



## LICENSING COMMITTEE REPORT

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### 1. Public Comment for Items Not on the Agenda

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

### 2. Pharmacy Technician Requirements Assessment

#### a. Pharmacy Technician Accreditation Commission (PTAC) Information

##### Relevant Law

Business and Professions Code Section 4202 establishes the general requirements for an applicant seeking licensure as a pharmacy technician and further requires the board to adopt regulations for the specification of training courses.

Title 16 CCR Sections 1793.5 provides the application requirements for a pharmacy technician license.

Title 16 CCR 1793.6 provides the requirements for acceptable training courses as one of the pathways to licensure as a pharmacy technician licensure.

##### Background

Currently law creates several pathways to licensure as a pharmacy technician, including the completion of a training program that meets one of the following criteria:

- Training program is accredited by the American Society of Health-System Pharmacists (ASHP)
- Training program is provided by a branch of the federal armed services
- Course provides a training period of at least 240 hours of instruction covering specified areas of pharmacy practice.

In 2013 the New Pharmacy Technician Accreditation Commission (PTAC) launched. The commission is a collaboration between (ASHP) and the Accreditation Council for Pharmacy Education (ACPE) and is tasked with assuring and advancing the quality of

pharmacy technician education and training programs.

During this Meeting

The committee will hear a presentation by Dr. Peter Vlasses, Executive Director, ACPE, on the Pharmacy Technician Accreditation Commission.

**Attachment 1** includes Frequently Asked Questions about the PTAC.

b. National Changes to the Pharmacy Technician Certification Board (PTCB)

Relevant Law

Business and Professions Code Section 4202 establishes the general requirements for an applicant seeking licensure as a pharmacy technician.

Background

Currently law creates several pathways to licensure as a pharmacy technician including certification by the Pharmacy Technician Certification Board (PTCB).

The Pharmacy Technician Certification Board (PTCB) starting implementing changes to the certification program in 2014 and will continue through 2020. The changes are designed to advance pharmacy technician qualifications by elevating PTCB's standards for certification and recertification. Details of the changes are below.

*Certification Changes:*

- Completion of an ASHP-accredited pharmacy technician education program by 2020

*Recertification Changes:*

- One hour of medication safety continuing education (CE) by 2014. This is in addition to the one hour of law CE currently required.
- Twenty hours of pharmacy technician-specific CE by 2015. As part of this implementation, PTCB will gradually reduce the number of hours that can be earned via college/university coursework as well as the number of hours that can be earned through in-services.

Additional information about the changes to the certification program is in **Attachment 2**.

**3. Discussion of Pharmacy Technician Licensure Requirements and Practice**

Relevant Law

Business and Professions Code Section 4038 defines a pharmacy technician as an individual who assists a pharmacist in a pharmacy in the performance of his or her pharmacy related duties as specified.

Business and Professions Code Section 4202 establishes the general requirements for an

applicant seeking licensure as a pharmacy technician.

Title 16 CCR Section 1793 provides additional context to the definition of a pharmacy technician including the duties that are performed (packaging, manipulative, repetitive or other nondiscretionary tasks related to the processing of a prescription in a pharmacy) under the direct supervision and control of a pharmacist.

Title 16 CCR 1793.2 further details the nondiscretionary tasks including:

- Removing the drug or drugs from stock
- Counting, pouring, or mixing pharmaceuticals
- Placing the product into a container
- Affixing the label or labels to the container
- Packaging and repackaging

Title 16 CCR 1793.5 provides the application requirements for a pharmacy technician license including:

- Identifying information
- Description of qualifications and supporting documentation
- Criminal background check
- Self-Query from the National Practitioner Data Bank

Title 16 CCR 1793.6 provides the requirements for acceptable training courses as one of the pathways to licensure as a pharmacy technician licensure.

- Training program accredited by the American Society of Health-System Pharmacists (ASHP)
- Training program provided by a branch of the federal armed services
- Course that provides training period of at least 240 hours of instruction covering specified areas of pharmacy practice.

Title 16 CCR 1793.7 establishes the requirements for pharmacies employing pharmacy technicians. The section includes provisions that the supervising pharmacist is fully aware of all activities of a pharmacy technician under his or her direct supervision. Further this section provides that a pharmacist shall be responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk to patients. This section also establishes the pharmacist to pharmacy technician ratio.

Title 16 CCR 1793.8 establishes the “technician check technician” program in acute care inpatient hospital pharmacy settings.

### Background

For several meetings the board has discussed different facets of the pharmacy technician program. Most recently, during the April 2015 Board Meeting, the board discussed their desire to raise the bar to qualify for licensure as a pharmacy technician. The board also

expressed concern with the training programs that are accepting students with criminal backgrounds, who will likely not become licensed. The board also requested that the committee consider the possibility of creating different types of pharmacy technician licensure (i.e., hospital, compounding, community, etc.).

#### During this Meeting

Chairperson Weisser will guide the discussion as the committee assesses the pharmacy technician licensure requirements and practice.

**Attachment 3** includes copies of the law for the above referenced sections.

#### **4. North American Pharmacist Licensure Examination (NAPLEX) Changes**

##### Relevant Law

Business and Professions Code Section 4200 establishes the requirements for pharmacist licensure, including a passing score on the NAPLEX examination.

##### Background

The NAPLEX examination is developed and administered by the National Associations of Boards of Pharmacy (NABP). On July 12, 2015, the NABP announced plans for enhancements across all of the NABP examination and assessment programs, including the NAPLEX. In November 2015 a new NAPLEX competency statement and a revised passing standard will be implemented. Further, the NAPLEX will make a progressive transition to a new administration model in 2016 after which the NAPLEX will increase in length from 185 items to 250 items.

Additional changes to the NAPLEX scoring are being evaluated as well; however, there is no proposal yet for state boards of pharmacy to consider.

**Attachment 4** includes the article detailing the changes to the NAPLEX as well as the basis for the recommendations.

#### **5. Accreditation Council for Pharmacy Education (ACPE) Updates of Curriculum Requirements**

##### Background

The Accreditation Council for Pharmacy Education (ACPE) is the national agency for the accreditation of professional degree programs in pharmacy. During its January 2015 meeting the ACPE Board of Directions announced its approval of new *Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor in Pharmacy Degree ("Standards 2016")*. In its press release the ACPE noted the following:

*"Standards 2016 are employed for quality assurance so graduates of pharmacy education programs are practice-ready and team-ready and therefore, prepared to directly provide*

*patient care in collaboration with other healthcare providers. Standards 2016 articulate the expectations of ACPE, the academy, the practice communication, and the U.S. Department of Education and are solidly based on evidence and experience.”*

The new standards and guidance will become effective July 1, 2016 and will be used in accreditation reviews beginning September 2016.

#### During this Meeting

The committee will hear a presentation from Dr. Peter Vlasser, Executive Director, ACPE, on the new standards.

A copy of the press release and new standards are provided in **Attachment 5**.

### **6. Implementation of Pharmacy Curriculum Outcomes Assessment (PCOA) to be used by Schools of Pharmacy**

#### Background

On June 23, 2015, the NABP released updated information about the status of implementation of the Pharmacy Curriculum Outcomes Assessment (PCOA) to all schools and colleges of pharmacy. In its release, the NABP indicates that administration of the PCOA at or near the end of the didactic curriculum will be at no cost. However if a school chooses to schedule a second administration for students the current fee of \$75.00 will apply.

NABP notes that the PCOA provides a valid and reliable assessment of student competency in four board science domains:

- Biomedical science
- Pharmaceutical science
- Social/Behavioral/Administrative science
- Clinical science

Although this assessment tool is not new, it will now be integrated into all colleges and schools of pharmacy consistent with ACPE standards. In addition the PCOA will be adjusted moving forward to conform to all of the new ACPE standards.

**Attachment 6** includes a memo from the NABP with information about the PCOA.

### **7. Competency Committee Report**

#### Examination Development

The competency committee held its annual meeting in August to discuss examination development as well as to begin the transition to the new content outline of the examination. It is anticipated that the new content outline will go into effect in early 2016.

Effective August 1, 2015 the board instituted a quality assurance review of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). This means that

during the quality assurance review, there is a delay in the release of all CPJE examination scores. This process is done periodically to ensure the reliability of the examination. The board anticipates the results to be released approximately October 31, 2015.

## **8. Advanced Practice Pharmacist (APP) Licensure (As Established in SB 493) - - Discussion on Qualifying Methods**

At the July Board Meeting, the board initiated a rulemaking to adopt the first requirements for advanced practice pharmacist licensure. The 45-day comment period for this regulation ends on September 14, 2015.

At this meeting, the committee will initiate discussions on additional routes of qualification for APP licensure. A group of three entities (CPhA, NACDS, and CRA) has asked for an opportunity to continue the discussion started at a prior meeting on a community pharmacy-based qualification program.

**Attachment 7** provides materials for the proposed program developed by the proponents. There will be a presentation and discussion time allocated for the committee to discuss this proposal with the proponents.

Also included at the back of **Attachment 7** are background materials previously reviewed by the SB 493 Implementation Committee and by the board at prior meetings that provide background on certificate programs, certification programs and credentialing programs.

The statutory provision that creates advanced practice pharmacist licensure provides that one route of qualification is via certification in a relevant area of practice (see section (a)(2)(A) below, highlighted). The board's pending regulation accepts pharmacist certification programs that have been accredited by the National Commission for Certification Agencies.

### **4210. Advanced Practice Pharmacist License**

(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).

## **9. Pending Regulations Related to Implementation of SB 493**

Senate Bill 493 requires that the board adopt a number of regulations, and in several cases, the board determined that promulgation of additional regulations should occur. The board's efforts are aimed at completing the adoption process for the regulations as close to January 2016 as possible.

Below is the status of the regulations:

### Waiting to be noticed for the initial 45-day comment period:

- travel medications

### Undergoing the initial 45-day comment period:

- APP licensure requirements (comments end Sept. 14)
- Vaccinations (comments end Sept. 7)

### Undergoing 15-day comment period:

- Permanent adoption of Naloxone protocol

### Board adopted and undergoing Administration review:

- Nicotine replacement products

### Needing return to Medical Board for approval:

- Hormonal contraception protocol

### Currently in effect:

- Emergency adoption of naloxone protocol

## **10. Pharmacy Application Requirements**

During the meeting staff will provide a presentation on the requirements for a completed pharmacy application.

## **11. Status of Implementation of Legislation (AB 2605) Regarding Third-Party Logistics Providers**

### Relevant Law

Business and Professions Code section 4160 and 4161 establishes the licensure requirements for Third-Party Logistics Providers. Business and Professions Code section 4053.1 establishes the licensure requirements for Designated Representatives – 3PL.

### Background

Effective January 1, 2015, the board implemented licensing Third-Party Logistics Providers in state and out of state as well as Designated Representatives-3PL based on the recent change in federal legislation that expressly states 3PLs cannot be licensed as wholesalers but as a unique licensure class.

### Current Status

In December 2014, the board received its first nonresident Third-Party Logistics Provider application. Staff initially processed the applications received for Third-Party Logistics Providers and Designated Representative – 3PL manually during the programming of the licensing category in the Applicant Tracking System (ATS) and the Consumer Affairs System (CAS). The board issued its first nonresident Third-Party Logistics Provider and Designated Representative – 3PL licenses in February 2015. The board issued temporary license numbers to these licensees until the department completed its programming of establishing these license types in ATS and CAS, which was fully migrated in May 2015.

As of July 31, 2015, the board has issued a total of 45 Designated Representative – 3PL licenses, 3 Third-Party Logistics Provider licenses, and 10 Nonresident Third-Party Logistics Providers licenses. For additional statistical information, please reference the licensing stats provided in the licensing packet. Additionally, consumers are able to verify these license types on the board’s web site.

The board is continuing to educate applicants and other states about the requirements for these three new license categories. On April 17, 2015, the board sent out a subscriber alert on “Guidance for Third-Party Logistics Providers Currently Licensed as Drug Wholesalers” in order inform consumers and licensees of the new law and to provide guidance on the licensure requirements.

## **12. Licensing Statistics**

### Licensing Statistics for July 1, 2015 – July 31, 2015

As of July 31, 2015 the board has 138,695 licensees, including almost 42,700 pharmacists and almost 74,800 pharmacy technicians. Unfortunately updated figures are not available at the time of this report, but should be available to provide during the committee meeting.

The board has received 3,013 applications and issued 2,546 licenses during the first two months of the fiscal year. The board has denied 22 applications during this time frame. In addition, the board received 4,474 status inquiries via e-mail and responded to 3,959. A

copy of the Licensing Statistics is provided in **Attachment 8**.

During the July Board Meeting, the board discussed processing times for various application types. Staff shared some challenges with retrieving this information from the existing computer system and reported that staff had requested assistance from the department to develop a more robust report. Board staff was recently advised that this report will not be available until December.

In the interim, in an attempt to provide general processing information by license type, the below reflects the current processing time for new applications. The times below reflect from the time an application is received by the board through the time either a deficiency letter is issued or a license is issued. If an incomplete application is received, there will be additional processing time involved.

<b>Site Application Type</b>	<b>Number of Days</b>
Pharmacy	29
Nonresident Pharmacy	40
Sterile Compounding	17
Nonresident Sterile Compounding	15
Hospital	15
Clinic	40
Wholesaler	22
Nonresident Wholesaler	29
Third-Party Logistics Provider	15
Nonresident Third-Party Logistics Provider	15

<b>Individual Application Type</b>	<b>Number of Days</b>
Pharmacist Exam	40
Pharmacist Initial License	7
Pharmacy Technician	35
Intern Pharmacist	20
Designated Representative	22
Designated Representative – 3PL	12

In addition, the processing time for evaluating deficiency mail is averaging between 35 days to 13 days depending on the license type.

**13. Request for a Waiver Under California Business and Professions Code Section 4118 Pertaining to Licensure as a Centralized Hospital Packaging Pharmacy, Sections 4128 et seq. Requests Are from Three Hospitals:**

Background

In 2012 the California Society of Health System Pharmacists and the California Hospital Association sponsored legislation to establish a centralized hospital packaging license which

would allow a hospital chain under common ownership to consolidate packaging operations into a single location in a specialized pharmacy to prepare single dose medications that are barcoded. The specific provisions were contained in AB 377 (Solorio, Chapter 687, Statutes of 2012).

Included in the provisions of this measure was the requirement that the unit dose medications filled by the centralized hospital packaging license be barcoded to be readable at the inpatient's bedside and specifies the information that must be retrievable when the barcode is read. The board supported this measure and actively advocated for its passage because of the significant positive impact the use of barcoding would have on the reduction of medication errors that occur in hospitals. Specifically, the board's letter to the governor included the following:

*"...Bar coding is important for patient safety. Before a medication is administered to a patient, by scanning the bar code on a medication, a patient's chart and a patient's wristband the right medication, in the right dose will be ensured at the patient's bedside. This provides an important step forward to improve patient safety and decrease the rate of medication errors and potential adverse drug events..."*

Since January 2014, the board has considered and approved seven requests from hospitals seeking an exemption to allow them to secure a centralized packaging license – where the board has interpreted the barcode requirements specified in Section 4128.4 more broadly to allow additional time following licensure for the hospitals to fully comply with the requirements of the statute.

#### Recent Update

Assembly Bill 486 (Bonilla, Chapter 241, Statutes of 2015) was signed by the governor on September 2, 2015. As AB 486 contained an "Urgency" clause; upon the Governor's signature and upon filing with the Secretary of State, the new law will be in effective, thereby making the waivers sought unnecessary.

**Attachment 9** includes the chaptered version of the measure.

#### **14. Discussion on Waivers Previously Granted by the Board Pursuant to Business and Professions Code Section 4118 Relating to Centralized Hospital Packaging Licensing**

As discussed in the previous agenda item, the initial legislation for Centralized Hospital Packaging Licensing included requirements that could not be satisfied because to technology implementation. In recognition of the benefits to patient care such a license would offer to patients admitted to hospitals, the board has considered and granted several waiver requests to exempt certain elements of the technology requirements if the elements could otherwise be achieved. These waivers have been granted for a five-year period.

Assembly Bill 486 (Bonilla) is legislation that would address these impediments on a

permanent basis. Specifically, AB 486 will amend the language in section 4028.4 to require that any unit dose medication produced by a centralized hospital packaging pharmacy shall be barcoded to be “machine readable” at the inpatient’s bedside with software that shall permit the health care practitioner to ensure that, before a medication is administered to the inpatient, it is the right medication, for the right inpatient, in the right dose, and being administered via the right route. The board has a support position on this measure and was recently signed by the governor.

This legislation contains an urgency clause which will make the provisions effective immediately. Should this occur the committee and board need to decide how best to address the waivers previously granted.

Staff Recommendation

Staff prepares correspondence advising appropriate parties that because of changes in the law, the waiver is no longer necessary. The committee and board may choose to also include as part of this correspondence that we encourage development in technology to address the current limitations and to ultimately achieve all of the bar coding requirements originally envisioned in AB 377 (Solario, Chapter 687, Statutes of 2012).

**15. Future Committee Meeting Dates for 2016**

The following dates have been established for future meetings:

January 6, 2016

March 30, 2016

May 26, 2016

September 21, 2016

# Attachment 1

# Pharmacy Technician Accreditation Commission

A Collaboration between the  
American Society of Health System Pharmacists and the  
Accreditation Council for Pharmacy Education

## Frequently Asked Questions

### 1. What is this new Commission?

The Pharmacy Technician Accreditation Commission (PTAC) is being formed through a new collaboration between ASHP and ACPE and will serve both boards of directors as the accrediting review committee for pharmacy technician education and training programs. Since 1982, ASHP has served the role of accreditor of such programs and was advised through the work of its Commission on Credentialing. Starting in fall 2014, both ASHP and ACPE Boards of Directors will act on the accreditation recommendations from PTAC.

### 2. Why was this new Commission formed? What is the benefit?

Since its inception in 1932, ACPE has accredited professional degree programs in pharmacy and plays an important role in assuring the quality of pharmacy education. ASHP has accredited pharmacy technician programs since 1982, serving as the only pharmacy profession programmatic accreditor for technician education and training programs. In 2013, ASHP had 258 programs in the accreditation process. The need for standardized, quality, accredited training of technicians continues to be recognized by employers and pharmacists in all pharmacy settings. Many have suggested that ACPE should be involved in accrediting technician education and training programs, given their role in accrediting Doctor of Pharmacy degree programs. This collaboration brings together ACPE's expertise along with ASHP's strength of accrediting pharmacy technician education and training programs to form PTAC and a joint approval process to move the profession forward in addressing pharmacy technician accreditation. The collaboration is a win-win for both technician programs and for those who will benefit from the work of pharmacy technicians. It is believed that ACPE's involvement in the process will help bring wider acceptance and demand for accredited training across pharmacy and the health care continuum.

### 3. What will the new Commission mean to existing technician training programs accredited by ASHP?

Those programs currently accredited by ASHP will transition over to be granted accreditation by both ASHP and ACPE effective fall 2014. In the beginning programs will remain on their same accreditation cycle (surveyed every six years), and will not need to go through an additional survey or provide an additional report at the beginning of this transition. Programs scheduled for survey through May 31, 2014 will still be reviewed by the ASHP Commission on Credentialing, just prior to the transition to PTAC.

**4. What will happen with new programs or those scheduled for survey after May 2014?**

Unaccredited training programs seeking to become accredited will apply for accreditation through a process similar to the past with ASHP, but the accreditation review and recommendation process will be through PTAC instead of the ASHP Commission on Credentialing. Surveys will continue to be scheduled by ASHP, reports will continue to be sent to ASHP, however all accreditation recommendations will be made based on survey findings and recommendations by PTAC. Recommendations from PTAC will be reviewed and approved by both the Board of Directors at ASHP and ACPE. In the interim, programs being surveyed between now and May 31, 2014 will have their accreditation considered by the ASHP Commission on Credentialing. Existing programs that have surveys scheduled after May 2014 will continue as scheduled; however, be reviewed by PTAC.

