriculum.

A pharmacist commented that he does not feel that pharmacists, particularly in chain stores, should do travel immunizations as they have not received training. He also added that as a recent graduate, he did not receive any training on smoking cessation. President Weisser asked if he was a graduate of a California school of pharmacy and the pharmacists responded that he was a graduate of a Rhode Island school of pharmacy.

Ms. Veale asked the pharmacist that if training was provided would he still feel a protocol would be necessary for travel medications. He responded that he still feels protocols should be in place. Ms. Veale commented that with travel medications things can change very quickly and a protocol may make it very difficult for a pharmacist to provide care if a rapid change is needed. However, if training was provided pharmacists could use their education to very quickly modify their care based on new travel information. The pharmacist stated that without a protocol employers could force pharmacist to provide travel medications even if they are not comfortable doing so. Ms. Herold stated that if you are not willing to walk away from an order that could potentially harm a patient you are not a health care professional.

Dr. Sally Rafie, from the University of California, San Diego, commented that developing a very detailed protocol for travel medication may not be necessary as the CDC already has information that the board could leverage. Dr. Rafie expressed her support for curriculum based training for oral contraception and smoking cessation as opposed to a CE based training. Dr. Gutierrez asked if the schools provided any documentation for students when they complete the training. Dr. Rafie responded that UCSD currently provided certificated to students. Dr. Gutierrez asked how long the schools feel that curriculum-based training should be valid before they need subsequent training. Dr. Hill-Besinque commented that legally there is not a time limit; however as a healthcare professional they should update their knowledge if they are providing care.

Dr. Lisa Kroon, Department Chair for Clinical Pharmacy at the University of California, San Francisco, expressed her support for curriculum based training. She added that the schools should provide the board with information on the content of the training they provide in the curriculum. President Weisser asked how long after graduation would she recommend allowing curriculum-based training to be valid. Dr. Kroon commented that as long as the person is a practicing pharmacist who is maintaining their CE, the curriculum-based training should be valid for as far back as the school could provide documentation.

Jon Roth, CEO of CPHA, encouraged the board not to implement rigid protocols. The passage of SB 493 illustrated that both lawmakers and the medical profession feel that pharmacists possess the professional knowledge, skills and training to provide patient care. Mr. Roth added that the board would need to have documentation that the curriculum based training occurred so they could validate that the pharmacist was operating within the guidelines of the training.

President Weisser asked Mr. Roth how CPHA feels about the board requiring content-specific continuing education. Mr. Roth responded that they oppose this requirement as it should be the responsibility of the health care professional to determine what CE they need to provide patient care. President Weisser commented that he is always surprised about how many people are discovered to have not completed the required CE when the board audits their renewal.

The committee discussed whether a pharmacist should be required to complete ongoing CE in smoking cessation, hormonal contraceptives and travel medications; or if they would just have to provide documentation of initial training in the area and then use their professional judgment to complete CE as needed. Felix Pham, pharmacist, commented that he would support a one-time training verification.

Michelle Tenerelli, Rite Aid pharmacist, commented that she would encourage the board not to create additional protocols. However, as an employer for a chain pharmacy she would support training programs, as a company is responsible anything a pharmacist does while working for them. She added that in California five Rite Aid locations provide travel medication services and the pharmacists all receive training and have resources available to them.

A pharmacist commented that he does not feel that curriculum-based training is sufficient and encouraged the board require additional CE in those areas only for pharmacists who choose to provide the services in SB 493.

Dr. Hill-Besinque commented that in regards to emergency contraception she feels that the board could create protocols as long as they were not too prescriptive and referenced the CDC guidelines. Referencing the CDC guidelines would allow for the protocols to remain current without having to go through a long process every time there was an update at the CDC. Dr. Hill-Besinque added that curriculum-based training provided better education than most continuing education courses.

Three Western University School of Pharmacy students provided the committee with insight into the type of education they have received during pharmacy school. They all expressed that they would feel comfortable in providing patient care in smoking cessation, hormonal contraception and travel medicine based on the education they have received in school.

The committee recessed for a break at 11:05 a.m. and resumed at 11:20 a.m.

Ms. Tenerelli, asked if pharmacists who attended school prior to the time when ACPE started endorsing schools of pharmacy would need to be re-trained. Ms. Herold confirmed they would.

President Weisser commented that the previous discussion had covered multiple agenda items and asked that the committee return to agenda item 3(c) - Ordering and Interpreting Tests to Monitor and Manage Drug Therapies.

CSHP created a committee to develop guidelines for ordering and interpreting tests after the passage of SB 439. The committee created draft guidelines for the board to review. President Weisser thanked CSHP for their work and reminded the public and the committee that the responsibility for the implementation of SB 493 ultimately fell to the board.

Robert Deamer, a member of the CSHP committee, provided the committee with highlights from the guidelines they created as follows:

Note: The committee and the audience were provided with copies of the entire guideline document at the meeting. This document can be found immediately following these meeting minutes.

CSHP Draft Guidelines for Pharmacists Ordering and Managing Tests to Ensure Safe and Appropriate Medication Therapy

The purpose of this guideline is to identify the professional standards pharmacists should follow when ordering and interpreting tests for the purpose of monitoring the efficacy and safety or drug therapy. Specific objectives are as follows:

- Establish best practices for pharmacists ordering and managing tests in the course of monitoring and managing the efficacy and safety of medication therapy in collaboration with the patient's primary care provider, diagnosing prescriber, medical home, etc. The priority of these best practices is to ensure that test ordering by pharmacists is performed only when necessary and that results are managed appropriately and promptly. These best practices are based on research, government reports, and decades of combined experience from California and other states.
- Provide resources to educate other healthcare professionals, testing organizations, health plans, and other third party payers about the role of pharmacists in ordering and managing tests in coordination with primary care providers and other members of the healthcare team.
- Describe payment models for test ordering by pharmacists.

Key principles for test ordering, interpretation, and management by pharmacists are:

- Testing should be for ensuring safe and effective medication therapy in coordination with the patient's primary care provider or diagnosing prescriber.

- Tests must only be ordered when necessary.
- Test results must be managed appropriately and promptly;
- Patients should receive feedback on their tests in a timely manner.
- Quality assurance should be integrated into the test ordering, interpretation, and management process.

Responsibility: Pharmacists are individually responsible for personal competence in ordering tests and interpreting results. Variables that may impact test results must be considered by pharmacists when interpreting results including timing of testing, medications, renal or hepatic function, fluid status, lab error, etc.

Using test results: In situations where tests could impact medication therapy decisions or medication therapy might alter testing results, pharmacists should review relevant tests that are required to make this determination. If required tests are not available, e.g., tests that are mandated in current treatment guidelines, FDA recommendations, or medication prescribing information, then the pharmacist should consider ordering or facilitating the ordering of these tests in collaboration with the relevant medical entity.

Ordering tests:

- If specific tests are important for determining the appropriateness, efficacy, or safety of medication therapy and test results have not been previously ordered or are out of date then pharmacists should order the tests or follow the procedure within their collaborative practice to ensure that the appropriate test is ordered.
- Pharmacists must pursue all reasonable approaches to ensuring that tests are not duplicative prior to ordering, e.g., review of the electronic health record, contact with test technician if such a line of communication is available. An exception is when a result is questionable and warrants a repeat test (e.g., abnormal potassium level and suspected hemolysis of blood sample based on previous test results).
- Pharmacists should only order those tests that they are personally competent to order; otherwise, an appropriate authority should be consulted.
- Tests must be necessary (e.g., per treatment guidelines, government mandates, prescribing information; clinical evaluation requirement) and limited to patients under the care of the pharmacist / pharmacy service.

Interpretation of test results:

- Pharmacists should only order tests that they are experienced in interpreting. An exception is when a test is necessary and, in a pre-arranged collaboration, the test is ordered but planned for interpretation by a qualified healthcare professional.
- Pharmacist must use professional judgment and consider all variables when interpreting test results.

Following-up on test results:

- Pharmacists who order tests must have a procedure established to ensure that results are followed-up appropriately. Pharmacists should either be available at any time of the day every day or establish an alternative plan for responding to critical test results, e.g., on-call groups, agreements with medical home providers, etc.
- Patients should be informed of what to expect by having the pharmacist order tests, e.g., who will follow-up and how soon.
- If tests are necessary for treatment decisions and results are not available in a timely manner, it is the pharmacist's responsibility to follow-up with either the testing organization or patient to determine the status of the test and whether rescheduling / reordering is necessary.
- Pharmacists must take appropriate action if the result of a lab test ordered is a critical value, defined as, "A laboratory test result that represents a pathophysiologic state at such variance with normal as to be life-threatening unless something is done promptly and for which some corrective action could be taken".
- At minimum, a pharmacist who receives a critical value should contact the physician responsible for the care of the patient at the time of notification.

Standards for documentation:

- As required by SB 493, all actions related to test ordering, interpretation, and management (including subsequent medication therapy changes and altered treatment or monitoring plans) must be documented within 24 hours in a system readily accessible to all involved healthcare team members involved.

President Weisser asked Mr. Deamer how he would define "coordination" between a pharmacist and physician. Mr. Deamer responded that communication is key. The electronic

system in place in many health care systems makes this communication between health care providers much easier.

Dr. Gutierrez asked to clarify if any pharmacist could order test or if it is only something that an APP pharmacist can do. It was confirmed that any pharmacist could order and interpret tests, not just those who have APP licensure. Mr. Deamer commented that doctor groups were hesitant about pharmacists ordering and interpreting tests. The challenge was to show that pharmacists have the knowledge and skills needed, and especially in the case of drug therapy management, excel at interpreting results.

Ms. Herold asked if there was no primary care provider could a pharmacist still order tests. Mr. Deamer responded that the pharmacist could refer the patient to a physician within the health system or in the community. He added that the pharmacist may need to refuse to order a test until the patient is seen by a physician. Ms. Herold noted that the committee needs to consider that a patient may change physicians without telling their pharmacist.

Dr. Gutierrez expressed concern that the pharmacist may order tests that result in the need for a diagnosis, which would need to be handled by a physician, not the pharmacist. Ms. Veale commented that she envisioned pharmacists ordering test that would determine the effectiveness of a drug therapy, not a new test used to diagnose. She added that if a test the pharmacist ordered did reveal a problem that needed diagnosis it would be the responsibility of the pharmacist to contact the physician and discuss it with them. Dr. Gutierrez stated that she is not as concerned about pharmacists who are practicing within a health system being able to contact the physician if a diagnosis is needed; rather pharmacists who are practicing independently. Ms. Veale responded that as a health care provider, the pharmacist should do what they need to do to contact the physician. Ms. Herold reported that for years pharmacists have been able to order tests to evaluate drug therapies, however SB 493 gives them autonomy previously not allowed. She concluded that the committee will need to address this new autonomy.

Jon Roth clarified that SB 493 allows all pharmacists to order and interpret tests *only* for efficacy and toxicity related to a drug therapy. An APP pharmacist is allowed to order and interpret tests related to drug therapy. Mr. Roth said the language sets two different requirements for regular pharmacists and APP pharmacists. President Weisser asked if there is any concern with patients diagnosis shopping. Mr. Roth responded that as at least in the near future, patients will have to pay out-of-pocket for these tests and he does not see much incentive.

Ryan Gates, clinical pharmacist, commented that historically pharmacists have not had access to critical information related to patient care. SB 493 is intended to give the pharmacist more information and make them part of the medical team. Mr. Gates noted that they were very careful to use language that required the pharmacist to coordinate testing with the primary care provider to eliminate redundant testing.

A compounding pharmacist specializing in hormone replacement therapy, commented that ordering and interpreting tests for drug efficacy is already a common practice with compounding pharmacists. She described how collaboration between the patient, pharmacist and physician occurs in her practice.

Dr. Robertson, Dean of Western University, commented he would estimate that about 70 percent of the curriculum in schools focuses on drug therapy management. SB 493 gives pharmacists access to lab testing to allow them to effectively monitor the drug therapy for patients. Dr. Robertson added that he does not think that testing should be limited to only pharmacists who work in a health system.

John Simimi, acute care pharmacist, commented that he feels there should be a strong protocol in place regarding testing. Ms. Veale said she would prefer there not be a protocol for everything that a pharmacist does, as it could minimize the effectiveness of the bill.

The committee discussed issues that may arise regarding payment for testing as insurance companies adjust to pharmacists having provider status.

Dr. Gray, CSHP, reminded the committee that SB 493 was created to address the health care shortage. He added that during the development of the bill, physicians asked that pharmacists be allowed to order tests to evaluate a drug therapy so that they can make recommendations about patient care based on objective results.

Dr. Gray commented that the language was specific to say “testing” rather than “lab testing” so that pharmacists could order tests like X-rays to monitor for osteoporosis. He added that pharmacist will now be able to order tests to determine if a patient has opioids in their system. If the results show that there are no opioids in their system then it could point to the patient selling the drugs to others.

Sarah McBane, pharmacist from North Carolina, commented that protocols could potentially overly restrict the pharmacist and harm patient care.

Mr. Gates commented that if test results come back showing there are critical, potentially life threatening problems, the pharmacist may not discontinue the drug therapy but they should at least hold the prescription until they can talk to the physician. He added that they may even send the patient to the emergency room for immediate treatment if the results are serious enough.

Andrew Lowe, clinical pharmacist, commented that he sees many patients who regularly switch primary care providers. To address this, they require asking the patient to confirm if they are still seeing the last physician they have on record to be part of every consultation.

The committee recessed for a break at 12:24 p.m. and resumed at 1:21 p.m.

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

(a) Board of Pharmacy Specialties Certification Programs

At the request of President Weisser, Ms. Veale briefly review the presentation that Brian Lawson and Andrea Ianucci, from Board of Pharmacy Specialties (BPS), gave at the February 12, 2014 Licensing Committee meeting.

Megan Coder, consultant for BPS, described the qualification process for taking the BPS exam.

Ms. Coder commented that the BPS program is not accredited by ACPE. However the continuing education that BPS offers is accredited by ACPE.

Ms. Coder reported that BPS recently added two specialties: Critical Care and Pediatrics. She added that any organizations that would like to see additional specialties added they could petition BPS.

