



April 2, 2024

California State Board of Pharmacy  
2720 Gateway Oaks Drive  
Suite 100  
Sacramento, California 95833

Dear Dr. Seung Oh,

We are writing today to address the recent proposed amendments to Article 2, Section 1707.4 of Division 17 of Title 16 of the California Code of Regulations (the "Amendment"). The Amendment proposes some substantial changes pertaining to central fill arrangements, notably introducing a requirement that at least one of the pharmacies in a central fill arrangement be physically located in California. This is in stark contrast to the permissive view of central fill and shared services that the Board has taken over the last few years, and directly impacts pharmacies, including Biologics by McKesson ("Biologics"), that have developed such arrangements to better serve California patients. We ask that this Committee reconsider the sweeping and significant impacts that this Amendment would have on the ability of pharmacies like Biologics to address the needs of California patients.

As technology and operations have evolved, pharmacies all over the country have begun to rely on alternative arrangements like central fill to expand their reach and serve patients across the country. Biologics is one such pharmacy, delivering oncology and rare disease medications to patients across the United States. In just one quarter, Biologics touched over 200,000 souls, many of whom suffer from cancer or other rare diseases. **In the first quarter of 2024, over 8,300 California residents received their therapies from Biologics.**

We have strategically selected our two pharmacy locations in Cary, North Carolina and Forth Worth, Texas to best serve patients across the country, including California. Because Biologics does not have a California-based location, this proposed Amendment would have the immediate effect of disrupting care for thousands of Californians.

Specialty pharmacies like Biologics often provide services that go well beyond dispensing medications. Given the disease states at issue, specialty pharmacies like Biologics are often called upon to become a part of the patients' overall care continuum, regularly collaborating with patients' providers and patients themselves to help overcome challenges to medication adherence. Biologics has addressed this challenge by identifying these barriers for patients – including affordability, education, and emotional support – and developing financial assistance and patient engagement programs to support patients on their journey to stay adherent to their medications and at a price they can afford. In fact, in its most recent quarter, Biologics helped secure approximately \$15,000,000 in financial assistance for patients.

Owing in no small part to these additional services, Biologics and other specialty pharmacies are often in the unique position of being selected by biopharmaceutical and life science companies as parts of limited pharmacy networks with access to their therapies. **Biologics carries over 200 cancer and rare disease medications and**

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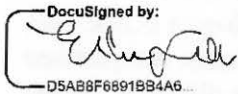
**is part of a limited distribution network for at least 92 of those. For 18 of those therapies, Biologics is the exclusive pharmacy provider or the only available pharmacy from which that drug can be dispensed.** Were the proposed Amendment to go into effect, access to at least these medications – and even to those medications in limited networks where other available pharmacies lack a California location – would present a significant access barrier to California patients.

While undoubtedly well-intentioned, the proposed Amendment would have a significant and severe impact on the thousands of Californians served by Biologics and countless other Californians serviced by other pharmacies that are reliant on central fill models. Instead, we ask that this Committee reconsider requiring a pharmacy to have a California location in order to execute on a central fill model. These arrangements have grown exponentially over the last few years and have gained acceptance from pharmacy Boards across the fifty states, and we hope that the California Board will follow suit by revising this proposed Amendment.

We thank this Committee for the work that you do to ensure safe access to medications for all California residents. We look forward to working together to facilitate continued access to these specialty medications.

Thank you for considering our stance on this matter.

Sincerely,

DocuSigned by:  
  
DSAB8F6691BB4A6...

Ela Lourido

VP/GM Specialty Pharmacy Solutions



April 5, 2024

California State Board of Pharmacy  
2720 Gateway Oaks Dr., Ste 100  
Sacramento, CA 95833

RE: April 2024 Licensing Committee Meeting; Proposed Amendments to Central Fill Pharmacy Regulation

Dear President Oh:

Kaiser Permanente appreciates the opportunity to provide feedback to the California Board of Pharmacy's Licensing Committee on the proposed amendments to the Board's regulations pertaining to central fill pharmacy practice. Kaiser Permanente comprises the non-profit Kaiser Foundation Health Plan, the non-profit Kaiser Foundation Hospitals, and the Permanente Medical Groups, self-governed physician group practices that exclusively contract with Kaiser Foundation Health Plan. These entities work together seamlessly to meet the health needs of Kaiser Permanente's nine million members in California. Kaiser Permanente's pharmacy enterprise in California is comprised of hundreds of licensed pharmacies that are staffed by thousands of individual pharmacy licentiates.