**5. What standards will be used by the PTAC?**

PTAC will use the ASHP *Accreditation Standards for Pharmacy Technician Education and Training Programs* (<http://www.ashp.org/PharmTechAccred2014>) approved in April 2013 that go into effect in January 2014. The ACPE Board of Directors has adopted the new ASHP standards to initiate the collaboration. Procedures for accreditation under the new collaboration will be adapted from ASHP's *Regulations on Accreditation of Pharmacy Technician Training Programs*. Moving forward, PTAC will revise and update standards and policies/regulations periodically following best practices for accreditation, and eventually will create all changes to the standards and policies/regulations, with approval from the ASHP and ACPE Boards.

**6. What role will the ASHP Commission on Credentialing play with technician programs?**

The ASHP COC will continue to review technician programs and survey results through August 2014. Following that time, all related accreditation recommendations to both the ASHP and ACPE Boards regarding pharmacy technician programs will be through the PTAC. The ASHP Commission on Credentialing will then only review pharmacy residency programs for accreditation decisions.

**7. What role will ASHP have with the new Commission?**

ASHP will continue to schedule accreditation surveys, and prepare information for the Pharmacy Technician Accreditation Commission. Accreditation fees will continue to be paid to ASHP to run the operations related to accreditation for PTAC. Any inquiries about the pharmacy technician accreditation process can still be sent to ASHP Accreditation Services at [ASD@ashp.org](mailto:ASD@ashp.org). Additionally, since ASHP is part of the collaboration, the ASHP Board of Directors will approve accreditation actions through PTAC instead of the Commission on Credentialing.

**8. What role will ACPE have with the new Commission?**

ACPE will collaborate with ASHP on the appointment of PTAC members and both organizations will provide staff support and a board liaison for PTAC. ACPE along with ASHP will develop a nominating committee to make recommendations for Commission

appointments; will provide communications about PTAC to various stakeholder groups; and provide education to state boards of pharmacy, regulatory bodies or other groups about the value of accreditation in assuring quality pharmacy technician education and training. Like ASHP, the ACPE Board of Directors will need to approve any recommendations made by PTAC.

**9. How many Commissioners will be on PTAC?**

PTAC will consist of 9 voting members and 3 non-voting members. Members will be considered from pharmacists and pharmacy technicians who bring experience and perspectives from a wide variety of pharmacy practice areas (e.g. community, health-system, long term care), pharmacy technician educators from a variety of settings, pharmacists involved in the regulation of the profession, and a public member. In addition there will be 3 non-voting members: a secretary staff member from ASHP or ACPE, as well as board liaisons from ASHP and ACPE.

**10. How will Commissioners be identified to become members of PTAC?**

A nominating committee will be made up of 3 ASHP and 3 ACPE appointees. The nominating committee will put forth a slate of candidates for appointment to PTAC, and the individuals must be approved by both the ASHP and ACPE Board of Directors. The nominating committee will seek candidates through a call for names to the general pharmacy community with specific requests to member organizations that are relevant stakeholders (e.g., Joint Commission of Pharmacy Practitioners (JCPP) organizations), and relevant pharmacy technician communities (e.g., Pharmacy Technician Educators Council, and other pharmacy technician organizations).

**11. What is the length of appointment to PTAC?**

Full terms will be for three years. Commissioners can be appointed for two terms in a row (i.e., maximum of 6 years). Initially, some Commissioners will be asked to have shortened terms of office, to ensure a manageable roll over of appointees each year.

**12. What are the requirements to be considered as a Commissioner for PTAC?**

Each Commissioner, with the exception of public members, must have expertise and experience in quality assurance of pharmacy technician education and training and/or the contemporary education, training or practice of pharmacy technicians. The ASHP and ACPE Boards will ensure the composition of PTAC reflects a commitment to diversity and geographic representation. All prospective Commissioners will be required to complete a disclosure form for any potential conflicts before they are recommended for appointment or review any programs.

**13. What functions will PTAC have?**

All recommendations of PTAC related to the following functions will be approved by both the ASHP and ACPE Board of Directors. PTAC will:

- Review applications for accreditation of pharmacy technician education and training programs.

- Evaluate pharmacy technician education and training programs for recommendations on accreditation status.
- Make recommendations regarding standards, policies and procedures and other matters related to PTAC activities and accreditation services.
- Assist in strategic planning in matters related to pharmacy technician education and training accreditation.
- Identify potential activities and collaborative opportunities.
- Solicit and receive input and advice from other stakeholders to obtain a broad perspective to help assure the quality, validity and improvement of ASHP/ACPE Accreditation Standards, activities and services.

**14. What responsibilities will Commissioners have?**

- Prepare for and participate in PTAC meetings
- Ensure effective planning and implementation of the PTAC functions
- Participate in on site surveys.

**15. How often will PTAC meet?**

PTAC will meet at least twice a year. Infrequently, additional meetings (in person or telephonic) of PTAC may be convened when needed to conduct business.

# Attachment 2

# Pharmacy Technician Certification Board

## Certification Program Changes

The Pharmacy Technician Certification Board (PTCB) is implementing changes to the PTCB Certification Program beginning in 2014 and continuing through 2020. These new changes advance pharmacy technician qualifications by elevating PTCB's standards for certification and recertification.

PTCB requirements have remained largely unchanged since the organization's founding in 1995. The Board of Governors decisions to implement program changes were initiated by a 2011 summit focused on five areas related to pharmacy technicians: *Consumer Awareness, Resources, Education, State Policy and Testing* (C.R.E.S.T.). Summit findings, combined with results from two profession-wide surveys, called for PTCB and the pharmacy profession to make decisive changes in certification standards.

PTCB engaged stakeholders and the pharmacy community by collecting feedback on the new requirements through May 2013.

## Program Changes

### Certification

To qualify for PTCB certification, each new candidate must complete a(n):

- Criminal background check by a future date to be announced\*
- ASHP-accredited pharmacy technician education program by 2020

### Recertification

To qualify for PTCB recertification, each Certified Pharmacy Technician (CPhT) must complete:

- One hour of medication safety continuing education (CE) by 2014
- Twenty hours of *pharmacy technician-specific* CE by 2015

The number of CE hours accepted will be modified for those earned:

- Via college/university coursework—from 15 to 10 hours by 2016
- Through in-services—from 10 to 5 hours in 2015, and from 5 to 0 in 2018

## PTCB Certification Program

### Criminal Background Checks\*

Criminal background checks will be required for new candidates applying for PTCB certification by a future date to be announced.\*

*Description and Proposed Plan:*

In a March 2012 survey, 88% of 17,400 respondents recommended that PTCB require background checks for technicians applying for the PTCB Certification Program. Many employers already require background checks as a condition of employment.

- Work with state boards of pharmacy and ASHP-accredited pharmacy technician education programs to determine how to synchronize existing systems and most efficiently implement background checks for new PTCB candidates.
- Collaborate with the National Association of Boards of Pharmacy (NABP) to integrate and standardize systems.
- Conduct research regarding the processing and cost implications of background checks.

***\*UPDATE: As of December 2014, PTCB has decided not to broaden our role by requiring criminal background checks for initial applicants.***

### **ASHP-Accredited Pharmacy Technician Education Program**

Successful completion of an American Society of Health-System Pharmacists (ASHP) accredited pharmacy technician education program will become a requirement for initial PTCB certification.

#### *Description and Proposed Plan:*

Leaders in the profession have demonstrated a desire for pharmacy technicians to follow the same credentialing model as pharmacists by becoming certified and registered with the state. Pharmacists are required to graduate from an accredited pharmacy school before they sit for the NAPLEX board exam and become licensed by their state board of pharmacy.

The number of ASHP-accredited pharmacy technician education programs is growing in both community and hospital settings. ASHP-accredited programs include practical experience in addition to didactic course work, thereby providing well-rounded training for technicians. Many large employers have also begun developing their own training programs and seeking ASHP accreditation. In the March 2012 survey, 78% of respondents agreed that 2020 is a reasonable year by which to implement accredited education.

- National pharmacy technician associations will be consulted to successfully complete this transition.
- This requirement will affect new individuals applying for national certification following the implementation date. It will not affect already certified pharmacy technicians applying for PTCB recertification or reinstatement.

### **PTCB Recertification Program**

### **Medication Safety CE (Equivalent to Patient Safety CE)**

As part of the 20 hours of CE currently required for PTCB recertification, CPhTs will need to complete one CE hour of medication safety (equivalent to patient safety, as defined by ACPE as topic 05) by 2014, in addition to the one hour of law CE currently required.

#### *Description and Proposed Plan:*

Pharmacy technicians assist pharmacists with duties that impact patient care and safety. It is important that technicians continue to be educated on how their routine responsibilities shape the medication distribution system. By learning to identify potential errors in the system and how to report these, pharmacy technicians can affect the medication safety culture within pharmacies. 89% of respondents to the March 2012 survey supported this decision.

- Encourage pharmacy associations and other national CE providers to create patient safety CE programs specifically for pharmacy technicians.
- Highlight new patient safety CE programs on [ptcb.org](http://ptcb.org).

### **Pharmacy Technician-Specific CE**

PTCB will require all CE hours to be *pharmacy technician-specific* by 2015.

#### *Description and Proposed Plan:*

It is important for pharmacy technicians to be educated through programs designed specifically to address their responsibilities and knowledge requirements in the workplace. Many CE providers currently offer pharmacy-technician specific CE, with others looking to expand their offerings.

In order to qualify for this designation, CE programs must have pharmacy technician-specific objectives written for the course. An acceptable CE program may have two sets of objectives written for it, one for pharmacists and one for pharmacy technicians.

Pharmacy technician-specific objectives will be based upon the Accreditation Council for Pharmacy Education (ACPE) CE designations; however, PTCB will not require programs to be offered only by ACPE-accredited providers.

- Work with CE providers to encourage the creation of pharmacy technician- specific objectives for all CE programs.
- Continue to feature CE programs for pharmacy technicians on [ptcb.org](http://ptcb.org).

### **Acceptable CE: College Courses**

PTCB will reduce the number of CE hours that can be earned via college/university coursework from 15 to 10 by 2016.

*Description and Proposed Plan:*

Due to the importance of pharmacy technicians completing technician-focused CE, leaders from the pharmacy profession encouraged greater emphasis on attaining technician-specific knowledge, with less allowance for broad academic courses.

PTCB will educate technicians eligible for recertification and reinstatement prior to their certification expiration dates.

**Acceptable CE: In-Service Courses**

PTCB will reduce the allowable number of CE hours to be earned through in-services from 10 to 5 in 2015, and from 5 to 0 in 2018.

*Description and Proposed Plan:*

It is important that pharmacy technicians be educated through quality, standardized CE programs. In-service CEs will be phased out to eliminate inconsistencies.

- Work with employers through the target implementation date to standardize the information being provided through in-services.
- Educate technicians eligible for recertification and reinstatement prior to their certification expiration dates.

**Online Comment Period**

PTCB conducted an open comment period through May 2013, inviting members of the pharmacy community to share feedback and insight on implementing the new requirements. Visit [ptcb.org](http://ptcb.org) for more information and access to the feedback form.

**Open Forums**

PTCB plans to work closely with educators, employers, boards of pharmacy, and state/national organizations to best implement these decisions. During 2013, PTCB asked for live feedback from pharmacy technicians and stakeholders at the following open forums across the country:

**American Pharmacists Association (APhA) Annual Meeting and Exposition 2013**

Session: Sunday, March 3 from 2:00-3:00 pm in room 153B, in Los Angeles, CA

**California Pharmacists Association West Coast Pharmacy Exchange**

Session: Sunday, March 17 from 5:00-6:00 pm, in Monterey, CA

**South Carolina Society of Health-System Pharmacists (SCSHP) 2013 Annual Meeting**

Sessions: Sunday, March 24 & Monday, March 25 from 3:30-4:30 pm, in Charleston, SC

**Pharmacy Society of Wisconsin (PSW) Educational Conference**

Session: Thursday, April 18 from 1:00-2:00 pm, in Madison, WI

**North Dakota Pharmacists Association (NDPhA) Annual Convention**

Session: Friday, April 26, in Dickinson, ND

**Texas Society of Health-System Pharmacists (TSHP) 2013 Annual Meeting**

Session: Saturday, April 27 in Austin, TX

# Attachment 3

**Business and Professions Code Section 4038(a)**

"Pharmacy technician" means an individual who assists a pharmacist in a pharmacy in the performance of his or her pharmacy related duties, as specified in Section 4115.

**Title 16 CCR Section 1793 - Definition**

"Pharmacy technician" means an individual who, under the direct supervision and control of a pharmacist, performs packaging, manipulative, repetitive, or other nondiscretionary tasks related to the processing of a prescription in a pharmacy, but who does not perform duties restricted to a pharmacist under section 1793.1. Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code. Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

**Title 16 CCR Section 1793.2. - Duties of a Pharmacy Technician.**

"Nondiscretionary tasks" as used in Business and Professions Code section 4115, include:

- (a) removing the drug or drugs from stock;
- (b) counting, pouring, or mixing pharmaceuticals;
- (c) placing the product into a container;
- (d) affixing the label or labels to the container;
- (e) packaging and repackaging.

**Title 16 CCR Section 1793.2. - Duties of a Pharmacy Technician.**

"Nondiscretionary tasks" as used in Business and Professions Code section 4115, include:

- (a) removing the drug or drugs from stock;
- (b) counting, pouring, or mixing pharmaceuticals;
- (c) placing the product into a container;
- (d) affixing the label or labels to the container;
- (e) packaging and repackaging.

**Title 16 CCR Section 1793.3. - Other Non-Licensed Pharmacy Personnel.**

(a) In addition to employing a pharmacy technician to perform the tasks specified in section 1793.2, a pharmacy may employ a non-licensed person to type a prescription label or otherwise enter prescription information into a computer record system, but the responsibility for the accuracy of the prescription information and the prescription as dispensed lies with the registered pharmacist who initials the prescription or prescription record. At the direction of the registered pharmacist, a non-licensed person may also request and receive refill authorization.

(b) A pharmacist may supervise the number of non-licensed personnel performing the duties specified in subdivision (a) that the pharmacist determines, in the exercise of his or her professional judgment, does not interfere with the effective performance of the pharmacist's responsibilities under the Pharmacy Law.

(c) A pharmacist who, exercising his or her professional judgment pursuant to subdivision (b), refuses to supervise the number of non-licensed personnel scheduled by the pharmacy, shall notify the pharmacist-in-charge in writing of his or her determination, specifying the circumstances of concern with respect to the pharmacy or the non-licensed personnel that have led to the determination, within a reasonable period, but not to exceed 24 hours, after the posting of the relevant schedule.

(d) No entity employing a pharmacist may discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this section.

**Title 16 CCR Section 1793.5. - Pharmacy Technician Application.**

The "Pharmacy Technician Application (Form 17A-5(Rev. 01/11)), incorporated by reference herein, required by this section is available from the Board of Pharmacy upon request.

(a) Each application for a pharmacy technician license shall include:

(1) Information sufficient to identify the applicant.

(2) A description of the applicant's qualifications, and supporting documentation for those qualifications.

(3) A criminal background check that will require submission of fingerprints in a manner specified by the board and the fee authorized in Penal Code section 11105(e).

(4) A sealed, original Self-Query from the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) dated no earlier than 60 days of the date an application is submitted to the board.

(b) The applicant shall sign the application under penalty of perjury and shall submit it to the Board of Pharmacy.

(c) The board shall notify the applicant within 30 days if an application is deficient; and what is needed to correct the deficiency. Once the application is complete, and upon completion of any investigation conducted pursuant to section 4207 of the Business and Professions Code, the board will notify the applicant within 60 days of a license decision.

(d) Before expiration of a pharmacy technician license, a pharmacy technician must renew that license by payment of the fee specified in subdivision (r) of section 4400 of the Business and Professions Code.

**Title 16 CCR Section 1793.6. - Training Courses Specified by the Board.**

A course of training that meets the requirements of Business and Professions Code section 4202 (a)(2) is:

(a) Any pharmacy technician training program accredited by the American Society of Health-System Pharmacists,

(b) Any pharmacy technician training program provided by a branch of the federal armed services for which the applicant possesses a certificate of completion, or

(c) Any other course that provides a training period of at least 240 hours of instruction covering at least the following:

(1) Knowledge and understanding of different pharmacy practice settings.

(2) Knowledge and understanding of the duties and responsibilities of a pharmacy technician in relationship to other pharmacy personnel and knowledge of standards and ethics, laws and regulations governing the practice of pharmacy.

(3) Knowledge and ability to identify and employ pharmaceutical and medical terms, abbreviations and symbols commonly used in prescribing, dispensing and record keeping of medications.

(4) Knowledge of and the ability to carry out calculations required for common dosage determination, employing both the metric and apothecary systems.

(5) Knowledge and understanding of the identification of drugs, drug dosages, routes of administration, dosage forms and storage requirements.

(6) Knowledge of and ability to perform the manipulative and record-keeping functions involved in and related to dispensing prescriptions.

(7) Knowledge of and ability to perform procedures and techniques relating to manufacturing, packaging, and labeling of drug products.

**Title 16 CCR Section 1793.7. - Requirements for Pharmacies Employing Pharmacy Technicians.**

(a) Except as otherwise provided in section 1793.8, any function performed by a pharmacy technician in connection with the dispensing of a prescription, including repackaging from bulk and storage of pharmaceuticals, must be verified and documented in writing by a pharmacist. Except for the preparation of

prescriptions for an inpatient of a hospital and for an inmate of a correctional facility, the pharmacist shall indicate verification of the prescription by initialing the prescription label before the medication is provided to the patient.

(b) Pharmacy technicians must work under the direct supervision of a pharmacist and in such a relationship that the supervising pharmacist is fully aware of all activities involved in the preparation and dispensing of medications, including the maintenance of appropriate records.

(c) A pharmacy technician must wear identification clearly identifying him or her as a pharmacy technician.

(d) Any pharmacy employing or using a pharmacy technician shall develop a job description and written policies and procedures adequate to ensure compliance with the provisions of Article 11 of this Chapter, and shall maintain, for at least three years from the time of making, records adequate to establish compliance with these sections and written policies and procedures.

(e) A pharmacist shall be responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients.

(f) For the preparation of a prescription for an inpatient of a licensed health facility and for a patient of a licensed home health agency, the ratio shall not be less than one pharmacist on duty for a total of two pharmacy technicians on duty. Pursuant to Business and Professions Code section 4115(g)(1), this ratio shall not apply to the preparation of a prescription for an inmate of a correctional facility of the Department of the Youth Authority or the Department of Corrections, or for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services, or the Department of Veterans Affairs.

#### **Title 16 CCR Section 1793.8 - Technicians in Hospitals with Clinical Pharmacy Programs.**

(a) A general acute care hospital, as defined in Health and Safety Code 1250 (a), that has an ongoing clinical pharmacy program may allow pharmacy technicians to check the work of other pharmacy technicians in connection with the filling of floor and ward stock and unit dose distribution systems for patients admitted to the hospital whose orders have previously been reviewed and approved by a licensed pharmacist. Only inpatient hospital pharmacies as defined in 4029(a) that maintain a clinical pharmacy services program as described in 4052.1 may have a technician checking technician program as described. The pharmacy shall have on file a description of the clinical pharmacy program prior to initiating a technician checking technician program.

(1) This section shall only apply to acute care inpatient hospital pharmacy settings.

(2) Hospital pharmacies that have a technician checking technician program shall deploy pharmacists to the inpatient care setting to provide clinical services.

(b) Compounded or repackaged products must have been previously checked by a pharmacist and then may be used by the technician to fill unit dose distribution systems, and floor and ward stock.

(c) To ensure quality patient care and reduce medication errors, programs that use pharmacy technicians to check the work of other pharmacy technicians pursuant to this section must include the following components:

(1) The overall operation of the program shall be the responsibility of the pharmacist-in-charge.

(2) The program shall be under the direct supervision of a pharmacist and the parameters for the direct supervision shall be specified in the facility's policies and procedures

(3) The pharmacy technician who performs the checking function has received specialized and advanced training as prescribed in the policies and procedures of the facility.

(4) To ensure quality there shall be ongoing evaluation of programs that use pharmacy technicians to check the work of other pharmacy technicians.