President Weisser asked Ms. Coder if all of the BPS tests offered are psychometrically sound. Ms. Coder responded that all of the tests are psychometrically valid across the United States; this is ensured by an independent vendor.

Ms. Veale commented that while BPS is a great program, the committee hopes that there will be additional avenues available for licensees.

Dr. Gutierrez asked what the difference is between the BPS program and a certificate program. Ms. Coder and Ms. McBane explained that a certificate program is a one-time class that usually lasts about 15 hours and has no ongoing education once the class is completed. They added that programs like BPS require extensive continuing education.

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

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

Commission for Certification in Geriatric Pharmacy (CCGP)

CCGP

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

Accreditation

- CCGP is accredited by the National Commission for Certifying Agencies
- NCCA is the nationally recognized accrediting body for certification organizations and establishes standards

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

CCGP Overview

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

Recognition

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

Development

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

Administration

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

Eligibility

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

Recertification

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

Summary

- CCGP examination is a rigorous board certification examination that meets all applicable quality standards
- The CCGP examination is accessible to California pharmacists with 16 test centers and exam administration throughout the year

- The CCGP examination is particularly well suited to the requirements of the California legislation, with a good match to the CGP content outline

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

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

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

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

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

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

Dr. Robertson commented that the language in SB 493 states that the certification program must be recognized by ACPE or the Board of Pharmacy. However, ACPE does not recognize certification programs. Dr. Robertson concluded that the in the future they could look at a legislative change to the language. President Weisser asked how difficult it would be to change the language. Ms. Herold advised that as this bill is somewhat controversial they might want to hold off on making changes by using an omnibus bill. It was noted that an easier solution might be for the board to recognize NCCA as the appropriate accreditation body.

(c) <u>Other Programs Envisioned or Under Development</u>

President Weisser asked the public if there was anyone who would like to discuss other programs.

Eric Gupta, from Western University, brought the Clinical Lipid Specialist Exam to the committee's attention. He noted that while it is mostly taken by physicians, it is available to pharmacists.

Lisa Kroon, from UCSF, highlighted the Certified Diabetes Educator and the American Academy of HIV Medicine as two existing certification programs. Ms. Veale asked if they were both recognized by NCCA. Dr. Kroon responded that she thought they were, but she would need to confirm.

Ryan Gates, clinical pharmacist, commented that after the passage of SB 493 he expects to see more pharmacists becoming certified and feels that pharmacists will come from other states to practice in California. He encouraged the board to be sure that whatever certification program is approved ensures patient safety. Mr. Gates also noted that when the board is considering programs, they should compare the scope of the content of the exam and the scope of the duties and requirements for an APP pharmacist.

Ms. Veale commented that she does not want to have multiple programs petitioning the committee. The committee should create objective criteria that programs must meet to be considered.

Ms. Herold commented that programs should come before the committee similar to how BPS and CCGP have done.

Mr. Veale noted that even if an APP does a one-time certificate course they are still required to complete 10 additional continuing education hours in their specialty area before they can renew their board license.

Mary Staples, from the National Association of Chain Drug Stores, commented that NACDS supports multiple pathways for certification. She provided the committee with a list of certification programs, which can be found immediately following these meeting minutes.

Lisa Kroon commented that there is an online, 20-week program offered by the Canadian Pharmacists Association. The course is practice-based and focuses on patient care skills. The program has a class size of 13-14 pharmacists and has a coach who monitors the learning taking place. President Weisser asked if the program was academically rigorous. Dr. Kroon responded that she found the program to be extremely high quality. Dr. Gutierrez asked if there is a test at the end of the program. Dr. Kroon responded that at the end of the program the student creates an action plan for a complicated sample patient and the plan is graded. President Weisser asked if someone could provide a presentation on the Canadian program.

Dr. Kroon also suggested that the committee consider the use of an Objective Structured Clinical Exam (OSCE). These exams are hands-on and are used in schools of pharmacy and in other medical professions.

Ms. Herold commented that before organizations give presentations on their programs, criteria should be developed by the committee.

Dr. Gray commented that OSCE programs are not standardized and differ depending who administers the exam. Dr. Gray agreed that the committee should first develop program criteria before allowing numerous groups to come before the committee. Ms. Herold and Dr. Gutierrez agreed and asked legal counsel to look at the law to see what the board has the authority to require.

Ms. Herold pointed out that there is a requirement in California that all exams must be validated; this might be particularly difficult for OSCE-type exams. Dr. Gray commented that there are currently pharmacists who are doing APP-type work that could be observed to validate tests.

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

Ms. Herold reviewed Code Section 4233 outlining the renewal requirements for the APP license. Ms. Herold noted that currently about 20 percent of pharmacists audited cannot provide proof of their continuing education at the time of renewal. One of the new staff positions the board will be receiving will be responsible for auditing the APP renewals.

Jon Roth, CPHA, commented that it is important to note that the continuing education required for APP renewal must be in the subject area specific to their practice area.

Sara McBane asked how soon the board would have electronic renewals, as other states have online renewals where the pharmacist enters in the ACPE continuing education completion number. Ms. Herold responded that the online renewal date is still uncertain and noted that the board does not require continuing education to be from an ACPE course (for example C.E. for attending board meetings).

Ms. Herold noted that APP pharmacists pay their APP and regular license renewal at the same time.

Ms. Veale asked that before the conclusion of the meeting the committee review the previous agenda items to develop a work list for the next meeting. The two items below were mentioned and President Weisser asked that Ms. Herold work with legal counsel, Michael Santiago, to determine if there are additional items.

- What criteria, if any, does the board have the authority to develop for certification programs.
- All pharmacists can order tests for toxicity and efficacy of drug therapy, what are the implications of this for the duties of pharmacists? For example, will pharmacists be required to review test results prior to dispensing a particular medication. Does this change their corresponding responsibility when dispensing opioids?

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

Ms. Herold reported that there would be a one-day board meeting on June 26, focused mainly on the compounding regulation. There will be a two-day board meeting on July 30-31. Ms. Herold reported that July 30 will be the board business day and July 31 will be a mini prescription label summit.

A pharmacist commented that he does not feel that pharmacists should be required to provide consultations to each patient and suggested that if a patient does not speak English the pharmacist should have the right to fuse to fill the prescription. President Weisser noted that the committee could not comment in accordance with the Open Meetings Act.

Guidelines for Pharmacists Ordering and Managing Tests to Ensure Safe and Appropriate Medication Therapy (Version 5)

Last Updated: May 19, 2014

Subcommittee Members:
Steven Chen, PharmD (Chair)
Robert Chun, PharmD (Sutter Health)
Rebecca Cupp, PharmD (Ralphs Pharmacies)
Robert Deamer, PharmD (Kaiser Permanente)
Hyunah Eom, PharmD (Sutter Health)
Paul Gregerson, MD, MBA (JWCH Institute)
Ashley Gutierrez, PharmD (PGY1 Resident, USC)
Michael Hochman, MD (AltaMed Health Services)
Paul Huynh, PharmD (Walgreens Pharmacies)
Rory O'Callaghan, PharmD (USC)
Michelle Schlueter, PharmD (UCSD)
Ken Thai, PharmD (Independent Pharmacy)
Robert Young, MD (Assistant VP of Patient Financial Services, AltaMed Health Services)

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I. Purpose and Objectives

The purpose of this guideline is to identify the professional standards pharmacists should follow when ordering and interpreting tests for the purpose of monitoring the efficacy and safety or drug therapy. Specific objectives are as follows:

1. Establish best practices for pharmacists ordering and managing tests in the course of monitoring and managing the efficacy and safety of medication therapy in collaboration with the patient's primary care provider, diagnosing prescriber, medical home, etc. The priority of these best practices is to ensure that test ordering by pharmacists is performed only when necessary and that results are managed appropriately and promptly. These best practices are based on research, government reports, and decades of combined experience from California and other states.
2. Provide resources to educate other healthcare professionals, testing organizations, health plans, and other third party payers about the role of pharmacists in ordering and managing tests in coordination with primary care providers and other members of the healthcare team.
3. Describe payment models for test ordering by pharmacists.

II. Background / Rationale

With the signing of Senate Bill 493 by Governor Brown in 2013, California licensed pharmacists are now recognized as healthcare providers and are granted certain authorities in all practice settings that had previously been limited to inpatient settings or integrated systems. One of these authorities is ordering and interpreting tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies. Specifically, the section of SB 493 that describes this authority is as follows:[1]

> *4052.(a)(12) 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 prescriber, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by that prescriber*

The basis for this authorization includes decades of published experience and evidence demonstrating that granting pharmacists the clinical privilege to order medication-related tests is associated with improvements in healthcare quality measures, medication safety, and overall healthcare costs. The literature containing this information is best summarized by the

1: Official California Legislation Information, available at: http://www.leginfo.ca.gov/pub/13-14/bill/sen/sb_0451-0500/sb_493_bill_20131001_chaptered.pdf

U.S. Public Health Service.[2] In addition, the importance of these clinical privileges on patient and health system outcomes is emphasized by many government and interdisciplinary national healthcare organizations such as HRSA, CDC, and the Patient Center Primary Care Collaborative.[3,4,5] In fact, the services outlined in SB 493, including ordering tests, are already performed by pharmacists in California health system settings working collaboratively in accordance with physician-endorsed policies and procedures and evidence-based practice guidelines s as well as in other states. For over five decades, pharmacists have been engaged as primary care providers in team-based federal health care models such as the Indian Health Service, Department of Veterans Affairs and Department of Defense. Kaiser Permanente has similarly integrated pharmacists into their medical practices for over 30 years. The California Right Care Initiative, from the California Department of Managed Healthcare, recognizes pharmacists with clinical privileges as a key to improving health outcomes and is supporting efforts to help health plans and medical groups identify methods for initiating or expanding clinical pharmacy programs.[6] Ultimately, a pharmacist's responsibility as a member of the healthcare team is to consider all relevant information when determining the appropriateness, safety, and effectiveness of medication therapy, and oftentimes test results are essential to make such a determination. Examples include individualizing dosing for drugs with narrow therapeutic windows or requiring dosage adjustment in renal or hepatic impairment, ruling out an adverse drug reaction, monitoring a chemistry panel for patients receiving medications that can alter electrolytes or renal function markers, or screening patients for untreated medical conditions that may prompt further follow-up with the assigned primary care provider.

III. Guidelines for Test Ordering, Interpretation, and Management by Pharmacists

Key principles for test ordering, interpretation, and management by pharmacists are:

- Testing should be for ensuring safe and effective medication therapy in coordination with the patient's primary care provider or diagnosing prescriber.
- Tests must only be ordered when necessary.
- Test results must be managed appropriately and promptly;
- Patients should receive feedback on their tests in a timely manner.
- Quality assurance should be integrated into the test ordering, interpretation, and management process.

2: Giberson S, Yoder S, Lee MP. Improving patient and health system outcomes through advanced pharmacy practice. A report to the U.S. Surgeon General. Washington, DC: Office of the Chief Pharmacist, U.S. Public Health Service; 2011.

3: HRSA Patient Safety and Clinical Pharmacy Services Collaborative (PSPC), Available at: http://www.hrsa.gov/publichealth/clinical/patientsafety/

4: The Centers for Disease Control. A Program Guide for Public Health: Partnering with Pharmacists in the Prevention and Control of Chronic Diseases (2012). National Center for Chronic Disease Prevention and Health Promotion. Available at: http://www.cdc.gov/dhdsp/programs/nhdsp_program/docs/pharmacist_guide.pdf

5: The Patient-Centered Primary Care Collaborative. Integrating Comprehensive Medication Management to Optimize Patient Outcomes, Second Edition. June 2012. Available at: http://www.pcpcc.net/files/medmanagement.pdf

6: The California Right Care Initiative. Available at: http://www.dmhc.ca.gov/healthplans/gen/gen_rci.aspx

A. Responsibility[7]

Pharmacists are individually responsible for personal competence in ordering tests and interpreting results. Variables that may impact test results must be considered by pharmacists when interpreting results including timing of testing, medications, renal or hepatic function, fluid status, lab error, etc. The Advanced Pharmacist Practitioner designation as described in SB493 is designed to establish a minimum level of competence. Pharmacists are expected to maintain competency demonstrated with ongoing education, training, and experience. Specific institutions or third party payers may apply their own credentialing and privileging requirements, to enhance requirements for specific needs, within their organizations.

B. Using test results

In situations where tests could impact medication therapy decisions or medication therapy might alter testing results, pharmacists should review relevant tests that are required to make this determination. If required tests are not available, e.g., tests that are mandated in current treatment guidelines, FDA recommendations, or medication prescribing information, then the pharmacist should consider ordering or facilitating the ordering of these tests in collaboration with the relevant medical entity (see section III.C.) Examples where a review of test results is indicated include but are not limited to:

1. Individualizing drug dosing
    a. Serum drug levels for medications with narrow therapeutic indexes (e.g., lithium, antipsychotics, anticonvulsants)
    b. INR for warfarin patients
    c. Renal and hepatic function tests for medications requiring dose adjustment in renal or hepatic impairment.
    d. Culture and sensitivity results for antibiotic therapy

2. Selection of appropriate drug therapy (Note per section III.D. that the pharmacist is not necessarily the individual who will interpret the test results, depending on expertise and training.)
    a. Patient with unspecified heart failure (e.g., no echo report, PCP and other members of healthcare team unaware of ejection fraction and other information relevant to treatment).
    b. Adult patient diagnosed with new onset asthma with vague symptoms and no history of spirometry testing.
    c. Patient with diagnosis of Type 2 diabetes and no response to oral diabetes medications or very widely fluctuating glucose levels with

7 : Guidelines for Pharmacists Ordering Laboratory Tests and Using Laboratory Data. Alberta College of Pharmacists. Available at: https://pharmacists.ab.ca/Content_Files/Files/GuidelinesForOrderingLabTests.pdf

minor changes in insulin doses, no history of insulin antibody and C-peptide testing.

d. Chest X-ray to screen for long-term adverse drug effects (e.g., amiodarone)

3. Attainment of patient specific treatment goals outlined in established guidelines and government standards
    a. A1c for diabetes treatments
    b. Thyroid function tests for thyroid replacement therapy
    c. Uric acid for gout therapy

4. Medication safety and monitoring, as mandated by guidelines and government standards
    a. INR for change in medications/diet/ health that may affect warfarin therapy
    b. Chemistry panel for patients with recent changes in doses of diuretics, ACE-inhibitors, ARBs, etc., particularly those at risk for renally-related adverse effects (e.g., heart failure, renal impairment).
    c. Liver function tests for Tb treatment, methotrexate therapy, etc.
    d. Urine drug test screening
    e. EKG for QT interval screening
    f. Pregnancy testing for risk evaluation and mitigation programs (urine beta-HCG)
    g. Lab monitoring for alcohol use disorders (AST, ALT, MCV, GGT)

5. Recognition of untreated health conditions: screen patients at risk of developing various health conditions
    a. Bone density test for individuals at risk for osteoporosis
    b. Patient with Type 2 diabetes for several years and no history of UACR testing
    c. Metabolic panel and weight gain monitoring with antipsychotics
    d. Patient assessment with PHQ-9 for depression

C. Ordering tests

1. If specific tests are important for determining the appropriateness, efficacy, or safety of medication therapy and test results have not been previously ordered or are out of date then pharmacists should order the tests or follow the procedure within their collaborative practice to ensure that the appropriate test is ordered.

