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INSURANCE COMMISSIONER

May 11, 2022

SENT VIA ELECTRONIC MAIL

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The Honorable Donna McDowell White,
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Re: Session Law 2021-161, Senate Bill 257

Dear Chairmen:

Session Law 2021-161 directed the Department of Insurance to assemble a Specialty Pharmacy Stakeholder Workgroup to study and recommend a single, unified process to accredit specialty pharmacies in the State and report its findings and recommendations to the Joint Legislative Oversight Committee on Health and Human Services, the Senate Health Care Committee, and the House Health Committee no later than May 15, 2022.

The Department of Insurance facilitated the meetings and presents the report of the Specialty Pharmacy Stakeholder Workgroup along with attachments to the Committee Members.

I would like to sincerely thank the members of the Workgroup. The report is the product of a lot of hard work on their part and benefits from the different perspectives they brought to the task.

Should you have any questions regarding this report, please contact Robert Mays, DOI - Legislative Liaison at robert.mays@ncdoi.gov or George Robinson, DOI - Legislative Liaison at george.robinson@ncdoi.gov.

Sincerely

Mike Causey
N.C. Commissioner of Insurance

cc: Specialty Pharmacy Stakeholder Workgroup Members

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Specialty Pharmacy Stakeholder Workgroup Report

Prepared in Response to
Session Law 2021-161, Senate Bill 257

May 11, 2022

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Scope

As requested under Session Law 2021-161 Senate Bill 257, The North Carolina Department of Insurance shall study and recommend a single, unified process to accredit specialty pharmacies in the State. The workgroup shall examine at least the regulatory, administrative, and financial challenges facing those who wish to gain specialty pharmacy status.

The workgroup shall be composed of at least two representatives from each of the following: independent pharmacies, pharmacy service administrative organizations, pharmacy benefits managers, and insurers who offer health benefit plans.

Specialty Pharmacy Stakeholder Workgroup was comprised of twelve members. The membership included representatives from independent pharmacies, pharmacy benefits managers, insurers who offer health benefit plans, hospitals, pharmacy service administrative organizations, and accreditation organizations.

The group received and reviewed four presentations from the following volunteers: URAC and ACHC accreditation organizations, a Pharmacy Benefit Manager (Prime Therapeutics), the National Association of Specialty Pharmacy (NASP), and the North Carolina Association of Pharmacists (NCAP).

Executive Summary

The Specialty Pharmacy Stakeholder Workgroup over the course of eight meetings addressed the many aspects of specialty pharmacies.

Specialty Medications:

Specialty medications are more complex than most prescription medications. They are used to treat patients with more severe and life-threatening conditions, including rare or orphan diseases. The drug's formulation, administration, side effects, cost, prior authorization requirements, manufacturer required record keeping, and/or other characteristics can contribute to its designation as a specialty medication.

Due to the number and scope of factors that influence whether a medication is handled by a specialty pharmacy, the term "specialty medication" does not have a nationally accepted definition. Medicare & Medicaid Services (CMS) and a few states have opted to not define specialty medications because of the numerous considerations needed to categorize these medications. Some definitions include costs while others do not. CMS has defined specialty drug tier placement based on a minimum monthly cost. In 2021, that minimum monthly cost was \$670.00. In 2022, CMS increased the minimum monthly cost to \$780.00. For the discussion of accreditation, a set definition is not required.

Specialty Pharmacies:

Like traditional retail pharmacies, specialty pharmacies are licensed and regulated by the state. Specialty pharmacies go one step further by obtaining accreditation from an independent, third-party, nationally recognized accrediting body or bodies. Achieving accreditation validates specialty pharmacies' commitment to consistent quality of care for these particular patients.

In a specialty pharmacy, teams are created to focus on specific diseases and provide in-depth support for the patient. These teams provide in-depth patient education, coordination of care with the healthcare provider, proactive monitoring to ensure patients are taking the medication as prescribed, financial assistance through manufacturer, and foundational assistance. They also monitor drug supply issues, manage complex medication temperature requirements, coordinate the administration of a drug in home or in a doctor's office, and provide payor and/or manufacturer reporting.

The report outlines a few reasons a traditional retail or mail order pharmacy does not routinely dispense specialty medications. The report also provides an in-depth breakdown of the processes a specialty pharmacy utilizes to dispense specialty medications for patients on these therapies.

Specialty Pharmacy Accreditation:

In North Carolina, all pharmacies must be licensed by the North Carolina Board of Pharmacy, addressing functions such as pharmacy access and inventory standards, as well as requirements for labeling, physical pharmacy layout, record keeping, controlled substances, and compounding. There is no pharmacy licensure category or recognition for the specialty services that are provided by specialty pharmacies.

Accreditation is provided by national, independent organizations that develop and validate compliance with quality standards. Accreditation standards are developed by expert advisory groups and are based on best clinical practices. Standards are revised periodically to ensure relevance.