While Kaiser Permanente does not currently operate a conventional central fill pharmacy in California, we do have a handful of suggestions that we believe would improve the Board's central fill pharmacy regulation both for consumers and the regulated public. First, we appreciate that the draft regulations clarify that a central fill pharmacy can process requests for both initial and refills of prescriptions. We encourage the committee to rework the regulation to clarify that the central fill pharmacy may either (1) provide the filled prescription back to the originating pharmacy for fulfillment or (2) ship the filled prescription directly (e.g. by mail or delivery) to the patient.

The proposed amendments to the regulation would require a pharmacist at the originating pharmacy to perform final product verification prior to dispensing the prescription to the patient. We believe that there are several logistical constraints that make this proposed requirement impractical. First, it is likely that many pharmacy dispensing systems do not have the functionality to perform and document two product verification steps on the same prescription. Additionally, it is possible, if not likely, that the medications purchased by two pharmacies might be produced by different manufacturers and therefore have different physical appearances. This could lead to confusion when the pharmacist at the originating pharmacy performs product verification and the medication being verified has a different physical appearance than they are accustomed to. Finally, pharmacy organizations typically choose to engage in central fill arrangements to promote efficiency in the dispensing process, which is realized through specialization and economies of scale. We believe that requiring a pharmacist at the originating pharmacy to perform product verification is likely to significantly reduce the efficiency benefits associated with central fill arrangements. Therefore, we encourage the committee to delete the requirement that that a "pharmacist working at the originating pharmacy must perform final product verification prior to dispensing."

To further clarify the intent of the regulation and to align with the suggested changes above, we recommend that the committee rewrite the proposed definition of the term "central fill pharmacy" and add a definition of the term "originating pharmacy." Please see the two proposed definitions below:

(b) For the purposes of this section "Central Fill Pharmacy" means a California licensed pharmacy that provides centralized prescription filling for both initial or prescription refills on behalf of an originating pharmacy. The central fill pharmacy may also arrange for the delivery of the filled prescription to the patient.

(c) For the purposes of this section "Originating Pharmacy" means a pharmacy located and licensed in California that receives a patient's or a prescribing practitioner's request to fill a prescription. This pharmacy maintains ownership of a prescription that is filled by a central fill pharmacy.



Finally, we encourage the committee and the Board to continue discussing and ultimately to advise the regulated public on its position regarding the use of technology-assisted product verification in all pharmacy practice settings. The committee briefly discussed technology-assisted product verification as part of the central fill pharmacy agenda item during its January 2024 meeting; however, the meeting materials for the upcoming April 2024 committee meeting do not include any reference to technology-assisted product verification. Specifically, we encourage the Board to affirm that the guidance provided in the January 2005 and October 2005 issues in *The Script* newsletter remains consistent with the Pharmacy Law and reflects the Board's current policy on technology-assisted product verification.

Kaiser Permanente appreciates the committee's consideration of these suggestions related to the Board's central fill pharmacy regulation. If you have questions, please contact John Gray (562.417.6417; john.p.gray@kp.org) or Rebecca Cupp (562.302.3217; rebecca.l.cupp@kp.org).

Respectfully,

A handwritten signature in black ink, appearing to read "J. Gray", with a long, sweeping horizontal line extending to the right.