2. Pharmacists must pursue all reasonable approaches to ensuring that tests are not duplicative prior to ordering, e.g., review of the electronic health record, contact with test technician if such a line of communication is available. An exception is when a result is questionable and warrants a repeat test (e.g., abnormal potassium level and suspected hemolysis of blood sample based on previous test results).

3. Pharmacists should only order those tests that they are personally competent to order; otherwise, an appropriate authority should be consulted.

4. Tests must be necessary (e.g., per treatment guidelines, government mandates, prescribing information; clinical evaluation requirement) and limited to patients under the care of the pharmacist / pharmacy service.

D. Interpretation of test results

1. Pharmacists should only order tests that they are experienced in interpreting. An exception is when a test is necessary and, in a pre-arranged collaboration, the test is ordered but planned for interpretation by a qualified healthcare professional.

2. Pharmacist must use professional judgment and consider all variables when interpreting test results. For example, tests can be influenced by multiple variables including lab error, gender, other drugs, pregnancy, diet, organ function, genetics, or incorrect timing of tests.

E. Following-up on test results

1. Pharmacists who order tests must have a procedure established to ensure that results are followed-up appropriately. Pharmacists should either be available at any time of the day every day <u>or</u> establish an alternative plan for responding to critical test results, e.g., on-call groups, agreements with medical home providers, etc.

2. Patients should be informed of what to expect by having the pharmacist order tests, e.g., who will follow-up and how soon. The timeliness of follow up will depend on multiple variables such as the urgency of the test or the availability of the patient; in some cases (e.g., homeless or transient patients), the next appointment may acceptable for follow up.

   It may be reasonable to involve capable patients in following up on their own test results after an appropriate time interval. This does not relieve the pharmacist of their duty to follow up, but add a level of safety to the test follow-up process while engaging patients in their own care.

3. If tests are necessary for treatment decisions and results are not available in a timely manner, it is the pharmacist's responsibility to follow-up with either the testing organization or patient to determine the status of the test and whether rescheduling / reordering is necessary.

4. Pharmacists must take appropriate action if the result of a lab test ordered is a critical value, defined as, "A laboratory test result that represents a pathophysiologic state at such variance with normal as to be life-threatening unless something is done promptly and for which some corrective action could

be taken".[8] No national standard exists for critical value thresholds; these values are best defined by healthcare organizations utilizing the literature, local and national peer institutions or networks, and input from medical service groups or healthcare leadership committees.

5. At minimum, a pharmacist who receives a critical value should contact the physician responsible for the care of the patient at the time of notification (e.g., PCP, MOD). Examples of other actions taken by the pharmacist include, but are not limited to:
   - Repeat the test if the value does not seem plausible based on other subjective and objective findings or consult with the testing organization about the abnormal finding.
   - Discuss the results with the patient in an attempt to correlate results with clinical presentation
   - Consult with other members of the healthcare team, in particular informing the assigned primary care provider regardless of the action(s) taken
   - If the test relates to an existing diagnosis, modify drug therapy or (depending on collaborative practice agreement) recommend modifying drug therapy to the primary care provider in accordance with test results.
   - If the test suggests a new medical problem, refer the patient to the appropriate member of the healthcare team.

F. Standards for documentation

1. As required by SB 493, all actions related to test ordering, interpretation, and management (including subsequent medication therapy changes and altered treatment or monitoring plans) must be documented within 24 hours in a system readily accessible to all involved healthcare team members involved. The documentation system of choice, the electronic health record, should be made available to pharmacists who are part of the care team regardless of location / care venue (e.g., integrated into medical home, community pharmacies, remote telehealth clinical pharmacy services). In addition to supporting real-time communication, EHR access will reduce the likelihood of unnecessary or duplicative testing.

2. Documentation of pharmacist decisions involving test results should include:
   - Interpretation of the result
   - Rationale for the decision based on the result and any other patient-related information

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8: Lundberg GD. When to panic over abnormal values. MLO Med Lab Obs. 1972;4:47-54.

- What was communicated to the patient and other healthcare team members involved in the patient's care

G. Quality Assurance of Testing Management

1. A quality assurance program is essential for ensuring the reliability of the testing process used by any healthcare professional. It is recommended that pharmacists work with collaborating healthcare organizations to determine the most effective and efficient method of integrating a quality assurance process. One approach may be to include pharmacists in the organization's existing peer review process.

2. Tools are available to examine how tests are being managed, from ordering to patient notification of results and any decisions made as a result of the tests. A recent quality assurance resource for testing from AHRQ requires the following elements for adoption:[9]
   - A commitment to improvement
   - Senior leadership support for quality and safety improvement
   - Teamwork and an acceptance that everyone is responsible for the success of the process
   - Commitment to honest and open communication.
   - Regular peer review and sharing of performance results among staff.
   - A focus on systems / processes instead of blame on individuals.

IV. Information and Resources for Other Stakeholders / Partners Regarding Pharmacists Ordering, Interpreting, and Managing Tests

Every stakeholder and partner involved with patient care needs to understand the pharmacist's role in ordering, interpreting, and managing tests under SB 493. Information shared should include background about provider status under SB 493 and reference to language in the bill regarding test ordering and interpretation by pharmacists. Other clarifying information may include the rationale for pharmacists ordering tests, procedures used to ensure that test results are managed appropriately and in a timely manner, methods of communication / documentation, and quality assurance of the testing process. A sample 1-page (double-sided) Q&A information sheet is attached in Appendix A that may be appropriate for healthcare professionals, third party payers, and testing organizations.

9: Improving Your Office Testing Process: A Toolkit for Rapid-Cycle Patient Safety and Quality Improvement. Available at: http://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/office-testing-toolkit/

V. Reimbursement for Tests Ordered and Managed by Pharmacists

Section 4052.(a)(12) of SB493 states that pharmacists are able to, "*Order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies*." Furthermore, the section clarifies that the ordering of tests by pharmacists must be, *"…done in coordination with the patient's primary care provider or diagnosing prescriber..."* As a result, reimbursement for tests ordered and managed by pharmacists is achieved through agreements between the pharmacist / pharmacy, primary care provider or diagnosing prescribers, and third party payers. Third party payers need to understand the role of pharmacists in ordering and managing tests to ensure that tests ordered by pharmacists in collaboration with the appropriate care provider are accepted and processed. The nature of reimbursement will vary, ranging from negotiated fees for specific tests to shared payments under value-based reimbursement contracts.

In other states where pharmacists have provider status, test ordering by pharmacists in and of itself is not directly reimbursed. For example, test ordering by pharmacists in North Carolina is facilitated through collaborative practice agreements, signed by supervising physicians, that list "approved tests". Some but not all institutions have pharmacists undergo credentialing and privileging. The benefits to institutions from allowing pharmacists to order and manage tests include finances to the institution through billing for tests (fee for service) and improvement in healthcare quality and safety through improved monitoring and attainment of treatment goals, as well as increased physician access as patients requiring greater time and resources for monitoring are managed by the pharmacist (value-based).

Appendix A: Information about pharmacists ordering and managing tests

In October of 2013 Governor Brown signed Senate Bill 493, making California the 4th state in the nation to recognize pharmacists as healthcare providers. A primary driver behind the Governor's decision to sign the bill is the proven impact pharmacists have on improving healthcare quality and safety while reducing healthcare costs. To accomplish this, pharmacists must consider all information relevant to the safety and efficacy of medication therapy, including tests results. As a result, one of the authorities granted to pharmacists in SB493 is ordering and interpreting tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies, in coordination with the patient's primary care provider or diagnosing prescriber.[10]

Q: What qualifies pharmacists to order tests?

A: All pharmacy schools today confer the Doctor of Pharmacy degree to graduates, requiring didactic and experiential training in comprehensive management of medication therapy including testing relevant to medication efficacy and safety. In addition, residency training for pharmacists provides in-depth experience with direct management of patient drug therapy, and board certification for pharmacists provides ongoing assessment to achieve a high level of clinical knowledge that includes appropriate use of tests. Every healthcare institution or third party payer should apply credentialing standards for pharmacists that are similar to other healthcare providers.

Q: Won't pharmacists ordering tests lead to duplication and wasted resources?

A: Pharmacists review all sources of test results before ordering any test, and tests ordered by pharmacists should be for the purpose of, "…monitoring and managing the efficacy and toxicity of drug therapy."[8]

Q: Who interprets tests ordered by pharmacists?

A: Pharmacists only order tests that they are experienced in interpreting UNLESS a pre-arranged collaboration is established for a qualified individual to interpret the test result. Pharmacist are trained to use professional judgment and consider all relevant variables when interpreting test results including lab error, gender, other drugs, pregnancy, diet, organ function, genetics, or incorrectly timing of tests.

Q: Who is responsible for following-up and managing tests ordered by pharmacists?

A: Pharmacists who order tests will have a procedure established to ensure that results are followed-up appropriately. Pharmacists should either be available at any time of the day every day <u>or</u> establish an alternative plan for responding to critical test results, e.g., on-call groups, agreements with medical home providers, etc. Patients will be informed of what to expect by having the pharmacist order the test, e.g., who will follow-up and how soon. If tests are necessary for treatment decisions and results are not available in a timely manner, it is the pharmacist's responsibility to follow-up with either the testing organization or patient to determine the status of the test and whether rescheduling / reordering is necessary.

10: Official California Legislation Information, available at: http://www.leginfo.ca.gov/pub/13-14/bill/sen/sb_0451-0500/sb_493_bill_20131001_chaptered.pdf

Q: How will pharmacists manage highly abnormal test results ("critical values")?

A: Pharmacists must take appropriate action if the results of a lab test that ordered is highly abnormal and exceeds critical value limits established by the collaborating healthcare organization. . Examples of such actions, established in agreement with the appropriate primary care provider or prescriber, include:

- Repeat the test if the value does not seem plausible based on other subjective and objective findings or consult with the testing organization about the abnormal finding.
- Discuss the results with the patient in an attempt to correlate results with clinical presentation
- Consult with other members of the healthcare team, in particular informing the assigned primary care provider regardless of the action(s) taken
- If the test relates to an existing diagnosis, modify drug therapy or (depending on collaborative practice agreement) recommend modifying drug therapy to the primary care provider in accordance with test results.
- If the test suggests a new medical problem, refer the patient to the appropriate member of the healthcare team.

Q: How will pharmacists communicate their decisions and actions to other members of the healthcare team?

A: All actions related to test ordering, interpretation, and management (including subsequent medication therapy changes and altered treatment or monitoring plans) will be documented within 24 hours in a system readily accessible to all involved healthcare team members involved. The documentation system of choice, the electronic health record, should be made available to pharmacists who are part of the care team regardless of location / care venue (e.g., integrated into medical home, community pharmacies, remote telehealth clinical pharmacy services). In addition to supporting real-time communication, EHR access will reduce the likelihood of unnecessary or duplicative testing. Documentation of pharmacist decisions involving test results should include:

- Interpretation of the result
- Rationale for the decision based on the result and any other patient-related information
- What was communicated to the patient and other healthcare team members involved in the patient's care

Q: How will pharmacists ensure that the process used to order and managed tests remains safe, appropriate, and effective?

A: Pharmacists are responsible for ensuring that a quality assurance assurance is in place for verifying that the testing process is safe, appropriate, and effective. In many instances, collaborating healthcare organizations can integrate pharmacists into their internal peer review process for test ordering and other quality measures. Tools such as the AHRQ Toolkit for Rapid-Cycle Patient Safety and Quality Improvement for Testing (http://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/office-testing-toolkit/) can be utilized for this purpose.

Commission for Certification in Geriatric Pharmacy

"The mark of excellence in geriatric care"

CCGP Overview

CCGP

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

CCGP Governance

- Established as independent non-profit organization with separate Board of Commissioners
- A member of ASCP Board serves as non-voting member of CCGP Board

NCCA Accreditation

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

NCCA Accreditation

- CCGP adheres to nationally recognized standards for certification
- CCGP is accountable to an external third party for quality & oversight
- CCGP also member of Institute for Credentialing Excellence, and Council on Credentialing in Pharmacy

CCGP Overview

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

CGP Credential

Recognition

- Australia – CGP credential recognized by Australian government as one of two pathways for pharmacists to qualify for payment for HMR and RMR
- North Carolina – CGP credential recognized as one of qualifications for Clinical Pharmacist Practitioner

Recognition

- Missouri – CGP credential recognized as one of the eligibility criteria for pharmacists to qualify for "certificate of medication therapeutic authority from the Missouri State Board of Pharmacy to provide medication therapy services that include initiating or implementing a modification of a patient's medication therapy or device usage."

