



# Specialty Pharmacy...Past, Present, and Future

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# Meet The Presenter



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(NASP)*



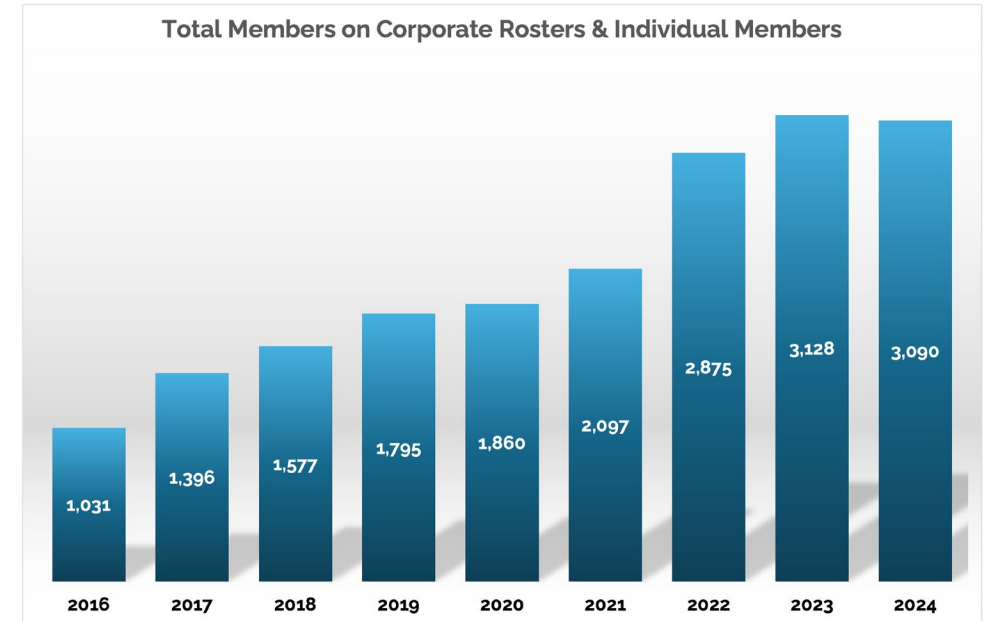
# Who is NASP?

- The National Association of Specialty Pharmacy- NASP ([www.naspnet.org](http://www.naspnet.org)) is the only national association representing all stakeholders in the specialty pharmacy industry.
- Core mission: to provide educational programs to pharmacists and other healthcare professionals; promote specialty pharmacist certification for those working in specialty pharmacy.
- NASP is committed to educating and advocating on behalf of its multi-stakeholder membership to ensure specialty patients receive high-quality patient care services from the pharmacy of their choosing and to transform the delivery of specialty healthcare through active engagement with improving the patient experience, enhanced clinical outcomes and by fostering the education and certification of pharmacists focused on specialty drug /disease management.



# NASP Membership

- 180+ Corporate Members and over 3,000 total members.
- NASP Members include:
  - The nation's leading specialty pharmacies
  - Pharmaceutical & biotechnology manufacturers
  - Group purchasing organizations
  - Patient Advocacy Groups
  - Integrated delivery systems and health plans
  - Technology & data management vendors
  - Wholesalers/Distributors
  - Practicing pharmacists, nurses, and pharmacy team members.



Unifying the Voices of Specialty Pharmacy in the United States.

All NASP members in some way touch the specialty pharmacy patient along the patient care journey.



