

NASP – ACPE Standards 2025 Call for Comments

Problem Summary

The ACPE Board of Directors and Staff are beginning work on the next revision of the **Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree**. The current version (“**Standards 2016**”) became effective July 1, 2016. The ACPE Board has approved a plan that will release the final version of the new standards in June 2024 with implementation planned on July 1, 2025. The new standards will be known as “**Standards 2025.**” **As part of the revision process, ACPE is accepting public comment on Standards 2016 through 12/31/2021. Public comments will be submitted through a portal on the ACPE website, and hold the potential to be incorporated into Standards 2025.**

The SASP Committee recognizes this as an opportunity to incorporate specialty pharmacy-focused verbiage into the standards used in accrediting pharmacy schools across the United States. As such, the Committee has orchestrated a call-to-action email for NASP general membership and University partners, urging them to provide their own comments on how to incorporate specialty pharmacy-focused verbiage into Standards 2025. In addition, the Committee has compiled its own revisions to these standards and provided them below. We request the Board’s review of these revisions and approval to submit them to ACPE on behalf of NASP.

SASP Committee Recommendations

Standard 3.6

Revise: “The graduate is able to effectively communicate verbally and nonverbally when interacting with individuals, groups, and organizations.” to “The graduate is able to effectively communicate verbally (in person and telephonically) and nonverbally when interacting with individuals, groups, and organizations.”

Standard 12.6

Revise: “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” to “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, specialty pharmacy and institutional health-system settings.”

NASP – ACPE Standards 2025 Call for Comments

Standard 12.7

Revise: “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” to **“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, specialty pharmacy 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 13.1

Revise: “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.” to **“Collectively, APPEs emphasize continuity of care and incorporate acute, chronic, and wellness-promoting patient-care services in outpatient (community, ambulatory care, specialty pharmacy, and mail order), inpatient (hospital/health system) settings, and other (managed care, industry) settings.”**

Standard 13.6

Revise: “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” to **“Required APPEs occur in six practice settings: (1) community pharmacy; (2) ambulatory patient care; (3) hospital/health system pharmacy; (4) inpatient general medicine patient care; (5) specialty pharmacy; and (6) managed care/industry.”**

Appendix 1:

Add required education on:

- **Bioequivalence** – The absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study.
- **Biological Products** – A diverse category of products and are generally large, complex molecules. These products may be produced through biotechnology in a living system, such as a microorganism, plant cell, or animal cell, and are often more difficult to

NASP – ACPE Standards 2025 Call for Comments

characterize than small molecule drugs. There are many types of biological products approved for use in the United States, including therapeutic proteins, monoclonal antibodies, and vaccines.

- **Biosimilar Products** - A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product.

Specialty Pharmacy –

Specialty drugs are the fastest-growing segment of the pharmacy market—specialty drug share of net expenditures across institutional and retail settings rose from 27% in 2010 to 53% in 2020, according to a report from the IQVIA Institute even though these medications account for only 2 percent of the total prescription volume.¹

A specialty pharmacy is a state-licensed pharmacy that solely or largely provides medications for people living with serious health conditions requiring treatment with complex therapies. These may include:

- Cancer
- Cystic fibrosis
- Hemophilia/other bleeding disorders
- Hepatitis
- HIV/AIDS
- Human growth hormone deficiencies
- Multiple sclerosis
- Organ transplantation
- Rheumatoid arthritis

Along with being state-licensed and regulated, specialty pharmacies are accredited by independent third parties such as the Accreditation Commission for Health Care (ACHC), The National Committee for Quality Assurance (NCQA), The Joint Commission and URAC. Accreditation demonstrates commitment to quality, safety, accountability, and adoption of nationally recognized standards of practice.

A specialty drug is more complex than most prescription medications and are often biologics that are injectable or infused, although some are oral medications. The complexity of these medications may be due to the drug itself, the way it is administered, the management of its side effect profile, the disease or condition it is used to treat, special access conditions required by the manufacturer, payer authorization or benefit requirements, patient financial hardship or any combination of these.

A specialty pharmacy's model is designed to provide a comprehensive and coordinated model of care for patients diagnosed with chronic illnesses and complex medical conditions, achieve superior clinical and economic outcomes, and expedite patient access to care.

NASP – ACPE Standards 2025 Call for Comments

Specialty pharmacies connect patients who are severely ill with the medications that are prescribed for their conditions, provide the patient care services that are required for these medications, and support patients who are facing reimbursement challenges for these life-changing and often times life-saving, but also frequently expensive medications.

These unique pharmacies provide services that include training on how to use these medications, comprehensive treatment assessment, patient monitoring, and frequent communication with caregivers and the patient’s physician or other healthcare providers.

The expert services that specialty pharmacies provide drive adherence and persistency, proper management of medication dosing and side effects, and ensure appropriate medication use. A high performing specialty pharmacy intersects at the “5 Ps”: Patient, Prescriber, Pipeline, Payer, and Pharma.

Specific areas of required education focused on Specialty Pharmacy include:

- Define specialty pharmaceuticals and specialty pharmacy practice.
- Summarize the specialty pharmacy prescription process from intake to fulfillment.
- Summarize the roles of the four main specialty pharmacy stakeholders: patient, provider, payor, pharmaceutical manufacturer.
- Develop a basic understanding of operations and business strategy for specialty pharmaceutical companies.
- Educate students on non-clinical aspects of patient care in a specialty setting; co-pay assistance, cost-savings strategies, etc.
- Provide students with opportunities to advance their knowledge in various operational departments and stakeholder relationships that are managed in a specialty pharmacy setting.
- Explain the role of external accreditation bodies in specialty pharmacy and how pharmacies successfully meet their standards.
- Compare and contrast the various specialty pharmacy practice settings (e.g., hospital, retail).
- Recognize disease states, therapies, and strategies employed in the management of specific specialty pharmacy populations.
- Outline opportunities for pharmacists practicing within the specialty pharmacy sector.

Add required education on the future of pharmacy to deliver insights about pharmaceutical economics, the drug distribution system, industry trends, and emerging careers in pharmacy.

References:

1. IQVIA National Sales Perspectives, IQVIA Institute, May 2021