Development

- Role delineation study conducted every five years, to define scope of "geriatric pharmacy practice"
- Result is content map or content outline for CGP examination
- Every exam item is linked to element on content outline

Development

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

Administration

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

Eligibility

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

Recertification

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

Board Review Courses

Live Courses

- UCLA Intensive Course – Geriatric Medicine & Pharmacy Board Review – Sept. 10-13, 2014 at Los Angeles Airport Marriott
- Ontario Pharmacists Association
- ASCP – July 17-18, 2014 - Chicago

Online Courses

- Only one online course, available as package of modules through ASCP: http://education.ascp.com/gpr

Suitability of CGP Credential for California APP

Comparison

Senate Bill 493

- A pharmacist recognized by the board as an advanced practice pharmacist may do all of the following:

CGP Content Outline

- Corresponding elements on the Certified Geriatric Pharmacist content outline

Comparison

Senate Bill 493

- Perform patient assessments
- Order and interpret drug-therapy related tests

CGP Content Outline

- II. B. 1-19 Geriatric Assessment
- II. B. 13. Recommend laboratory tests for the older adult.

  II. B. 14. Interpret laboratory results for the older adult.

Comparison

Senate Bill 493

- Refer patients to other health care providers

CGP Content Outline

- II. B. 18. Recognize need for referral of patients to other healthcare professionals

Comparison

Senate Bill 493

- Participate in evaluation & management of diseases & health conditions in collaboration with other health care providers

CGP Content Outline

- I. B. 7. Collaborate with older adults, their caregivers, and the healthcare team during care planning and implementation.
- II. D. 2. Develop an individualized treatment plan, in collaboration with other caregivers, based on older adult's preferences & goals, & their physical, psychological, social, & spiritual needs.

Comparison

Senate Bill 493

- Initiate, adjust, or discontinue drug therapy

CGP Content Outline

- II. D. 1. Define therapeutic goals incorporating patient-specific principles (e.g., age, functionality, patient preference, quality of life).
- II. D. 1-7 Treatment
- II. E. 1-3 Monitoring

Summary

- CGP examination is a rigorous board certification examination that meets all applicable quality standards
- The CGP examination is accessible to California pharmacists with 16 test centers and exam administration throughout the year

Summary

- The CGP examination is particularly well suited to the requirements of the California legislation, with a good match to the CGP content outline

Questions?

Terminology

SB493

- "A person who seeks recognition as an advanced practice pharmacist shall … earn certification in a relevant area of practice including, but not limited to, …"
- The legislation lists nine topics – geriatric pharmacy, plus the 8 programs currently certified by BPS

SB493

- "Earn certification … from an organization recognized by the Accreditation Council for Pharmacy Education or another entity recognized by the Board"
- ACPE does not recognize certification organizations

Certificate vs. Certification

- Confusion exists between these terms
- A pharmacist may claim to be "certified" in immunization or MTM – but no certifications exist in these areas
- Some educational programs provide a "certificate" of completion

ACPE & Certificate

- ACPE stopped using the term "certificate program" in 2009
- ACPE now recognizes "Practice-based continuing pharmacy education activities" which replaced the "Certificate Programs in Pharmacy" terminology

Practice-based CPE

- 15 credit-hour minimum
- Didactic and practice experience component
- Formative and summative assessments included
- Assessment feedback provided to all participants

NCCA Definition

An ***assessment-based certificate program*** is a non-degree granting program that:

a) provides instruction and training to aid participants in acquiring specific knowledge, skills, and/or competencies associated with intended learning outcomes;

b) evaluates participants' accomplishment of the intended learning outcomes; and

c) awards a certificate only to those participants who meet the performance, proficiency, or passing standard for the assessment(s)

NCCA Definition

- Professional or personnel ***certification*** is a voluntary process by which a non-governmental body grants time-limited recognition and use of a credential to individuals who have demonstrated that they have met predetermined and standardized criteria for required knowledge, skills, or competencies.

CERTIFICATION PROGRAMS FOR PHARMACISTS

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

CERTIFICATION PROGRAMS FOR PHARMACISTS

PHARMACIST-ONLY CERTIFICATIONS

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

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

CERTIFICATION PROGRAMS FOR PHARMACISTS

7. Recertification requirements:

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

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

  OR

  Earning approved continuing education credit provided by a professional development program approved by BPS (details unavailable at this time).Earning 100 hours of continuing education credit provided by the professional development programs offered by American College of Clinical Pharmacy (ACCP) and/or the joint program offered by the American Society of Health-System Pharmacists (ASHP) and the American Pharmacists Association (APhA). No more than 50 hours will be accepted by BPS during the first 3 years of the certification cycle.
- Further, Ambulatory Care Pharmacy Preparatory Review and Recertification Courses offered by either of the approved providers may only be completed for recertification up to two times, in nonconsecutive years, during the 7-year recertification cycle.
- All candidates for recertification must have a current active license to practice pharmacy

8. Examination specifics:

- **Paper & Pencil or computer-based:**
  Paper and pencil
- **Number of questions:**
  200
- **Question format:**
  The multiple-choice format is used exclusively. Four possible answers are provided for each question, with only ONE designated as the correct or best choice. It is to the candidate's advantage to answer every question on the examination, since the final score is based on the total number of questions answered correctly. There is no penalty for selecting an incorrect choice.
- **Cost:**
  - Certification Application Fee=$600
  - Recertification Application Fee=$400
  - Certification Retake Fee (Within 2 Years)=$300
  - Recertification Retake Fee (Within 1 Year)=$200
  - Annual Fee for All BPS-Certified Pharmacists=$100 (not required for the year of re-certification)
- **Frequency of exam:**
  Once yearly. BPS will establish test sites in approximately 77 cities worldwide for administration of its specialty certification examinations. Alternate sites could be identified and requested as per the guidelines in http://www.bpsweb.org/apply/altersiterequest.cfm
- **Exam Pass Rate:**
  Undetermined. First administration scheduled for 2011.

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

CERTIFICATION PROGRAMS FOR PHARMACISTS

9. Certification associated with specific training programs? No	**Offered by whom?** N/A
10. Certification exam prep courses/materials available? Yes	**Offered by whom?** BPS does NOT provide review information, preparatory courses, or study guides. However, such materials are available from outside organizations, state or local professional associations and colleges of pharmacy. The American College of Clinical Pharmacy, American Pharmacists Association, and the American Society of Health-system Pharmacists plan to provide resources to aid in test preparation. **Suggested preparation:** Could include residency or other formal training; study of journal articles, textbooks, or other publications related to the content outline; continuing education programs and courses in specialized pharmacy practice; study groups and examination preparation courses (see above); and reviewing sample test questions on the BPS website.
11. Other Pertinent Information: • BPS is an autonomous division of the American Pharmacists Association (APhA) organized in 1976 as an independent certification agency of APhA. • Each specialty exam has a separate Content Outline (available online) validated through a national survey of pharmacist specialists. • Content Outlines provide details on major areas of responsibility for a specialist, the tasks required to fulfill these responsibilities, and the knowledge that underlies the performance of these tasks. • Each exam question is linked to a specific domain, task, and knowledge statement. • BPS utilizes the psychometric and exam administration services of Professional Examination Service of New York City in administration of its specialty certification programs.	

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CERTIFICATION PROGRAMS FOR PHARMACISTS

CARDIOLOGY (PHARMACOTHERAPY ADDED QUALIFICATIONS)		
1. Name of credential(s): Board Certified Pharmacotherapy Specialist with Added Qualifications in Cardiology		
2. Responsible Organization: Board of Pharmacy Specialties (BPS)	**Address:**	Board of Pharmacy Specialties 2215 Constitution Avenue, NW Washington, DC 20037
	Telephone:	202-429-7591
	Fax:	202-429-6304
	E-mail:	info@bpsweb.org
	Web site:	www.bpsweb.org
3. Certification Body Accredited? Yes	**By what organization?** The National Commission for Certifying Agencies (NCCA)	
4. Disciplines certified (in addition to pharmacists): None		
5. Eligibility criteria for pharmacists: The pharmacist must be a current Board Certified Pharmacotherapy Specialist (BCPS). In addition, he/she must submit one electronic copy of a portfolio that contains sufficient information to justify this additional credential and clearly defines the distinction between the individual and other BCPS who do not qualify for this additional recognition. The required elements of the portfolio are listed below: • Letter from applicant requesting review of portfolio for purpose of granting Added Qualifications in Cardiology Pharmacotherapy. • Detailed summary of each of the elements presented in the application form with examples and timeframes (where applicable) below each statement whether or not included in CV. Current curriculum vitae		
6. Duration of initial certification: 7 years		
7. Recertification requirements: Maintenance of BCPS status and resubmission of an electronic portfolio		
8. Examination specifics: This qualification does not require an exam beyond the one necessary to become a Board Certified Pharmacotherapy Specialist (BCPS). Please see other sheet for details on the Pharmacotherapy exam. A portfolio is required to receive cardiology added qualifications. Specifics referring to portfolio submission are listed below. • **Cost:** - Application for Added Qualifications=$100 - Renewal Application (every seven years) =$50 - Annual Fee for Added Qualifications=No charge - Reconfirmation of Added Qualifications=50% of Current Added Qualifications Application Fee		

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

• **Frequency of portfolio review:** Once yearly (Deadline: December 31)	
9. Certification associated with specific training programs? No	**Offered by whom?** N/A
10. Certification exam prep courses/materials available? No	**Offered by whom?** N/A
11. Other Pertinent Information: • BPS is an autonomous division of the American Pharmacists Association (APhA) organized in 1976 as an independent certification agency of APhA. • Each specialty exam has a separate Content Outline (available online) validated through a national survey of pharmacist specialists. • Content Outlines provide details on major areas of responsibility for a specialist, the tasks required to fulfill these responsibilities, and the knowledge that underlies the performance of these tasks. • Each exam question is linked to a specific domain, task, and knowledge statement. • BPS utilizes the psychometric and exam administration services of Professional Examination Service of New York City in administration of its specialty certification programs.	

CERTIFICATION PROGRAMS FOR PHARMACISTS

GERIATRIC PHARMACY		
1. Name of credential(s): Certified Geriatric Pharmacist		
2. Responsible Organization: Commission for Certification in Geriatric Pharmacy	**Address:**	Commission for Certification in Geriatric Pharmacy 1321 Duke Street Suite 400 Alexandria, VA 22314-3563
	Telephone:	703-535-3036
	Fax:	703-739-1500
	E-mail:	info@ccgp.org
	Web site:	www.ccgp.org/
3. Certification Body Accredited? Yes	**By what organization?** The National Commission for Certifying Agencies (NCCA)	
4. Disciplines certified (in addition to pharmacists): None		
5. Eligibility criteria for pharmacists: Applicants must currently be a licensed pharmacist and must have a minimum of two years of experience as a licensed pharmacist. There are no continuing education requirements for certification.		
6. Duration of initial certification: 5 years		
7. Recertification requirements: Recertification is by examination or by successful completion of the Professional Development Program for CGP Recertification. Under the Professional Development Program for Recertification, candidates must successfully complete 75 hours of designated Accreditation Council for Pharmacy Education (ACPE) accredited continuing education programs sponsored by the American Society of Consultant Pharmacists. ASCP uses its website, http://education.ascp.com/gpr, for delivery of the education programs.		
8. Examination specifics: • **Paper & Pencil or computer-based:** Computer-based • **Number of questions:** 150 • **Question format:** Multiple-choice (3 hours) • **Cost:** - New applicant exam fee - $ 600 - Reapplicant exam fee - $ 300 - Recertification by **exam**- $ 400		

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

- Recertification by **Professional Development Program** - $ 400 - Certification Administration Fee - $ 250 per five years • **Frequency of exam:** 4 testing windows: Jan/Feb, April/May, July/Aug, and Oct/Nov. Exam is administered by appointment only Mon through Fri at 9:00 A.M. and 1:30 P.M. Available dates are scheduled on a first-come, first-served basis.	
9. Certification associated with specific training programs? No	**Offered by whom?** N/A
10. Certification exam prep courses/materials available? Yes	**Offered by whom?** American Society of Consultant Pharmacists (ASCP) offers an online review course in geriatric pharmacy practice. This course provides continuing education credit. The package of introductory courses is available for purchase containing 20 modules and 3 case studies, with 60.25 hours of continuing education credit. (http://education.ascp.com/gpr) Geriatric Pharmacotherapy Practice Resource Center has links to wide variety of resources and websites on geriatrics and geriatric drug therapy. (http://www.ascp.com/GeriPharm) CCGP Self-Assessment Examination – Online and paper format of the self-assessment examination available for purchase. This examination is similar in length and format to the actual Certified Geriatric Pharmacist examination. Live Review Courses – not endorsed or approved by the CCGP - California Geriatric Education Center and the Western University of Health Sciences College of Pharmacy conduct an annual Intensive Course in Geriatric Pharmacy and Board Review. The next offering of the program is September 19-22, 2012 in Los Angeles, CA. (http://geronet.ucla.edu/IC_2012_pharmacy.pdf) - The Ontario Pharmacists Association offers a six-day preparatory course in geriatric

	pharmacy practice in Canada. The next offering of the course will be in November 2012.

11. Other Pertinent Information:

- CCGP contracted with a professional testing company, Applied Measurement Professionals (AMP), to assist in conducting the practice analysis and the examination development and administration.
- In 1997, American Society of Consultant Pharmacists (ASCP) Board of Directors voted to create CCGP to oversee the certification program. CCGP is a nonprofit corporation, autonomous from ASCP, and with its own governing Board of Commissioners.
- CCGP is responsible for establishing eligibility criteria to take the Certification Examination in Geriatric Pharmacy and establishing program policies.