# Education

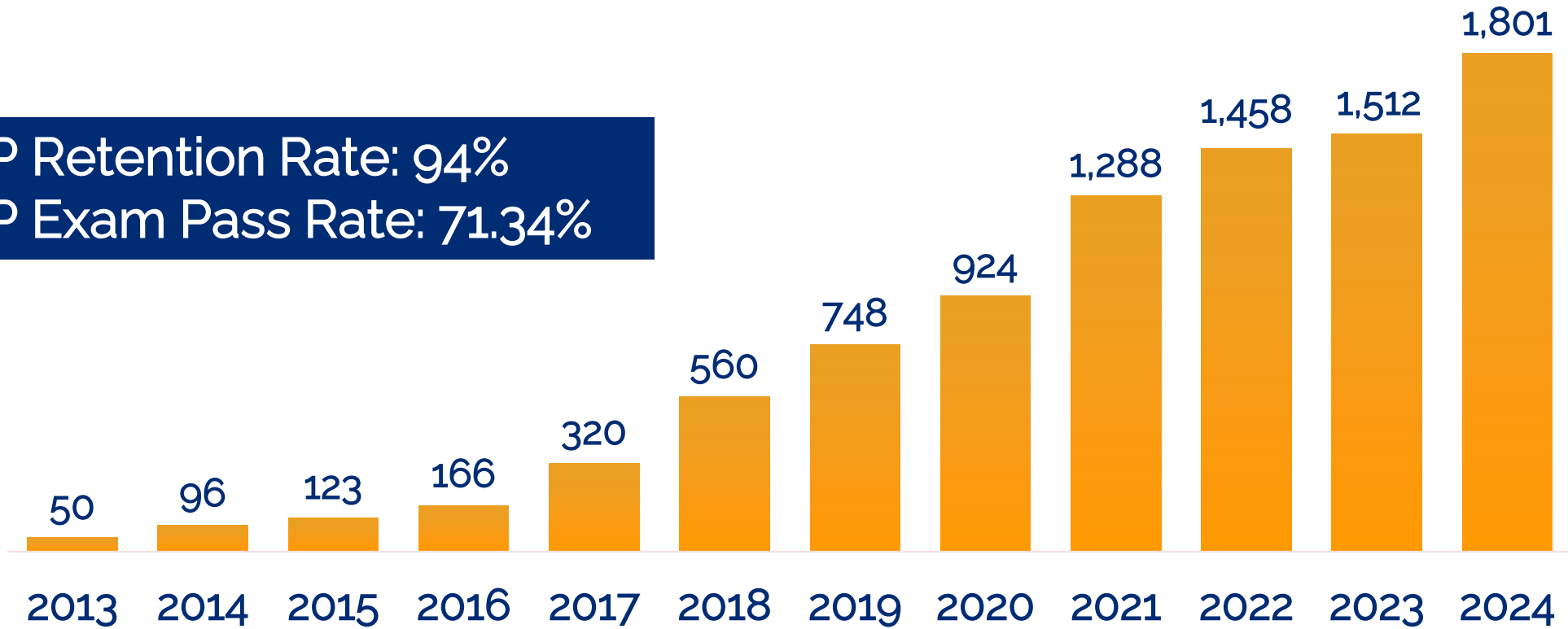
- Online education center with 75+ continuing pharmacy education programs
- Hosts Annual Meeting & Expo that offers education sessions and continuing education credits
- Hosts webinars and podcasts covering industry topics
- Has a growing student chapter program that is committed to investing in the future of pharmacy practice!



# Certification

The only organization that offers a certification program for specialty pharmacists.

CSP Retention Rate: 94%  
CSP Exam Pass Rate: 71.34%



As of 09.01.2024



# Advocacy: A Multi-Pronged Approach

- Congressional lobbying
- Advocating before federal agencies
- State-level monitoring and tracking
- Public affairs and grassroots efforts
- Enhanced collaboration with industry stakeholders and the pharmacy community





# Connectivity

- Spotlight-Corporate Members of the Month Program
- Monthly Lunch & Learn Programs
- NASP Annual Meeting Bucks,
- Members only discounted registration fees, discounts on sponsorship & exhibitor packages
- NASP Podcast
- Lunch with a Lawyer Quarterly webinar series
- RoundTable Webinars
- NASP MarketPlace
- Members Only Portal
- Women's Leadership Book Club
- New Member Welcome and Membership Committee Buddy Program