Specialty pharmacy accreditation ensures compliance with the provision of specific patient care services that are not addressed in licensure requirements including: disease-specific education, clinical monitoring, managing complex administration, distribution logistics (including specific temperature management requirements), health care team coordination, and prior authorization and copay assistance management. In addition, accreditation requires demonstration of fundamental quality principles. Accredited pharmacies track quality measures and implement quality improvement plans when performance measures are below acceptable goals.

Third-party stakeholders utilize specialty pharmacy accreditation to validate compliance with quality standards for specialty pharmacy services. Payors and manufacturers often utilize accreditation as one requirement for determining inclusion in their networks. Some specialty pharmacy networks require more than one accreditation for participation. While many of the fundamental standards may be similar among the available accreditation programs, these standards were developed independent of each other, and therefore may have some differences.

The report details the accreditation review process and the necessary steps a pharmacy needs to complete to become an accredited specialty pharmacy.

Administrative challenges to pharmacy providers:

Pharmacy providers who successfully complete a primary specialty pharmacy accreditation will prepare months leading up to the actual specialty pharmacy accreditation survey. The pharmacy will dedicate staffing to construct an action plan on how to meet the standards to satisfactorily complete the survey. These standards have been developed independently by the specialty pharmacy accreditors to assure quality and safety standards in the management of these expensive, complex, and potentially high-risk therapies.

Pharmacies who are required by payor or Pharmacy Benefit Manager (PBM) mandates or chooses to undertake secondary specialty pharmacy accreditation to increase the likelihood of network acceptance will assess the accreditation standards compared to their operation and the requirements of their primary specialty pharmacy accreditation. This assessment requires the pharmacy to understand how to manage dual accreditation from documentation, workflows, operations, data, and other activities necessary to successfully meet the secondary (and primary) accreditation standards. Overlap of duplicative standards can result in burdensome requirements to the pharmacy.

Specialty pharmacy medications often cannot be acquired by traditional retail or mail order pharmacies due to limitations by the product manufacturer as well as other factors including a pharmacy not having the necessary operational capacity, staffing, and training to manage certain specialty medications.

A pharmacy is required to submit data before, during, and after the specialty pharmacy accreditation if required by the accrediting body. This requires the pharmacy to dedicate resources to developing data management, conduits for sharing, and ensuring the data meets the standards/requirements of the accrediting body before and during an accreditation audit.

Financial challenges to pharmacy providers:

Each Specialty Pharmacy accretor requires the pharmacy to pay a fee, the cost which can be tens of thousands of dollars. The cost is largely dependent upon volume, sites, and/or other factors. Accreditations are generally structured as a three-year cycle. The accreditation fee is assessed once for each accreditation cycle (i.e., every three years). It is important to note, the requirements of accreditation and associated cost may be burdensome to a pharmacy. For this reason, pharmacies may choose to not pursue accreditation.

The accreditation/re-accreditation cost is one factor in the overall expense incurred by specialty pharmacies. Compliance with specialty pharmacy accreditation standards requires additional staff, supplies, and software when compared to non-specialty pharmacy operations. The additional requirements support data collection and management, packaging for shipping, tracking, and patient communication. While these enhancements may involve additional costs, they serve as the foundation necessary for a specialty pharmacy to promote patient safety and optimize clinical outcomes.

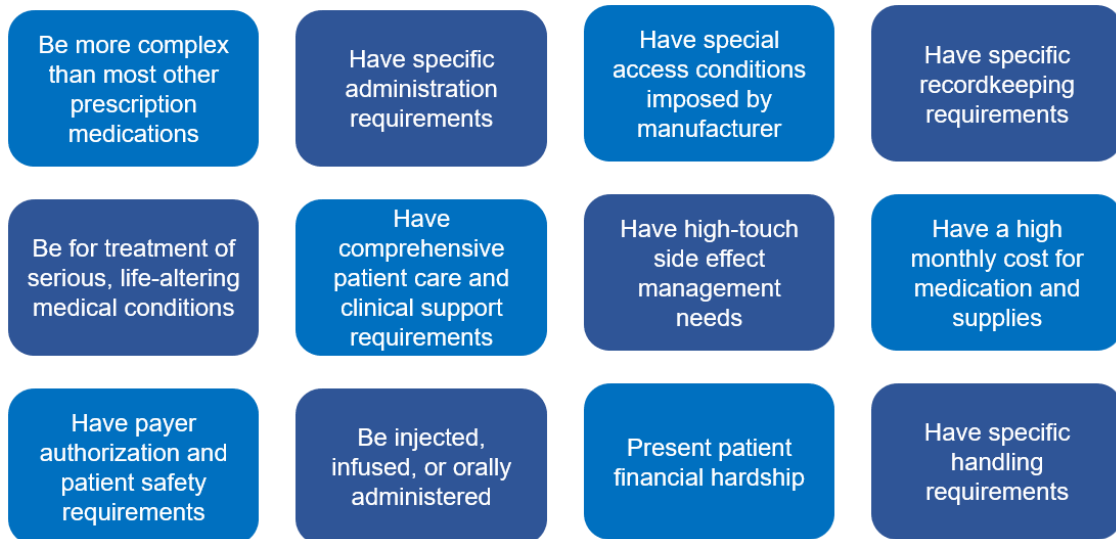
The report details a breakdown of the costs to become accredited by different organizations.