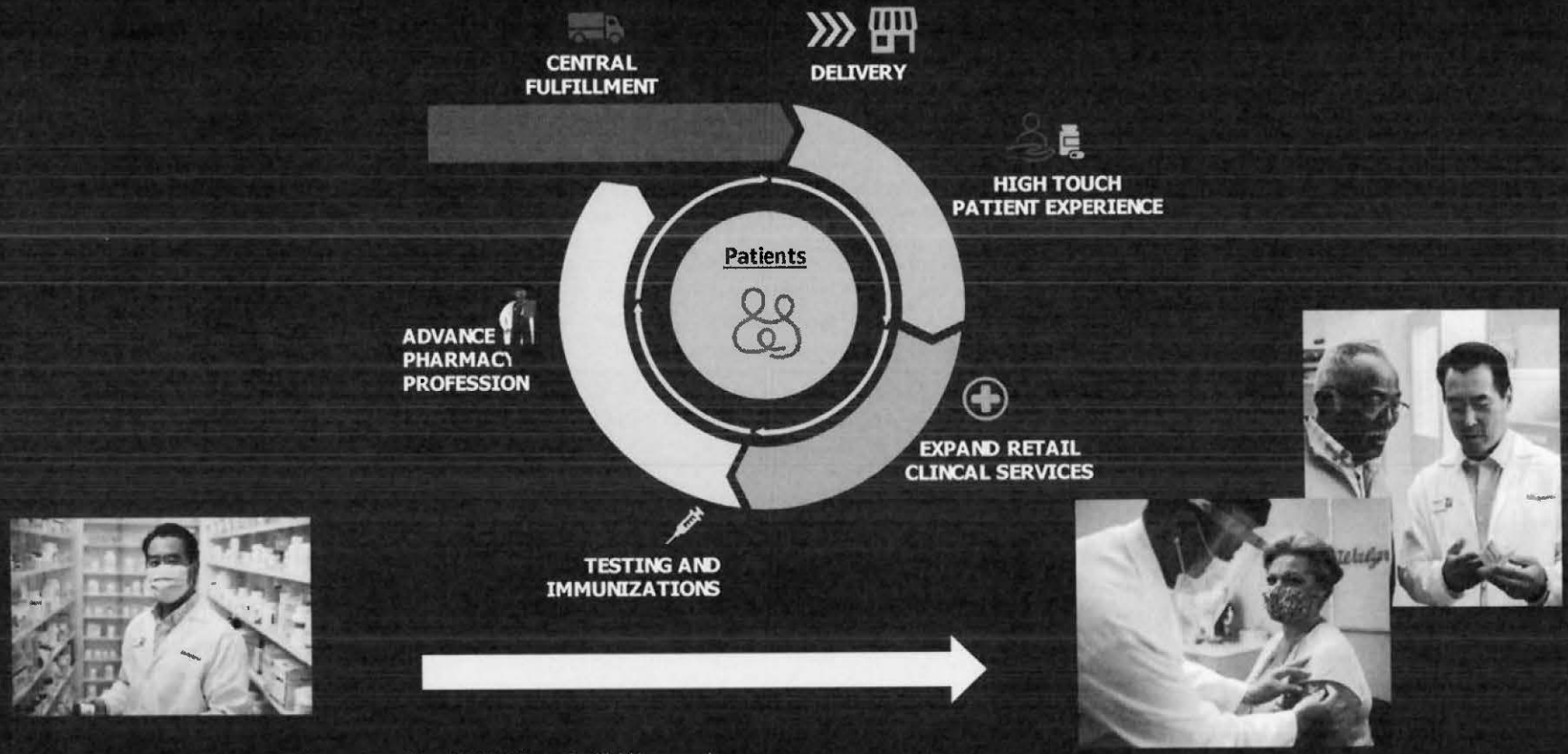
John P. Gray, PharmD, MSL  
Director, National Pharmacy Legislative and Regulatory Affairs  
Kaiser Permanente