CERTIFICATION PROGRAMS FOR PHARMACISTS

INFECTIOUS DISEASES (PHARMACOTHERAPY ADDED QUALIFICATIONS)		
1. Name of credential(s): Board Certified Pharmacotherapy Specialist with Added Qualifications in Infectious Diseases		
2. Responsible Organization: Board of Pharmacy Specialties (BPS)	**Address:**	Board of Pharmacy Specialties 2215 Constitution Avenue, NW Washington, DC 20037
	Telephone:	202-429-7591
	Fax:	202-429-6304
	E-mail:	info@bpsweb.org
	Web site:	www.bpsweb.org
3. Certification Body Accredited? Yes	**By what organization?** The National Commission for Certifying Agencies (NCCA)	
4. Disciplines certified (in addition to pharmacists): None		
5. Eligibility criteria for pharmacists: The pharmacist must be a current Board Certified Pharmacotherapy Specialist (BCPS). In addition, he/she must submit one electronic copy of a portfolio that contains sufficient information to justify this additional credential and clearly defines the distinction between the individual and other BCPS who do not qualify for this additional recognition. The required elements of the portfolio are listed below. • Letter from applicant requesting review of portfolio for purpose of granting Added Qualifications in Infection Diseases Pharmacotherapy. • Detailed summary of each of the elements presented in the application form with examples and timeframes (where applicable) below each statement whether or not included in CV. • Current curriculum vitae		
6. Duration of initial certification: 7 years		
7. Recertification requirements: Maintenance of BCPS status and resubmission of an electronic portfolio		
8. Examination specifics: This qualification does not require an exam beyond the one necessary to become a Board Certified Pharmacotherapy Specialist (BCPS). A portfolio is required to receive infectious diseases qualifications. Specifics referring to portfolio submission are listed in the following website (http://bpsweb.org/specialties/Portfolio_Requirements_Infectious_Diseases.pdf) • **Cost:** - Application for Added Qualifications=$100 - Renewal Application=$50 - Annual Fee for Added Qualifications=No charge - Reconfirmation of Added Qualifications=50% of Current Added Qualifications Application Fee		

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

• **Frequency of portfolio review:** Once yearly (Deadline: December 31st)	
9. Certification associated with specific training programs? No	**Offered by whom?** N/A
10. Certification exam prep courses/materials available? No	**Offered by whom?** N/A
11. Other Pertinent Information: • BPS is an autonomous division of the American Pharmacists Association (APhA) organized in 1976 as an independent certification agency of APhA. • Each specialty exam has a separate Content Outline (available online) validated through a national survey of pharmacist specialists. • Content Outlines provide details on major areas of responsibility for a specialist, the tasks required to fulfill these responsibilities, and the knowledge that underlies the performance of these tasks. • Each exam question is linked to a specific domain, task, and knowledge statement. • BPS utilizes the psychometric and exam administration services of Professional Examination Service of New York City in administration of its specialty certification programs.	

CERTIFICATION PROGRAMS FOR PHARMACISTS

NUCLEAR PHARMACY		
1. Name of credential(s): Board Certified Nuclear Pharmacist (BCNP)		
2. Responsible Organization: Board of Pharmacy Specialties (BPS)	**Address:**	Board of Pharmacy Specialties 2215 Constitution Avenue, NW Washington, DC 20037
	Telephone:	202-429-7591
	Fax:	202-429-6304
	E-mail:	info@bpsweb.org
	Web site:	www.bpsweb.org
3. Certification Body Accredited? Yes	**By what organization?** The National Commission for Certifying Agencies (NCCA)	
4. Disciplines certified (in addition to pharmacists): None		
5. Eligibility criteria for pharmacists: • Graduation from an ACPE accredited program or a program outside the U.S. that qualifies the individual to practice in the jurisdiction. Foreign trained pharmacist must pass the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination. • Current active license to practice pharmacy in the US or another jurisdiction • 4,000 hours of training/experience in nuclear pharmacy practice: academic (up to 2,000 hours), and training/practice (up to 4,000 hours). • Achieving a passing score on the Nuclear Pharmacy Specialty Certification Examination		
6. Duration of initial certification: 7 years		
7. **Recertification requirements:** Recertification for BCNP is a three-step process: • Self-evaluation: Review of the nuclear pharmacy practice activities/functions that have changed since initial certification or last recertification • Peer review: Documentation of nuclear pharmacy practice activities over the 7 year certification period, which are then reviewed by the Specialty Council on Nuclear Pharmacy • Formal Assessment: This assessment of a practitioner's knowledge and skills will be accomplished through one of two methods: 1) achieving a passing score on the 100-item, multiple-choice objective recertification examination, based on the content outline of the certification examination; or 2) earning 70 hours of continuing education credit provided by a professional development program approved by BPS. At least 30 of these hours must be earned in the last three years of the certification period. **Fees:** Maintenance fee of $ 100 each year for years one through six and a $ 400 recertification fee in year seven.		
8. Examination specifics: • **Paper & Pencil or computer-based:** Paper & pencil		

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

• **Number of questions:** 200 • **Question format:** multiple choice • **Cost:** $600 ($300 certification retake application fee) • **Frequency of exam:** Once a year (1st Saturday of October*)* • **Exam Pass Rate:** ~70% (based on 2009 exam data)	
9. Certification associated with specific training programs? No	**Offered by whom?** N/A
10. Certification exam prep courses/materials available? Yes, though not endorsed/sponsored by BPS	**Offered by whom?** APhA, University of New Mexico College of Pharmacy
11. Other Pertinent Information: • BPS is an autonomous division of the American Pharmacists Association (APhA) organized in 1976 as an independent certification agency of APhA. • Each specialty exam has a separate Content Outline (available online) validated through a national survey of pharmacist specialists. • Content Outlines provide details on major areas of responsibility for a specialist, the tasks required to fulfill these responsibilities, and the knowledge that underlies the performance of these tasks. • Each exam question is linked to a specific domain, task, and knowledge statement. • BPS utilizes the psychometric and exam administration services of Professional Examination Service of New York City in administration of its specialty certification programs.	

CERTIFICATION PROGRAMS FOR PHARMACISTS

NUTRITION SUPPORT PHARMACY		
1. Name of credential(s): Board Certified Nutrition Support Pharmacist (BCNSP)		
2. Responsible Organization: Board of Pharmacy Specialties (BPS)	**Address:**	Board of Pharmacy Specialties 2215 Constitution Avenue, NW Washington, DC 20037
	Telephone:	202-429-7591
	Fax:	202-429-6304
	E-mail:	info@bpsweb.org
	Web site:	www.bpsweb.org
3. Certification Body Accredited? Yes	**By what organization?** The National Commission for Certifying Agencies (NCCA)	
4. Disciplines certified (in addition to pharmacists): None		
5. Eligibility criteria for pharmacists: • Graduation from a pharmacy degree program accredited by the Accreditation Council for Pharmacy Education (ACPE) or program outside the U.S. that qualifies the individual to practice in the jurisdiction. • Current, active license to practice pharmacy in the U.S. or another jurisdiction. • Completion of three (3) years practice experience with at least 50% of time spent in nutrition support pharmacy activities (as defined by the BPS Nutrition Support Content Outline) or • Completion of a (PGY2) residency* in nutrition support pharmacy. *Effective January 1, 2013, only residencies accredited by the American Health-System Pharmacists or other recognized bodies are creditable for this purpose.		
6. Duration of initial certification: 7 years		
7. **Recertification requirements:** Recertification BCNSP is based on the following activities: • Earning a minimum of 3.0 continuing education units (CEU) in nutrition support with no less than 1.0 CEU earned every two years. These CEU must be from providers accredited by the Accreditation Council for Pharmacy Education (ACPE). Note: 1.0 CEU equals 10 hours of approved continuing education. • Achieving a passing score on the 100-item, multiple-choice recertification examination, which is based on the content outline of the certification examination Fees: Maintenance fee of $ 100 each year for years one through six and a $ 400 recertification fee in year seven.		
8. Examination specifics: • **Paper & Pencil or computer-based:** Paper & pencil • **Number of questions:** 200		

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

CERTIFICATION PROGRAMS FOR PHARMACISTS

• **Question format:** multiple choice • **Cost:** $600 ($300 certification retake application fee) • **Frequency of exam:** Once a year (1st Saturday of October*)* • **Exam Pass Rate:** ~69% (based on 2009 exam data)	
9. Certification associated with specific training programs? No	**Offered by whom?** N/A
10. Certification exam prep courses/materials available? Yes, though not endorsed/sponsored by BPS	**Offered by whom?** American Society for Parenteral and Enteral Nutrition
11. Other Pertinent Information: • BPS is an autonomous division of the American Pharmacists Association (APhA) organized in 1976 as an independent certification agency of APhA. • Each specialty exam has a separate Content Outline (available online) validated through a national survey of pharmacist specialists. • Content Outlines provide details on major areas of responsibility for a specialist, the tasks required to fulfill these responsibilities, and the knowledge that underlies the performance of these tasks. • Each exam question is linked to a specific domain, task, and knowledge statement. • BPS utilizes the psychometric and exam administration services of Professional Examination Service of New York City in administration of its specialty certification programs.	

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

CERTIFICATION PROGRAMS FOR PHARMACISTS

ONCOLOGY PHARMACY		
1. Name of credential(s): Board Certified Oncology Pharmacist		
2. Responsible Organization: Board of Pharmacy Specialties (BPS)	**Address:**	Board of Pharmacy Specialties 2215 Constitution Avenue, NW Washington, DC 20037
	Telephone:	202-429-7591
	Fax:	202-429-6304
	E-mail:	info@bpsweb.org
	Web site:	www.bpsweb.org
3. Certification Body Accredited? Yes	**By what organization?** The National Commission for Certifying Agencies (NCCA)	
4. Disciplines certified (in addition to pharmacists): None		
5. Eligibility criteria for pharmacists: • Graduation from a pharmacy degree program accredited by the Accreditation Council for Pharmacy Education (ACPE) or a program outside the U.S. that qualifies the individual to practice in the jurisdiction. • Current, active license to practice pharmacy in the U.S. or another jurisdiction. • Completion of four (4) years of practice experience with at least 50% of time spent in oncology pharmacy activities (as defined by the BPS oncology pharmacy content outline) **OR** Completion of a PGY2 residency* in oncology pharmacy plus one (1) additional year of practice with at least 50% of time spent in oncology pharmacy activities * Effective January 1, 2013, only residencies accredited by the American Society of Health-System Pharmacists or other recognized bodies are creditable for this purpose. • Achieving a passing score on the Oncology Pharmacy Specialty Certification Examination		
6. Duration of initial certification: 7 years		
7. **Recertification requirements:** • Achieving a passing score on the 100-item, multiple-choice objective recertification examination, based on the content outline of the certification examination; **OR** • Earning 100 hours of continuing education credit provided by a professional development program approved by BPS. Fees: Maintenance fee of $ 100 each year for years one through six and a $ 400 recertification fee in year seven.		
8. Examination specifics: • **Paper & Pencil or computer-based:** Paper & pencil • **Number of questions:**		

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

200 • **Question format:** multiple choice • **Cost:** $600 ($300 certification retake application fee) • **Frequency of exam:** Once a year (1st Saturday of October*)* • **Exam Pass Rate:** Not Available	
9. Certification associated with specific training programs? No	**Offered by whom?** N/A
10. Certification exam prep courses/materials available? Yes; practice exam questions	**Offered by whom?** BPS Also, the Hematology Oncology Pharmacy Association, American Society of Health-System Pharmacists, and the American College of Clinical Pharmacy are good sources for learning.
11. Other Pertinent Information: • BPS is an autonomous division of the American Pharmacists Association (APhA) organized in 1976 as an independent certification agency of APhA. • Each specialty exam has a separate Content Outline (available online) validated through a national survey of pharmacist specialists. • Content Outlines provide details on major areas of responsibility for a specialist, the tasks required to fulfill these responsibilities, and the knowledge that underlies the performance of these tasks. • Each exam question is linked to a specific domain, task, and knowledge statement. • BPS utilizes the psychometric and exam administration services of Professional Examination Service of New York City in administration of its specialty certification programs.	

CERTIFICATION PROGRAMS FOR PHARMACISTS

PHARMACOTHERAPY

1. Name of credential(s):
Board Certified Pharmacotherapy Specialist (BCPS)

2. Responsible Organization: Board of Pharmacy Specialties (BPS)	**Address:**	Board of Pharmacy Specialties 2215 Constitution Avenue, NW Washington, DC 20037
	Telephone:	202-429-7591
	Fax:	202-429-6304
	E-mail:	info@bpsweb.org
	Web site:	www.bpsweb.org

3. Certification Body Accredited? Yes	**By what organization?** The National Commission for Certifying Agencies (NCCA)

4. Disciplines certified (in addition to pharmacists):
None

5. Eligibility criteria for pharmacists:

- Graduation from a pharmacy degree program accredited by the Accreditation Council for Pharmacy Education (ACPE) or a program outside the U.S. that qualifies the individual to practice in the jurisdiction.
- Current, active license to practice pharmacy in the U.S. or another jurisdiction.
- Achieving a passing score on the Pharmacotherapy Specialty Certification Examination
- Completion of three (3) years of practice experience with at least 50% of time spent in pharmacotherapy activities (as defined by the BPS Pharmacotherapy Content Outline)

OR

Completion of a PGY1 residency. (Effective January 1, 2013, only residencies accredited by the American Society of Health-System Pharmacists or other recognized bodies are creditable for this purpose.)

6. Duration of initial certification:
7 years

7. Recertification requirements:
A current, active license to practice pharmacy is required for recertification. In addition, recertification for Board Certified Pharmacotherapy Specialists (BCPS) is an assessment of a practitioner's knowledge and skills through one of two methods:

- Achieving a passing score on the 100-item, multiple-choice objective recertification examination, based on the content outline of the certification examination

OR

- Earning 120 hours of continuing education credit provided by a professional development program approved by BPS.

8. Examination specifics:

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

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

- **Number of questions:**
  200
- **Question format:**
  The multiple-choice format is used exclusively. Four possible answers are provided for each question, with only one designated as the correct or best choice. It is to the candidate's advantage to answer every question on the examination, since the final score is based on the total number of questions answered correctly. There is no penalty for selecting an incorrect choice.
- **Cost:**
  Certification Application Fee=$600
  Recertification Application Fee=$400
  Certification Retake Fee (Within 2 Years)=$300
  Recertification Retake Fee (Within 1 Year)=$200
  Annual Fee for All BPS-Certified Pharmacists=$100 (not required for the year of re-certification)
- **Frequency of exam:**
  Once yearly. BPS will establish test sites in 35 cities for the administration of its specialty certification examinations in 2010.
- **Exam Pass Rate:**
  70%

9. Certification associated with specific training programs? No	**Offered by whom?** N/A
10. Certification exam prep courses/materials available? Yes	**Offered by whom?** BPS does not provide review information, preparatory courses, or study guides. However, such materials are available from outside organizations, state or local professional associations and colleges of pharmacy. The American College of Clinical Pharmacy offers resources to aid in test preparation.