Background

Overview

Accreditation by an independent, third-party organization is a primary market standard of a pharmacy's commitment to consistency, quality, and safety when dispensing specialty medications. Accreditation is used to ensure a specialty pharmacy has the infrastructure and essential requirements needed to support patients who are prescribed specialty medications. Historically, accreditation has been used by manufacturers and PBMs/payors as part of access to dispense specialty medications to patients.

What are specialty medications?

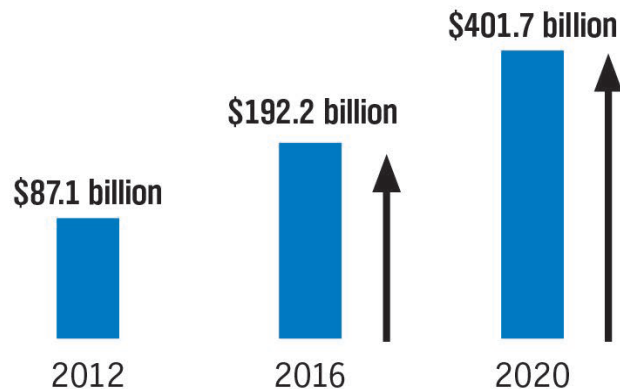


Specialty medications are more complex than most prescription medications. They are used to treat patients with more severe and life-threatening conditions, including rare or orphan diseases. The drug's formulation, administration, side effects, cost, prior authorization requirements, manufacturer-required record keeping, and/or other characteristics can contribute to its designation as a specialty medication.

Due to the number and scope of factors that influence whether a medication is handled by a specialty pharmacy, the term "specialty medication" does not have a nationally accepted definition. The Centers for CMS and a few states have opted to not define specialty medications because of the numerous considerations needed to categorize these medications. Some definitions include costs while others do not. CMS has defined specialty drug tier placement based on a minimum monthly cost. In 2021, that minimum monthly cost was \$670.00. In 2022, CMS increased the minimum monthly cost to \$780.00. For the discussion of accreditation, a set definition is not required.

In 2014, blockbuster specialty drug treatments for Hepatitis C were introduced to the drug market. These specialty medications cost nearly \$27,000 per month and require strict adherence. If a patient misses a dose, the medication must be restarted. After 2014, similar specialty medications were introduced to the drug market, driving specialty medication costs upward to \$401.7B in 2018. Today, specialty medications account for 3% of prescription volume, but for 44% of drug costs. Many specialty medications enter the market with a high cost, ranging as high as \$1.8M or more for genetic therapies.

Specialty drug spending is on the rise*



*PwC website: Medical Cost Trend: Behind the Numbers 2015 (accessed November 2016); pwc.com.

Due to the complexities involved with these medications, patients being treated with specialty drugs often require comprehensive patient care, clinical management, financial assistance, and product support services provided by a specialty pharmacy.

What is a specialty pharmacy and how is it different than a traditional retail pharmacy?

While both traditional retail and specialty pharmacies are licensed and regulated by the state, specialty pharmacies go one step further by obtaining accreditation from an independent, third-party, nationally recognized accrediting body or bodies. Achieving accreditation validates specialty pharmacies' commitment to consistent quality of care for these particular patients.

Specialty medications are not routinely dispensed at a traditional retail or mail order pharmacy for the following reasons:

- Traditional retail pharmacies may not have access to medications that have restricted pharmacy provider networks by the drug manufacturer. (See Appendix, example 2 for illustration).
- Traditional retail pharmacies may find the implementation of processes that align with quality and safety standards to be burdensome and cost prohibitive. Such standards are fundamental to specialty pharmacy accreditation.
- Traditional retail pharmacies may lack the disease state expertise and time commitment required to manage the care of patients taking specialty medications. Specialty pharmacies must maintain expertise in medication, disease state, and clinical management to achieve patient treatment goals and ensure optimal care. Some accrediting organizations evaluate a pharmacy's knowledge and resources to ensure patient safety.

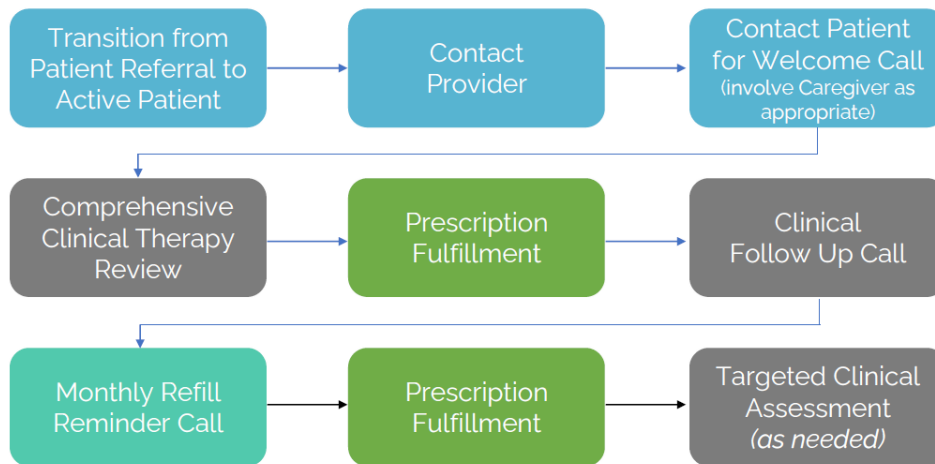
Lastly, pharmacies serving patients who are treated with specialty medications typically provide clinical and operational services above and beyond those in the retail setting. As an example, these services can include more intensive patient management interactions and documentation and are driven to ensure optimal for the patient and maintain compliance with accreditation standards.