# Walgreens Centralized Prescription Dispensing

Lorri Walmsley, RPh, FAzPA

Director, Pharmacy Affairs

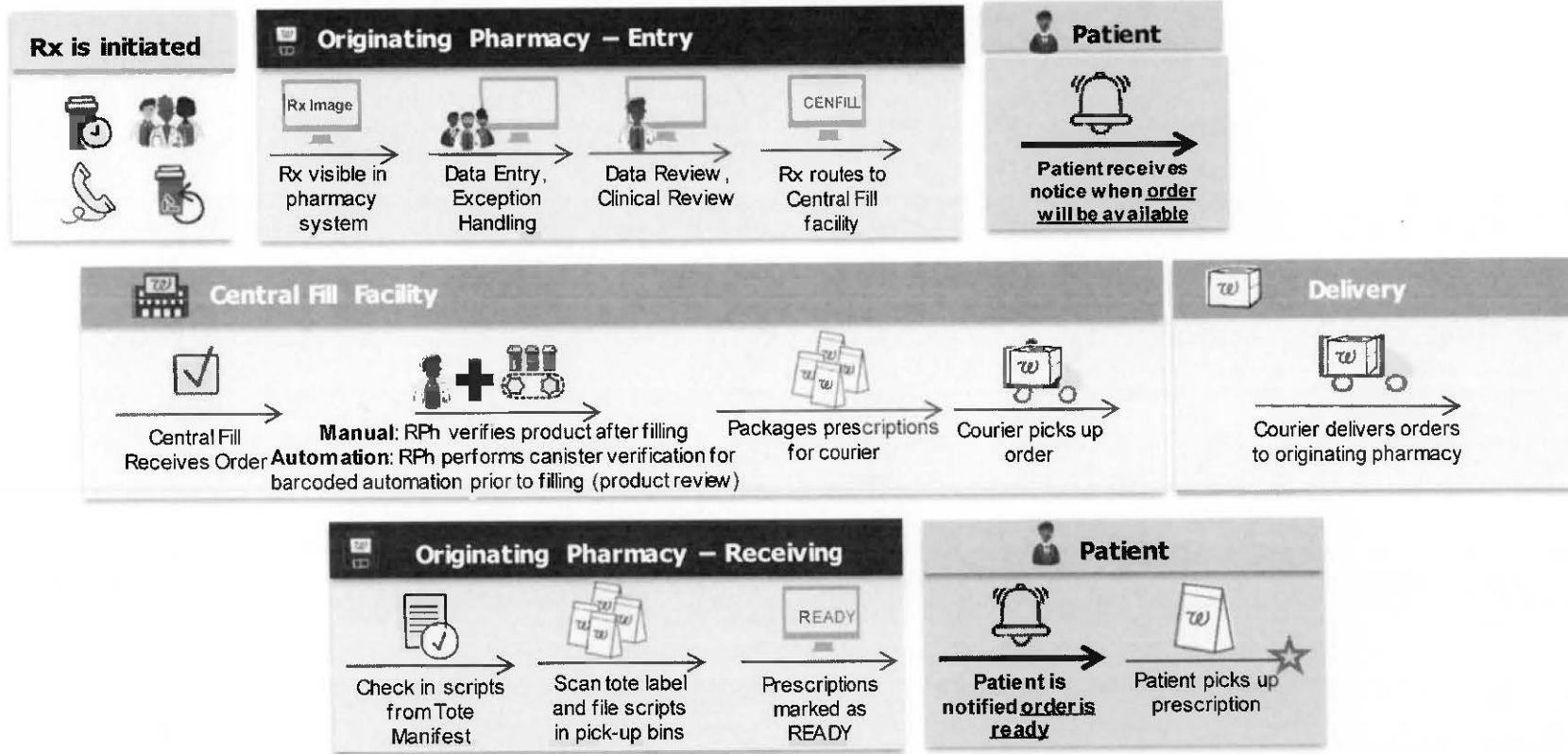
# Central Fulfillment enables the Future of Pharmacy







# Journey for Centrally Filled Prescriptions





## Prescription Record Keeping

\*Automation Central Fill

Maintained and retrievable across  
the entire fulfillment process

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### Audit / Board of Pharmacy Inspection Report

Rx #: 9398046-1

Store #: 59750

Sold Date: 04/26/2022

#### Annotations

This prescription does not have Annotations.

#### Prescription Information

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##### Patient

Name: PAUL CARL  
Address:  
2001 AKF COOK ROAD  
NASHVILLE, VA 37219  
(768) 768-7876  
Date of Birth: 04-20-1990  
Allergies/Health Conditions: No known allergies.

##### Drug

Drug: 1 IPITOR 10MG TABLETS  
MEC: PILLR  
NDC: 00071-0155-23  
Generic for:  
Drug Class: RX  
Directions: 1x 1 T PO QD

Qty: 30 Days Supply: 30  
Original Date: 04/26/2022 00:00  
Refills remaining when entered: 3

##### Prescriber

Name: ANDERSON WESS  
DEA #: 101849996  
Address:  
100 WILMOT RD  
GRAYSON AVE, IL 60030  
(847) 826-9979

##### Fill History

Scanning overridden  
Pat selected by J. PERICO on 04-26-2022 11:01:25 at 59750  
Pbr selected by J. PERICO on 04-26-2022 11:01:25 at 59750  
Entered by J. M. PERICO on 04-26-2022 11:01:25 at 59750  
Pat Pbr rev. by J. M. PERICO on 04-26-2022 11:02:32 at 59750  
Data Prod rev. by J. M. PERICO on 04-26-2022 11:02:32 at 59750  
Robotic Central Fill  
Filled by B. CAPA on 04-26-2022 11:15:28 at 21389  
Prod rev. by B. GREEN on 04-26-2022 11:15:33 at 21389  
Sold Date: 04/26/2022 15:03:07  
RPH of Record: J. M. PERICO

##### DUR

This report is considered a confidential Walgreens document. It is intended to be used for Board of Pharmacy inspections and Third Party audits. Professional discretion should be used prior to releasing this document.