11. Other Pertinent Information:

- BPS is an autonomous division of the American Pharmacists Association (APhA) organized in 1976 as an independent certification agency of APhA.
- Each specialty exam has a separate Content Outline (available online) validated through a national survey of pharmacist specialists.
- Content Outlines provide details on major areas of responsibility for a specialist, the tasks required to fulfill these responsibilities, and the knowledge that underlies the performance of these tasks.
- Each exam question is linked to a specific domain, task, and knowledge statement.
- BPS utilizes the psychometric and exam administration services of Professional Examination Service of New York City in administration of its specialty certification programs.

CERTIFICATION PROGRAMS FOR PHARMACISTS

PSYCHIATRIC PHARMACY		
1. Name of credential(s): Board Certified Psychiatric Pharmacist		
2. Responsible Organization: Board of Pharmacy Specialties (BPS)	**Address:**	Board of Pharmacy Specialties 2215 Constitution Avenue, NW Washington, DC 20037
	Telephone:	202-429-7591
	Fax:	202-429-6304
	E-mail:	info@bpsweb.org
	Web site:	www.bpsweb.org
3. Certification Body Accredited? Yes	**By what organization?** The National Commission for Certifying Agencies (NCCA)	
4. Disciplines certified (in addition to pharmacists): None		
5. Eligibility criteria for pharmacists: • Graduation from a pharmacy degree program accredited by the Accreditation Council for Pharmacy Education (ACPE) or a program outside the U.S. that qualifies the individual to practice in the jurisdiction. • Current, active license to practice pharmacy in the U.S. or another jurisdiction. • Completion of four (4) years of practice with at least 50% of time spent in psychiatric pharmacy activities (as defined by the BPS Psychiatric Pharmacy Content Outline) **OR** completion of a PGY2 residency* in psychiatric pharmacy plus one (1) additional year of practice with at least 50% of time spent in psychiatric pharmacy activities (as defined by the BPS Psychiatric Pharmacy Content Outline) *Effective January 1, 2013, only residencies accredited by the American Society of Health-System Pharmacists or other recognized bodies are creditable for this purpose.		
6. Duration of initial certification: 7 years		
7. **Recertification requirements:** • Achieving a passing score on the 100-item multiple choice recertification examination, based on the content outline of the certification examination **OR** By earning 100 hours of continuing education credit provided by a professional development program approved by BPS. A current, active license to practice pharmacy is required for recertification. • Special notes o BCPPs recertifying via continuing education are required to complete the review course a minimum of once during their 7-year recertification cycle o BCPPs recertifying via continuing education can use the Review Course a maximum of twice for recertification credit during their 7-year recertification cycle. o The Review Course is revised and released every other year on the event year (2012,		

2014...). Given this revision cycle, individuals cannot repeat the current edition of the Review Course for BCPP Recertification or ACPE credit.

Fees: Maintenance fee of $ 100 each year for years one through six and a $ 400 recertification fee in year seven.

8. Examination specifics:

- **Paper & Pencil or computer-based:**
  Paper & pencil
- **Number of questions:**
  200
- **Question format:**
  multiple choice
- **Cost:**
  600 ($300 certification retake application fee)
- **Frequency of exam:**
  Annually on the first Saturday in October

9. Certification associated with specific training programs?	**Offered by whom?**
No	N/A

10. Certification exam prep courses/materials available?	**Offered by whom?**
Yes	College of Psychiatric and Neurologic Pharmacists http://cpnp.org/recertification/preparation

11. Other Pertinent Information:

- BPS is an autonomous division of the American Pharmacists Association (APhA) organized in 1976 as an independent certification agency of APhA.
- Each specialty exam has a separate Content Outline (available online) validated through a national survey of pharmacist specialists.
- Content Outlines provide details on major areas of responsibility for a specialist, the tasks required to fulfill these responsibilities, and the knowledge that underlies the performance of these tasks.
- Each exam question is linked to a specific domain, task, and knowledge statement.
- BPS utilizes the psychometric and exam administration services of Professional Examination Service of New York City in administration of its specialty certification programs.

CERTIFICATION PROGRAMS FOR PHARMACISTS

MULTIDISCIPLINARY CERTIFICATIONS

ANTICOAGULATION CARE		
1. Name of credential(s): Certified Anticoagulation Care Provider (CACP)		
2. Responsible Organization: National Certification Board for Anticoagulation Providers (NCBAP)	**Address:**	National Certification Board for Anticoagulation Providers 333 W. Olmos Dr. #116 San Antonio, TX 78212
	Telephone:	866-963-2588
	Fax:	866-963-2588
	E-mail:	info@ncbap.org
	Web site:	www.ncbap.org/index.aspx
	Candidate Handbook	www.ncbap.org/CACP_Candidate_Handbook_2010.pdf
3. Certification Body Accredited? No	**By what organization?** N/A	
4. Disciplines certified (in addition to pharmacists): Registered Nurse (RN), Advance Practice Nurse (NP), Licensed Physician (MD), or Physician Assistant (PA)		
5. Eligibility criteria for pharmacists: • The candidate must hold his/her professional license for a minimum of 2 years prior to the application deadline and must provide a copy of a current United States (or territories) license, registration or certification. • When completing the online application, the applicant must attest to having provided a minimum of 750 hours of active anticoagulation patient management. This experience must have been accrued within the 18 months immediately preceding the application deadline. • The applicant must also provide a written description of current activities pertaining to anticoagulation therapy management. The written description should be 500 words or fewer and should describe the applicant's general practice and experience specifically in antithrombotic therapy management. Duration and types of activities should be described, including number of patients, practice setting, management of clinic, the applicant's roles and responsibilities, and co-workers, etc. Paragraph format should be used; a resume or curriculum vitae will not suffice. • The applicant must provide a work email address (i.e. no hotmail, Gmail, etc.) for his/her direct supervisor so that information provided by the applicant can be verified.		
6. Duration of initial certification: 5 years		
7. **Recertification requirements:** All CACPs must recertify by examination every five (5) years. At least 10 weeks prior to his/her		

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

credential expiration date and the desired exam date, an applicant for recertification should submit a new application packet according to the current application procedures as described on the NCBAP website. The applicant should note available recertification dates and ensure that he/she applies in time to sit for an examination scheduled on or before the date on which his/her credential expires. Applicants for recertification are required to meet the same professional qualification and experience eligibility requirements imposed on first-time applicants. (see above)	
8. Examination specifics: • **Paper & Pencil or computer-based:** Computer-based • **Number of questions:** 160 (150 are graded, 10 are pilot) • **Question format:** multiple choice • **Length of Exam** 2.5 Hours • **Cost:** $400.00 is due with the application packet. All payments are collected online. Approved testing sites may charge the applicant a fee for administering the exam. Fees charged by exam sites are typically less than $25. Any such fees should be paid directly to the exam site and are in addition to the application/exam fee charged by the NCBAP. • **Frequency of exam:** Approximately two exams per month. The CACP exam is available online but must be taken at an approved exam site on a scheduled exam date. • **Score Needed to Pass** An applicant must correctly answer 80% of the scored items in order pass the exam.	
9. Certification associated with specific training programs? No	**Offered by whom?** N/A
10. Certification exam prep courses/materials available? Yes. The NCBAP does not endorse, financially benefit from, nor participate in the development of any preparatory or review courses or other published materials purporting to be study guides for the CACP Examination. (visit http://ncbap.org/CACP_Candidate_Handbook.pdf for more details on the exam)	**Offered by whom?** http://health.usi.edu/certificate/anticoagulationtherapy.asp

CERTIFICATION PROGRAMS FOR PHARMACISTS

ASTHMA EDUCATION		
1. Name of credential(s): Certified Asthma Educator (AE-C)		
2. Responsible Organization: National Asthma Educator Certification Board (NAECB)	**Address:**	National Asthma Educator Certification Board PO BOX 781275 San Antonio, TX 78278
	Telephone:	877-408-0072
	Fax:	210-408-1799
	E-mail:	info@naecb.org
	Web site:	www.naecb.org
	Candidate Handbook	http://naecb.com/pdf/NAECBhandbook.pdf
3. Certification Body Accredited? No	**By what organization?** N/A	
4. **Disciplines certified (in addition to pharmacists):** Licensed or credentialed health care professionals: Physicians (MD, DO) Physician Assistants (PA-C) Nurse Practitioners (NP) Nurses (RN, LPN) Respiratory Therapists (RRT, CRT) Pulmonary Function Technologists (CPFT, RPFT) Social Workers (CSW) Health Educators (CHES) Physical Therapists (PT) Occupational Therapists (OT) **OR** Individuals providing professional asthma education and counseling with a minimum of 1,000 hours experience in these activities. These individuals do not need to be health care professionals. NAECB may verify the eligibility of these candidates by notarized letters from a supervisor.		
5. Eligibility criteria for pharmacists: Current license		
6. Duration of initial certification: 7 years		
7. Recertification requirements: Re-examination		
8. Examination specifics: • **Paper & Pencil or computer-based:** Computer-based • **Number of questions:**		

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175 (25 pre-test questions and 150 graded questions)

- **Question format:**
  Multiple-choice. The questions with for possible answers (A, B, C, D) appear on the screen. Questions can be skipped, bookmarked, or changed at anytime during the exam. Buttons allow the person taking the exam to move forward and backward throughout the questions. There is no penalty for guessing.
- **Length of Exam**
  A time limit of 3.5 hours is enforced.
- **Cost:**
  New candidate=$295
  Repeat candidate=$195
  Recertification fee=$245
- **Frequency of exam:**
  Exams are administered at AMP Assessment Centers located at 110 locations throughout the United States. The examination is administered by appointment only Monday through Saturday at 9:00 a.m. and 1:30 p.m. Candidates are scheduled on a first-come, first-served basis.
- **Exam Pass Rate**
  67.3%

9. Certification associated with specific training programs? No	**Offered by whom?** N/A
10. Certification exam prep courses/materials available? Yes.	**Offered by whom?** NAECB recognizes that accreditation regulations do not allow for certifying bodies to also provide training to take certification tests. Organizations that have provided courses in the past include the Association of Asthma Educators, American Lung Association, American Association for Respiratory Care, American College of Asthma, Allergy, & Immunology among others. NAECB is not affiliated with any of these programs. NAECB does, however, offer a Self Assessment Examination (SAE) to provide additional resources for test preparation at a cost of $65. The SAE is comprised of 75 questions, modeled on the type and style of questions you will see on the actual examination. In addition, NAECB offers a list of references and a detailed content outline to aid in studying.

CERTIFICATION PROGRAMS FOR PHARMACISTS

CARDIOVASCULAR/LIFE SUPPORT		
1. Name of credential(s): Advanced Cardiovascular Life Support (ACLS), Pediatric Cardiovascular Life Support (PALS)		
2. Responsible Organization: American Heart Association	**Address:**	American Heart Association 7272 Greenville Ave. Dallas, TX 75231
	Telephone:	800-AHA-USA-1
	E-mail:	info@naecb.org
	Web site:	http://www.heart.org/HEARTORG/CPRAndECC/HealthcareTraining/AdvancedCardiovascularLifeSupportACLS/Advanced-Cardiovascular-Life-Support-ACLS_UCM_001280_SubHomePage.jsp
3. Certification Body Accredited? Yes	**By what organization?** Continuing Education Coordinating Board for Emergency Medical Services: http://www.cecbems.org/	
4. Disciplines certified (in addition to pharmacists): For healthcare providers working in emergency treatment, intensive care or critical care, and other professionals who may need to respond to a cardiovascular emergency. As long as you are in the healthcare field, you can take the class.		
5. Eligibility criteria for pharmacists: No verification of healthcare provider status		
6. Duration of initial certification: American Heart Association ACLS for Healthcare Providers Course Completion Card valid for two years.		
7. Recertification requirements: Have to retake the class after two years or a recertification course can be taken before the end of the month in which the card expires.		
8. Examination specifics: • **Paper & Pencil or computer-based:** Paper and pencil taken right after the class, includes a skills test • **Cost:** Costs for courses and materials determined by Training Centers or Instructors and may vary. The AHA does not regulate price; however, provides its authorized distributors suggested retail pricing on course materials. • **Frequency of exam:** Varies		
9. Certification associated with specific training programs? Yes	**Offered by whom?** Various Centers	

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

CERTIFICATION PROGRAMS FOR PHARMACISTS

10. Certification exam prep courses/materials available? Yes.	**Offered by whom?** AHA
11. Other Pertinent Information: The course is administered through various independent training centers and healthcare facilities therefore times/dates and costs of the program will vary across the nation. The course however is standardized.	