**Business and Professions Code Section 4202. - Pharmacy Technician: License Requirements for Education, Experience; Board Regulations; Criminal Background Check; Discipline**

(a) The board may issue a pharmacy technician license to an individual if he or she is a high school graduate or possesses a general educational development certificate equivalent, and meets any one of the following requirements:

- (1) Has obtained an associate's degree in pharmacy technology.
- (2) Has completed a course of training specified by the board.
- (3) Has graduated from a school of pharmacy recognized by the board.
- (4) Is certified by the Pharmacy Technician Certification Board.

(b) The board shall adopt regulations pursuant to this section for the licensure of pharmacy technicians and for the specification of training courses as set out in paragraph (2) of subdivision (a). Proof of the qualifications of any applicant for licensure as a pharmacy technician shall be made to the satisfaction of the board and shall be substantiated by any evidence required by the board.

(c) The board shall conduct a criminal background check of the applicant to determine if an applicant has committed acts that would constitute grounds for denial of licensure, pursuant to this chapter or Chapter 2 (commencing with Section 480) of Division 1.5.

(d) The board may suspend or revoke a license issued pursuant to this section on any ground specified in Section 4301.

(e) Once licensed as a pharmacist, the pharmacy technician registration is no longer valid and the pharmacy technician license shall be returned to the board within 15 days.

# Attachment 4



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## NABP and Member Boards of Pharmacy Continue Legacy of Innovations in Test Development

July 12, 2015 4:20 PM | Topics: [Pharmacist License](#), [Mpje](#), and [Naplex](#)

The National Association of Boards of Pharmacy® (NABP®) and its member state boards of pharmacy continue the tradition of excellence in test development with plans for enhancements across all of the NABP examination and assessment programs. The enhancements are in response to the evolving practice of pharmacy and direction from the state boards of pharmacy, who legally determine pharmacists' competence to practice and the content of the Association's licensure examinations.

The North American Pharmacist Licensure Examination® (NAPLEX®) program has recently undergone evaluations of its content and test specifications, test design and assembly, administration processes, scoring, and passing standard. The new NAPLEX competency statements and revised passing standard will be implemented in November 2015. In addition, the NAPLEX will make a progressive transition to a new administration model in 2016. At that time, the NAPLEX will increase in length from 185 items to 250 items. The recommendation to increase the depth and breadth of the NAPLEX came as a result of the national NABP Pharmacy Practice Analysis Survey conducted in 2014. Over 4,700 respondents to the Survey (pharmacy regulators, practitioners, and academicians) recognized the value in testing entry-level candidates on a variety of patient-centered, clinically based topics necessary for safe and effective practice. NABP is also reviewing a proposal to move the NAPLEX scoring results to a pass/fail platform. The benefits and concerns with such a transition must be evaluated before such an action can be proposed to the state boards of pharmacy.

In support of the need for a national evaluation of foundational knowledge in the PharmD curriculum, and in compliance with the Accreditation Council for Pharmacy Education (ACPE) *Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree (Standards 2016)* requirement, NABP will be providing the Pharmacy Curriculum Outcomes Assessment® (PCOA®) to all students nearing completion of the didactic curriculum (ie, third year or equivalent). The PCOA is the only nationally administered examination that covers the four

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- Prescription Drug Abuse
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- Prescription Monitoring Program
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- Vaccinations

foundational sciences in pharmacy curriculum as outlined by the ACPE *Standards 2016* and the 2013 Center for the Advancement of Pharmacy Education outcomes. The PCOA has been administered to over 32,000 students enrolled in ACPE-accredited PharmD programs and is used by the schools and colleges of pharmacy as evidence of student progress and growth throughout the PharmD curriculum.

Both the PCOA and the NAPLEX provide descriptive data for the schools and colleges to evaluate in relation to student performance at the program as well as the national level. In addition, aggregate outcomes from these examinations present comparisons of student performance among the various PharmD curriculums in the United States.

In collaboration with its member boards, NABP is moving forward with a communication skills assessment. The 2014 NABP Pharmacy Practice Analysis Survey provided strong evidence that pharmacist communication skills are of paramount importance for safe and effective practice and that entry-level pharmacists deficient in communication skills could place the public health at risk. In response, NABP will develop an integrated pharmacist communication skills assessment that could be used by its member boards as an additional component for licensure beginning in 2018.

Rounding out the ongoing exam development efforts, NABP conducted a review of the Multistate Pharmacy Jurisprudence Examination® (MPJE®) content domains followed by a survey of pharmacist and pharmacy regulators. The MPJE domain survey addressed the key areas required for practitioner compliance with state and federal laws and regulations. Recognizing the importance of quality control measures, sterile and nonsterile compounding regulations, and compliance with the standards of pharmacy practice, NABP has revised the MPJE content domains to reflect contemporary practice.

The current and future NABP examination and assessment programs provide the state boards of pharmacy and academic institutions with critical data to affirm preparedness for pharmacist practice and make evidenced-based evaluations and decisions for licensure. NABP is committed to high standards of excellence for test design, development, and defensibility of its programs and looks forward to collaborating with other organizations invested in the excellence of pharmacy practice.

*NABP is the independent, international, and impartial Association that assists its state member boards and jurisdictions for the purpose of protecting the public health.*

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# Attachment 5



**FOR IMMEDIATE RELEASE**

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February 3, 2014

## **ACPE Releases Draft Standards 2016**

**Chicago, IL** – The Accreditation Council for Pharmacy Education (ACPE) has released the *Draft Revised Standards for the Professional Program Leading to the Doctor of Pharmacy Degree (i.e., Draft Standards 2016)* and the Guidance Document to Standards 2016 for public review and comment. *Draft Standards 2016* are designed to ensure that graduates of pharmacy education programs are practice-ready and team-ready and therefore, prepared to directly provide patient care in collaboration with other healthcare providers. *Draft Standards 2016* articulate the expectations of ACPE, the academy, the practice community, and the U.S. Department of Education and are solidly based on evidence and experience. It is anticipated that the final *Standards 2016* would be effective in July 2016.

*Draft Standards 2016* were developed by a working group advised by input from a broad range of individuals and organizations over the past 3 years. Over a thousand interested individuals participated in the Standards revision process by responding to surveys, participating in ACPE's 2012 Invitational Conference, and sharing best practices that were the foundation of the Standards revision process. *Draft Standards 2016* integrate AACP's 2013 CAPE Educational Outcomes as a basis of its minimum requirements and are designed to assure quality in pharmacy education while allowing for educational advancement that focuses on the preparation of pharmacy graduates capable of improving healthcare.

According to Robert S. Beardsley, RPh, PhD, Past President of ACPE and Co-chair of the Standards Revision Subcommittee, "Throughout the Standards Revision Process, ACPE restructured, simplified, and clarified requirements in *Draft Standards 2016* based on stakeholder feedback and insights. The revision provides for greater flexibility and innovation in teaching, learning and assessment methods."

"ACPE proactively engaged stakeholders in the evolution of the revised Standards to ensure graduates are prepared to meet the needs and expectations of society. These revised *Draft Standards 2016* represent evolutionary change rather than revolutionary change," added Jeffrey W. Wadelin, PhD, ACPE Associate Executive Director and Co-chair of the Standards Revision Subcommittee. "Although there is a generous timeline that allows for planning, evolution, and adaptation of professional degree programs, professional degree programs in pharmacy should not wait to innovate!"

ACPE welcomes and encourages feedback on *Draft Standards 2016* from all ACPE stakeholders. Comments can be provided online, by e-mail, by mail, or through participation in open hearings at professional meetings. You can access copies of *Draft Standards 2016*, the Guidance document, an overview of how to provide feedback and a link to the online comment survey at <https://www.acpe-accredit.org/deans/2014StandardsRevision.asp>. **Interested individuals and organizations can provide comments through any of the provided mechanisms until December 15, 2014.**

### **About the Accreditation Council for Pharmacy Education**

ACPE is the national agency for the accreditation of professional degree programs in pharmacy and providers of continuing pharmacy education. In collaboration with the American Society of Health-System Pharmacists, ACPE accredits pharmacy technician education and training programs. ACPE also offers evaluation and certification of professional degree programs internationally. The mission of ACPE is to assure and advance excellence in education for the profession of pharmacy. ACPE is an autonomous and independent agency whose Board of Directors is derived through the American Association of Colleges of Pharmacy (AACP), the American Pharmacists Association (APhA), the National Association of Boards of Pharmacy (NABP), and the American Council on Education (ACE). To learn more about ACPE, visit [www.acpe-accredit.org](http://www.acpe-accredit.org) or follow us on [Facebook](#), [LinkedIn](#), and [Twitter](#).

###

**ACCREDITATION COUNCIL FOR PHARMACY EDUCATION**



**ACCREDITATION STANDARDS AND KEY ELEMENTS FOR THE  
PROFESSIONAL PROGRAM IN PHARMACY LEADING TO  
THE DOCTOR OF PHARMACY DEGREE**

**(“STANDARDS 2016”)**

**APPROVED January 25, 2015**

**RELEASED February 2, 2015**

**Accreditation Council for Pharmacy Education  
Chicago, Illinois  
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# ACCREDITATION COUNCIL FOR PHARMACY EDUCATION

## STANDARDS 2016

### *PREAMBLE*

#### **Accreditation Council for Pharmacy Education (ACPE)**

The Accreditation Council for Pharmacy Education (ACPE) is the national agency for the accreditation of professional degree programs in pharmacy and providers of continuing pharmacy education. ACPE (until 2003 known as the American Council on Pharmaceutical Education) was established in 1932 for the accreditation of professional degree programs in pharmacy, and in 1975 its scope was broadened to include accreditation of providers of continuing pharmacy education ([www.acpe-accredit.org](http://www.acpe-accredit.org)). ACPE expanded its activities to include evaluation and certification of professional degree programs internationally in 2011 and entered into a collaboration with the American Society of Health-System Pharmacists (ASHP) to accredit pharmacy technician education and training programs beginning in 2014. The mission of ACPE is to assure and advance quality in pharmacy education. ACPE is an autonomous and independent agency whose Board of Directors is appointed by the American Association of Colleges of Pharmacy (AACP), the American Pharmacists Association (APhA), the National Association of Boards of Pharmacy (NABP) (three appointments each), and the American Council on Education (ACE) (one appointment). Since the inception of its accreditation agency recognition program in 1952, the U.S. Department of Education (USDE) has continuously recognized ACPE. ACPE also gained recognition by the Council for Higher Education Accreditation (CHEA) in April 2004. State boards of pharmacy require that licensure applicants from the United States have graduated from an accredited pharmacy degree program to be eligible to sit for the North American Pharmacist Licensure Examination™ (NAPLEX®).

#### **Importance of Standards**

To achieve and maintain ACPE accreditation, professional Doctor of Pharmacy (PharmD) degree programs (hereafter described as ‘programs’) must meet the standards contained in this document. ACPE standards are minimum requirements, and it is expected that programs will exceed these required standards through initiatives designed to ensure continuous quality improvement. These standards describe the various elements needed for quality-assured professional education and are based on evidence and experience. They articulate expectations that ACPE (as well as pharmacy practice and the pharmacy academy) has of academic institutions offering the PharmD degree. ACPE standards also reflect the expectations that the U.S. Department of Education and state boards of pharmacy have of the colleges and schools, and of ACPE, regarding the quality of professional degree programs.

These standards have been developed with input from a broad range of constituents interested in and affected by pharmacy education. They focus on the educational outcomes required of PharmD programs and the assessment of those outcomes. They also address the structural and process-related elements within pharmacy education necessary to implement evidence-based outcome measures that document achievement of the standards. In addition, these standards describe areas where programs can experiment and innovate within the didactic and experiential components of their curricula to meet the required Educational Outcomes (Standards 1–4). Establishing a commitment to continuing professional development (CPD) by

students and graduates is also addressed, as are contemporary educational concepts such as student readiness to:

- Enter advanced pharmacy practice experiences (APPE-ready)
- Provide direct patient care in a variety of healthcare settings (Practice-ready)
- Contribute as a member of an interprofessional collaborative patient care team (Team-ready)

### **Revision of Standards: Background**

All accrediting bodies, including ACPE, periodically review and revise their standards. A number of environmental factors prompted ACPE to conduct a careful reassessment of the standards. These factors included:

- The experience gained by ACPE in its accreditation reviews since the adoption of the Doctor of Pharmacy standards in 2007
- Feedback from ACPE stakeholders regarding quality improvement of the standards
- The reports of the Institute of Medicine (IOM) ([www.iom.edu](http://www.iom.edu)) noting needed changes in our healthcare system to improve medication safety and patient outcomes, including the five competencies that all healthcare professionals should attain during their education:
  - Provide patient-centered care
  - Work in interprofessional teams
  - Employ evidence-based practice
  - Apply quality improvement
  - Utilize informatics
- Expansion of the scope of pharmacy practice in state laws and regulations to include collaborative practice with prescribers
- The revision of the AACP's Center for the Advancement of Pharmacy Education (CAPE) Educational Outcomes in 2013, which are intended to be the target toward which the evolving pharmacy curriculum should be aimed  
<http://www.aacp.org/resources/education/cape/Pages/default.aspx>
- The Joint Commission of Pharmacy Practitioners' (JCPP) *Vision of Pharmacy Practice*, accepted by the governing boards of 10 pharmacy organizations, including ACPE, and released in 2013  
<http://www.amcp.org/Tertiary.aspx?id=8463>
- The document *Pharmacists' Patient Care Process*, developed by a work group from 11 national pharmacy organizations to promote a consistent approach to the process of care. This document was endorsed by the Joint Commission of Pharmacy Practitioners in 2014.  
[http://www.pharmacist.com/sites/default/files/JCPP\\_Pharmacists\\_Patient\\_Care\\_Process.pdf](http://www.pharmacist.com/sites/default/files/JCPP_Pharmacists_Patient_Care_Process.pdf)
- Health Professionals for a New Century: Transforming education to strengthen health systems in an interdependent world  
[http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(10\)61854-5/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(10)61854-5/fulltext)

- Core Competencies for Interprofessional Collaborative Practice  
<http://www.aacn.nche.edu/education-resources/ipecreport.pdf>
- Revised NAPLEX Competency Statements  
<http://www.nabp.net/programs/examination/naplex/naplex-blueprint>

### **Revision of Standards: Process Employed**

In January 2012, ACPE announced to its stakeholders (including pharmacy colleges and schools, professional pharmacy organizations, student pharmacist organizations, and other accrediting bodies) its intent to revise the Doctor of Pharmacy degree standards. Written comments were solicited from stakeholders, and many were received. In addition, a Web-based survey that allowed anonymous completion was distributed to all the college or school of pharmacy deans. ACPE also held a multi-stakeholder invitational conference in fall, 2012<sup>1</sup> to discuss issues facing pharmacy practice and education. The results of the conference influenced the direction and content of these revised standards. The first draft of the revised standards was approved by the ACPE Board of Directors in January 2014 and distributed to ACPE stakeholders in February 2014. Subsequently, a series of open hearings was conducted at national pharmacy meetings. Another Web-based survey that allowed anonymous completion by stakeholders was conducted during 2014, and an extensive review of the draft standards was completed by an advisory group from various sections of the academic and practice communities. The ACPE Board of Directors approved the revised standards on **January 21–25, 2015** with an effective date of **July 1, 2016**. The new standards will be referred to as “Standards 2016.” Colleges and schools being evaluated by ACPE beginning in the fall of 2016 must comply with the new standards.

### **Revision of Standards: What’s Different?**

- *Format* – The standards revision process yielded two distinct documents: **Standards** and **Guidance**. The *Standards* document includes the 25 standards, required (key) elements, assessment elements, and required documentation for each individual standard. The *Guidance* document was developed to support colleges’ and schools’ efforts to enhance the quality of their PharmD programs and includes suggested strategies, additional examples of compliance evidence, and other important information to facilitate meeting standards. ACPE expects programs to be in compliance with all elements outlined in the *Standards* document and to use the information within the *Guidance* document to improve the quality of their programs. In other words, the *Standards* document contains required elements that all accredited Doctor of Pharmacy programs must meet, while the *Guidance* document contains clarifying statements and suggested strategies for improvement.
- *Philosophy and Emphasis* – Based on stakeholder feedback, the Standards have been refined to ensure that graduating students are “practice-ready” and “team-ready,” that is, prepared to directly contribute to patient care working in collaboration with other healthcare providers. The revision has also placed greater emphasis on critical educational outcomes identified by CAPE and the assessment of the level of student

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<sup>1</sup> Zellmer WA, Vlasses PH, Beardsley RS. Summary of the ACPE Consensus Conference on Advancing Quality in Pharmacy Education. Am J Pharm Educ. 2013; 77, 3, Article 44.

achievement of these outcomes. The Standards focus on the (1) development of students' professional knowledge, skills, abilities, behaviors, and attitudes, including scientific foundation, knowledge application, and practice competencies, (2) the manner in which programs assess students' acquisition of knowledge and application of knowledge to practice, (3) mastery of skills and achievement of competencies, and (4) the importance of both curricular and co-curricular experiences in advancing the professional development of students. Throughout the revision process, ACPE has focused on addressing the environmental factors noted above in *Revision of Standards: Background*.

- *Importance of Assessment* – Based on feedback from the academy and other stakeholders, the new Standards emphasize assessment as a means of improving the quality of pharmacy education. Having valid and reliable assessment mechanisms in place will provide additional insights to programs regarding their strengths and deficiencies. Throughout the Standards, terms such as “adequate,” “sufficient,” and “appropriate” appear in several areas. Programs are expected to utilize assessment outcome data to determine if the available resources are adequate, sufficient, etc. to allow for compliance with the Standards.
- *Organization of Standards* – Although, at a minimum, the Standards address the same critical areas as in previous versions, they have been restructured, simplified, and clarified. The Standards are organized into three major sections (Educational Outcomes; Structure and Process to Promote Achievement of Educational Outcomes; and Assessment). The Structure and Process section is further organized into four subsections: (1) Planning and Organization, (2) Educational Program for the Doctor of Pharmacy Degree, (3) Students, and (4) Resources. In the third section, Standards 24 and 25 list the assessment elements for Educational Outcomes and Structure and Process, respectively. Standards and Key Elements are phrased as declarative statements describing the various attributes of an accredited Doctor of Pharmacy program. Programs not meeting the expectations and requirements outlined within these statements will be out of compliance with the Standards. Standards annotated with an asterisk (\*) are appropriate for new program initiatives and alternate pathways to degree completion, such as an accelerated curriculum, geographically dispersed campuses, online or distance-learning-based programs, and other educational innovations. Three appendices are included within the Standards. Appendix 1 is a revision of the former Appendix B in Standards 2007 and describes the required elements of the didactic component of the PharmD curriculum. Appendix 2 (formerly Appendix C in Standards 2007) describes the expectations of the experiential learning component of the curriculum. Appendix 3 outlines the documentation needed for the Standards and Key Elements.
- *Organization of Guidance* – Materials are provided in this document to help colleges and schools of pharmacy: (1) understand the breadth and scope of issues underlying the achievement of each standard and (2) achieve academic program enhancement. Suggested strategies for quality improvement are based on evidence gleaned from the literature and/or the evaluation of successful programs.
- *Innovation* – Colleges or schools may choose avenues other than those suggested in the guidance document to achieve compliance with the Standards. In all cases, however, ACPE requires evidence that standards are being met.

- *Style* – The Chicago Manual of Style, 15<sup>th</sup> Edition, Chicago: The University of Chicago Press, 2003, was used in the preparation of the standards and guidelines.

### **Summary**

ACPE looks forward to working with colleges and schools of pharmacy during the transition to the revised professional degree program Standards. Through its strategic plan, ACPE will also be investigating opportunities for better and more standardized ways to evaluate the achievement of the Standards, including the identification of valid outcome measures to be monitored across all accredited programs. In addition, ACPE will be improving its policies and procedures to allow for greater standardization, consistency, efficiency, and effectiveness in its accreditation activities and evaluations. Feedback from ACPE stakeholders is always invited and valued.