# NASP Definition of a Specialty Pharmacy

- Pharmacies that solely or largely provides only medications for people with serious health conditions requiring complex therapies
- State-licensed and regulated (and DEA licensed/regulated if dispensing controlled substances)
- Specialty pharmacies are accredited by an independent third party, nationally recognized accreditor; ensures consistent quality of care
- Specialty pharmacies function in the following ways:
  - Connect patients who are seriously ill with the medications that are prescribed for their conditions
  - Provide patient care services that are required for these medications
  - Support patients who are facing reimbursement challenges for these highly needed but costly medications



# Conditions Historically Managed by a Specialty Pharmacy

- Chron's Disease
- Cystic Fibrosis
- Hemophilia & Other Bleeding Disorders
- Hepatitis C
- HIV/AIDS
- Human Growth Hormone Deficiency
- Multiple Sclerosis
- Oncology (Cancer)
- Organ Transplantation
- Psoriatic Arthritis
- Psoriasis
- Rare Diseases
- Rheumatoid Arthritis



- 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 highly needed but also frequently costly medications.
- Specialty 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. The specialty pharmacy's patient-centric model is designed to provide a comprehensive and coordinated model of care for patients with chronic illnesses and complex medical conditions, achieve superior clinical and economic outcomes, and expedite patient access to care.
- A high-performing SP operates at the intersection of the "5 Ps":
  - Patient
  - Prescriber
  - Payer
  - Drug Pipeline
  - Pharmaceutical Manufacturer



# What is a Specialty Drug?

- A universal definition of specialty medication has yet to be accepted.
- Defining the term “specialty drug” can be a challenge
- The FDA, employers, health plans, PBMs and trade associations each have their own definitions
- CMS confounds the issue with its specialty tier
  - CMS defines a specialty medication as a medication costing more than \$950 per month
- There is a general consensus that the following elements currently define specialty drugs:
  - Treat complex chronic and/or life-threatening conditions
  - Have a high cost per unit
  - Require special storage, handling, and administration
  - Involve a significant degree of patient education, monitoring, and management



# NASP Definition of a Specialty Drug

More complex than most other prescription medications

Special or complex administration requirements

Special access conditions required by manufacturer

Require comprehensive patient care, clinical management and product support

Treats patients with serious, often altering, sometimes life-threatening conditions

Management of side effect profile

Payer authorization or benefit requirements

May be taken orally, but often injected or infused

Patient financial hardship

Condition it is used to treat



# Evolution of Specialty Pharmacy Practice

- In its infancy specialty pharmacy (SP) truly was a niche industry serving a limited number of patients with a small number of high-cost, low-volume conditions such as hemophilia and Gaucher's disease
- Specialty pharmacies have their roots in the 1970s when they began delivering temperature-controlled drugs to treat cancer, HIV, infertility, and hemophilia.
- Specialty pharmacies came into existence as a result of unmet needs. As more drugs became available for patients to administer or inject themselves and as insurers sought to manage expenses for patients with chronic conditions.



- They were able to keep these specialty drugs in stock when most retail pharmacies could not. In this way they could intervene for patients who needed immediate access to therapies to prevent organ rejection but who did not have the money for such payments, nor did they have the expertise they needed to complete the forms.
- They also coordinated referrals from hospital discharge planners and delivered the medication to the patients' homes to allow therapy to begin immediately upon hospital discharge.
- Specialty pharmacies grew through word of mouth; nurses and physicians heard from their patients about the “special services” provided by these pharmacies and started to refer patients who requires this white glove, high touch service.





# History of Specialty Pharmacy

## In the Beginning ... 1992

- Stadtlanders was a grassroots company in Pittsburgh, PA
- Occupied 1 floor of 7 story office building
- Handful of employees
- Dispensed drugs via mail order for chronic diseases – transplant, HIV and multiple sclerosis
- Retail pharmacies did not stock product

## 1995-2000

- Stadtlanders provided support for additional conditions, including growth hormone therapy
- As more expensive lifesaving therapies became available, they offered more services
- Facilitated completion of insurance paperwork, coordinated insurance benefits to reduce enormous out-of-pocket costs