## Prescription Record Keeping

\*Manual Central Fill

Maintained and retrievable across  
the entire fulfillment process

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### Audit / Board of Pharmacy Inspection Report

Rx #: 2501017-2

Store #: 59403

Sold Date: 10/06/2021

#### Annotations

This prescription does not have Annotations.

#### Prescription Information

All times are Central Standard Time except DRG comments which is local time

Patient	DUR
<b>Name:</b> JULY CASH <b>Address:</b> 755 WINDSOR RD CHAMPAIGN, IL 61822 (887) 364-3224 <b>Date of Birth:</b> 01/01/2001 <b>Allergies/Health Conditions:</b> No known allergies.	
<b>Drug</b> <b>Drug:</b> ATORVASTATIN 10MG TABLETS <b>MFG:</b> DR REDDY'S <b>NDC:</b> 55111-0121-05 <b>Generic for:</b> <b>Drug Class:</b> RX <b>Directions:</b> 1K 1 T PO QD	
<b>Qty:</b> 12 <b>Days Supply:</b> 12 <b>Original Date:</b> 10/04/2021 09:00 <b>Refills remaining when entered:</b> 5	
<b>Prescriber</b> <b>Name:</b> KUAN KUAN <b>DEA #:</b> SA123333 <b>Address:</b> N STREET I GRAND PRAIRIE, NY 75001 (847) 444-4444	
<b>Fill History</b> Scanning overridden Pat selected by J. PERK O on 10/04/2021 14:16:10 at 59403 Pho selected by J. PERK O on 10/04/2021 14:16:10 at 59403 Entered by J. M. PERK O on 10/04/2021 01:50:03 at 59403 Pat/Pho rev by J. M. PERK O on 10/04/2021 01:46:36 at 59403 Data Prod rev by J. M. PERK O on 10/04/2021 01:46:36 at 59403	
<b>Manual Central Fill</b> Filled by M. MONROE on 10/05/2021 07:07:20 at 21372 Prod rev by M. MONROE on 10/05/2021 07:07:32 at 21372 Sold Date: 10/06/2021 12:31:56 RPH of Record: J. M. PERK O	

This report is considered a confidential Walgreens document. It is intended to be used for Part 1 of Pharmacy inspections and 1) of Part 2 and 3. Professional discretion should be used prior to releasing this document.

**ASHP/ACPE ACCREDITATION FOR PHARMACY TECHNICIAN  
EDUCATION AND TRAINING PROGRAMS**

**Lisa S. Lifshin, BS.Pharm.**

**Sr. Director, Pharmacy Technician Program  
Accreditation & Residency Services**



# About the Presenter



**Lisa S. Lifshin, BS.Pharm.**

Sr. Director, Pharmacy Technician Program Accreditation & Residency Services

Accreditation Services, ASHP



# ASHP / ACPE Collaboration

- ASHP has been accrediting technician programs in the 1980's on a voluntary basis
- In 2012, NABP requests for ACPE to participate in pharmacy technician education and training accreditation
- PTAC formed through ASHP/ACPE collaboration in 2013
- ACPE Board approved ASHP standards, guidelines, and procedures for PTAC
- PTAC recommendations require approval of both ASHP and ACPE Boards
- First PTAC recommendations to ASHP and ACPE boards for accreditation actions occurred at their June 2015 meetings and were approved
- There are 250+ ASHP/ACPE accredited pharmacy technician education and training programs and an estimated greater number of unaccredited programs



# ASHP WEBSITE

The screenshot shows the ASHP website homepage. The top navigation bar includes the ASHP logo, the tagline 'pharmacists advancing healthcare', and links for ASHP Foundation, About ASHP, CEO Blogs, Store, AJHP, Login, and a 'JOIN ASHP' button. Below the navigation bar are several menu items: PRACTICE RESOURCES, PROFESSIONAL DEVELOPMENT, MEETINGS & CONFERENCES, ADVOCACY, and MEMBER CENTER. The main content area features a grid of nine cards, each with a title and a 'LEARN MORE' button. The card titled 'Accreditation Standards, Regulations, and Other Tools' is highlighted with a red border and a red arrow pointing to it from the right side of the image.