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CERTIFICATION PROGRAMS FOR PHARMACISTS

CLINICAL PHARMACOLOGY		
1. Name of credential(s): Accredited in Applied Pharmacology (AP)		
2. Responsible Organization: American Board of Clinical Pharmacology (ABCP)	**Address:**	American Board of Clinical Pharmacology Administrative Office PO Box 40278 San Antonio, Texas 78229-1278
	Telephone:	210-567-8505
	Fax:	210-567-8509
	E-mail:	Colunga@uthscsa.edu
	Web site:	www.abcp.net/index.html
3. Certification Body Accredited? No	**By what organization?** N/A	
4. Disciplines certified (in addition to pharmacists): Physician Category Non-Physician and Non-licensed Physician category		
5. Eligibility criteria for pharmacists: Applicants for the ABCP examinations will be judged individually, based on training and experience. The Credentials Committee of the ABCP determines the eligibility of each applicant. To be eligible for certification by the ABCP, individuals must: 1) MEET THE CRITERIA DEFINED HERE: PHYSICIANS or NON-PHYSICIANS 2) complete the application forms 3) provide the supporting credentials required; and 4) pass the examinations in the subsequent examination period.		
6. Duration of initial certification: 5 years.		
7. Recertification requirements: Continuing education or related examination; or documentation of also minimum 1000 hours of professional practice during 5 year certification.		
8. Examination specifics: • **Paper & Pencil or computer-based:** Computer-based • **Number of Questions:** 300 • **Question Format:** Varied • **Cost:** Application fee: $350. General Examination (including sub-section examination): $450. Late fee: $200. Renewal: $250 ($100 non-refundable) TOTAL COST: $950 or $1150		

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CERTIFICATION PROGRAMS FOR PHARMACISTS

• **Frequency of exam:** Bi-Annually • **Exam Pass Rate** Average is about 8 out of 10 students pass.	
9. **Certification associated with specific training programs?** Instructions - Fellowship Training Programs in Clinical Pharmacology Download Acrobat .pdf *or* MS Word .doc Qualified fellowship training programs in clinical pharmacology must provide the intellectual environment, formal instruction, peer interaction, and clinical experience necessary for fellows to acquire knowledge, skills, and attitudes essential to the practice of clinical pharmacology. An accredited fellowship program in clinical pharmacology will provide at least two years of well-supervised educational experience. Application for registration of a clinical pharmacology fellowship program Download Acrobat .pdf *or* MS Word .doc Application for accreditation of a clinical pharmacology fellowship program Download Acrobat .pdf *or* MS Word .doc	**Offered by whom?** Please see list of providers at http://www.abcp.net/training.html
10. Certification exam prep courses/materials available? Yes.	**Offered by whom?** Suggested Preparation: Reading and Reviewing Materials for Examination Candidates A review of a general text of clinical pharmacology and therapeutics would be appropriate. No one single text is absolutely recommended since the examination for physicians and non-physicians covers a broad spectrum of clinical pharmacology and related therapeutics. Examples of suitable text would be: Basic and Clinical Pharmacology: Editor B. G. Katzung; Publ. *Appleton and Lange.*

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	Principles of Clinical Pharmacology; Atkinson, Daniels, Dedrick, Grudsinskasand Markey eds. *Academic Press, 2001.* Melmon and Morrelli's Clinical Pharmacology, fourth edition, Editors: S. George Carruthers, Brian B. Hoffman, Kenneth L. Melmon, and David W. Nierenberg; published by *McGraw-Hill, Medical Publishing Division, copyright 2000.* (ISBN 0-07-105406-5) Mant TGK, Lewis LD, Ferro A, Ritter JM. Clinical Pharmacology and Therapeutics: Questions for Self Assessment (Paperback), 256 pages; published by *Hodder Arnold; third Edition (25 April 2008) Language English.* (ISBN-10: 0340947438 & ISBN-13: 978-0340947432). Reading of the current journals of Clinical Pharmacology is also recommended.
11. Other Pertinent Information: NOTICE: Future examinations will require that the examinee have completed a Clinical Pharmacology training fellowship, usually of two years duration, at a program in Clinical Pharmacology accredited or registered by the American Board of Clinical Pharmacology.	

CERTIFICATION PROGRAMS FOR PHARMACISTS

DIABETES EDUCATION		
1. Name of credential(s): Certified Diabetes Educator (CDE)		
2. Responsible Organization: National Certification Board for Diabetes Educators (NCBDE)	**Address:**	National Certification Board for Diabetes Educators 330 East Algonquin Road, Suite 4 Arlington Heights, IL 60005
	Telephone:	847-228-9795; 877-239-3233
	Fax:	847-228-8469
	E-mail:	info@ncbde.org
	Web site:	www.ncbde.org
3. Certification Body Accredited? No	**By what organization?** N/A	
4. **Disciplines certified (in addition to pharmacists):** Clinical psychologist, registered nurse, occupational therapist, optometrist, physical therapist, physician (M.D. or D.O.), or podiatrist holding a current, active, unrestricted license from the United States or its territories. **OR** Dietitian holding active registration with the Commission on Dietetic Registration, physician assistant holding active registration with the National Commission on Certification of Physician Assistants, or exercise physiologist holding active certification as an American College of Sports Medicine Registered Clinical Exercise Physiologist® (minimum of a master's degree). **OR** Health care professional with a minimum of a master's degree* in social work from a United States college or university accredited by a nationally recognized regional accrediting body. **OR** Health care professional with a minimum of a master's degree in nutrition, health education, or specified areas of public health from a United States college or university accredited by a nationally recognized regional accrediting body.		
5. Eligibility criteria for pharmacists: A current, active, unrestricted license from the United States or its territories **AND** Minimum of two (2) years to the day of professional practice experience in pharmacy **AND** Minimum of 1000 hours of diabetes self-management education (DSME) experience with a minimum of 40% of those hours (400 hours) accrued in the most recent year preceding application. **AND** Minimum of 15 clock hours of continuing education activities applicable to diabetes within the two (2) years prior to applying for certification.		
6. Duration of initial certification: 5 years.		

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CERTIFICATION PROGRAMS FOR PHARMACISTS

7. Recertification requirements: • Individuals must continue to hold the license or registration for the same discipline held at the time of initial certification. This license or registration must be current, active, and unrestricted at the time of renewal. • Accrual of a minimum of 1,000 hours of professional practice experience during the five-year certification cycle Once the individual meets these requirements, renewal of certification must be completed during the calendar year in which a CDE's credential expires and may be done either by continuing education or by taking the Examination	
8. Examination specifics: • **Paper & Pencil or computer-based:** Computer-based • **Number of Questions:** 200 • **Question Format:** Multiple-choice, objective questions. Twenty-five of the 200 questions are new questions that have not been used on previous examinations. Inclusion of these questions allows for collection of meaningful statistics about new questions, but are not used in the determination of individual examination scores. Questions can be skipped, bookmarked, or changed at anytime during the exam. Buttons allow the person taking the exam to move forward and backward throughout the questions. There is no penalty for guessing. A time limit of 4 hours is enforced. • **Cost:** Initial certification=$350 Renewal=$250 • **Frequency of exam:** The examination is administered twice a year by computer at more than 170 Assessment Centers throughout the United States and selected international locations. The examination is administered by appointment only, Monday through Saturday at 9:00 a.m. and 1:30 p.m. Available dates will be indicated when scheduling your examination. Scheduling is done on a first-come, first-served basis.	
9. Certification associated with specific training programs? No	**Offered by whom?** N/A
10. Certification exam prep courses/materials available? No specific programs listed by NCBDE. NCBDE has developed the CDE® Practice Examination as one possible option for preparing for the Examination. The practice exam is provided in an on-line format that an individual can access from their computer. With 50 multiple-choice	**Offered by whom?** N/A

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questions, the practice exam is illustrative of the type and format of questions included on the actual Examination and allows an individual to practice taking an abbreviated version of the Examination. There is also an examination content outline in the Examination Handbook that may highlight areas for additional study using references specific to those areas.	

CERTIFICATION PROGRAMS FOR PHARMACISTS

DIABETES MANAGEMENT - ADVANCED		
1. Name of credential(s): Board Certified-Advanced Diabetes Management (BC-ADM)		
2. Responsible Organization: The American Association of Diabetes Educators (AADE)	**Address:**	American Association of Diabetes Educators 200 W. Madison Street, Suite 800 Chicago, IL 60606
	Telephone:	800-338-3633
	E-mail:	education@aadenet.org
	Web site:	www.diabeteseducator.org
3. Certification Body Accredited? No	**By what organization?** N/A	
4. **Disciplines certified (in addition to pharmacists):** Clinical Nurse Specialists, Nurse Practitioners, Registered Dietitians, physicians, and physician assistants.		
5. Eligibility criteria for pharmacists: Hold a current, active pharmacist registration in a state or territory of the U.S. or professional, legally-recognized equivalent in another country. Hold a Master's or higher degree in pharmacy from an ACPE accredited school. Within 48 months of sitting for the exam, complete a minimum of 500 clinical hours in advanced diabetes management after obtaining registration as a pharmacist.		
6. Duration of initial certification: 5 years.		
7. Recertification requirements: • Hold a current, active license in a state or territory of the United States or the professional, legally-recognized equivalent in another country • Hold a current BC-ADM certification • Complete the professional development requirements for your certification specialty (must be completed within the 5 years preceding your renewal application submission) • Complete a minimum of 1,000 practice hours in your certification role and population/specialty (must be completed within the 5 years preceding your renewal application submission) • Pay the renewal fee. Recertification $500 (AADE), $800 (non-member). Retest $220 (AADE), $340 (non-members)		
8. Examination specifics: • **Paper & Pencil or computer-based:** Computer-based • **Number of Questions:** 175 • **Question Format:** 175 multiple choice (150 scored/25 pretest not scored) • **Cost:** Initial $600 (AADE members) $900 (non-members, membership NOT included)		

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

International test fee: $150 Late fee: $50 • **Frequency of exam:** Bi-annually	
9. Certification associated with specific training programs? No	**Offered by whom?** N/A
10. Certification exam prep courses/materials available? No specific programs were listed by AADE. The AADE states that any available prep courses are not affiliated with their institution. It does, however, include a list of references that may aid in studying for the exam	**Offered by whom?** N/A

CERTIFICATION PROGRAMS FOR PHARMACISTS

HIV/AIDS		
1. Name of credential(s): HIV Specialist™ (AAHIVS) or HIV Expert (AAHIVE) or HIV Pharmacist (AAHIVP)		
2. Responsible Organization: The American Academy of HIV Medicine (AAHIVM)	**Address:**	The American Academy of HIV Medicine 1705 DeSales Street NW, Suite 700 Washington, D.C. 20036
	Telephone:	202-659-0699
	Fax:	202-659-0976
	E-mail:	info@aahivm.org
	Web site:	www.aahivm.org
3. Certification Body Accredited? No	**By what organization?** N/A	
4. **Disciplines certified (in addition to pharmacists):** MD, DO, PA, or NP		
5. Eligibility criteria for pharmacists: PharmD licensure from an accredited school of pharmacy, direct involvement in the care of the minimum 20 HIV patients is acceptable to meet the experience requirement and complete a minimum of 30 credits of HIV-related Category 1 CME/CEU/CE within the 24 months preceding the date of application		
6. Duration of initial certification: 2 years.		
7. Recertification requirements: Providers whose certification has expired and who are recertifying are not subject to any additional requirements than those certifying for the first time.		
8. Examination specifics: • **Paper & Pencil or computer-based:** Both • **Number of Questions:** 125 • **Question Format:** Case-based, 5-option multiple choice items **Cost:** Member: $240 (online), $290 (written) Non-member: $290 (online), $340 (written) • **Frequency of exam:** August 16th – October 1st of every year		
9. Certification associated with specific training programs? No	**Offered by whom?** N/A	

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CERTIFICATION PROGRAMS FOR PHARMACISTS

10. Certification exam prep courses/materials available? The AAHIVM Fundamentals of HIV Medicine - 2012 Edition along with the included 2010/2011 Fundamentals CD Supplement is offered as a resource to prepare for and complete the exam, and also serves as a clinical reference. Fundamentals of HIV Medicine are not included in the exam application fee, but are available for purchase with the credentialing application. Clinical information links are available as resources for exam prep.	**Offered by whom?** AAHIVM

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CERTIFICATION PROGRAMS FOR PHARMACISTS

HEALTH INFORMATION TECHNOLOGY		
1. Name of credential(s): Certified Professional in Electronic Health Records (CPEHR) Certified Professional in Health Information Technology (CPHIT) Certified Professional in Health Information Exchange (CPHIE) Certified Professional for Operating Rules Administration (CPORA)		
2. Responsible Organization: Health IT Certification	**Address:**	Health IT Certification 4676 Commercial St. Suite 127 Salem, OR 97302-1902
	Telephone:	888-228-5021
	Fax:	858-228-1743
	E-mail:	registration@HealthITCertification.com
	Web site:	www.healthitcertification.com
3. Certification Body Accredited? No	**By what organization?** N/A	
4. **Disciplines certified (in addition to pharmacists):** Targeted to those responsible for planning, selecting, implementing, using, and managing electronic health records (EHR), participating in health information exchange (HIE), other health information technology (HIT), and those responsible for technical and business operations implementation of the Affordable Care Act operating rules. This includes practice administrators, information technology steering committee members, information systems analysts, data analysts, and clinicians (physicians, nurses, and other direct caregivers) evaluating electronic prescribing systems, clinical messaging, electronic health records, and other health information technology.		
5. Eligibility criteria for pharmacists: No specific educational or experiential requirements for taking the CPEHR, CPHIE, CPHIT or CPORA certification examinations. It is recommended that individuals either have healthcare experience with plans to participate in EHR, HIE, HIT and/or ORA acquisition, use, and operations; or have information system experience with the intent of assisting healthcare organizations acquire and deploy an EHR, HIE, HIT or ORA.		
6. Duration of initial certification: 2 years.		
7. Recertification requirements: Earn CE and pay the $100 maintenance of certification fee on a bi-annual basis. Applicable CE activities include attendance at seminars, training programs, audio-conferences, journal clubs, and demonstrations sponsored by healthcare professional associations, societies, or other organizations providing information new to you on EHR, HIT, HIE and ORA, as well as other CE activities relating to EHR, HIT, HIE and ORA that provide you with new information on EHR, HIT, HIE and ORA and are recognized for their contribution by healthcare professional associations, publishers, or other organizations relating to EHR, HIT, HIE and ORA (e.g., article on EHR).		