**ACPE Board of Directors and Staff  
January 25, 2015**

## **STANDARDS AND KEY ELEMENTS**

### **SECTION I: EDUCATIONAL OUTCOMES**

The educational outcomes<sup>2</sup> described herein have been deemed essential to the contemporary practice of pharmacy in a healthcare environment that demands interprofessional collaboration and professional accountability for holistic patient well-being.

#### **Standard 1: Foundational Knowledge**

The professional program leading to the Doctor of Pharmacy degree (hereinafter “the program”) develops in the graduate the knowledge, skills, abilities, behaviors, and attitudes necessary to apply the foundational sciences to the provision of patient-centered care.

##### **Key Element:**

**1.1. Foundational knowledge** – The graduate is able to develop, integrate, and apply knowledge from the foundational sciences (i.e., biomedical, pharmaceutical, social/behavioral/administrative, and clinical sciences) to evaluate the scientific literature, explain drug action, solve therapeutic problems, and advance population health and patient-centered care.

#### **Standard 2: Essentials for Practice and Care**

The program imparts to the graduate the knowledge, skills, abilities, behaviors, and attitudes necessary to provide patient-centered care, manage medication use systems, promote health and wellness, and describe the influence of population-based care on patient-centered care.

##### **Key Elements:**

**2.1. Patient-centered care** – The graduate is able to provide patient-centered care as the medication expert (collect and interpret evidence, prioritize, formulate assessments and recommendations, implement, monitor and adjust plans, and document activities).

**2.2. Medication use systems management** – The graduate is able to manage patient healthcare needs using human, financial, technological, and physical resources to optimize the safety and efficacy of medication use systems.

**2.3. Health and wellness** – The graduate is able to design prevention, intervention, and educational strategies for individuals and communities to manage chronic disease and improve health and wellness.

**2.4. Population-based care** – The graduate is able to describe how population-based care influences patient-centered care and the development of practice guidelines and evidence-based best practices.

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<sup>2</sup> Adapted from the American Association of Colleges of Pharmacy’s Center for the Advancement of Pharmacy Education (CAPE) Educational Outcomes, 2013.

### **Standard 3: Approach to Practice and Care**

The program imparts to the graduate the knowledge, skills, abilities, behaviors, and attitudes necessary to solve problems; educate, advocate, and collaborate, working with a broad range of people; recognize social determinants of health; and effectively communicate verbally and nonverbally.

#### **Key Elements:**

- 3.1. Problem solving** – The graduate is able to identify problems; explore and prioritize potential strategies; and design, implement, and evaluate a viable solution.
- 3.2. Education** – The graduate is able to educate all audiences by determining the most effective and enduring ways to impart information and assess learning.
- 3.3. Patient advocacy** – The graduate is able to represent the patient’s best interests.
- 3.4. Interprofessional collaboration** – The graduate is able to actively participate and engage as a healthcare team member by demonstrating mutual respect, understanding, and values to meet patient care needs.
- 3.5. Cultural sensitivity** – The graduate is able to recognize social determinants of health to diminish disparities and inequities in access to quality care.
- 3.6. Communication** – The graduate is able to effectively communicate verbally and nonverbally when interacting with individuals, groups, and organizations.

### **Standard 4: Personal and Professional Development**

The program imparts to the graduate the knowledge, skills, abilities, behaviors, and attitudes necessary to demonstrate self-awareness, leadership, innovation and entrepreneurship, and professionalism.

#### **Key Elements:**

- 4.1. Self-awareness** – The graduate is able to examine and reflect on personal knowledge, skills, abilities, beliefs, biases, motivation, and emotions that could enhance or limit personal and professional growth.
- 4.2. Leadership** – The graduate is able to demonstrate responsibility for creating and achieving shared goals, regardless of position.
- 4.3. Innovation and entrepreneurship** – The graduate is able to engage in innovative activities by using creative thinking to envision better ways of accomplishing professional goals.
- 4.4. Professionalism** – The graduate is able to exhibit behaviors and values that are consistent with the trust given to the profession by patients, other healthcare providers, and society.

## **SECTION II: STRUCTURE AND PROCESS TO PROMOTE ACHIEVEMENT OF EDUCATIONAL OUTCOMES**

The Educational Outcomes articulated in Section I can only be fully achieved in an academic culture purposely designed to nurture learners and to support the administrators, faculty, preceptors, and staff who mentor them. The standards in Section II describe essential structures and processes that provide the organizational stability and potential for advancement critical to continuous quality improvement in pharmacy education.

### **Subsection IIA: Planning and Organization**

#### **Standard 5: Eligibility and Reporting Requirements**

The program meets all stated degree-granting eligibility and reporting requirements.

##### **Key Elements:**

**5.1. Autonomy** – The academic unit offering the Doctor of Pharmacy program is an autonomous unit organized as a college or school of pharmacy (within a university or as an independent entity). This includes autonomy to manage the professional program within stated policies and procedures, as well as applicable state and federal regulations.

**5.2. Legal empowerment** – The college or school is legally empowered to offer and award the Doctor of Pharmacy degree.

**5.3. Dean's leadership** – The college or school is led by a dean, who serves as the chief administrative and academic officer of the college or school and is responsible for ensuring that all accreditation requirements of ACPE are met.

**5.4. Regional/institutional accreditation** – The institution housing the college or school, or the independent college or school, has (or, in the case of new programs, is seeking) full accreditation by a regional/institutional accreditation agency recognized by the U.S. Department of Education.

**5.5. Regional/institutional accreditation actions** – The college or school reports to ACPE within 30 days any issue identified in regional/institutional accreditation actions that may have a negative impact on the quality of the professional degree program and compliance with ACPE standards.

**5.6. Substantive change** – The dean promptly reports substantive changes in organizational structure and/or processes (including financial factors) to ACPE for the purpose of evaluation of their impact on programmatic quality.

#### **Standard 6: College or School Vision, Mission, and Goals**

The college or school publishes statements of its vision, mission, and goals.

##### **Key Elements:**

**6.1. College or school vision and mission** – These statements are compatible with the vision and mission of the university in which the college or school operates.

**6.2. Commitment to educational outcomes** – The mission statement is consistent with a commitment to the achievement of the Educational Outcomes (Standards 1–4).

**6.3. Education, scholarship, service, and practice** – The statements address the college or school's commitment to professional education, research and scholarship, professional and community service, pharmacy practice, and continuing professional development.

**6.4. Consistency of initiatives** – All program initiatives are consistent with the college or school's vision, mission, and goals.

**6.5. Subunit goals and objectives alignment** – If the college or school organizes its faculty into subunits, the subunit goals are aligned with those of the college or school.

### **Standard 7: Strategic Plan**

The college or school develops, utilizes, assesses, and revises on an ongoing basis a strategic plan that includes tactics to advance its vision, mission, and goals.

#### **Key Elements:**

**7.1. Inclusive process** – The strategic plan is developed through an inclusive process, including faculty, staff, students, preceptors, practitioners, and other relevant constituents, and is disseminated in summary form to key stakeholders.

**7.2. Appropriate resources** – Elements within the strategic plan are appropriately resourced and have the support of the university administration as needed for implementation.

**7.3. Substantive change planning** – Substantive programmatic changes contemplated by the college or school are linked to its ongoing strategic planning process.

### **Standard 8: Organization and Governance**

The college or school is organized and staffed to advance its vision and facilitate the accomplishment of its mission and goals.

#### **Key Elements:**

**8.1. Leadership collaboration** – University leadership and the college or school dean collaborate to advance the program's vision and mission and to meet ACPE accreditation standards. The dean has direct access to the university administrator(s) with ultimate responsibility for the program.

**8.2. Qualified dean** – The dean is qualified to provide leadership in pharmacy professional education and practice, research and scholarship, and professional and community service.

**8.3. Qualified administrative team** – The dean and other college or school administrative leaders have credentials and experience that have prepared them for their respective roles and collectively have the needed backgrounds to effectively manage the educational program.

**8.4. Dean's other substantial administrative responsibilities** – If the dean is assigned other substantial administrative responsibilities, the university ensures adequate resources to support the effective administration of the affairs of the college or school.

**8.5. Authority, collegiality, and resources** – The college or school administration has defined lines of authority and responsibility, fosters organizational unit collegiality and effectiveness, and allocates resources appropriately.

**8.6. College or school participation in university governance** – College or school administrators and faculty are effectively represented in the governance of the university, in accordance with its policies and procedures.

**8.7. Faculty participation in college or school governance** – The college or school uses updated, published documents, such as bylaws, policies, and procedures, to ensure faculty participation in the governance of the college or school.

**8.8. Systems failures** – The college or school has comprehensive policies and procedures that address potential systems failures, including technical, administrative, and curricular failures.

**8.9. Alternate pathway equitability\*** – The college or school ensures that any alternative pathways to the Doctor of Pharmacy degree are equitably resourced and integrated into the college or school's regular administrative structures, policies, and procedures, including planning, oversight, and evaluation.

## **Standard 9: Organizational Culture**

The college or school provides an environment and culture that promotes self-directed lifelong learning, professional behavior, leadership, collegial relationships, and collaboration within and across academic units, disciplines, and professions.

### **Key Elements:**

**9.1. Leadership and professionalism** – The college or school demonstrates a commitment to developing professionalism and to fostering leadership in administrators, faculty, preceptors, staff, and students. Faculty and preceptors serve as mentors and positive role models for students.

**9.2. Behaviors** – The college or school has policies that define expected behaviors for administrators, faculty, preceptors, staff, and students, along with consequences for deviation from those behaviors.

**9.3. Culture of collaboration** – The college or school develops and fosters a culture of collaboration within subunits of the college or school, as well as within and outside the university, to advance its vision, mission, and goals, and to support the profession.

## **Subsection IIB: Educational Program for the Doctor of Pharmacy Degree**

### **Standard 10: Curriculum Design, Delivery, and Oversight**

The curriculum is designed, delivered, and monitored by faculty to ensure breadth and depth of requisite knowledge and skills, the maturation of professional attitudes and behaviors, and the

opportunity to explore professional areas of interest. The curriculum also emphasizes active learning pedagogy, content integration, knowledge acquisition, skill development, and the application of knowledge and skills to therapeutic decision-making.

**Key Elements:**

**10.1. Program duration** – The professional curriculum is a minimum of four academic years of full-time study or the equivalent.

**10.2. Curricular oversight** – Curricular oversight involves collaboration between faculty and administration. The body/bodies charged with curricular oversight: (1) are representative of the faculty at large, (2) include student representation, (3) effectively communicate and coordinate efforts with body/bodies responsible for curricular assessment, and (4) are adequately resourced to ensure and continually advance curricular quality.

**10.3. Knowledge application** – Curricular expectations build on a pre-professional foundation of scientific and liberal studies. The professional curriculum is organized to allow for the logical building of a sound scientific and clinical knowledge base that culminates in the demonstrated ability of learners to apply knowledge to practice.

**10.4. Skill development** – The curriculum is rigorous, contemporary, and intentionally sequenced to promote integration and reinforcement of content and the demonstration of competency in skills required to achieve the Educational Outcomes articulated in Section I.

**10.5. Professional attitudes and behaviors development** – The curriculum inculcates professional attitudes and behaviors leading to personal and professional maturity consistent with the Oath of the Pharmacist.

**10.6. Faculty and preceptor credentials/expertise** – All courses in the curriculum are taught by individuals with academic credentials and expertise that are explicitly linked to their teaching responsibilities.

**10.7. Content breadth and depth** – Programs document, through mapping or other comparable methods, the breadth and depth of exposure to curricular content areas deemed essential to pharmacy education at the doctoral level (Appendices 1 and 2).

**10.8. Pharmacists' Patient Care Process** – The curriculum prepares students to provide patient-centered collaborative care as described in the *Pharmacists' Patient Care Process* model endorsed by the Joint Commission of Pharmacy Practitioners.

**10.9. Electives** – Time is reserved within the core curriculum for elective didactic and experiential education courses that permit exploration of and/or advanced study in areas of professional interest.

**10.10. Feedback** – The curriculum allows for timely, formative performance feedback to students in both didactic and experiential education courses. Students are also provided the opportunity to give formative and/or summative feedback to faculty, including preceptors, on their perceptions of teaching/learning effectiveness.

**10.11. Curriculum review and quality assurance** – Curriculum design, delivery, and sequencing are regularly reviewed and, when appropriate, revised by program faculty to ensure optimal achievement of educational outcomes with reasonable student workload expectations.

**10.12. Teaching and learning methods** – The didactic curriculum is delivered via teaching/learning methods that: (1) facilitate achievement of learning outcomes, (2) actively engage learners, (3) promote student responsibility for self-directed learning, (4) foster collaborative learning, and (5) are appropriate for the student population (i.e., campus-based vs. distance-based).

**10.13. Diverse learners** – The didactic curriculum incorporates teaching techniques and strategies that address the diverse learning needs of students.

**10.14. Course syllabi** – Syllabi for didactic and experiential education courses, developed and updated through a faculty-approved process, contain information that supports curricular quality assurance assessment.

**10.15. Experiential quality assurance** – A quality assurance procedure for all pharmacy practice experiences is established and implemented to: (1) facilitate achievement of stated course expectations, (2) standardize key components of experiences across all sites offering the same experiential course, and (3) promote consistent assessment of student performance.

**10.16. Remuneration/employment** – Students do not receive payment for participating in curricular pharmacy practice experiences, nor are they placed in the specific practice area within a pharmacy practice site where they are currently employed.<sup>3</sup>

**10.17. Academic integrity\*** – To ensure the credibility of the degree awarded, the validity of individual student assessments, and the integrity of student work, the college or school ensures that assignments and examinations take place under circumstances that minimize opportunities for academic misconduct. The college or school ensures the correct identity of all students (including distance students) completing proctored assessments.

## **Standard 11: Interprofessional Education (IPE)**

The curriculum prepares all students to provide entry-level, patient-centered care in a variety of practice settings as a contributing member of an interprofessional team. In the aggregate, team exposure includes prescribers as well as other healthcare professionals.

### **Key Elements:**

**11.1. Interprofessional team dynamics** – All students demonstrate competence in interprofessional team dynamics, including articulating the values and ethics that underpin interprofessional practice, engaging in effective interprofessional communication, including conflict resolution and documentation skills, and honoring interprofessional roles and responsibilities. Interprofessional team dynamics are

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<sup>3</sup> A professional degree program in an institution that meets the definition of and has an institution-wide commitment to “cooperative education” (Cooperative Education and Internship Association; <http://www.ceiainc.org>) may apply to ACPE for a waiver of this requirement.

introduced, reinforced, and practiced in the didactic and Introductory Pharmacy Practice Experience (IPPE) components of the curriculum, and competency is demonstrated in Advanced Pharmacy Practice Experience (APPE) practice settings.

**11.2. Interprofessional team education** – To advance collaboration and quality of patient care, the didactic and experiential curricula include opportunities for students to learn about, from, and with other members of the interprofessional healthcare team. Through interprofessional education activities, students gain an understanding of the abilities, competencies, and scope of practice of team members. Some, but not all, of these educational activities may be simulations.

**11.3. Interprofessional team practice** – All students competently participate as a healthcare team member in providing direct patient care and engaging in shared therapeutic decision-making. They participate in experiential educational activities with prescribers/student prescribers and other student/professional healthcare team members, including face-to-face interactions that are designed to advance interprofessional team effectiveness

## **Standard 12: Pre-Advanced Pharmacy Practice Experience (Pre-APPE) Curriculum**

The Pre-APPE curriculum provides a rigorous foundation in the biomedical, pharmaceutical, social/administrative/behavioral, and clinical sciences, incorporates Introductory Pharmacy Practice Experience (IPPE), and inculcates habits of self-directed lifelong learning to prepare students for Advanced Pharmacy Practice Experience (APPE).

### **Key Elements:**

**12.1. Didactic curriculum** – The didactic portion of the Pre-APPE curriculum includes rigorous instruction in all sciences that define the profession (see Appendix 1). Appropriate breadth and depth of instruction in these sciences is documented regardless of curricular model employed (e.g., blocked, integrated, traditional ‘stand-alone’ course structure, etc.).

**12.2. Development and maturation** – The Pre-APPE curriculum allows for the development and maturation of the knowledge, skills, abilities, attitudes, and behaviors that underpin the Educational Outcomes articulated in Standards 1–4 and within Appendices 1 and 2.

**12.3. Affective domain elements** – Curricular and, if needed, co-curricular activities and experiences are purposely developed and implemented to ensure an array of opportunities for students to document competency in the affective domain-related expectations of Standards 3 and 4. Co-curricular activities complement and advance the learning that occurs within the formal didactic and experiential curriculum.

**12.4. Care across the lifespan** – The Pre-APPE curriculum provides foundational knowledge and skills that allow for care across the patient’s lifespan.

**12.5. IPPE expectations** – IPPEs expose students to common contemporary U.S. practice models, including interprofessional practice involving shared patient care decision-making, professional ethics and expected behaviors, and direct patient care activities. IPPEs are structured and sequenced to intentionally develop in students a

clear understanding of what constitutes exemplary pharmacy practice in the U.S. prior to beginning APPE.

**12.6. IPPE duration** – IPPE totals no less than 300 clock hours of experience and is purposely integrated into the didactic curriculum. A minimum of 150 hours of IPPE are balanced between community and institutional health-system settings.

**12.7. Simulation for IPPE** – Simulated practice experiences (a maximum of 60 clock hours of the total 300 hours) may be used to mimic actual or realistic pharmacist-delivered patient care situations. However, simulation hours do not substitute for the 150 clock hours of required IPPE time in community and institutional health-system settings. Didactic instruction associated with the implementation of simulated practice experiences is not counted toward any portion of the 300 clock hour IPPE requirement.

### **Standard 13: Advanced Pharmacy Practice Experience (APPE) Curriculum**

A continuum of required and elective APPEs is of the scope, intensity, and duration required to support the achievement of the Educational Outcomes articulated in Standards 1–4 and within Appendix 2 to prepare practice-ready graduates. APPEs integrate, apply, reinforce, and advance the knowledge, skills, attitudes, abilities, and behaviors developed in the Pre-APPE curriculum and in co-curricular activities.

#### **Key Elements:**

**13.1. Patient care emphasis** – Collectively, APPEs emphasize continuity of care and incorporate acute, chronic, and wellness-promoting patient-care services in outpatient (community/ambulatory care) and inpatient (hospital/health system) settings.

**13.2. Diverse populations** – In the aggregate, APPEs expose students to diverse patient populations as related to age, gender, race/ethnicity, socioeconomic factors (e.g., rural/urban, poverty/affluence), and disease states)

**13.3. Interprofessional experiences** – In the aggregate, students gain in-depth experience in delivering direct patient care as part of an interprofessional team.

**13.4. APPE duration** – The curriculum includes no less than 36 weeks (1440 hours) of APPE. All students are exposed to a minimum of 160 hours in each required APPE area. The majority of APPE is focused on direct patient care.

**13.5. Timing** – APPEs follow successful completion of all IPPE and required didactic curricular content. Required capstone courses or activities that provide opportunity for additional professional growth and insight are allowed during or after completion of APPEs. These activities do not compromise the quality of the APPEs, nor count toward the required 1440 hours of APPE.

**13.6. Required APPE** – Required APPEs occur in four practice settings: (1) community pharmacy; (2) ambulatory patient care; (3) hospital/health system pharmacy; and (4) inpatient general medicine patient care.

**13.7. Elective APPE** – Elective APPEs are structured to give students the opportunity to: (1) mature professionally, (2) secure the breadth and depth of experiences needed to

achieve the Educational Outcomes articulated in Standards 1–4, and (3) explore various sectors of practice.

**13.8. Geographic restrictions** – Required APPEs are completed in the United States or its territories or possessions. All quality assurance expectations for U.S.-based experiential education courses apply to elective APPEs offered outside of the U.S.

### **Subsection IIC: Students**

#### **Standard 14: Student Services**

The college or school has an appropriately staffed and resourced organizational element dedicated to providing a comprehensive range of services that promote student success and well-being.

##### **Key Elements:**

**14.1. FERPA** – The college or school has an ordered, accurate, and secure system of student records in compliance with the Family Educational Rights and Privacy Act (FERPA). Student services personnel and faculty are knowledgeable regarding FERPA law and its practices.