## 2000 - today

- Stadtlanders and others like them grew through word of mouth
- Stadtlanders generated revenue of \$500 million
- Stadtlanders purchased by CVS
- Majority of smaller SPs acquired by national competitors
- Today's marketplace dominated by PBMs, retail-based or insurer-owned



# Specialty vs. Retail

## RETAIL Pharmacy


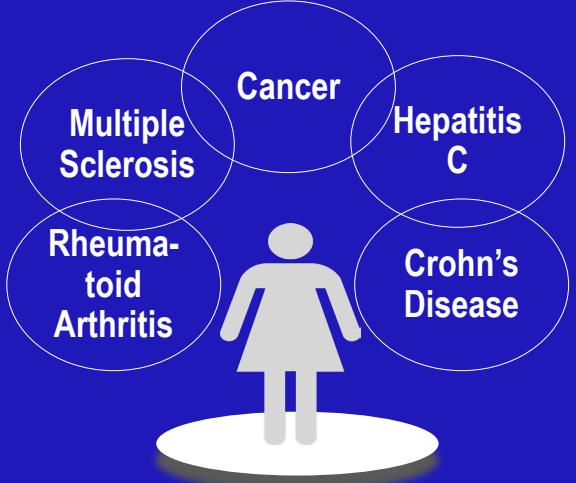
*Basic Health & Wellness*




- General prescriptions
- Pick up medications
- Cold medicine
- Toiletries
- First aid

## SPECIALTY Pharmacy

*Specialized Care for Complex Conditions*

- Benefits investigation
- Co-pay assistance
- Prior authorization support
- Specialty medication
  - not normally found in retail
- Therapy Management
  - Side effects management
  - Medication adherence
  - Drug-drug interaction management
- 24/7 clinical support
  - Pharmacist, nursing and specialist support

- Patient education
- Injection training



# Goals of Specialty Pharmacy



Ensure appropriate use of medications



Maximize drug adherence



Enhance patient satisfaction through direct interaction with healthcare professionals



Minimize cost impact to patients



Optimize pharmaceutical outcomes & delivery of information



What else is *SPECIAL*  
about Specialty Pharmacy?

# Manufacturers & Payers Partner with Specialty Pharmacy to Dispense Orphan Drugs

- Orphan drugs are used for rare diseases such as Huntington's disease, ALS, and muscular dystrophy which affect small numbers of individuals living in the United States.
- The U.S. Orphan Drug Act of 1983 (ODA) was enacted to facilitate development of orphan drugs.
  - At that time, drug therapies for such diseases were rarely developed. Three decades later, a growing proportion of industry research and development (R&D) and regulatory drug approvals target diseases affecting fewer than 200,000 persons in the United States, the prevalence-based threshold of rare disease under the ODA.
- The FDA has approved over 650 orphan drugs since the passage of the ODA.
- Specialty Pharmacy's business model and infrastructure best position this practice setting to dispense these medications, to understand the unique challenges of and to effectively manage these patients and disease states.



# Drugs with Risk Evaluation & Mitigation Strategies (REMS)

- On September 27, 2007, President George W. Bush amended the Food and Drug Administration Amendments Act of 2007 (FDAAA) authorizing the FDA to require "risk evaluation and mitigation strategies (REMS) on medications if necessary to minimize the risks associated with some drugs.
- These medications were designated as specialty drugs and required dispensing by specialty pharmacies.
- When the FDA approves a new drug, they may require a REMS program which may contain any combination of 5 criteria: Medication Guide, Communication Plan, Elements to Assure Safe Use, Implementation System, and Timetable for Submission of Assessments.
- The FDA has approved more than 300 REMS programs.



# Breakthrough Therapies

- In 2013 the FDA introduced the breakthrough therapy designation program which cut the development process of new therapies by several years. This meant that the FDA could introduce important medicines to the market based on very promising phase 2 rather than phase 3 clinical trial results.
- In January 2013, ivacaftor became the first drug to receive the breakthrough therapy designation.
- Often, the FDA mandates post-drug approval market research and specialty pharmacy's technical ability to capture the required data elements enables them to best support these requirements.