**ashp**  
pharmacists advancing healthcare®

ASHP Foundation About ASHP CEO Blogs Store AJHP Login **JOIN ASHP**

PRACTICE RESOURCES PROFESSIONAL DEVELOPMENT MEETINGS & CONFERENCES ADVOCACY MEMBER CENTER Q

**Pharmacy Technician Training Program Directory**  
GO TO DIRECTORY

**ASHP/ACPE Pharmacy Technician Accreditation Commission**  
LEARN MORE

**Accreditation Standards, Regulations, and Other Tools**  
LEARN MORE

**Starting a Pharmacy Technician Training Program**  
LEARN MORE

**Sample Forms**  
LEARN MORE

**Applying for Accreditation**  
LEARN MORE

**Preparing for an Accreditation Survey**  
LEARN MORE

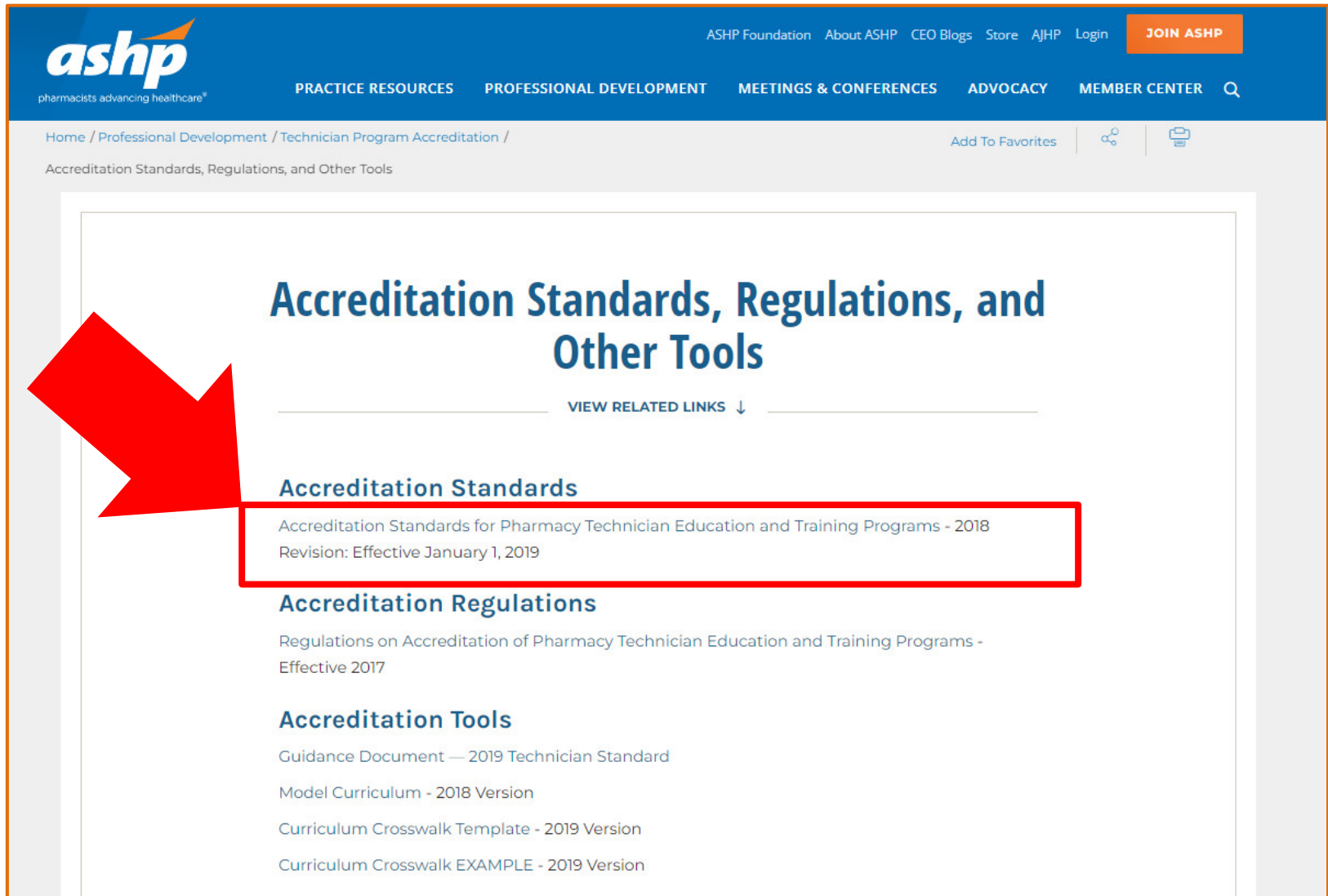
**Other Professional Organizations**  
LEARN MORE