**14.2. Financial aid** – The college or school provides students with financial aid information and guidance by appropriately trained personnel.

**14.3. Healthcare** – The college or school offers students access to adequate health and counseling services. Appropriate immunization standards are established, along with the means to ensure that such standards are satisfied.

**14.4. Advising** – The college or school provides academic advising, curricular and career-pathway counseling, and information on post-graduate education and training opportunities adequate to meet the needs of its students.

**14.5. Nondiscrimination** – The college or school establishes and implements student service policies that ensure nondiscrimination as defined by state and federal laws and regulations.

**14.6. Disability accommodation** – The college or school provides accommodations to students with documented disabilities that are determined by the university Disability Office (or equivalent) to be reasonable, and provides support to faculty in accommodating disabled students.

**14.7. Student services access\*** – The college or school offering multiple professional degree programs (e.g., PharmD/MPH) or pathways (campus and distance pathways) ensures that all students have equitable access to a comparable system of individualized student services (e.g., tutorial support, faculty advising, counseling, etc.).

#### **Standard 15: Academic Environment**

The college or school develops, implements, and assesses its policies and procedures that promote student success and well-being.

**Key elements:**

**15.1. Student information** – The college or school produces and makes available to enrolled and prospective students updated information of importance, such as governance documents, policies and procedures, handbooks, and catalogs.

**15.2. Complaints policy** – The college or school develops, implements, and makes available to students a complaints policy that includes procedures for how students may file complaints within the college or school and also directly to ACPE regarding their college or school's adherence to ACPE standards. The college or school maintains a chronological record of such student complaints, including how each complaint was resolved.

**15.3. Student misconduct** – The college or school develops and implements policies regarding academic and non-academic misconduct of students that clearly outline the rights and responsibilities of, and ensures due process for, all parties involved.

**15.4. Student representation** – The college or school considers student perspectives and includes student representation, where appropriate, on committees, in policy-development bodies, and in assessment and evaluation activities.

**15.5. Distance learning policies\*** – For colleges and schools offering distance learning opportunities, admissions information clearly explains the conditions and requirements related to distance learning, including full disclosure of any requirements that cannot be completed at a distance.

**Standard 16: Admissions**

The college or school develops, implements, and assesses its admission criteria, policies, and procedures to ensure the selection of a qualified and diverse student body into the professional degree program.

**Key elements:**

**16.1. Enrollment management** – Student enrollment is managed by college or school administration. Enrollments are in alignment with available physical, educational, financial, faculty, staff, practice site, preceptor, and administrative resources.

**16.2. Admission procedures** – A duly constituted committee of the college or school has the responsibility and authority for the selection of students to be offered admission. Admission criteria, policies, and procedures are not compromised regardless of the size or quality of the applicant pool.

**16.3. Program description and quality indicators** – The college or school produces and makes available to the public, including prospective students: (1) a complete and accurate description of the professional degree program; (2) the program's current accreditation status; and (3) ACPE-required program performance information including on-time graduation rates and most recent NAPLEX first-attempt pass rates.

**16.4. Admission criteria** – The college or school sets performance expectations for admission tests, evaluations, and interviews used in selecting students who have the potential for success in the professional degree program and the profession. Applicant

performance on admission criteria is documented; and the related records are maintained by the college or school as per program/university requirements.

**16.5. Admission materials** – The college or school produces and makes available to prospective students the criteria, policies, and procedures for admission to the professional degree program. Admission materials clearly state academic expectations, required communication skills, types of personal history disclosures that may be required, and professional and technical standards for graduation.

**16.6. Written and oral communication assessment** – Written and oral communication skills are assessed in a standardized manner as part of the admission process.

**16.7. Candidate interviews** – Standardized interviews (in-person, telephonic, and/or computer-facilitated) of applicants are conducted as a part of the admission process to assess affective domain characteristics (i.e., the Personal and Professional Development domain articulated in Standard 4).

**16.8. Transfer and waiver policies** – A college or school offering multiple professional degree programs, or accepting transfer students from other schools or colleges of pharmacy, establishes and implements policies and procedures for students who request to transfer credits between programs. Such policies and procedures are based on defensible assessments of course equivalency. A college or school offering multiple pathways to a single degree has policies and procedures for students who wish to change from one pathway to another.

## **Standard 17: Progression**

The college or school develops, implements, and assesses its policies and procedures related to student progression through the PharmD program.

### **Key elements:**

**17.1. Progression policies** – The college or school creates, makes available to students and prospective students, and abides by criteria, policies, and procedures related to:

- Academic progression
- Remediation
- Missed course work or credit
- Academic probation
- Academic dismissal
- Dismissal for reasons of misconduct
- Readmission
- Leaves of absence
- Rights to due process
- Appeal mechanisms (including grade appeals)

**17.2. Early intervention** – The college or school's system of monitoring student performance provides for early detection of academic and behavioral issues. The college or school develops and implements appropriate interventions that have the potential for successful resolution of the identified issues.

## **Subsection IID: Resources**

### **Standard 18: Faculty and Staff—Quantitative Factors**

The college or school has a cohort of faculty and staff with the qualifications and experience needed to effectively deliver and evaluate the professional degree program.

#### **Key Elements:**

**18.1. Sufficient faculty** – The college or school has a sufficient number of faculty members to effectively address the following programmatic needs:

- Teaching (didactic, simulation, and experiential)
- Professional development
- Research and other scholarly activities
- Assessment activities
- College/school and/or university service
- Intraprofessional and interprofessional collaboration
- Student advising and career counseling
- Faculty mentoring
- Professional service
- Community service
- Pharmacy practice
- Responsibilities in other academic programs (if applicable)
- Support of distance students and campus(es) (if applicable)\*

**18.2. Sufficient staff** – The college or school has a sufficient number of staff to effectively address the following programmatic needs:

- Student and academic affairs-related services, including recruitment and admission
- Experiential education
- Assessment activities
- Research administration
- Laboratory maintenance
- Information technology infrastructure
- Pedagogical and educational technology support
- Teaching assistance
- General faculty and administration clerical support
- Support of distance students and campus(es) (if applicable)\*

### **Standard 19: Faculty and Staff—Qualitative Factors**

Faculty and staff have academic and professional credentials and expertise commensurate with their responsibilities to the professional program and their academic rank.

### **Key Elements:**

**19.1. Educational effectiveness** – Faculty members have the capability and demonstrate a continuous commitment to be effective educators and are able to effectively use contemporary educational techniques to promote student learning in all offered pathways.

**19.2. Scholarly productivity** – The college or school creates an environment that both requires and promotes scholarship and also develops mechanisms to assess both the quantity and quality of faculty scholarly productivity.

**19.3. Service commitment** – In the aggregate, faculty engage in professional, institutional, and community service that advances the program and the profession of pharmacy.

**19.4. Practice understanding** – Faculty members, regardless of their discipline, have a conceptual understanding of and commitment to advancing current and proposed future pharmacy practice.

**19.5. Faculty/staff development** – The college or school provides opportunities for career and professional development of its faculty and staff, individually and collectively, to enhance their role-related skills, scholarly productivity, and leadership.

**19.6. Policy application** – The college or school ensures that policies and procedures for faculty and staff recruitment, performance review, promotion, tenure (if applicable), and retention are applied in a consistent manner.

### **Standards 20: Preceptors**

The college or school has a sufficient number of preceptors (practice faculty or external practitioners) to effectively deliver and evaluate students in the experiential component of the curriculum. Preceptors have professional credentials and expertise commensurate with their responsibilities to the professional program.

### **Key Elements:**

**20.1. Preceptor criteria** – The college or school makes available and applies quality criteria for preceptor recruitment, orientation, performance, and evaluation. The majority of preceptors for any given student are U.S. licensed pharmacists.

**20.2. Student-to-preceptor ratio** – Student to precepting pharmacist ratios allow for the individualized mentoring and targeted professional development of learners.

**20.3. Preceptor education and development** – Preceptors are oriented to the program's mission, the specific learning expectations for the experience outlined in the syllabus, and effective performance evaluation techniques before accepting students. The college or school fosters the professional development of its preceptors commensurate with their educational responsibilities to the program.

**20.4. Preceptor engagement** – The college or school solicits the active involvement of preceptors in the continuous quality improvement of the educational program, especially the experiential component.

**20.5. Experiential education administration** – The experiential education component of the curriculum is led by a pharmacy professional with knowledge and experience in experiential learning. The experiential education program is supported by an appropriate number of qualified faculty and staff.

### **Standard 21: Physical Facilities and Educational Resources**

The college or school has adequate and appropriately equipped physical and educational facilities to achieve its mission and goals.

#### **Key Elements:**

**21.1. Physical facilities** – The college or school's physical facilities (or the access to other facilities) meet legal and safety standards, utilize current educational technology, and are clean and well maintained.

**21.2. Physical facilities' attributes** – The college or school's physical facilities also include adequate:

- Faculty office space with sufficient privacy to permit accomplishment of responsibilities
- Space that facilitates interaction of administrators, faculty, students, and interprofessional collaborators
- Classrooms that comfortably accommodate the student body and that are equipped to allow for the use of required technology
- Laboratories suitable for skills practice, demonstration, and competency evaluation
- Access to educational simulation capabilities
- Faculty research laboratories with well-maintained equipment including research support services within the college or school and the university
- Animal facilities that meet care regulations (if applicable)
- Individual and group student study space and student meeting facilities

**21.3. Educational resource access** – The college or school makes available technological access to current scientific literature and other academic and educational resources by students, faculty, and preceptors.

**21.4 Librarian expertise access** – The college or school has access to librarian resources with the expertise needed to work with students, faculty, and preceptors on effective literature and database search and retrieval strategies.

### **Standard 22: Practice Facilities**

The college or school has the appropriate number and mix of facilities in which required and elective practice experiences are conducted to accommodate all students. Practice sites are appropriately licensed and selected based on quality criteria to ensure the effective and timely delivery of the experiential component of the curriculum.

**Key Elements:**

**22.1. Quality criteria** – The college or school employs quality criteria for practice facility recruitment and selection, as well as setting forth expectations and evaluation based on student opportunity to achieve the required Educational Outcomes as articulated in Standards 1–4.

**22.2. Affiliation agreements** – The college or school secures and maintains signed affiliation agreements with the practice facilities it utilizes for the experiential component of the curriculum. At a minimum, each affiliation agreement ensures that all experiences are conducted in accordance with state and federal laws.

**22.3. Evaluation** – Practice sites are regularly evaluated. Quality enhancement initiatives and processes are established, as needed, to improve student learning outcomes.

**Standard 23: Financial Resources**

The college or school has current and anticipated financial resources to support the stability of the educational program and accomplish its mission, goals, and strategic plan.

**Key Elements:**

**23.1. Enrollment support** – The college or school ensures that student enrollment is commensurate with resources.

**23.2. Budgetary input** – The college or school provides input into the development and operation of a budget that is planned, executed, and managed in accordance with sound and accepted business practices.

**23.3. Revenue allocation** – Tuition and fees for pharmacy students are not increased to support other educational programs if it compromises the quality of the professional program.

**23.4. Equitable allocation** – The college or school ensures that funds are sufficient to maintain equitable facilities (commensurate with services and activities) across all program pathways.

### **SECTION III: ASSESSMENT OF STANDARDS AND KEY ELEMENTS**

In the spirit of continuous quality improvement and transparency, colleges and schools evaluate and report to constituents the extent to which they meet their programmatic goals. Insights gained from the valid and reliable assessment of outcomes related to mission, strategic planning, educational programs, and other key institutional initiatives are channeled into constructive change to enhance programmatic quality.

#### **Standard 24: Assessment Elements for Section I: Educational Outcomes**

The college or school develops, resources, and implements a plan to assess attainment of educational outcomes to ensure that graduates are prepared to enter practice.

##### **Key Elements:**

**24.1. Formative and summative assessment** – The assessment plan incorporates systematic, valid, and reliable knowledge-based and performance-based formative and summative assessments.

**24.2. Standardized and comparative assessments** – The assessment plan includes standardized assessments as required by ACPE (see Appendix 3) that allow for national comparisons and college- or school-determined peer comparisons.

**24.3. Student achievement and readiness** – The assessment plan measures student achievement at defined levels of the professional competencies that support attainment of the Educational Outcomes in aggregate and at the individual student level. In addition to college/school desired assessments, the plan includes an assessment of student readiness to:

- Enter advanced pharmacy practice experiences
- Provide direct patient care in a variety of healthcare settings
- Contribute as a member of an interprofessional collaborative patient care team

**24.4. Continuous improvement** – The college or school uses the analysis of assessment measures to improve student learning and the level of achievement of the Educational Outcomes.

#### **Standard 25: Assessment Elements for Section II: Structure and Process**

The college or school develops, resources, and implements a plan to assess attainment of the Key Elements within Standards 5–23.

##### **Specific Key Elements:**

**25.1. Assessment of organizational effectiveness** – The college or school's assessment plan is designed to provide insight into the effectiveness of the organizational structure in engaging and uniting constituents and positioning the college or school for success through purposeful planning.

**25.2. Program evaluation by stakeholders** – The assessment plan includes the use of data from AACP standardized surveys of graduating students, faculty, preceptors, and alumni.

**25.3. Curriculum assessment and improvement** – The college or school systematically assesses its curricular structure, content, organization, and outcomes. The college or school documents the use of assessment data for continuous improvement of the curriculum and its delivery.

**25.4. Faculty productivity assessment** – The college or school systematically assesses the productivity of its faculty in scholarship, teaching effectiveness, and professional and community service.

**25.5. Pathway comparability\*** – The assessment plan includes a variety of assessments that will allow comparison and establishment of educational parity of alternative program pathways to degree completion, including geographically dispersed campuses and online or distance learning-based programs.

**25.6. Interprofessional preparedness** – The college or school assesses the preparedness of all students to function effectively and professionally on an interprofessional healthcare team.

**25.7. Clinical reasoning skills** – Evidence-based clinical reasoning skills, the ability to apply these skills across the patient's lifespan, and the retention of knowledge that underpins these skills, are regularly assessed throughout the curriculum.

**25.8. APPE preparedness** – The Pre-APPE curriculum leads to a defined level of competence in professional knowledge, knowledge application, patient and population-based care, medication therapy management skills, and the attitudes important to success in the advanced experiential program. Competence in these areas is assessed prior to the first APPE.

**25.9. Admission criteria** – The college or school regularly assesses the criteria, policies, and procedures to ensure the selection of a qualified and diverse student body, members of which have the potential for academic success and the ability to practice in team-centered and culturally diverse environments.

## **Appendix 1 Required Elements of the Didactic Doctor of Pharmacy Curriculum<sup>4</sup>**

The following didactic content areas and associated learning expectations are viewed as central to a contemporary, high-quality pharmacy education and are incorporated at an appropriate breadth and depth in the required didactic Doctor of Pharmacy curriculum. Where noted, content areas may be addressed in the pre-professional curriculum (i.e., as requirements for admission). Required content areas may be delivered within individual or integrated courses, and may involve multiple disciplines.

This appendix was purposely written at the level of broad learning outcomes. It was constructed to provide statements of concepts and understandings essential for pharmacists to master, rather than a list of required topics to cover in the didactic curriculum. The goal is to ensure that critical areas of learning are included in the curricula of all programs without dictating how the lessons are structured, organized, or delivered.

The clear expectation embedded within Appendix 1 is that students will develop the comprehensive knowledge base required to be ‘practice ready’ and that they will be able to retain, recall, build upon, and apply that knowledge to deliver quality patient care in a variety of entry-level practice settings.

**NOTE:** The topics under each Science category are organized in alphabetical order.

**Biomedical Sciences** (may be addressed in the pre-professional curriculum)

### Biochemistry

- Structure, properties, biological functions, applicable kinetics, and metabolic fate of macromolecules essential to life (proteins, lipids, carbohydrates, and nucleic acids). Application of these concepts to identify endogenous targets for drug therapy and rational drug design strategies.

### Biostatistics

- Appropriate use of commonly employed statistical tests, management of data sets, and the evaluation of the validity of conclusions generated based on the application of those tests to the data sets.

### Human Anatomy

- Structure of major human body systems at the cellular, tissue, organ, and system level.

### Human Physiology

- Homeostatic function and normal response reactions across the lifespan of non-diseased human cells, organs, and systems.

### Immunology

- Human immune system components, innate and adaptive immune responses to infection, injury and disease, and augmentation of the human immune system to prevent disease.

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<sup>4</sup> Revised Appendix B from Standards 2007.

### Medical Microbiology

- Structure, function, and properties of microorganisms (bacteria, viruses, parasites, and fungi) responsible for human disease, and rational approaches to their containment or eradication.

### Pathology/Pathophysiology

- Basic principles, mechanisms, functional changes and metabolic sequelae of human disease impacting cells, organs, and systems.

## **Pharmaceutical Sciences**

### Clinical Chemistry

- Application of clinical laboratory data to disease state management, including screening, diagnosis, progression, and treatment evaluation.

### Extemporaneous Compounding

- Preparation of sterile and non-sterile prescriptions which are pharmaceutically accurate regarding drug product and dose, free from contamination, and appropriately formulated for safe and effective patient use. Analysis of the scientific principles and quality standards upon which these compounding requirements are based.

### Medicinal Chemistry

- Chemical basis of drug action and behavior in vivo and in vitro, with an emphasis on pharmacophore recognition and the application of physicochemical properties, structure-activity relationships, intermolecular drug-receptor interactions and metabolism to therapeutic decision-making.

### Pharmaceutical Calculations

- Mastery of mathematical skills required to accurately prepare prescriptions (including extemporaneously compounded dosage forms) that are therapeutically sound and safe for patient use. Calculation of patient-specific nutritional and drug dosing/delivery requirements.

### Pharmaceutics/Biopharmaceutics

- Physicochemical properties of drugs, excipients, and dosage forms important to the rational design and manufacture of sterile and non-sterile products. Application of physical chemistry and dosage form science to drug stability, delivery, release, disposition, pharmacokinetics, therapeutic effectiveness, and the development of quality standards for drug products.

### Pharmacogenomics/genetics

- Genetic basis for disease and individual differences in metabolizing enzymes, transporters, and other biochemicals impacting drug disposition and action that underpin the practice of personalized medicine.

### Pharmacokinetics

- Mathematical determination of the rate of drug movement from one therapeutic or physiologic compartment to another. Application of physicochemical and kinetic principles and parameters to therapeutically important issues, such as drug delivery, disposition, therapeutic effectiveness, and beneficial or adverse interactions in general and specific populations.

### Pharmacology

- Pharmacodynamics, mechanisms of therapeutic and adverse drug actions and interactions, lifespan-dependent variations in physiology or biochemistry that impact drug action and effectiveness, and application of these principles to therapeutic decision-making.

### Toxicology

- Pharmacodynamics, mechanisms, prevention, and treatment of the toxic effects of drugs and poisons, including poisons associated with bioterrorism.

## **Social/Administrative/Behavioral Sciences**

### Cultural Awareness

- Exploration of the potential impact of cultural values, beliefs, and practices on patient care outcomes.

### Ethics

- Exploration of approaches for resolving ethical dilemmas in patient care, with an emphasis on moral responsibility and the ability to critically evaluate viable options against the needs of patients and other key stakeholders.

### Healthcare Systems

- Examination of U.S. health systems and contemporary reimbursement models in which patient-centered and/or population-based care is provided and paid for, and how social, political, economic, organizational, and cultural factors influence providers' ability to ensure patient safety and deliver coordinated interprofessional care services.

### History of Pharmacy

- Exploration of the evolution of pharmacy as a distinct profession, the transition from a focus on the drug to a focus on the patient and the drug (including pharmacist-provided patient care), and major milestones and contributors in the evolution of pharmacy.

### Pharmacoeconomics

- Application of economic principles and theories to the provision of cost-effective pharmacy products and services that optimize patient-care outcomes, particularly in situations where healthcare resources are limited.

### Pharmacoepidemiology

- Cause-and-effect patterns of health and disease in large populations that advance safe and effective drug use and positive care outcomes within those populations.

### Pharmacy Law and Regulatory Affairs

- Federal and appropriate state-specific statutes, regulations, policies, executive orders, and court decisions that regulate the practice of pharmacy, including the mitigation of prescription drug abuse and diversion.