# Specialty Market Participants

- Employers
- Health Plans
- Pharmacy Benefit Managers (PBMs)
- Independent Specialty Pharmacies
- PBM/Health Plan Owned Specialty Pharmacies
- Community Hybrid Pharmacies – Specialty @ Retail
- Grocers
- Hospital/Health Systems
- Physician Dispensing
- Accreditation Organizations
- Technology & Data Management Vendors
- GPOs, Wholesalers, Distributors
- Patient Advocacy Groups
- Medication management companies who partner with payers to provide a single source for high-touch patient care management to control side effects, patient support and education to ensure compliance or continued treatment, and specialized handling and distribution of medications directly to the patient or care provider as specialty medications may be covered under either a medical or pharmacy benefit.







# Challenges & Opportunities

# The Specialty Pharmacy Boom is Expected to Continue

- Implications of everyone wanting to be a Specialty Pharmacy:
  - PBMs, pharmacies, wholesalers, health plans, and providers are battling for control of the specialty market and the patient journey
  - Manufacturers' specialty network design will be critical and have far-reaching impact
  - Channel control will continue to migrate from manufacturers to PBMs and payers
  - Coevolving economics will consolidate specialty pharmacy market structure
  - Organized channels—new ownership and partnering relationships—will emerge



# Market Dynamics & Evolving Industry

- The current complexities of the market landscape continue to pose challenges:
  - Specialty Drug, Specialty Pharmacy Definitions....or the lack thereof.....
    - A universal definition of specialty drug has yet to be accepted. Defining the term “specialty drug” can be a challenge.
    - As a result, specialty pharmacy is not afforded the regulatory protections that our retail and mail order pharmacy counterparts are which encourage and foster competition which drives innovation and the delivery of high-quality care.
  - The current clinical measures used for the purposes of evaluating specialty pharmacy performance are based on primary care measures rather than the drugs dispensed by specialty pharmacy and the disease states managed.



## Minimum Network Adequacy Standards

Currently regulatory language does not ensure Medicare access to SP however does establish minimum convenient standards for retail, mail order, home infusion long term care pharmacy and I/T/U (Indian Health Service/Tribal/Urban Indian Health) pharmacy if applicable

## Reimbursement

- Current regulatory language states that reimbursement rates cannot be used to subvert the convenient access standards, and it is not reasonable nor relevant to offer reimbursement that is below acquisition cost
- Lack of existing oversight and enforcement of these regulations
- PBMs design pharmacy reimbursement rates based on different criteria and networks. Often the contracting for all available networks and corresponding rates are not transparent.



# Mergers & Alliances

- Walgreens & Rite Aid
- Albertsons & Rite Aid
- Walmart & McKesson Alliance
- Walgreens & PharMerica
- Amazon & Whole Foods
- Amazon, Berkshire Hathaway, & JPMorgan Chase
- CVS & Aetna
- Express Scripts & Cigna
- Optum & DaVita's Medical Group
- CVS & Target



# Vertical Integration

- Market Share
  - Two-thirds of all covered pharmacy lives are managed by the top 3 PBMs (ESI, CVS, and Optum).
  - These PBMs also own their own specialty pharmacies.
  - Consumers are forced to use 'in-house' pharmacy instead of independent specialty pharmacy, thus eliminating choice and impacting the quality of care provided.
  - Vertical integration continues to drive policies and processes that ensure exclusion rather than promoting inclusion and provide unfair competitive advantage to PBM-owned specialty pharmacies.