The following list is an example of health conditions managed by a specialty pharmacy (not inclusive of all diseases):

- Hemophilia or other bleeding disorders
- Cancer
- Hepatitis C
- Rheumatoid Arthritis
- HIV/AIDS
- Human Growth Hormone (HGH) deficiencies
- Multiple Sclerosis (MS)
- Organ Transplantation
- Cystic Fibrosis
- Crohn's disease
- Rare and orphan disease

What services does a specialty pharmacy provide?

Specialty Pharmacy Patient Journey Example



The operations of a specialty pharmacy differ from traditional retail and mail order pharmacies to meet the elevated educational and clinical needs of specialty pharmacy patients, PBM/payor expectations, and accreditation standards. Specialty pharmacy teams include specialty-trained patient care coordinators, pharmacy technicians, pharmacists, and nurses, who focus on specific diseases and 1. provide in-depth patient education, 2. coordinate care with the healthcare provider, 3. proactively monitor the patient to ensure they are taking the medication as prescribed, 4. provide financial assistance through manufacturer and foundational assistance, 5. monitor drug supply issues, 6. coordinate the administration of a drug in home or in a doctor's office, and 7. provide payor and/or manufacturer reporting.

When a prescription (or referral) is received in a specialty pharmacy, several activities occur prior to dispensing the medication. The staff contacts the provider to gather additional information not provided on the intake/referral documents. If necessary, the pharmacy may also contact the patient. The specialty pharmacy completes a benefit investigation including coordination of medical and pharmacy benefits and facilitation of the prior authorization review process, if required. This is important as some PBMs/payors limit which pharmacies are in network. Additionally, drug manufacturers limit the network of certain medications available to pharmacies, typically called Limited Distribution Drugs.

After it is confirmed the specialty pharmacy can fill the medication and ancillary supplies, as applicable, the pharmacy then coordinates any necessary financial support for the individual patient. By completing the benefits check first, specialty pharmacies save time and prevent delays to therapy. Once the patient confirms the cost is acceptable, the pharmacy will perform a clinical assessment (e.g., check applicable lab values, patient weight, etc.) and facilitate care coordination with other healthcare providers. This step is necessary to ensure the patient is getting a safe and appropriate medication therapy. This coordination of care is the step where a specialty pharmacy removes the barriers preventing the best care for the patient.

After care coordination and clinical assessments are complete, the specialty pharmacy will contact the patient to provide education and support. A pharmacist or nurse will review the process with the patient, double-check scheduling, discuss payment, and review any questions the patient may have. The specialty team maintains a continual relationship with the patient to help them achieve their treatment goals and partners with the provider to help promote medication adherence.

Upon education, the last step is dispensing the medication at or near the time the patient needs it. A specialty pharmacy will package the medication and all necessary supplies for administration to save the patient time and effort (See Appendix, example 3, for illustration). The pharmacy will use all methods to ensure the medication arrives in time, including courier services or overnight delivery, if necessary.

Specialty pharmacies must consider the appropriate temperature ranges for the medications they dispense. Special storage and distribution considerations must be addressed; for example, cold chain technologies should be utilized for refrigerated medications. (See Appendix, example 1, for illustration). Utilizing appropriate packaging that maintains the proper temperature range is critical to ensure that the medication is safe and effective for patient use.

Once the medication is dispensed and shipped, the specialty pharmacy will bill the benefits, assistance programs, and the patient for their cost-share. While the specialty medication is going through the shipment process, the specialty pharmacy tracks the delivery of the package until it reaches the delivery location. If there are delays, the specialty pharmacy will use any method necessary to get the patient the medications they need in a timely manner.

The specialty pharmacy team routinely contacts the patient to perform clinical assessments involving medication issues, side effects, quality of life, financial challenges, etc. If any adverse side effects occur, the patient will receive support to manage those side effects and the specialty pharmacy will report those side effects to the FDA, the PBM/payor (and/or the manufacturer), and the provider team. As an example, a patient with Multiple Sclerosis may be screened for adherence to their drug therapy, any flare-up or disease progression, the outcome of treatment for the flare-up, and their quality-of-life (See Appendix,

example 4, for illustration). Peer-reviewed studies have shown that specialty pharmacies and the services they provide increase patient adherence to therapy (See Appendix, example 5, for illustration).