### Practice Management

- Application of sound management principles (including operations, information, resource, fiscal, and personnel) and quality metrics to advance patient care and service delivery within and between various practice settings.

### Professional Communication

- Analysis and practice of verbal, non-verbal, and written communication strategies that promote effective interpersonal dialog and understanding to advance specific patient care, education, advocacy, and/or interprofessional collaboration goals. Exploration of technology-based communication tools and their impact on healthcare delivery, healthcare information, and patient empowerment.

### Professional Development/Social and Behavioral Aspects of Practice

- Development of professional self-awareness, capabilities, responsibilities, and leadership. Analysis of contemporary practice roles and innovative opportunities, and inculcation of professional attitudes, behaviors, and dispositions.

### Research Design

- Evaluation of research methods and protocol design required to conduct valid and reliable studies to test hypotheses or answer research questions, and to appropriately evaluate the validity and reliability of the conclusions of published research studies.

## **Clinical Sciences**

### Clinical Pharmacokinetics

- Application of basic pharmacokinetic principles and mathematical models to calculate safe and effective doses of drugs for individual patients, and adjust therapy as appropriate through the monitoring of drug concentration in biological fluids.

### Health Informatics

- Effective and secure design and use of electronic and other technology-based systems, including electronic health records, to capture, store, retrieve, and analyze data for use in patient care, and confidentially/legally share health information in accordance with federal policies.

### Health Information Retrieval and Evaluation

- Critical analysis and application of relevant health sciences literature and other information resources to answer specific patient-care and/or drug-related questions and provide evidence-based therapeutic recommendations to healthcare providers or, when appropriate, the public.

### Medication Dispensing, Distribution and Administration

- Preparation, dispensing and administration of prescriptions, identification and prevention of medication errors and interactions, maintaining and using patient profile systems and

prescription processing technology and/or equipment, and ensuring patient safety. Educating about appropriate medication use and administration.

#### Natural Products and Alternative and Complementary Therapies

- Evidence-based evaluation of the therapeutic value, safety, and regulation of pharmacologically active natural products and dietary supplements. Cultural practices commonly selected by practitioners and/or patients for use in the promotion of health and wellness, and their potential impact on pharmacotherapy.

#### Patient Assessment

- Evaluation of patient function and dysfunction through the performance of tests and assessments leading to objective (e.g., physical assessment, health screening, and lab data interpretation) and subjective (patient interview) data important to the provision of care.

#### Patient Safety

- Analysis of the systems- and human-associated causes of medication errors, exploration of strategies designed to reduce/eliminate them, and evaluation of available and evolving error-reporting mechanisms.

#### Pharmacotherapy

- Evidence-based clinical decision making, therapeutic treatment planning, and medication therapy management strategy development for patients with specific diseases and conditions that complicate care and/or put patients at high risk for adverse events. Emphasis on patient safety, clinical efficacy, pharmacogenomic and pharmacoeconomic considerations, and treatment of patients across the lifespan.

#### Public Health

- Exploration of population health management strategies, national and community-based public health programs, and implementation of activities that advance public health and wellness, as well as provide an avenue through which students earn certificates in immunization delivery and other public health-focused skills.

#### Self-Care Pharmacotherapy

- Therapeutic needs assessment, including the need for triage to other health professionals, drug product recommendation/selection, and counseling of patients on non-prescription drug products, non-pharmacologic treatments and health/wellness strategies.

## **Appendix 2 Expectations within the APPE Curriculum**

**Builds on IPPE.** APPE follows IPPE, which is designed to progressively develop the professional insights and skills necessary to advance into responsibilities in APPE. Colleges and schools use a variety of IPPE delivery mechanisms to ensure students are ready to meet the expectations of APPE. IPPE involves interaction with practitioners and patients to advance patient welfare in authentic practice settings, and provides exposure to both medication distribution systems and high-quality, interprofessional, team-based patient care.

**APPE curriculum.** APPE ensures that students have multiple opportunities to perform patient-centered care and other activities in a variety of settings. Experiences are in-depth, structured, and comprehensive in the aggregate, and carefully coordinated with other components of the PharmD curriculum. Collectively, APPE hones the practice skills, professional judgment, behaviors, attitudes and values, confidence, and sense of personal and professional responsibility required for each student to practice independently and collaboratively in an interprofessional, team-based care environment.

**Learning outcomes.** General and experience-specific learning outcomes are established for all APPEs. Learning outcomes identify the competencies to be achieved, expected patient populations (if applicable), level of student responsibility, and the setting needed for the outcomes to be met. Learning outcomes for each experience are mapped to the professional practice competencies outlined in the Standards, as well as to any additional competencies developed by the school or college.

**Assessment.** Colleges and schools assess student achievement of APPE competencies within their assessment plans using reliable, validated assessments. Formative feedback related to specific performance criteria is provided to students throughout the experience. At a minimum, performance competence is documented midway through the experience and at its completion.

**Learning activities.** The APPE curriculum, in the aggregate, includes but is not limited to: (1) direct patient care, (2) interprofessional interaction and practice, (3) medication dispensing, distribution, administration, and systems management, and (4) professional development. Examples of possible activities within these broad areas are listed in the Guidance document.

**Interprofessional interaction.** The need for interprofessional interaction is paramount to successful treatment of patients. Colleges and schools provide pharmacy students the opportunity to gain interprofessional skills using a variety of mechanisms including face-to-face interactions in clinical settings or in real-time telephonic or video-linked interactions. Regardless of the methods used, students demonstrate those interprofessional skills articulated in Standard 11.

**Direct patient care focus.** The majority of student time in APPE is focused on the provision of direct patient care to both inpatients and outpatients. APPE is of sufficient length to permit continuity of care of individual patients and documentation of achievement of competencies associated with the APPE curriculum.

**Practice settings.** Students demonstrate competence within four main practice types: community, ambulatory care, general medicine, and health system pharmacy. Colleges and

schools draft competency statements for each type of setting along with appropriate assessment plans.

**Ambulatory care.** 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.<sup>5</sup> The ambulatory care setting involves interprofessional communication and collaboration to provide acute and chronic patient care that can be accomplished outside the inpatient setting.

**Blended environments.** The literature documents that the demarcations between various types of pharmacy practice are blurring. A specific APPE may involve skill-development activities in more than one of the four required practice settings (i.e., the 'blending' of two or more of the four required practice types within one APPE). In addition, 'longitudinal' experiences may exist where students participate in more than one of the four required APPEs within the same institution (i.e., taking a general medicine APPE, an ambulatory care APPE, and a health system pharmacy APPE in the same hospital). The key is that a college or school documents how its APPE program is balanced between the four required practice areas and how all program outcomes, student performance competencies, and ACPE standards are met.

**Elective APPE.** Elective rotations allow students to explore areas of professional interest and/or expand their understanding of professional opportunities. Elective APPE may include a maximum of two experiences without a patient care focus.

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<sup>5</sup> [www.bpsweb.org/specialties/AmbulatoryCarePharmacy.cfm](http://www.bpsweb.org/specialties/AmbulatoryCarePharmacy.cfm)

### **Appendix 3 Required Documentation for Standards and Key Elements 2016**

To provide evidence of achievement of the standards and key elements, colleges and schools provide, at a minimum, the following outcomes data and documentation. Many of these documents are embedded within the *Assessment and Accreditation Management System* (AAMS) system (co-developed and managed by the American Association of Colleges of Pharmacy and ACPE), while others are created by individual colleges and schools to be shared with ACPE at appropriate times during the quality improvement process (e.g., within self-study submissions or during site visits). As noted below, an individual document may be used for multiple standards. Colleges and schools are encouraged to develop additional documentation processes to meet their mission-specific quality assurance needs.

#### **Standard 1 – Foundational Knowledge**

- Student academic performance throughout the program (e.g., progression rates, academic probation rates, attrition rates)
- Annual performance of students nearing completion of the didactic curriculum on the Pharmacy Curriculum Outcomes Assessment (PCOA) - an assessment of knowledge of the essential content areas identified in Appendix 1
- Performance of graduates (passing rate) on NAPLEX
- Performance of graduates in the various NAPLEX competency areas
- Performance of graduates on Multistate Pharmacy Jurisprudence Examination (MPJE) and/or other state required law examination

#### **Standard 2 – Essentials for Practice and Care**

- Outcome data from assessments summarizing overall student achievement of relevant didactic, IPPE, and APPE learning objectives

#### **Standard 3 – Approach to Practice and Care**

- Examples of student participation in Interprofessional Education activities (didactic, simulation, experiential)
- Outcome data from assessments summarizing overall student achievement of relevant didactic, IPPE, and APPE learning objectives
- Outcome data from assessments summarizing overall student participation in Interprofessional Education activities
- Examples of curricular and co-curricular experiences made available to students to document developing competence in affective domain-related expectations of Standard 3
- Outcome data from assessments of student achievement of problem-solving and critical thinking capabilities
- Outcome data from assessments of students' ability to communicate professionally, advocate for patients, and educate others
- Outcome data from assessments of students' demonstration of cultural awareness and sensitivity.

#### **Standard 4 – Personal and Professional Development**

- Outcome data from assessments summarizing students' overall achievement of relevant didactic, IPPE, and APPE learning objectives
- Examples of curricular and co-curricular experiences made available to students to document developing competence in affective domain-related expectations of Standard 4

- Outcome data from assessments summarizing students' overall achievement of professionalism, leadership, self-awareness, and creative thinking expectations
- Description of tools utilized to capture students' reflections on personal/professional growth and development
- Description of processes by which students are guided to develop a commitment to continuous professional development and to self-directed lifelong learning

**Standard 5 – Eligibility and Reporting Requirements**

- Legal authority to offer/award the Doctor of Pharmacy degree
- Documents verifying institutional accreditation
- Accreditation reports identifying deficiencies (if applicable)
- University organizational chart
- Description of level of autonomy of the college or school

**Standard 6 – College or School Vision, Mission, and Goals**

- Vision, mission, and goal statements (college, school, parent institution, department/division)
- Outcome data from assessments summarizing the extent to which the college or school is achieving its vision, mission, and goals

**Standard 7 – Strategic Plan**

- Strategic planning documents, including a description of the process through which the strategic plan was developed.
- Outcome data from assessments summarizing the implementation of the strategic plan

**Standard 8 - Organization and Governance**

- Curriculum vitae of the dean and others on the administrative leadership team
- Organization chart of the college or school
- Responsibilities of dean and other administrative leadership team members
- Faculty governance documents (by-laws, policies, procedures, etc.)
- List of committees and designated charges
- Evidence of faculty participation in university governance
- Policies and procedures related to system failures, data security and backup, and contingency planning
- Outcome data from assessments (e.g., AACP faculty, preceptor, graduating student and alumni surveys) summarizing the effectiveness of the organizational structure and governance

**Standard 9 – Organizational Culture**

- Policies describing expectations of faculty, administrators, students, and staff behaviors
- Examples of intra/interprofessional and intra/interdisciplinary collaboration
- Affiliation agreements for purposes of research, teaching, or service (if applicable)
- Outcome data from AACP faculty and graduating student surveys related to collaboration, morale, professionalism, etc.

**Standard 10 - Curriculum Design, Delivery, and Oversight**

- Description of curricular and degree requirements, including elective didactic and experiential expectations
- All required and elective didactic and experiential course syllabi
- Mapping of required curricular content and experiential education expectations to individual courses
- Curriculum vitae of faculty teaching within the curriculum
- A tabular display of courses, faculty members assigned to each course and their role, and credentials supporting the teaching assignments

- List of Curriculum Committee (or equivalent) members with position/affiliation within college/school
- List of charges, assignments, and accomplishments of Curriculum Committee over the last 1–3 years
- Examples of tools (e.g., portfolios) used by students to document self-assessment of, and reflection on, learning needs, plans and achievements, and professional growth and development
- Sample documents used by faculty, preceptors, and students to evaluate learning experiences and provide formative and/or summative feedback
- Policies related to academic integrity
- Policies related to experiential learning that ensures compliance with Key Element 10.15
- Examples of instructional methods used by faculty and the extent of their employment to:
  - Actively engage learners
  - Integrate and reinforce content across the curriculum
  - Provide opportunity for mastery of skills
  - Instruct within the experiential learning program
  - Stimulate higher-order thinking, problem-solving, and clinical-reasoning skills
  - Foster self-directed lifelong learning skills and attitudes
  - Address/accommodate diverse learning styles
  - Incorporate meaningful interprofessional learning opportunities

#### **Standard 11 - Interprofessional Education (IPE)**

- Vision, mission, and goal statements related to IPE
- Statements addressing IPE and practice contained within student handbooks and/or catalogs
- Relevant syllabi for required and elective didactic and experiential education courses that incorporate elements of IPE to document that concepts are reinforced throughout the curriculum and that IPE-related skills are practiced at appropriate times during pre-APPE
- Student IPPE and APPE evaluation data documenting extent of exposure to interprofessional, team-based patient care
- Outcome data from assessments summarizing students' overall achievement of expected interprofessional educational outcomes in the pre-APPE and APPE curriculum

#### **Standard 12 - Pre-APPE Curriculum**

- Description of curricular and degree requirements, including elective didactic and experiential expectations
- A tabular display of courses, faculty members assigned to each course and their role, and credentials supporting the teaching assignments
- Curriculum maps documenting breadth and depth of coverage of Appendix 1 content and learning expectations in the professional (and, if appropriate, preprofessional) curriculum
- Examples of curricular and co-curricular experiences made available to students to document developing competence in affective domain-related expectations of Standards 3 and 4
- Outcome data from assessments of student preparedness to progress to APPE (e.g., comprehensive assessments of knowledge, skills, and competencies)
- Description of the IPPE learning program and its goals, objectives, and time requirements
- List of simulation activities and hours counted within the IPPE 300 hour requirement
- IPPE course syllabi including general and rotation-specific learning objectives and extent of IPE exposure

- IPPE student and preceptor manuals
- IPPE student and preceptor assessment tools
- IPPE preceptor recruitment and training manuals and/or programs
- List of active preceptors with credentials and practice site
- Outcome data from assessments summarizing overall student achievement of Pre-APPE educational outcomes

#### **Standard 13 – APPE Curriculum**

- Overview of APPE curriculum (duration, types of required and elective rotations, etc.)
- APPE course syllabi including general and experience-specific learning objectives
- APPE student and preceptor manuals
- APPE student and preceptor assessment tools
- Preceptor recruitment and training manuals and/or programs
- List of active preceptors with credentials and practice site
- Student APPE evaluation data documenting extent of exposure to diverse patient populations and interprofessional, team-based patient care
- Outcome data from assessments summarizing students' overall achievement of APPE educational outcomes

#### **Standard 14 - Student Services**

- Organizational chart depicting Student Services unit and responsible administrators
- Synopsis of curriculum vitae of Students Services administrative officer(s) and staff
- Student Handbook and/or Catalog (college, school or university), and copies of additional information distributed to students regarding student service elements (financial aid, health insurance, etc.)
- Copies of policies that ensure nondiscrimination and access to allowed disability accommodations
- Results from AACCP graduating student survey
- Student feedback on the college/school's self-study

#### **Standard 15 - Academic Environment**

- Student Handbook and/or Catalog (college, school, or university), and copies of additional information distributed to students regarding the academic environment
- URL or link to program information on college or school's website
- Copy of student complaint policy related to college or school adherence to ACPE standards
- Number and nature of student complaints related to college or school adherence to ACPE standards (inspection of the file by evaluation teams during site visits)
- List of committees involving students with names and professional years of current student members
- College or school's code of conduct (or equivalent) addressing professional behavior

#### **Standard 16 – Admissions**

- Organizational chart depicting Admissions unit and responsible administrator(s)
- Enrollment data for the past five years by year; and by branch campus or pathway (if applicable)
- Enrollment projections for the next five years
- Pharmacy College Aptitude Test (PCAT) scores (mean, maximum, and minimum), if required, for the past three admitted classes
- GPA scores (mean, maximum, and minimum) for preprofessional coursework for the past three admitted classes
- GPA scores (mean, maximum, and minimum) for preprofessional science courses for the past three admitted classes

- Comparisons of PCAT scores and preprofessional GPAs with peer schools for last admitted three admitted classes
- List of admission committee members with name and affiliation
- Policies and procedures regarding the admissions process including selection of admitted students, transfer of credit, and course waiver policies
- Professional and technical standards for school, college, and/or university (if applicable)
- List of preprofessional requirements for admission into the professional program
- Copies of instruments used during the admissions process including interview evaluation forms and assessment of written and oral communication
- Section of Student Handbook and/or Catalog (college, school, or university) regarding admissions
- Link to websites (or documentation of other mechanisms) that provide to the public information on required indicators of quality

**Standard 17 – Progression**

- Policies and procedures regarding student progression, early intervention, academic probation, remediation, missed course work or credit, leaves of absence, dismissal, readmission, due process, and appeals
- Section of Student Handbook and/or Catalog (college, school, or university) regarding student progression
- Student progression and academic dismissal data for the last three admitted classes
- Correlation analysis of admission variables and academic performance

**Standard 18 – Faculty and Staff – Quantitative Factors**

- Organizational chart depicting all full-time faculty by department/division
- List of full-time staff in each department/division and areas of responsibility
- ACPE documents (e.g., resource report) related to number of full-time and part-time faculty
- List of faculty turnover for the past five years by department/division with reasons for departure
- Description of coursework mapped to full-time and part-time faculty teaching in each course
- Results from AACF faculty survey regarding adequacy of quantitative strength of faculty and staff

**Standard 19 – Faculty and Staff – Qualitative Factors**

- Curriculum vitae of faculty and professional staff
- List of active research areas of faculty and an aggregate summary of faculty publications/presentations over the past three years.
- Procedures employed to promote a conceptual understanding of contemporary practice, particularly among non-pharmacist faculty
- Policies and procedures related to faculty recruitment, performance review, promotion, tenure (if applicable), and retention
- Faculty Handbook
- Data from AACF faculty survey regarding qualitative faculty factors

**Standard 20 - Preceptors**

- List of active preceptors with credentials and practice site
- Number, percentage of required APPE precepted by non-pharmacists categorized by type of experience.
- Description of practice sites (location, type of practice, student/preceptor ratios)
- Policies and procedures related to preceptor recruitment, orientation, development, performance review, promotion, and retention

- Examples of instruments used by preceptors to assess student performance
- Curriculum vitae of administrator(s) responsible for overseeing the experiential education component of the curriculum
- Description of the structure, organization and administrative support of the Experiential Education office (or equivalent)
- Results from AACP preceptor surveys

**Standard 21 – Physical Facilities and Educational Resources**

- Floor plans for college or school's facilities and descriptions of the use(s) of available space
- Description of shared space and how such space promotes interprofessional interaction
- Analysis of the quantity and quality of space available to the program and plans to address identified inadequacies.
- Documentation of Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) or other nationally recognized accreditation of animal care facilities, if applicable
- Results from AACP faculty, alumni, and graduating student surveys related to facilities
- Description of educational resources available to faculty, preceptors, and students (library, internet access, etc.)