**Pharmacy Technician TABLET Newsletter**  
LEARN MORE





# 2. Know the Standards



**ashp**  
pharmacists advancing healthcare®

ASHP Foundation About ASHP CEO Blogs Store AJHP Login **JOIN ASHP**

PRACTICE RESOURCES PROFESSIONAL DEVELOPMENT MEETINGS & CONFERENCES ADVOCACY MEMBER CENTER Q

Home / Professional Development / Technician Program Accreditation /  
Accreditation Standards, Regulations, and Other Tools

Add To Favorites

## Accreditation Standards, Regulations, and Other Tools

VIEW RELATED LINKS ↓

### Accreditation Standards

Accreditation Standards for Pharmacy Technician Education and Training Programs - 2018  
Revision: Effective January 1, 2019

### Accreditation Regulations

Regulations on Accreditation of Pharmacy Technician Education and Training Programs -  
Effective 2017

### Accreditation Tools

- Guidance Document — 2019 Technician Standard
- Model Curriculum - 2018 Version
- Curriculum Crosswalk Template - 2019 Version
- Curriculum Crosswalk EXAMPLE - 2019 Version



# MODEL CURRICULUM



**MODEL CURRICULUM  
FOR  
PHARMACY TECHNICIAN EDUCATION AND TRAINING PROGRAMS**

**FIFTH EDITION**

ASHP (American Society of Health-System Pharmacists)  
4500 East-West Highway, Suite 900  
Bethesda, MD 20814

Accreditation Council for Pharmacy Education (ACPE)  
190 S. LaSalle Street, Suite 2850  
Chicago, IL 60603

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The Model Curriculum for Pharmacy Technician Education and Training Programs (*Model Curriculum*) provides details on how to meet the new *ASHP/ACPE Accreditation Standards for Pharmacy Technician Education and Training Programs*



# Guidance Document

AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS  
ACCREDITATION COUNCIL FOR PHARMACY EDUCATION



**GUIDANCE DOCUMENT  
for**

**ASHP / ACPE ACCREDITATION STANDARDS FOR PHARMACY  
TECHNICIAN EDUCATION AND TRAINING PROGRAMS**

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APPROVED:  
June 2, 2018  
June 23, 2018

PUBLISHED:  
July 10, 2018

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Pharmacy Technician Accreditation Commission (PTAC)

The Guidance Document for the *ASHP/ACPE Accreditation Standards for Pharmacy Technician Education and Training Programs*:

- Clarifies how programs may meet the Key Elements
- Describes what materials and documentation your program may need to provide surveyors for accreditation purposes



# 3. Starting a Pharmacy Technician Education and Training Program



# 3. Starting a Pharmacy Tech. Education & Training Program

The screenshot displays the ASHP website's resource grid. The header includes the ASHP logo, navigation links for Practice Resources, Professional Development, Meetings & Conferences, Advocacy, and Member Center, and a 'JOIN ASHP' button. The main content area features nine cards, each with a title and a 'LEARN MORE' button. The card titled 'Starting a Pharmacy Technician Training Program' is highlighted with a red border and a red arrow pointing to it from the left.

Card Title	Action Button
Pharmacy Technician Training Program Directory	GO TO DIRECTORY
ASHP/ACPE Pharmacy Technician Accreditation Commission	LEARN MORE
Accreditation Standards, Regulations, and Other Tools	LEARN MORE
<b>Starting a Pharmacy Technician Training Program</b>	LEARN MORE
Sample Forms	LEARN MORE
Applying for Accreditation	LEARN MORE
Preparing for an Accreditation Survey	LEARN MORE
Other Professional Organizations	LEARN MORE
Pharmacy Technician TABLET Newsletter	LEARN MORE



# Types of Pharmacy Technician Education and Training Programs



# ENTRY vs. ADVANCED LEVEL

## Entry-Level

- The program prepares students for practice as Entry-level pharmacy technicians in a variety of contemporary settings (e.g., community, hospital, home care, long-term care) and has students acquire knowledge, skills, behaviors, and abilities needed for such practice.

## Advanced-Level

- The program prepares students for practice as Advanced-level pharmacy technicians, in a broad range of advanced roles in a variety of contemporary settings (e.g., community, hospital, home care, long-term care) and has students acquire additional knowledge, skills, behaviors, and abilities beyond those of the Entry-level pharmacy technician, needed for such advanced practice.