Manufacturers recognize specialty pharmacy services and value the data they can provide. As a result, they may limit the pharmacies allowed for dispensing their medications (also known as limited distribution, see Appendix, example 2, for illustration). Payors value specialty pharmacy capabilities over traditional retail pharmacies and establish limited networks for dispensing specialty drugs to ensure the safety of their enrollees.

Specialty Pharmacy Accreditation

Difference between pharmacy licensure, accreditation, and credentialing

Even though the terms are sometimes used interchangeably, there are important differences between pharmacy licensure and pharmacy accreditation. Licensure addresses fundamental pharmacy practice functions, and accreditation sets the bar for quality in patient care services.

In North Carolina, all pharmacies must be licensed by the North Carolina Board of Pharmacy, addressing functions such as pharmacy access and inventory standards, as well as requirements for labeling, physical pharmacy layout, record keeping, controlled substances, and compounding. There is no pharmacy licensure category or recognition for the specialty services that are provided by specialty pharmacies.

Accreditation is provided by national, independent organizations that develop and validate compliance with quality standards. Accreditation standards are developed by expert advisory groups and are based on best clinical practices. Standards are revised periodically to ensure relevance.

Specialty pharmacy accreditation ensures compliance with the provision of specific patient care services that are not addressed in licensure requirements including: disease-specific education, clinical monitoring, managing complex administration, distribution logistics (including specific temperature management requirements), health care team coordination, and prior authorization and copay assistance management. In addition, accreditation requires demonstration of fundamental quality principles. Accredited pharmacies track quality measures (e.g., dispensing accuracy) and implement quality improvement plans when performance measures are below acceptable goals.

In the absence of a universally accepted definition or licensure category for specialty pharmacy, accreditation defines which pharmacies provide specialty pharmacy services. Quite simply put, a specialty pharmacy is one that can become accredited.

Specialty pharmacies seeking to participate in a payor's network and dispense specialty medications to its enrollees must additionally become credentialed by that organization under North Carolina § 58-56A-4 (c). Provider credentialing is the process of obtaining and verifying the credentials of a provider to ensure that they have the required federal/state licenses, certifications, malpractice insurance and capabilities to provide care to a payor's enrollees. Credentialing requirements vary among payors, but specialty pharmacy accreditations are typically one of the requirements for a specialty pharmacy to become credentialed.

Differences between Licensure, Accreditation, and Credentialing

Licensure	Accreditation	Credentialing
<ul style="list-style-type: none">• States do not differentiate specialty pharmacy licensure from retail/community pharmacies• There is no “Specialty Pharmacy License”• Some self-identify their services (e.g., sterile compounding or specialty)• Boards of Pharmacy do not have statutory authority to credential or accredit pharmacies	<ul style="list-style-type: none">• Independent, national quality entities accredit specialty pharmacies: URAC, ACHC, Joint Commission• Certifies high standards of service and uniformity of care• Demonstrates the pharmacy’s commitment to quality, cost containment, and proper utilization of services• Goes beyond Board of Pharmacy’s scope of public health and safety• PBMs and payers should be able to dictate the terms and conditions for joining their networks, including accreditation requirements	<ul style="list-style-type: none">• Process used to obtain, verify, and assess a pharmacy’s basic qualifications to provide patient care• Evidence typically required may include:<ul style="list-style-type: none">• Description of pharmacy services• State licensure• Current federal DEA license• Current pharmacy malpractice insurance• Electronic claims processing and electronic prescribing capacity• Credit worthiness• Use of licensed wholesalers

Stakeholder value of specialty pharmacy services

Third-party stakeholders utilize specialty pharmacy accreditation to validate compliance with quality standards for specialty pharmacy services. Payors and manufacturers often utilize accreditation as one requirement for determining inclusion in their networks.

- PBMs and payors, such as health plans, employers, value specialty pharmacies capabilities over traditional retail pharmacies and establish limited networks for dispensing specialty drugs.
- Some manufacturers of specialty drugs recognize the value of an accredited specialty pharmacy when selecting distribution networks based upon the services they offer, as well as the data provided by pharmacies.

Some specialty pharmacy networks require more than one accreditation for participation. While many of the fundamental standards may be similar among the available accreditation programs, these standards were developed independent of each other, and therefore may have some differences. Also, there may be requirements in addition to accreditation for participation in a limited specialty pharmacy network (i.e., provider credentialing).

In addition to payors and manufacturers, regulators utilize accreditation to ensure the provision of quality care. Currently North Carolina utilizes accreditation to define which specialty pharmacies may provide hemophilia drugs for state-sponsored programs.

5.10 Hemophilia Specialty Pharmacy Program

The General Assembly [Session Law 2012-142, Section 10.48(a2)] mandates that the N.C. Medicaid and N.C. Health Choice Pharmacy programs establish a specialty pharmacy program for hemophilia (blood disorder) drugs.