**Standard 22 – Practice Facilities**

- Description of practice sites (location, type of practice, student:preceptor ratios) and involvement in IPPE, APPE, or both
- Policies and procedures related to site selection, recruitment, and assessment
- Examples of quality improvements made to improve student learning outcomes as a result of site/facility assessment
- Examples of affiliation agreements between college/school and practice sites (all agreements will be reviewed during site visits)
- ACPE IPPE and APPE Capacity Charts

**Standard 23 – Financial Resources**

- Detailed budget plan as defined by AACP (previous, current, and subsequent years)
- Description of college or school's budgetary processes
- In-state and out-of-state tuition compared to peer schools
- Results from AACP faculty survey regarding adequacy of financial resources

**Standard 24 – Assessment Elements for Section I**

- College or school's curriculum assessment plan(s)
- Description of formative and summative assessments of student learning and professional development used by college or school
- Description of standardized and comparative assessments of student learning and professional development used by college or school
- Description of how the college or school uses information generated within the curriculum assessment plan(s) to advance quality within its Doctor of Pharmacy program

**Standard 25 – Assessment Elements for Section II**

- College or school's program assessment plan(s)
- Description of how the college or school uses information generated by assessments related to its organizational effectiveness, mission and goals, didactic curriculum, experiential learning program, co-curriculum activities, and interprofessional education to advance overall programmatic quality

# Attachment 6



**nabp**  
**National Association of Boards of Pharmacy**  
1600 Feehanville Drive • Mount Prospect, IL 60056-6014  
Tel: 847/391-4406 • Fax: 847/391-4502  
Web Site: [www.nabp.net](http://www.nabp.net)

**TO:** DEANS – SCHOOLS AND COLLEGES OF PHARMACY  
**FROM:** Carmen A. Catizone, Executive Director/Secretary  
**DATE:** June 23, 2015  
**RE:** Forthcoming Information Regarding 2016 PCOA Registration and Administration

---

As part of the National Association of Boards of Pharmacy<sup>®</sup>'s (NABP<sup>®</sup>) continued commitment to partner with the schools and colleges of pharmacy to ensure the effective implementation of the Pharmacy Curriculum Outcomes Assessment<sup>®</sup> (PCOA<sup>®</sup>), the Association will soon be providing several sources of information regarding the registration and administration process. There will be changes in the 2016 registration and administration process to accommodate the increase in participating schools due to the new Accreditation Council for Pharmacy Education (ACPE) requirement, and to ensure that the PCOA administrations remain streamlined. This memo outlines the materials that will be provided to the schools and colleges in the next few months in preparation for the 2016 PCOA testing windows.

As detailed in NABP's February 3, 2015 memo regarding the PCOA requirement included in the *ACPE Standards 2016*, NABP will provide the PCOA at no cost for all students nearing the completion of their didactic curriculum. Please note that students in this group qualify to take the assessment one time at no cost. If the school/college chooses to schedule a second administration for students that already completed the PCOA at no cost, the current fee of \$75 per student will apply. If schools and colleges administer the PCOA to students other than those nearing the completion of their didactic curriculum, the current fee of \$75 per student will apply. The school/college is responsible for providing the testing facility, meeting the technical requirements for computer-based testing, and ensuring that all students have the appropriate hardware for the assessment. Please refer to the NABP website for current facility and technical guidelines.

The 2016 PCOA registration deadlines and administration windows will be available under PCOA in the Programs section of the NABP website by August 2015.

***Comprehensive Information Packet***

In late August, NABP will send the schools and colleges of pharmacy a comprehensive information packet. This resource is intended to lead administrators through the PCOA process from start to finish, as well as provide background information on the assessment. Key information will include:

- *PCOA Registration Form for Schools and Colleges of Pharmacy*
- *PCOA Registration Guide for Schools and Colleges of Pharmacy*: The guide will include instructions for registering the school/college for the PCOA; verifying the eligibility of students to take the PCOA; and obtaining, analyzing, and using score reports; among other topics.
- *PCOA Informational Flyer* (for students): The flyer will provide an overview of the PCOA and basic information that can be provided to students about registration. This flyer will also be provided electronically to schools/colleges for distribution to students. Please note that students will be required to establish an e-Profile in the NABP online system in order to be included on the school/college administration roster.

The aforementioned documents will also be available in the PCOA section of the NABP website.

If you have any questions regarding the information in this memo, please contact Lori Schumacher, PCOA manager, or Maria Incrocci, competency assessment senior manager, at PCOA@nabp.net or 847/391-4400.

cc: NABP Executive Committee

Executive Officers – State Boards of Pharmacy

Peter H. Vlasses, Accreditation Council for Pharmacy Education

Lucinda L. Maine, American Association of Colleges of Pharmacy

# Attachment 7

# Advanced Practice Pharmacist Program

## Required Program Competencies

*At completion of the program, pharmacists shall be able to:*

### *Patient Assessment (25%)*

- Demonstrate the ability to assess a patient for common acute and chronic disease states or conditions in a variety of settings, such as community pharmacies, ambulatory care clinics, hospitals and health systems, long-term care facilities, home-care agencies, and managed-care organizations.
- Demonstrate ability to assess patients by showing proficiency in the an array of patient assessment skill sets, including but not limited to: motivational interviewing skills to obtain medical history, correctly calculating and reporting pulse and respiratory rate, measuring blood pressure, taking temperature, etc.

### *Ordering Tests (15%)*

- Recognize when a treatment-related test should be ordered and communicate with patient's primary care provider. Document appropriate information in patient record system shared with prescriber(s) or transmit documentation to prescribers via other communication methods.
- Demonstrate the ability to order and interpret the results of certain treatment related-tests used to monitor common acute and chronic-disease states or conditions.
- List references to guide appropriate medication monitoring for safety and efficacy.

### *Patient Referral (10%)*

- Recognize the appropriate circumstances when a referral to another health care provider is indicated.
- Coordinate with other health care providers in the evaluation and management of acute and chronic diseases and health conditions for patients.
- Document appropriate information in patient record system shared with prescriber(s) or transmit documentation to prescribers via other communication methods.

### *Collaborative Drug Therapy Management and Effective Communication (30%)*

- Demonstrate the ability to appropriately manage drug therapy regimens:
  - a. Determine whether a drug therapy regimen(s) is appropriate/optimal, safe, cost-effective, patient-centered, and correctly used.
  - b. Recognize when a drug therapy regimen(s) needs to be initiated, substituted, adjusted, or discontinued.
  - c. Recognize appropriate monitoring and follow-up periods for drug therapy regimen(s).
  - d. Provide patient-centered education on disease states, treatments, and self-management strategies.
  - e. Utilize tools and resources to improve medication adherence.
- Demonstrate the ability to effectively communicate with a health care provider on changes to a drug therapy regimen or when ordering a test.

### *Documentation (20%)*

- Demonstrate the ability to accurately document care provided, including commonly accepted standards for documentation.

- Demonstrate the ability to document notes from patient cases using SOAP (Subjective, Objective, Assessment, and Plan). Provide verbal presentation of patient cases to other healthcare providers and stay current with literature and be able to cite specific guidelines, journal articles, and major studies supporting the SOAP.

### **Recommended Elements of a Program**

1. Program is peer reviewed by experts in the field who have subject matter expertise in the relevant areas of APP practice.
2. The program is developed and led by an advisory committee overseeing the program. The advisors are comprised of nationally-recognized experts in the field of clinical pharmacy practice.
3. Candidates for the program will have an opportunity to apply learnings in direct patient care situations including community and health system pharmacy practices.

### **Methods for Assessment of Competency**

1. Evaluation of base competency will be determined by a variety of assessment-based activities, such as written exams, OSCE-like patient profile review and skills application, proctored skills demonstrations, and other interactive written exercises and activities throughout the curricula.

### **Required Pre-requisite and Renewal**

1. Pre-requisite (minimal requirements to participate in program)
  - a. Currently licensed pharmacist in good standing with the state Board of Pharmacy.
2. Maintaining competency
  - a. Every two years, advanced practice pharmacists must demonstrate continued competency by updating his/her knowledge through continued commitment to learning. Renewal can be through various professional activities – continuing education (10 hours required in law), presentations, publications, etc.

### **Program Format/Components**

1. Mode of program educational delivery options
  - a. Online learning modules (self-study)
  - b. Live trainings, assessments, case studies and evaluation.

## **CPhA / NACDS Suggested Amendments to Proposed CCR Section 1730**

### 1730. Acceptable Certification Programs

(a) For purposes of this section and Business and Professions Code Section 4210(a)(2)(A), a “certification program” means a program designed to ensure that a pharmacist acquires or possesses specific knowledge and skills necessary for the competent practice as an advanced practice pharmacist and that assesses the pharmacist’s possession of that knowledge and ability to exercise those skills.

(b) In addition to programs recognized by the Accreditation Council for Pharmacy Education (ACPE) as described in Business and Professions Code section 4210(a)(2)(A), the board recognizes the pharmacy patient care certification programs that are accredited by the National Commission for Certification Agencies (NCCA) for purposes of satisfying the requirements in Business and Professions Code section 4210(a)(2)(A).

(c) A certification program that is accredited by NCCA shall comply with all of the following:

(1) The program shall measure advanced knowledge and skills required for competent performance in one or more areas of pharmacy practice through the use of written or practical knowledge assessments or examinations.

(2) The program shall award certification only to pharmacists who demonstrate competency in the designated practice area(s) by successfully meeting the performance, proficiency or passing standard for the required assessments.

(d) A certification program that is recognized by ACPE shall comply with all of the following:

(1) The program shall provide post-graduate instruction through recognized educational methods, such as self-study, direct patient care, classroom, and other educational components.

(2) The program shall evaluate participants’ achievement of the intended learning outcomes and assess competency through both written examinations and practical examinations.

(3) The program instruction and assessments shall focus on all of the following areas of advanced pharmacy practice:

(A) Patient assessment, including the ability to assess a patient for a particular disease state or condition.

(B) Ordering and interpreting treatment-related tests, including the ability to recognize when a treatment related test should be ordered and to interpret the results of particular treatment-related tests.

(C) Patient referral, including the ability to recognize appropriate circumstances when a referral to another healthcare provider is indicated.

(D) Collaborative drug therapy management, including the ability to determine whether a drug therapy regimen is appropriate, safe, patient-centered, and correctly used; to recognize when drug therapy should be initiated, substituted, adjusted, or discontinued; and an understanding of appropriate monitoring and follow-up.

(E) Appropriate and accurate clinical documentation.

(5) The program shall award certification only to pharmacists who demonstrate competency in the above areas by successfully meeting the performance, proficiency or passing standard for the required assessments.

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

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

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

Why Should You Care?

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

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

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

What's in a Name?

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

Which Option is Best?

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

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

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

Certification programs may be the best option when:

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

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

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

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

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

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

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

The authors welcome feedback on this article.

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

**Table 1 Distinctions Between Certificate and Certification Programs**

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

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

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

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

**Certificate Programs**

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

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

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

**Certification Programs**

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

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



## 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.<sup>1-4</sup>

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 <sup>a</sup> 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 <sup>b</sup> 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<sup>a</sup> 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<sup>a</sup> programs as outlined in the CCP Framework for Credentialing in Pharmacy Practice described in the Council's Scope of Contemporary Pharmacy Practice resource paper.<sup>2</sup>
4. Postgraduate education and training programs involve structured activities that should meet established professional standards. All credentialing<sup>a</sup> programs should be accredited.<sup>3,4</sup> 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<sup>a</sup> 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<sup>b</sup> 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<sup>b</sup> 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<sup>1</sup>

**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 (AACCP)
- 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

<sup>1</sup> 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](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,<sup>2</sup> site, or program that meets certain established qualifications or standards, as determined through initial and periodic evaluations.

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

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

## IMPORTANCE OF CREDENTIALS IN PHARMACY

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

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

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

## OVERVIEW OF CREDENTIALING IN PHARMACY – PHARMACISTS

### Introduction

Pharmacist credentials may be divided into three fundamental categories.

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

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

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

### Preparing for the Pharmacy Profession

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

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

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

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

State boards of pharmacy require a Pharm.D. or B.S. degree from a program approved by the boards (usually an ACPE-accredited program) to satisfy the educational requirements for a candidate to be eligible to take the state licensing examination. A listing of accredited professional programs offered by colleges and schools of pharmacy is published by ACPE and is available on the ACPE Web site ([www.acpe-accredit.org](http://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](http://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.<sup>3</sup> Development of these

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

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

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

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

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

ACPE accredits providers of CE,

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

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

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

### **Developing and Enhancing Knowledge and Skill**

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

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

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

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

### **Residencies**

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

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

ASHP is the recognized accrediting body for residency programs in

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

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

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

The Centers for Medicare and

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

#### • Fellowships<sup>4</sup>

- 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

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

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

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

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

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

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

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

#### • Certifications

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## OVERVIEW OF CREDENTIALING IN PHARMACY – PHARMACY TECHNICIANS

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

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

### Education and Training

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

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

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

### Regulation

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

### Certification

#### • Pharmacy Technician Certification Board

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

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

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

qualify for recertification, they must participate in at least 20 hours of approved pharmacy-related CE that includes 1 hour of pharmacy law. Information about PTCB and the PTCE is available at [www.ptcb.org](http://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](http://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](http://www.pharmacycredentialing.org/ccp/Files/CCP%20technician%20framework_08-09.pdf).

## **CREDENTIALING – THE FUTURE**

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

**Figure 1: U.S. Pharmacy Credentials and Oversight Bodies<sup>a</sup>**

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

<sup>a</sup>Oversight bodies are described in text.

<sup>b</sup>Effective January 2008, certificate programs are referred to as practice-based CPE activities in ACPE standards.

<sup>c</sup>State differences exist; refer to the main text.

## Appendix A: Glossary<sup>5</sup>

**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.

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

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

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

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

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

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

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

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

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

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

**Licensure:** The process of granting a license

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

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

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

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

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

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

## Appendix C: Credentialing Programs for Pharmacists

### CERTIFICATION PROGRAMS AVAILABLE TO PHARMACISTS<sup>1,2</sup>

Program	Certification Body	Credential Earned	Certification Body Accredited By
Ambulatory Care Pharmacy	Board of Pharmacy Specialties (BPS)	Board Certified Ambulatory Care Pharmacist (BCACS) <sup>3,4</sup>	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 <sup>3</sup>	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) <sup>3</sup>	
Health Information Technology	Health IT Certification	Certified Professional in Electronic Health Records (CPEHR)	
	Health IT Certification	Certified Professional in Health Information Technology (CPHIT)	
	Health IT Certification	Certified Professional in Health Information Exchange (CPHIE)	
HIV/AIDS	American Academy of HIV Medicine (AAHIVM)	HIV Expert (AAHIVE) <sup>5</sup>	
	American Academy of HIV Medicine (AAHIVM)	HIV Specialist (AAHIVS) <sup>5</sup>	
Infectious Diseases (Pharmacotherapy Added Qualifications)	Board of Pharmacy Specialties (BPS)	Board Certified Pharmacotherapy Specialist (BCPS) with Added Qualifications in Infectious Diseases <sup>3</sup>	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) <sup>3</sup>	National Commission for Certifying Agencies (NCCA)
Nutrition Support Pharmacy	Board of Pharmacy Specialties (BPS)	Board Certified Nutrition Support Pharmacist (BCNSP) <sup>3</sup>	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) <sup>3</sup>	National Commission for Certifying Agencies (NCCA)
Pain Education	American Society of Pain Educators (ASPE)	Certified Pain Educator (CPE)	
Pain Management	American Academy of Pain Management (AAPM)	Credentialed Pain Practitioner (CPP)	
Pharmacotherapy	Board of Pharmacy Specialties (BPS)	Board Certified Pharmacotherapy Specialist (BCPS) <sup>3</sup>	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) <sup>3</sup>	National Commission for Certifying Agencies (NCCA)
Toxicology	American Board of Applied Toxicology (ABAT)	Diplomat of the American Board of Applied Toxicology (DABAT)	

#### Notes:

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

## Appendix D: PGY2 Pharmacy Residencies

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

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

## Appendix E: Specialties Recognized by BPS

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

Domains of the BPS Ambulatory Care Pharmacy specialty examination include:

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

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

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

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

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

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

Domains of the BPS Nuclear Pharmacy specialty examination include:

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

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

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

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

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

Domains of the BPS Nutrition Support Pharmacy specialty examination include:

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

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

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

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

Domains of the BPS Oncology Pharmacy specialty examination include:

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

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

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

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

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

Domains of the BPS Pharmacotherapy specialty examination include:

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

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

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

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

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

Domains of the BPS Psychiatric Pharmacy specialty examination include:

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

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

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

## Appendix F: CCP Pharmacy Technician Credentialing Framework

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

See [http://www.pharmacycredentialing.org/ccp/Files/CCP%20technician%20framework\\_08-09.pdf](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.



# 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.

**Guiding Principles for Post-Licensure Credentialing of Pharmacists**

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

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

#### **How Individuals are Credentialed**

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

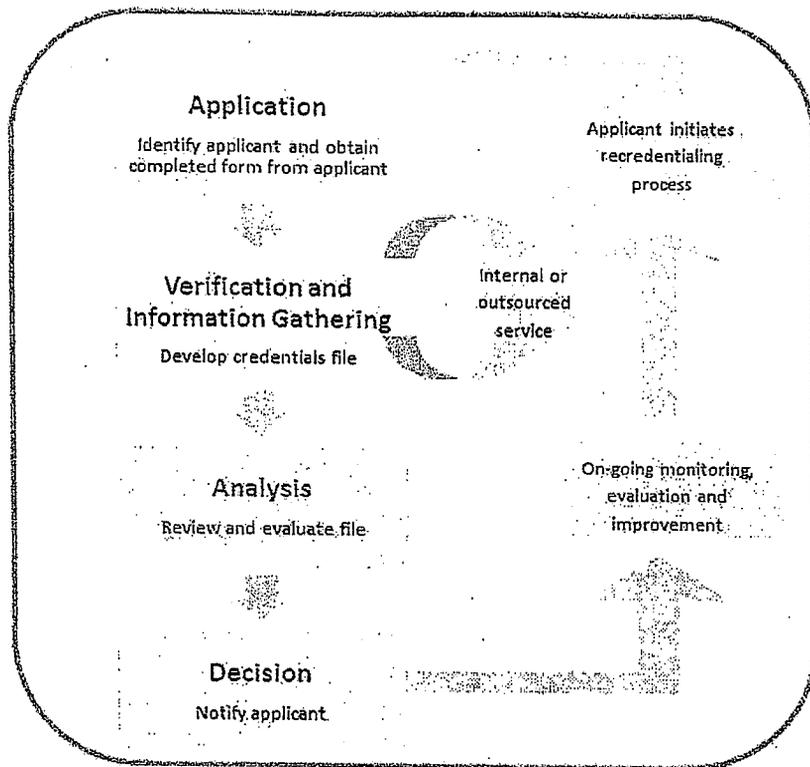


Figure 1. The Basic Credentialing Process Followed by Organizations

**Application** The credentialing process is commonly initiated using an application checklist. The individual pharmacist applies for employment or subsequently for 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.<sup>1</sup> 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.<sup>2</sup> 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

<sup>1</sup> 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.

<sup>2</sup> 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.<sup>3</sup> 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](http://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).

<sup>3</sup> 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](http://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)<sup>4</sup>
- Continuing Professional Development in Pharmacy Commentary (2004)<sup>5</sup>
- 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*, 2<sup>nd</sup> 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*, 2<sup>nd</sup> Ed., HCPro, Inc.; Marblehead, Massachusetts.
- Deutsch, S. & Mobley, C.S. (1999). *The Credentialing Handbook*. Jones and Bartlett Learning; Burlington, Massachusetts.
- Gassiot, C.A., Searcy, V.L., & Giles, C.W. (2011). *The Medical Staff Services Handbook Fundamentals and Beyond*. Jones and Bartlett Publishers, Sudbury Massachusetts.
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- 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>.

<sup>4</sup> 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.

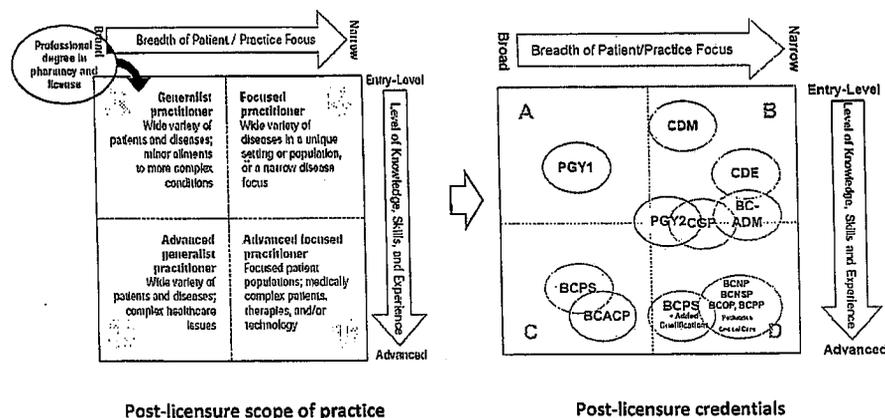
<sup>5</sup> Originally published in *J Am Pharm Assoc*. 2004; 44:517--520. ©2004, American Pharmacists Association (APhA). Reprinted by permission of APhA.