# Standard 9: Curricular Length

- **Entry-Level: 400 hours,  $\geq$  8 weeks**
  - 300 hours divided as:
    - Didactic – 120 hours
    - Simulation – 50 hours
    - Experiential – 130 hours
  - 100 hours allocated as program director and faculty see fit
- **Advanced-Level: 600 hours,  $\geq$  15 weeks (includes Entry-level hrs)**
  - 460 hours divided as:
    - Didactic – 160 hours (40 more hours beyond Entry-level)
    - Simulation – 100 hours (50 more beyond Entry-level)
    - Experiential – 200 hours (70 more hours beyond Entry-level)
  - 140 hours allocated as program director and faculty see fit



# Review of Standards



# Three Sections of the ASHP/ACPE Standards

- **SECTION I: COMPETENCY EXPECTATIONS**
  - Standards # 1 to 5
- **SECTION II: STRUCTURE AND PROCESS TO PROMOTE ACHIEVEMENT OF COMPETENCY EXPECTATIONS**
  - Standards # 6 to 13
- **SECTION III: ASSESSMENTS OF STANDARDS AND KEY ELEMENTS**
  - Standards # 14 to 15

# SECTION I: COMPETENCY EXPECTATIONS

- **Standard 1: Personal/Interpersonal Knowledge and Skills**
  - Entry-level: 8 Key Elements
  - Advanced-level: 4 Key Elements
- **Standard 2: Foundational Professional Knowledge and Skills**
  - Entry-level: 8 Key Elements
  - Advanced-level: 3 Key Elements
- **Standard 3: Processing and Handling of Medications and Medication Orders**
  - Entry-level: 22 Key Elements
  - Advanced-level: 9 Key Elements
- **Standard 4: Patient Care, Quality and Safety Knowledge and Skills**
  - Entry-level: 8 Key Elements
  - Advanced-level: 5 Key Elements
- **Standard 5: Regulatory and Compliance Knowledge and Skills**
  - Entry-level: 8 Key Elements
  - Advanced-level: 2 Key Elements

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

## Standard 9: Curricular Length

- **Entry-level: 400 hours,  $\geq$  8 weeks**
  - 300 hours divided as:
    - Didactic – 120 hours
    - Simulation – 50 hours
    - Experiential – 130 hours
  - 100 hours allocated as program director and faculty see fit
- **Advanced-level: 600 hours,  $\geq$  15 weeks (includes Entry-level hrs)**
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    - Experiential – 200 hours (70 more hours beyond Entry-level)
  - 140 hours allocated as program director and faculty see fit

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

- **Standard 6: Authority and Responsibility provided to Program Director**
  - 9 Key Elements
- **Standard 7: Strategic Plan**
  - 2 Key Elements
- **Standard 8: Advisory Committee**
  - 5 Key Elements
- **Standard 9: Curricular Length**
  - Entry-level: 4 Key Elements
  - Advanced-level: 2 Key Elements

## SECTION II: STRUCTURE AND PROCESS TO PROMOTE ACHIEVEMENT OF EDUCATIONAL OUTCOMES (cont.)

- **Standard 10: Curricular Composition and Delivery (includes distance learning expectations)**
  - 8 Key Elements; Distance Learning – 4 Key Elements
  - Entry-level: Students complete at least **one experiential rotation** in a dispensing pharmacy setting where the student will utilize skills learned during their entry-level curriculum
  - Advanced-level: Students complete at least **one additional experiential rotation**, in addition to any completed during an entry-level program. This advanced experiential rotation takes place in a facility where the student will utilize skills learned during the advanced-level curriculum.
- **Standard 11: Student Recruitment, Acceptance, Enrollment, and Representation** - 8 Key Elements
- **Standard 12: Faculty/Instructors** - 4 Key Elements
- **Standard 13: Documentation** - 8 Key Elements



# SECTION III: ASSESSMENTS OF STANDARDS AND KEY ELEMENTS



- **Standard 14: Assessment of Competency Expectations**
  - 14.1 Student Learning Assessments – 6 Key Elements
  - 14.2 Program assessments – 5 Key Elements
    - (a) program completion;
    - (b) performance on national certification examinations or; performance on a psychometrically valid evaluation;
    - (c) program satisfaction, including student, graduate, and employer satisfaction;
    - (d) job placement; and
    - (e) assessment data used in the continuous quality improvement process is actively maintained.
- **Standard 15: Assessments of Structure and Process**
  - 3 Key Elements



# Q & A



# Questions Later? Contact Me!

- Lisa Lifshin
- [llifshin@ashp.org](mailto:llifshin@ashp.org)