5.11 Provider Accreditation

To provide hemophilia drugs to Medicaid or NCHC beneficiaries, a pharmacy provider shall have a current national accreditation as a specialty pharmacy by one of the following organizations:

- a. Utilization Review Accreditation Commission (URAC)
- b. Accrediting Commission for Health Care (ACHC)
- c. The Joint Commission (TJC)

Pharmacy providers who are dispensing hemophilia medications to beneficiaries prior to the effective date of this policy have one year to obtain accreditation. Pharmacy providers who are not dispensing hemophilia medications to beneficiaries prior to the effective date of this policy must be accredited prior to initiating factor product dispensing and hemophilia related care for NC Medicaid and NC Health Choice beneficiaries

(Reference: <https://medicaid.ncdhhs.gov/media/7052/open>)

Overview of the accreditation review process

Each accreditation organization has its own processes for application review, but in general the process includes the following:

- **Payment:** Cost varies by accreditation organization, pharmacy size, and number of locations.
- **Application:** Submission of written documentation (e.g., policies, procedures, reports, etc.), that demonstrates how the pharmacy complies with accreditation standards.
- **Desktop Review:** A review of the submitted documentation for compliance to accreditation standards. The goal of the Desktop Review is for the pharmacy to demonstrate that they have documented processes for complying with the accreditation standards. The accreditation organization reviews submitted documentation for compliance. If the submitted documentation does not meet the intent of the standard, the pharmacy may be required to edit, revise, compose new documentation that demonstrates compliance with the standard.
- **Survey/Onsite Review:** Onsite survey to confirm compliance with accreditation standards. Onsite surveys are a rigorous review process that are generally conducted over 1-2 days consisting of interviews of leadership and staff, documentation review, case file audits, and observation of pharmacy operations.

Accreditation typically follows a three-year cycle after which reaccreditation is required. There may also be ongoing compliance requirements to ensure the pharmacy maintains compliance with the accreditation standards throughout the cycle, such as reporting of measure data and participating in monitoring reviews.

Accreditation Process



Accreditation organizations provide extensive education on the standards and the review process.

Challenges facing those who wish to gain specialty pharmacy status.

Regulatory

What are the regulatory challenges facing pharmacy providers?

- There are currently no regulatory challenges related to specialty pharmacies.

Administrative

What are administrative challenges facing pharmacy providers?

- Primary specialty pharmacy accreditation
 - Preparing and completing primary accreditation
 - Maintaining primary accreditation
- Secondary specialty pharmacy accreditation
 - Cross walk between primary and secondary specialty accreditation
 - Preparing and completing secondary accreditation
 - Maintaining primary accreditation
- Access to medications and payor contracts
- Labor and information technology/systems considerations
 - Data Sharing (i.e., annual data validation)

Primary Specialty Accreditation

Pharmacy providers who successfully complete specialty pharmacy accreditation will prepare for months leading up to the actual specialty pharmacy accreditation survey. This preparation begins with evaluating the specialty pharmacy accreditation standards compared to current operations. The pharmacy will construct an action plan to determine how to meet the standards to satisfactorily complete the survey. These standards are developed independently by specialty pharmacy accreditors to assure quality and safety in the management of these expensive, complex, and potentially high-risk therapies. To meet these standards, the pharmacy functions unlike a traditional retail or mail order pharmacy and implements different clinical, operational, and administrative processes to meet all the requirements of the accreditor (i.e., clinical follow-up and outreach, prior authorization/financial hardship support, documentation of compliance requirements, etc.).

Often, these preparations involve leadership, front-line staff, and regulatory/compliance team members who develop policies, procedures, prepare files/documentation, educate team members, and numerous other tasks. Pharmacies are required to conduct patient care activities aligned with the accreditation standards and to meet the expectations of the accreditation. It is critically important for the pharmacy to meet accreditation expectations for managing policies and procedures, sustaining regulatory readiness, quality management, and business continuity.

Upon successfully receiving accreditation, the pharmacy will continue to conduct its business to continuously meet the accreditation standards. This involves dedicating staff resources to continually manage policies, processes, documentation, and other activities which are needed to successfully demonstrate sustained quality performance to the accreditation standards. The work associated with maintaining accreditation is often dependent upon which accreditation vendor is chosen by the pharmacy as each vendor can be slightly or significantly different in terms of the demands upon the pharmacy.

Secondary Specialty Accreditation

Pharmacies who are required by payor or PBM mandates or choose to undertake secondary specialty pharmacy accreditation to increase the likelihood of network acceptance will assess the accreditation standards compared to their operation and the requirements of their primary specialty pharmacy accreditation. This assessment requires the pharmacy to understand how to manage dual accreditation from documentation, workflows, operations, data, and other activities necessary to successfully meet the secondary (and primary) accreditation standards. Overlap of duplicative standards can result in burdensome requirements to the pharmacy.

Like primary specialty pharmacy accreditation, the pharmacy may be required to submit data, policies/procedures, demonstrate workflows/patient management, and the like to successfully pass the specialty pharmacy accreditation audit.

Each subsequent specialty pharmacy accreditation requires the pharmacy to pay an additional accreditation fee, the cost like the primary accreditation which can be tens of thousands of dollars. The cost is largely dependent upon volume, sites, the pharmacy's practice, and/or other like factors.