## 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.<sup>6</sup> Figure 2 displays how the education, training and certification components of this framework relate to how pharmacists' scopes of practice exist. This model organizes pharmacists' scopes of practice into four possible quadrants (A through D).



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

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

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

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

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

*Post-licensure credentials provide evidence for the credentialing process.* These forms of post-licensure credentials provide some of the evidence needed for credentialing of pharmacists for purposes of practicing as a paid employee of an organization, or in some situations to receive payment or compensation for service provision. Pharmacists either *may* obtain or *must* obtain specific credentials, dependent upon the circumstances the pharmacist is in. For example, pharmacists may desire to have effective and comprehensive skills in providing asthma education services to patients. While a pharmacist could provide these patient care services as part of the scope of practice recognized through being licensed and therefore not required to obtain the credential, the pharmacist could also choose to obtain a credential through completion of the requirements to become a Certified Asthma Educator (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.<sup>7</sup>

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<sup>7</sup> <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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## Content Outline for the AMBULATORY CARE PHARMACY SPECIALTY CERTIFICATION EXAMINATION January 2010 (Systems & Patient Care Problems updated May 2010)

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

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

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

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

#### **Tasks:**

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

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

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

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

**Knowledge of:**

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

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

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

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

**Tasks:**

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

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

**Knowledge of:**

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

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

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

**Tasks:**

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

**Knowledge of:**

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

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

**Tasks:**

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

**Knowledge of:**

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

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

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

Tasks:

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

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

**Knowledge of:**

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

**SYSTEMS AND PATIENT-CARE PROBLEMS**

***Bone/Joint and Rheumatology***

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

***Cardiovascular***

- Arrhythmias
- Cardiopulmonary resuscitation

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

***Dermatologic***

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

***Endocrine***

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

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

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

***Fluid and Electrolyte/Nutrition***

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

***Gastrointestinal***

- Constipation
- Diarrhea
- Chronic liver disease and cirrhosis

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

***Genitourinary***

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

***Hematologic***

- Anemias
- Sickle cell disease
- Thrombocytopenia
- Hematologic miscellaneous

***Immunologic***

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

***Infectious Diseases***

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

- Urinary tract infections
- Infectious Diseases miscellaneous

### ***Neurological***

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

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

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

### ***Oncology***

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

### ***Psychiatric***

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

- Substance abuse
- Psychiatric miscellaneous

***Renal***

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

***Pulmonary***

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

***Health Maintenance/Public Health***

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

# Attachment 8

Board of Pharmacy Licensing Statistics - Fiscal Year 2015/16

**APPLICATIONS**

**Received**

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Designated Representatives (EXC)	35	70											105
Designated Representatives Vet (EXV)	0	1											1
Designated Representatives-3PL (DRL)	14	19											33
Intern Pharmacist (INT)	55	510											565
Pharmacist (exam applications)	194	124											318
Pharmacist (initial licensing applications)	138	603											741
Pharmacy Technician (TCH)	578	440											1018
Centralized Hospital Packaging (CHP)	0	0											0
Clinics (CLN)	6	6											12
Clinics Exempt (CLE)	3	3											6
Drug Room (DRM)	0	0											0
Drug Room Exempt (DRE)	0	0											0
Hospitals (HSP)	7	0											7
Hospitals - Temp	5	0											5
Hospitals Exempt (HPE)	0	0											0
Hypodermic Needle and Syringes (HYP)	0	0											0
Hypodermic Needle and Syringes Exempt (HYE)	0	0											0
Licensed Correctional Facility (LCF)	0	0											0
Pharmacy (PHY)	25	39											64
Pharmacy - Temp	5	17											22
Pharmacy Exempt (PHE)	0	0											0
Pharmacy Nonresident (NRP)	11	14											25
Pharmacy Nonresident Temp	1	0											1
Sterile Compounding (LSC)	10	11											21
Sterile Compounding - Temp	6	5											11
Sterile Compounding Exempt (LSE)	0	0											0
Sterile Compounding Nonresident (NSC)	2	3											5
Sterile Compounding Nonresident Temp	0	0											0
Third-Party Logistics Providers (TPL)	2	2											4
Third-Party Logistics Providers - Temp	0	0											0
Third-Party Logistics Providers Nonresident (NPL)	4	3											7
Third-Party Logistics Providers Nonresident Temp	0	0											0
Veterinary Food-Animal Drug Retailer (VET)	0	0											0
Veterinary Food-Animal Drug Retailer - Temp	0	0											0
Wholesalers (WLS)	11	8											19
Wholesalers - Temp	4	0											4
Wholesalers Exempt (WLE)	0	0											0
Wholesalers Nonresident (OSD)	7	10											17
Wholesalers Nonresident - Temp	2	0											2
<b>Total</b>	<b>1125</b>	<b>1888</b>	<b>0</b>	<b>3013</b>									

Board of Pharmacy Licensing Statistics - Fiscal Year 2015/16

APPLICATIONS (continued)													
Issued	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Designated Representatives (EXC)	34	39											73
Designated Representatives Vet (EXV)	0	0											0
Designated Representatives-3PL (DRL)	34	19											53
Intern Pharmacist (INT)	103	222											325
Pharmacist (initial licensing applications)	146	451											597
Pharmacy Technician (TCH)	717	592											1309
Centralized Hospital Packaging (CHP)	1	0											1
Clinics (CLN)	12	7											19
Clinics Exempt (CLE)	1	0											1
Drug Room (DRM)	1	0											1
Drug Room Exempt (DRE)	0	0											0
Hospitals (HSP)	0	5											5
Hospitals - Temp	1	0											1
Hospitals Exempt (HPE)	0	1											1
Hypodermic Needle and Syringes (HYP)	0	6											6
Hypodermic Needle and Syringes Exempt (HYE)	0	0											0
Licensed Correctional Facility (LCF)	0	0											0
Pharmacy (PHY)	30	36											66
Pharmacy - Temp	7	2											9
Pharmacy Exempt (PHE)	1	0											1
Pharmacy Nonresident (NRP)	3	9											12
Pharmacy Nonresident Temp	5	5											10
Sterile Compounding (LSC)	3	1											4
Sterile Compounding - Temp	2	6											8
Sterile Compounding Exempt (LSE)	0	0											0
Sterile Compounding Nonresident (NSC)	2	1											3
Sterile Compounding Nonresident Temp	0	0											0
Third-Party Logistics Providers (TPL)	3	1											4
Third-Party Logistics Providers-Temp	0	0											0
Third-Party Logistics Providers Nonresident (NPL)	10	2											12
Third-Party Logistics Providers Nonresident Temp	0	0											0
Veterinary Food-Animal Drug Retailer (VET)	0	0											0
Veterinary Food-Animal Drug Retailer - Temp	0	0											0
Wholesalers (WLS)	7	3											10
Wholesalers - Temp	0	0											0
Wholesalers Exempt (WLE)	0	0											0
Wholesalers Nonresident (OSD)	11	4											15
Wholesalers Nonresident - Temp	0	0											0
Total	1134	1412	0	0	0	0	0	0	0	0	0	0	2546

The number of temporary licenses issued is reported in the permanent license type.

Board of Pharmacy Licensing Statistics - Fiscal Year 2015/16

**APPLICATIONS (continued)**

**Pending**

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN
Designated Representatives (EXC)	228	257										
Designated Representatives Vet (EXV)	3	4										
Designated Representatives-3PL (DRL)	120	109										
Intern Pharmacist (INT)	102	384										
Pharmacist (exam applications)	905	805										
Pharmacist (eligible exam)	1981	1709										
Pharmacy Technician (TCH)	1228	992										
Centralized Hospital Packaging (CHP)	16	16										
Clinics (CLN)	66	72										
Clinics Exempt (CLE)	10	11										
Drug Room (DRM)	1	1										
Drug Room Exempt (DRE)	0	0										
Hospitals (HSP)	22	14										
Hospitals Exempt (HPE)	4	4										
Hypodermic Needle and Syringes (HYP)	14	8										
Hypodermic Needle and Syringes Exempt (HYE)	0	0										
Licensed Correctional Facility (LCF)	0	0										
Pharmacy (PHY)	210	208										
Pharmacy Exempt (PHE)	4	5										
Pharmacy Nonresident (NRP)	203	204										
Sterile Compounding (LSC)	44	44										
Sterile Compounding - Exempt (LSE)	6	7										
Sterile Compounding Nonresident (NSC)	38	40										
Third-Party Logistics Providers (TPL)	12	13										
Third-Party Logistics Providers Nonresident (NPL)	52	54										
Veterinary Food-Animal Drug Retailer (VET)	1	1										
Wholesalers (WLS)	57	61										
Wholesalers Exempt (WLE)	0	0										
Wholesalers Nonresident (OSD)	73	83										
<b>Total</b>	<b>5400</b>	<b>5106</b>	<b>0</b>									

The number of temporary applications are included in the primary license type.

Board of Pharmacy Licensing Statistics - Fiscal Year 2015/16

APPLICATIONS (continued)													
Withdrawn	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Designated Representatives (EXC)	1	5											6
Designated Representatives Vet (EXV)	0	0											0
Designated Representatives-3PL (DRL)	0	0											0
Intern Pharmacist (INT)	0	0											0
Pharmacist (exam applications)	0	1											1
Pharmacist (initial licensing applications)	0	0											0
Pharmacy Technician (TCH)	132	53											185
Centralized Hospital Packaging (CHP)	0	0											0
Clinics (CLN)	0	1											1
Clinics Exempt (CLE)	0	0											0
Drug Room (DRM)	0	0											0
Drug Room Exempt (DRE)	0	0											0
Hospitals (HSP)	0	4											4
Hospitals Exempt (HPE)	0	0											0
Hypodermic Needle and Syringes (HYP)	4	0											4
Hypodermic Needle and Syringes Exempt (HYE)	0	0											0
Licensed Correctional Facility (LCF)	0	0											0
Pharmacy (PHY)	0	1											1
Pharmacy Exempt (PHE)	0	0											0
Pharmacy Nonresident (NRP)	20	1											21
Sterile Compounding (LSC)	1	4											5
Sterile Compounding Exempt (LSE)	0	0											0
Sterile Compounding Nonresident (NSC)	0	0											0
Third-Party Logistics Providers (TPL)	0	0											0
Third-Party Logistics Providers Nonresident (NPL)	0	0											0
Veterinary Food-Animal Drug Retailer (VET)	0	0											0
Wholesalers (WLS)	1	0											1
Wholesalers Exempt (WLE)	0	0											0
Wholesalers Nonresident (OSD)	0	2											2
Total	159	72	0	0	0	0	0	0	0	0	0	0	231

The number of temporary applications withdrawn is reflected in the primary license type.

Board of Pharmacy Licensing Statistics - Fiscal Year 2015/16

APPLICATIONS (continued)													
Denied	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Designated Representatives (EXC)	1	0											1
Designated Representatives Vet (EXV)	0	0											0
Designated Representatives-3PL (DRL)	0	0											0
Intern Pharmacist (INT)	0	0											0
Pharmacist (exam applications)	2	0											2
Pharmacist (initial licensing applications)	0	0											0
Pharmacy Technician (TCH)	3	8											11
Centralized Hospital Packaging (CHP)	0	0											0
Clinics (CLN)	0	0											0
Clinics Exempt (CLE)	0	0											0
Drug Room (DRM)	0	0											0
Drug Room Exempt (DRE)	0	0											0
Hospitals (HSP)	0	0											0
Hospitals Exempt (HPE)	0	0											0
Hypodermic Needle and Syringes (HYP)	0	0											0
Hypodermic Needle and Syringes Exempt (HYE)	0	0											0
Licensed Correctional Facility (LCF)	0	0											0
Pharmacy (PHY)	1	6											7
Pharmacy Exempt (PHE)	0	0											0
Pharmacy Nonresident (NRP)	0	1											1
Sterile Compounding (LSC)	0	0											0
Sterile Compounding Exempt (LSE)	0	0											0
Sterile Compounding Nonresident (NSC)	0	0											0
Third-Party Logistics Providers (TPL)	0	0											0
Third-Party Logistics Providers Nonresident (NPL)	0	0											0
Veterinary Food-Animal Drug Retailer (VET)	0	0											0
Wholesalers (WLS)	0	0											0
Wholesalers Exempt (WLE)	0	0											0
Wholesalers Nonresident (OSD)	0	0											0
Total	7	15	0	0	0	0	0	0	0	0	0	0	22



Board of Pharmacy Licensing Statistics - Fiscal Year 2015/16

<b>Revenue Received</b>													
<b>A. Revenue Received</b>	JUL	AUG *	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Applications	203,149												\$203,149
Renewals	843,082												\$843,082
Cite and Fine	93,883												\$93,883
Probation/Cost Recovery	61,591												\$61,591
Request for Information/Lic. Verification	1,640												\$1,640
Fingerprint Fee	7,595												\$7,595
*CalStars Report not received for August.													
<b>B. Renewals Received</b>	JUL	AUG*	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Designated Representatives (EXC)	173												173
Designated Representatives Vet (EXV)	12												12
Designated Representatives-3PL (DRL)	0												0
Pharmacist (RPH)	1648												1648
Pharmacy Technician (TCH)	2569												2569
Centralized Hospital Packaging (CHP)	0												0
Clinics (CLN)	83												83
Clinics Exempt (CLE)	2												2
Drug Room (DRM)	2												2
Drug Room Exempt (DRE)	0												0
Hospitals (HSP)	19												19
Hospitals Exempt (HPE)	0												0
Hypodermic Needle and Syringes (HYP)	18												18
Hypodermic Needle and Syringes Exempt (HYE)	0												0
Licensed Correctional Facility (LCF)	0												0
Pharmacy (PHY)	213												213
Pharmacy Exempt (PHE)	0												0
Pharmacy Nonresident (NRP)	29												29
Sterile Compounding (LSC)	57												57
Sterile Compounding Exempt (LSE)	0												0
Sterile Compounding Nonresident (NSC)	7												7
Third-Party Logistics Providers (TPL)	0												0
Third-Party Logistics Providers Nonresident (NPL)	0												0
Veterinary Food-Animal Drug Retailer (VET)	3												3
Wholesalers (WLS)	44												44
Wholesalers Exempt (WLE)	0												0
Wholesalers Nonresident (OSD)	59												59
<b>Total</b>	<b>4938</b>	<b>0</b>	<b>4938</b>										

Board of Pharmacy Licensing Statistics - Fiscal Year 2015/16

Current Licensees													
	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Designated Representatives (EXC)	3080												3080
Designated Representatives Vet (EXV)	69												69
Designated Representatives-3PL (DRL)	45												45
Intern Pharmacist (INT)	6305												6305
Pharmacist (RPH)	42638												42638
Pharmacy Technician (TCH)	74728												74728
Centralized Hospital Packaging (CHP)	5												5
Clinics (CLN)	1168												1168
Clinics Exempt (CLE)	244												244
Drug Room (DRM)	25												25
Drug Room Exempt (DRE)	14												14
Hospitals (HSP)	400												400
Hospitals Exempt (HPE)	85												85
Hypodermic Needle and Syringes (HYP)	278												278
Hypodermic Needle and Syringes Exempt (HYE)	0												0
Licensed Correctional Facility (LCF)	53												53
Pharmacy (PHY)	6451												6451
Pharmacy Exempt (PHE)	124												124
Pharmacy Nonresident (NRP)	456												456
Sterile Compounding (LSC)	816												816
Sterile Compounding Exempt (LSE)	121												121
Sterile Compounding Nonresident (NSC)	91												91
Third-Party Logistics Providers (TPL)	3												3
Third-Party Logistics Providers Nonresident (NPL)	10												10
Veterinary Food-Animal Drug Retailer (VET)	24												24
Wholesalers (WLS)	619												619
Wholesalers Exempt (WLE)	16												16
Wholesalers Nonresident (OSD)	827												827
Total	138695	0	0	0	0	0	0	0	0	0	0	0	138695

# Attachment 9

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**Assembly Bill No. 486**

## CHAPTER 241

An act to amend Sections 4128, 4128.4, and 4128.5 of the Business and Professions Code, relating to pharmacy, and declaring the urgency thereof, to take effect immediately.

[Approved by Governor September 2, 2015. Filed with Secretary of State September 2, 2015.]

## LEGISLATIVE COUNSEL'S DIGEST

AB 486, Bonilla. Centralized hospital packaging pharmacies: medication labels.

The Pharmacy Law provides for the licensure and regulation of pharmacies, including hospital pharmacies, by the California State Board of Pharmacy, and makes a knowing violation of that law a crime. Existing law authorizes a centralized hospital packaging pharmacy to prepare medications for administration to inpatients within its own general acute care hospital or certain other commonly owned hospitals.

Existing law requires that these medications be barcoded to be readable at the inpatient's bedside in order to retrieve certain information, including, but not limited to, the date that the medication was prepared and the components used in the drug product.

This bill would require that this information be displayed on a human-readable unit-dose label, and that the information be retrievable by the pharmacist using the medication lot number or control number.

This bill would require that the medication's barcode be machine readable, using medication administration software, and that the software compare the information contained in the barcode to the electronic medical record of the inpatient in order to verify that the medication to be given is the correct medication, dosage, and route of administration for that patient.

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

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.

This bill would declare that it is to take effect immediately as an urgency statute.

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

SECTION 1. Section 4128 of the [Business and Professions Code](#) is amended to read:

4128. (a) Notwithstanding Section 4029, a centralized hospital packaging pharmacy may prepare medications, by performing the following specialized functions, for administration only to inpatients within its own general acute care hospital and one or more general acute care hospitals if the hospitals are under common ownership and located within a 75-mile radius of each other:

- (1) Preparing unit dose packages for single administration to inpatients from bulk containers, if each unit dose package is barcoded pursuant to Section 4128.4.
- (2) Preparing sterile compounded unit dose drugs for administration to inpatients, if each compounded unit dose drug is barcoded pursuant to Section 4128.4.
- (3) Preparing compounded unit dose drugs for administration to inpatients, if each unit dose package is barcoded pursuant to Section 4128.4.

(b) For purposes of this article, "common ownership" means that the ownership information on file with the board pursuant to Section 4201 for the licensed pharmacy is consistent with the ownership information on file with the board for the other licensed pharmacy or pharmacies for purposes of preparing medications pursuant to this section.

SEC. 2. Section 4128.4 of the Business and Professions Code is amended to read:

4128.4. (a) Any unit dose medication produced by a centralized hospital packaging pharmacy shall be barcoded to be machine readable at the inpatient's bedside using barcode medication administration software.

(b) The barcode medication administration software shall permit health care practitioners to ensure that, before a medication is administered to an inpatient, it is the right medication, for the right inpatient, in the right dose, and via the right route of administration. The software shall verify that the medication satisfies these criteria by

reading the barcode on the medication and comparing the information retrieved to the electronic medical record of the inpatient.

(c) For purposes of this section, "barcode medication administration software" means a computerized system designed to prevent medication errors in health care settings.

SEC. 3. Section 4128.5 of the Business and Professions Code is amended to read:

4128.5. (a) Any label for each unit dose medication produced by a centralized hospital packaging pharmacy shall display a human-readable label that contains all of the following:

- (1) The date that the medication was prepared.
- (2) The beyond-use date.
- (3) The established name of the drug.
- (4) The quantity of each active ingredient.
- (5) Special storage or handling requirements.
- (6) The lot number or control number assigned by the centralized hospital packaging pharmacy.

(7) The name of the centralized hospital packaging pharmacy.

(b) For quality control and investigative purposes, a pharmacist shall be able to retrieve all of the following information using the lot number or control number described in subdivision (a):

- (1) The components used in the drug product.
- (2) The expiration date of each of the drug's components.
- (3) The National Drug Code Directory number.

SEC. 4. 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.

SEC. 5. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

To eliminate, at the earliest possible time, requirements that exceed the current technological capabilities of hospitals and that create overly burdensome administrative costs for the California State Board of Pharmacy, it is necessary this act take effect immediately.

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