# Additional Considerations:

- IRA
  - Drug price negotiation
- MPPP
  - Medicare Part D OOP smoothing
- 340B
  - Contract pharmacies
- Biosimilars





# Looking to the Future



# Factors Affecting the Evolution of the Specialty Pharmacy Marketplace

- A wave of new treatments for diseases traditionally treated with small molecule therapies is on the horizon:
  - Alzheimer's, Asthma, Allergy, Parkinson's Disease, Heart Failure, COPD, OA, Stroke, pain.
  - Many are chronic diseases with large patient populations-high cost per patient is a major concern.
- The late phase R&D pipeline remains robust, and we will see a high number of new brand launches with 40-45 innovative medications launches each year.
- In the next 5 years Oncology, Autoimmune, and Diabetes will drive the therapeutic growth.
- Orphan drugs and cell and gene therapies will revolutionize health care and be disruptive.



- Nearly 50% of consumers have a pharmacy benefit deductible and the majority are part of an integrated medical-pharmacy deductible design.
- Payers are shifting more cost onto patients through benefit designs with higher co-pays and pharmacy deductibles.
- Coupons and manufacturer out-of-pocket offsets have increased steadily as patient cost exposure has increased.
- Affordability continues to be a major concern with industry expenditures on Patient Savings Programs topping billions each year.
- Abandonment of specialty brand prescriptions during the deductible phase of their benefit is especially problematic.



# Medication Adherence is at the Core of the Healthcare Value Equation Impacting All Stakeholders:

- **Patient**
  - Better health defined by:
    - Lower total medical costs
    - Less ER visits
    - Fewer hospitalizations and readmissions
- **Pharmacy**
  - Improved engagement
  - Rx growth
  - Enhanced clinical outcomes
- **Hospital**
  - Increased CMS reimbursements due to better patient outcomes
  - Reduced ER visits
  - Reduced admissions-particularly preventable patient readmissions
- **Physician**
  - Increased CMS reimbursements and improved patient ratings
  - Increase in patient engagements
  - Improved patient outcomes
- **Insurer**
  - Significant reduction in total allowable costs and increased CMS reimbursements particularly for the most vulnerable patient populations
  - Improved patient health
  - Improved relationship with members and providers
- **CMS**
  - Reduced total healthcare costs and improved patient outcomes



# Market Access Trends

- We are approaching the tipping point of payer price sensitivity and willingness to pay
- Employers and consumers will stretch the boundaries of meaningful differentiation and what is comparable as they both struggle with the rising costs of these medications.
- Stricter payer utilization management.
- Increased patient OOP.
- Increased focus on drug pricing and transparency and shift from deep rebate model to lowest net unit cost.
- Value based contracting will continue to be refined as payers want to contract not just on volume but on the outcome of the patient journey and share this financial responsibility with the manufacturer.
- More aggressive medical specialty drug benefit management and emphasis on care coordination.
- Collecting and using data to modify behavior and improve health outcomes will be increasingly important.



# SUMMARY

- Specialty continues to grow and is now ~53% of drug spending in the US but only represents 2-3 % of total prescriptions dispensed.
- Biosimilars will further penetrate the market.
- Abandonment and affordability is a concern, adherence and compliance a challenge and opportunity.
- Innovation is robust however, different with a focus on orphan drugs and biologics being developed for the treatment of diseases historically treated with small molecule therapies
- As the Administration and governmental agencies continue to focus on drug pricing, affordability, and transparency the specialty pharmacy industry will continue to be demanding, dynamic and disruptive.
- Specialty pharmacy is in a perfect position to enhance and tailor approaches to patient care, adapt operational processes and drive toward establishing standardizations as the health care delivery model changes and evolves.



- Specialty Pharmacy must turn their focus to demonstrating how the high-touch comprehensive patient care services they provide positively impacts quality and total cost of care and advocate for reimbursement for the clinical services they provide separate from the reimbursement for the drug
- Experienced and qualified specialty pharmacists and specialty pharmacy technicians will become increasingly important as payers and patients continue to struggle with the affordability and complexity of these medications and treatment regimens
- Certification and programs that demonstrate proficiency in the management of specialty pharmacy patients and diseases treated with specialty drugs will help to differentiate these experts
- Involvement with professional organizations and societies that focus on education and advocating on behalf of specialty pharmacy is key to ensuring competition, quality and patient access to the medications they need from the pharmacy of their own choosing.





QUESTIONS?



# Thank You

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