Access to Medications and Payor Contracts

Specialty pharmacy medications often cannot be acquired by traditional retail or mail order pharmacies due to limitations by the product manufacturer as well as other factors including a pharmacy not having the necessary operational capacity, staffing, and training to manage certain specialty medications. Specialty pharmacies become accredited to demonstrate that they can safely and appropriately dispense specialty drugs and care for specialty patients.

Plans/PBMs, North Carolina statutes, and manufacturers require specialty pharmacy accreditation to dispense specialty medications and to confirm compliance with standards designed to promote patient safety and optimize clinical outcomes. Accreditation reviews strive for a standard of care based upon the specific accreditation organization's standards.

Labor Considerations

Traditional retail or mail order pharmacies may lack the disease state expertise and time available to manage specialty patients to ensure optimal care. Pharmacies serving patients who are treated with specialty medications are providing services above and beyond those typically provided in the retail setting. As part of staff development, pharmacists, technicians, and other staff may pursue additional training (e.g., board certification) to build advanced knowledge to care for their patients. Accreditation is necessary to assess pharmacy staff knowledge and training to enhance patient safety.

Data Sharing

A pharmacy is required to submit data before, during, and after the specialty pharmacy accreditation if required by the accrediting body. This requires the pharmacy to dedicate resources to developing data management, conduits for sharing, and ensuring the data meets the standards/requirements of the accrediting body before and during an accreditation audit.

Certain accreditation organizations require annual validation reviews of the pharmacy's data to ensure submitted data to the accreditation vendor is accurately portraying the workflows of the pharmacy. This annual review typically requires the pharmacy team to dedicate time for preparing and completing this accreditation requirement.

Financial

What are the financial challenges facing pharmacy providers?

- Accreditation is costly
- Why do we pay for accreditation? Who looks at the data?
- What are the expenses?

Specialty pharmacy accreditation is based on nationally established standards developed by independent, third parties. Funding for the third-party accrediting organizations must come from pharmacies interested in becoming accredited so they can serve the needs of their patients for whom they dispense specialty medications. Payors, in particular, have a lot of skin in the game whenever it comes to reimbursing for high-cost specialty medications, which can easily cost \$100,000/year or more. "When these therapies are

administered and used properly, they can provide critical relief of symptoms, or even a cure, for patients, and that justifies the cost,” says Heather Bonome, PharmD, Director of Pharmacy with URAC, a specialty pharmacy accreditor. “Payers are also aware the improper use of these medications can lead to a worsening of the condition, which could lead to hospitalization and other high-cost interventions.” The data are useful for payors and manufacturers for establishing patient outcomes.

Specialty pharmacy accreditors require the pharmacy to pay a fee that is largely dependent upon volume, number of sites, and/or other like factors. Accreditations are generally structured as a three-year cycle, with associated fees for each cycle. It is important to note, the requirements of accreditation and associated cost may be challenging to a pharmacy. For this reason, pharmacies may choose to not pursue accreditation.

The accreditation/re-accreditation cost is one factor in the overall expense incurred by specialty pharmacies. Compliance with specialty pharmacy accreditation standards requires additional staff, supplies, and software when compared to non-specialty pharmacy operations. The additional requirements support data collection and management, packaging for shipping, tracking, and patient communication. While these enhancements may involve additional costs, they serve as the foundation necessary for a specialty pharmacy to promote patient safety and optimize clinical outcomes.

The table below outlines some costs for accreditation and software. When you add the cost of maintaining inventory of these medications and possibly the cost of dual accreditation, it is may be financially prohibitive for some pharmacies to participate in specialty accreditation.

Accreditation and Software Costs

Accreditation Organization	Cost of Accreditation <small>(Listed costs may not be all-inclusive.)</small>
Utilization Review Accreditation Commission (URAC)	A typical three-year fee ranges from \$35,000 - \$39,500. Pricing above this typical range represents larger, multi-site pharmacies. Pricing is based on pharmacy size and number of locations. For example, the three-year fee for a small independent pharmacy may be as low as \$14,000. In addition, fees for annual measure reporting average \$11,500 per year.
Accrediting Commission for Health Care (ACHC)	\$12,000 (three-year cycle per pharmacy)
American Society of Health-System Pharmacists (ASHP) – Center for Pharmacy Practice Accreditation (CPPA)	Cost is not applicable. ASHP/CPPA is no longer accepting applications for specialty pharmacy practice accreditation but is mentioned here for completeness.
The Joint Commission (TJC)	Three-year fee ranges from \$7,769 - \$13,740. Pricing based on pharmacy size.
Software Vendor	Cost
Various vendors such as Asembia, CPR+, Therigy, etc.)	Annual fees of \$18,000 and \$31,200 have been reported.

References:

<https://www.pppmag.com/article/2747>

<https://www.pharmaceuticalcommerce.com/view/specialty-pharmacy-accreditation-burden-and-benefit>

Recommendations

Please refer to the Specialty Pharmacy Stakeholder Workgroup Recommendations Chart as a separate document.