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CERTIFICATION PROGRAMS FOR PHARMACISTS

8. Examination specifics:

- **Paper & Pencil or computer-based:**
  Both
- **Number of Questions:**
  100
- **Question Format:**
  multiple choice (2 hours)
- **Cost:**
  Specific cost varies by options chosen. Overall, cost ranges from $1295 to $1,695 for the training and certification exam per person, whether taken at a hotel or on the Internet. Individual courses can be taken online for $145 each. A certificate of completion is provided for each course.
- **Frequency of exam:**
  - Programs and exams are offered periodically at hotel locations. Locations are posted on the www.healthitcertification.com/onsitelocations.html website.
  - Programs are also offered in a hybrid model, with one day of four courses offered as a preconference or post-conference, the remaining six to eight courses online, and the exam online.
  - The programs and certification exams are available online.
  - The programs may be conducted as in-house courses for organizations that want to offer the programs internally.
- **Exam Pass Rate:**
  70 – 80%

9. Certification associated with specific training programs?	**Offered by whom?**
Yes	Health IT Certification and Medical Education Collaborative • Individuals may attend the training program in a seminar setting, or via the Internet to master the EHR, HIE, and/or HIT body of knowledge. • Individuals choosing to take either of the certification examinations are demonstrating their interest in achieving a mark of distinction by mastering an important set of knowledge and skills. • Groups may wish to attend courses in a seminar setting, have the training program brought to their organization, or sign-up for online training. • Any or all of the members of the group may choose to take the certification examinations. • Individuals or groups may also take individual courses from the training program online • All attendees (live or online) receive certificates of attendance

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CERTIFICATION PROGRAMS FOR PHARMACISTS

10. Certification exam prep courses/materials available? No (see training program above)	**Offered by whom?** N/A
11. Other Pertinent Information: A candidate does not have to take the training program prior to taking a certification examination. An individual may prepare for the exam in his or her own manner	

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CERTIFICATION PROGRAMS FOR PHARMACISTS

LIPIDS		
1. Name of credential(s): Clinical Lipid Specialist		
2. Responsible Organization: Accreditation Council for Clinical Lipidology (ACCL)	**Address:**	Accreditation Council for Clinical Lipidology 6816 Southpoint Parkway, Suite 1000 Jacksonville, FL 32216
	Telephone:	904-309-6250
	Fax:	904-998-0855
	Web site:	www.lipidspecialist.org
3. Certification Body Accredited? No	**By what organization?** N/A	
4. **Disciplines certified (in addition to pharmacists):** Licensed nurses, nurse practitioners, physician assistants, dietitians, clinical exercise physiologists/specialists and other related health professionals who meet qualifying criteria.		
5. Eligibility criteria for pharmacists: PharmD licensure, AND BS/BA degree or higher in related health science and have 3,000 contact hours of demonstrated clinical experience in the management of patients with lipid disorders or other related disorders or Masters degree or higher in related health science and have 2,000 contact hours of demonstrated clinical experience in the management of patients with lipid disorders or other related disorders **PLUS** • Certification by a recognized board (e.g., Board of Pharmacy Specialties, • Relevant accredited postgraduate training of at least 1 year • Relevant academic practice and faculty appointment at a recognized institution • Clinical research and/or scholarly publications in the management of lipid disorders • 200 points must be obtained from the above criteria (point assignment is available on the website, www.lipidspecialist.org) **Balance of points not obtained above, must be earned through lipid focused continuing education credit obtained within the previous five calendar years.		
6. Duration of initial certification: 10 years.		
7. Recertification requirements: • Retake the exam prior to expiration of the last certification • Demonstrate 100 hours of continuing education completed in the 5 years prior to expiration of certification		
8. Examination specifics: • **Paper & Pencil or computer-based:** Computer-based; 4 hours • **Number of Questions:** 200 • **Question Format:**		

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upper-level of difficulty; multiple choice • **Cost:** $496 (combined application and examination fee) • **Frequency of exam:** 4 30-day testing windows (w/application deadlines)	
9. Certification associated with specific training programs? Yes; professional development pathway with intermediate to advanced training courses, self-assessment programs, and modules that will help prepare you for the exams	**Offered by whom?** National Lipid Association
10. Certification exam prep courses/materials available? CLS exam blueprint and the Core Curriculum in Clinical Lipidology	**Offered by whom?** ACCL

CERTIFICATION PROGRAMS FOR PHARMACISTS

NUTRITION SUPPORT		
1. Name of credential(s): Certified Nutrition Support Clinician (CNSC)		
2. Responsible Organization: National Board of Nutrition Support Certification, Inc. (NBNSC)	**Address:**	National Board of Nutrition Support Certification, Inc. 8630 Fenton Street, Suite 412, Silver Spring, MD 20910
	Telephone:	301-587-6315
	Fax:	301-587-2365
	E-mail:	nbnsc@nutr.org
	Web site:	www.nutritioncertify.org
	Candidate Handbook:	www.nutritioncare.org/WorkArea/showcontent.aspx?id=5226
3. Certification Body Accredited? No	**By what organization?** N/A	
4. **Disciplines certified (in addition to pharmacists):** Registered Nurse (RN), Registered Dietitian (RD), licensed physician (MD), or licensed physician assistant (PA)		
5. Eligibility criteria for pharmacists: NBNSC recommends that candidates have at least two years of experience in specialized nutrition support, but it is not required. Applicants must complete and file an Application for the Certification Examination for Nutrition Support Clinicians and pay the required fee.		
6. Duration of initial certification: 5 years.		
7. Recertification requirements: All CACPs must recertify by examination every five (5) years.		
8. Examination specifics: • **Paper & Pencil or computer-based:** Computer-based • **Question Format:** multiple choice • **Cost:** $295.00 ($395.00 for non-ASPEN members) is due with the application packet. • **Frequency of exam:** Two testing windows per year. Exams must be taken at an exam site on a scheduled exam date		
9. Certification associated with specific training programs? No	**Offered by whom?** N/A	

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CERTIFICATION PROGRAMS FOR PHARMACISTS

PAIN EDUCATION		
1. Name of credential(s): Credentialed Pain Educator (CPE)		
2. Responsible Organization: American Society of Pain Educators (ASPE)	**Address:**	American Society of Pain Educators 6 Erie Street Montclair, NJ 07042
	Telephone:	973-233-5570
	Fax:	973-453-8246
	E-mail:	info@paineducators.org
	Web site:	www.paineducators.org
3. Certification Body Accredited? No	**By what organization?** N/A	
4. Disciplines certified (in addition to pharmacists): Any health care professional		
5. Eligibility criteria for pharmacists: • Licensure - Applicant must hold a current license as a healthcare professional. • Clinical/Professional Experience – Applicant must have at least two (2) years of full-time experience or four (4) years of half-time experience in a position in which at least 10% of the applicant's time is devoted to providing pain-related education to clinical peers and/or patients (eg, 400 hours of pain education experience). Note: Experience must have accrued within the last five (5) years. • Certified Continuing Education Activities – Applicant must have completed at least 30 hours (credits) of pain-related educational activities certified for Category 1 CME, CPE, CE, or other professional credit. Note: Credits must have been earned within the last five (5) years.		
6. Duration of initial certification: 5 years.		
7. Recertification requirements: • Adhere to the ethical standards governing their profession • Keep their ASPE membership current • Remain a healthcare professional licensed by a recognized US jurisdiction		
8. Examination specifics: • **Paper & Pencil or computer-based:** Computer-based; 3 hours • **Number of Questions:** 120 • **Question Format:** multiple choice; 4 choices • **Cost:** $400 (including application and exam registration fees) • **Frequency of exam:** One exam window yearly		

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CERTIFICATION PROGRAMS FOR PHARMACISTS

9. Certification associated with specific training programs? No	**Offered by whom?** N/A
10. Certification exam prep courses/materials available? Yes; To help candidates prepare for the Certified Pain Educator (CPE) Examination, a list of resources used to prepare examination questions is provided	**Offered by whom?** ASPE
11. Other Pertinent Information: One must be a general member of the ASPE to take the exam	

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CERTIFICATION PROGRAMS FOR PHARMACISTS

PAIN MANAGEMENT

1. Name of credential(s):
Credentialed Pain Practitioner (CPP)

2. Responsible Organization: American Academy of Pain Management (AAPM)	**Address:**	American Academy of Pain Management 13947 Mono Way #A Sonora, CA 95370
	Telephone:	209-533-9744
	Fax:	209-533-9750
	E-mail:	rosemary@aapainmanage.org
	Web site:	www.aapainmanage.org

3. Certification Body Accredited? No	**By what organization?** N/A

4. Disciplines certified (in addition to pharmacists):
Any doctorate degree, fellow or clinical associate in a related health care field that includes 2 years of experience working with people in pain

5. Eligibility criteria for pharmacists:

- Current licensure to practice, if applicable.
- 100 hours of CMEs (of which 50 are related to pain or pain management) during the four-year time frame.
- Your promise to practice in accordance with the American Academy of Pain Management's Code of Ethics and Patient's Bill of Rights.
- Remaining in good standing with federal and state regulatory agencies and your professional organizations. Maintaining your annual general membership fee.
- Maintaining your re-credentialing fee every 4 years.

6. Duration of initial certification:
4 years.

7. Recertification requirements:

- To re-credential you must complete and return the Re-Credentialing Form which will be mailed to you approximately 2 months prior to your re-credentialing due date.
- The following will be requested:
  - Copy of your current license to practice, if applicable.
  - Attestation to:
    - Obtaining 100 hours of CMEs (of which 50 are related to pain or pain management) during the 4-year time frame.
    - Practicing in accordance with the American Academy of Pain Management's Code of Ethics and Patient's Bill of Rights.
    - Remaining in good standing with federal and state regulatory agencies and your professional organizations.
- Payment of fees:
  - General Membership annual fee - $195 USD

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o Recredentiailing fee - $100 USD	
8. Examination specifics: • **Paper & Pencil or computer-based:** Both; 2 hours • **Number of Questions:** 120 • **Question Format:** Not stated • **Cost:** $695 (including membership, application and exam registration fees) • **Frequency of exam:** Once yearly	
9. Certification associated with specific training programs? No	**Offered by whom?** N/A
10. Certification exam prep courses/materials available? Yes; Study *Weiner's Pain Management, A Practical Guide for Clinicians*, 7th Edition; Take the On-Line Self-Assessment Examination; Attend the Annual Clinical Meeting.	**Offered by whom?** AAPM
11. Other Pertinent Information: One must be a general member of the AAPM to take the exam	

CERTIFICATION PROGRAMS FOR PHARMACISTS

POISON INFORMATION		
1. Name of credential(s): Certified Specialist in Poison Information		
2. Responsible Organization: American Association of Poison Control Centers (AAPCC)	**Address:**	American Association of Poison Control Centers 515 King Street, Suite 510 Alexandria, VA 22314
	Telephone:	703-894-1858
	E-mail:	info@aapcc.org
	Web site:	www.aapcc.org/dnn/Home.aspx
3. Certification Body Accredited? No	**By what organization?** N/A	
4. Examination specifics: • **Paper & Pencil or computer-based:** Computer based, administered by Pearson Vue • **Number of Questions:** 160 questions, of which only 125 will be used to determine the candidates score • **Question Format:** Not stated • **Length of Exam:** up to 4 hours allowed • **Frequency of exam:** Once yearly		
5. Certification associated with specific training programs? No	**Offered by whom?** N/A	
6. Certification exam prep courses/materials available? No	**Offered by whom?** N/A	

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CERTIFICATION PROGRAMS FOR PHARMACISTS

TOXICOLOGY		
1. Name of credential(s): Diplomate of the American Board of Applied Toxicology (DABAT)		
2. Responsible Organization: American Board of Applied Toxicology (ABAT)	**Address:**	American Board of Applied Toxicology c/o California Poison Control System, San Francisco 951 Calle Verde Martinez, CA 94553
	Telephone:	415-502-6001
	E-mail:	fcantrel@ucsd.edu
	Web site:	www.clintox.org/ABAT_Main.cfm
3. Certification Body Accredited? No	**By what organization?** N/A	
4. Disciplines certified (in addition to pharmacists): A graduate of a college or university with an earned doctoral degree in a biomedical discipline. Applicants without doctoral degrees must possess a baccalaureate degree in a health science discipline, such as pharmacy or nursing, followed by a minimum of five years of full-time professional experience in applied clinical toxicology. Scholastic coursework is not considered to be professional experience. Applicants holding the Doctor of Medicine, Doctor of Osteopathy, or Doctor of Veterinary Medicine degree are not eligible to sit for the ABAT examination.		
5. Eligibility criteria for pharmacists: Completion of at least 12 months of post-doctoral training (i.e., residency or fellowship) in clinical toxicology or a closely related field. Applicants without post-doctoral training must have a minimum of at least three years of professional experience related to applied clinical toxicology after completion of their doctoral degree. To be prepared for the examination, candidates should have considerable clinical experience and an understanding of the clinical and environmental factors associated with various types of toxicological problems. Examples of activities related to the practice of applied clinical toxicology include consulting with medical personnel on patient care issues, administrative responsibility for a poison control center with consultative responsibilities, rendering opinions on product toxicity, teaching clinical toxicology to students, practitioners or colleagues, collaborating with medical toxicologists, and research in applied clinical toxicology. Applicants must demonstrate experience in all the areas of clinical, research and teaching activities, and leadership. An abundance of experience in one area will not substitute for lack of experience in another. Applicants holding a degree in a health care profession in which licensing is required must be in good standing with the appropriate jurisdictional board and must be eligible for, or possess, a valid, unrestricted license to practice. A copy of the license must accompany the application. Applicants must be members in good standing of the American Academy of Clinical Toxicology at the time of their application.		
6. Duration of initial certification: 5 years.		

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CERTIFICATION PROGRAMS FOR PHARMACISTS

7. Recertification requirements: Must do so every 5 years (format unknown)	
8. Examination specifics: • **Paper & Pencil or computer-based:** Paper & Pencil • **Number of Questions:** 125 short answer, 4 problem solving questions • **Question Format:** The first section is comprised of four multi-part, written, problem-solving case studies. These case studies cover a variety of topics including acute and chronic exposures, environmental or occupational toxicology, clinical study design and evaluation, expert testimony or the toxicology laboratory. The second is comprised of up to 125 short answer (multiple-choice) questions covering a variety of toxicology topics. These questions are meant to measure diversity of knowledge rather than trivia. • **Cost:** $500 • **Frequency of exam:** Annually at the North American Congress of Clinical Toxicology (NACCT) typically held during September or October	
9. Certification associated with specific training programs? No	**Offered by whom?** N/A
10. Certification exam prep courses/materials available? Yes	**Offered by whom?** www.clintox.org/ABAT/ABAT_Exam_Prep.pdf Mometrix Media http://www.flashcardsecrets.com/abat/

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