Conclusion

The workgroup established the need for achieving accreditation to validate a specialty pharmacy's commitment to consistent quality of care for patients on specialty medications.

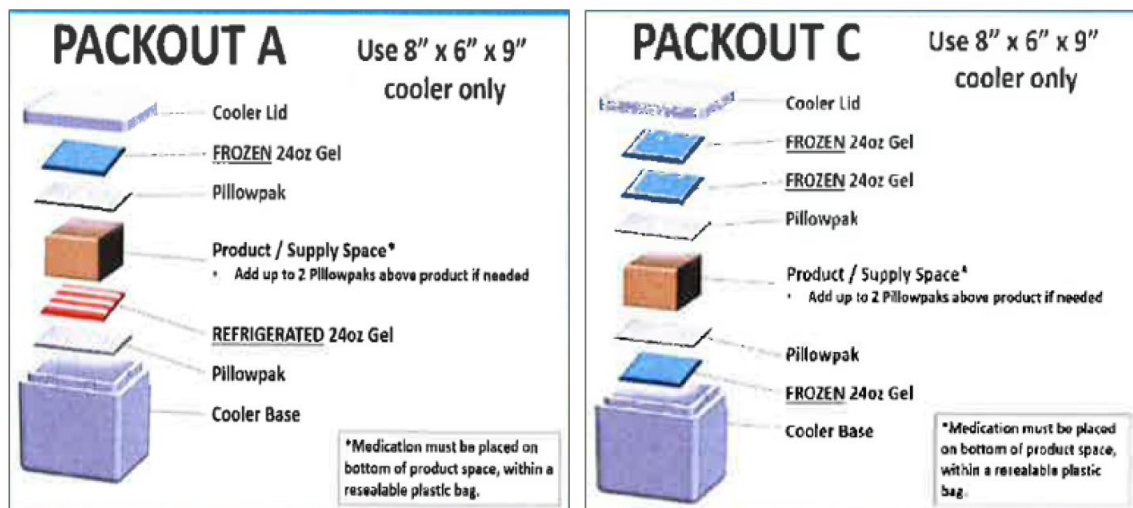
Specialty medications are complex medications and are used to treat patients with more severe and life-threatening conditions. For these reasons, specialty pharmacies dispensing specialty medications need continuous evaluation through accreditation to ensure safe dispensing practices.

Accreditation may be achieved through various nationally recognized organizations; however, the committee focused on the organizations outlined in the North Carolina Medicaid Hemophilia rule when reviewing standards and costs to become accredited.

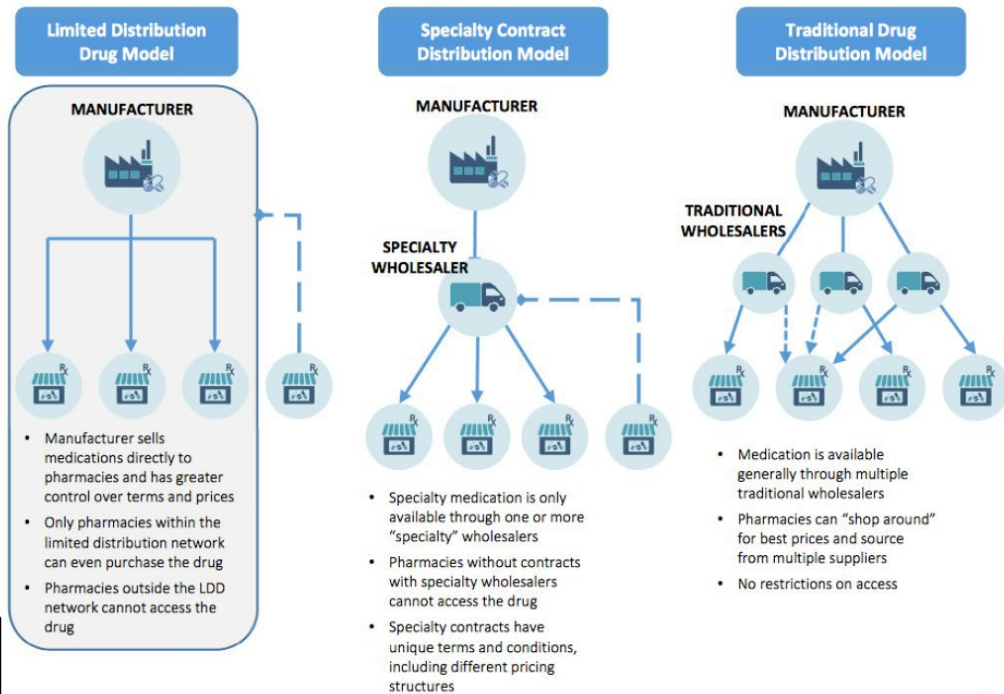
The committee proposed several recommendations to allow a pharmacy to dispense a specialty medication based upon Session Law 2021-161, Senate Bill 257, in compliance with other state and federal regulations.

Appendix

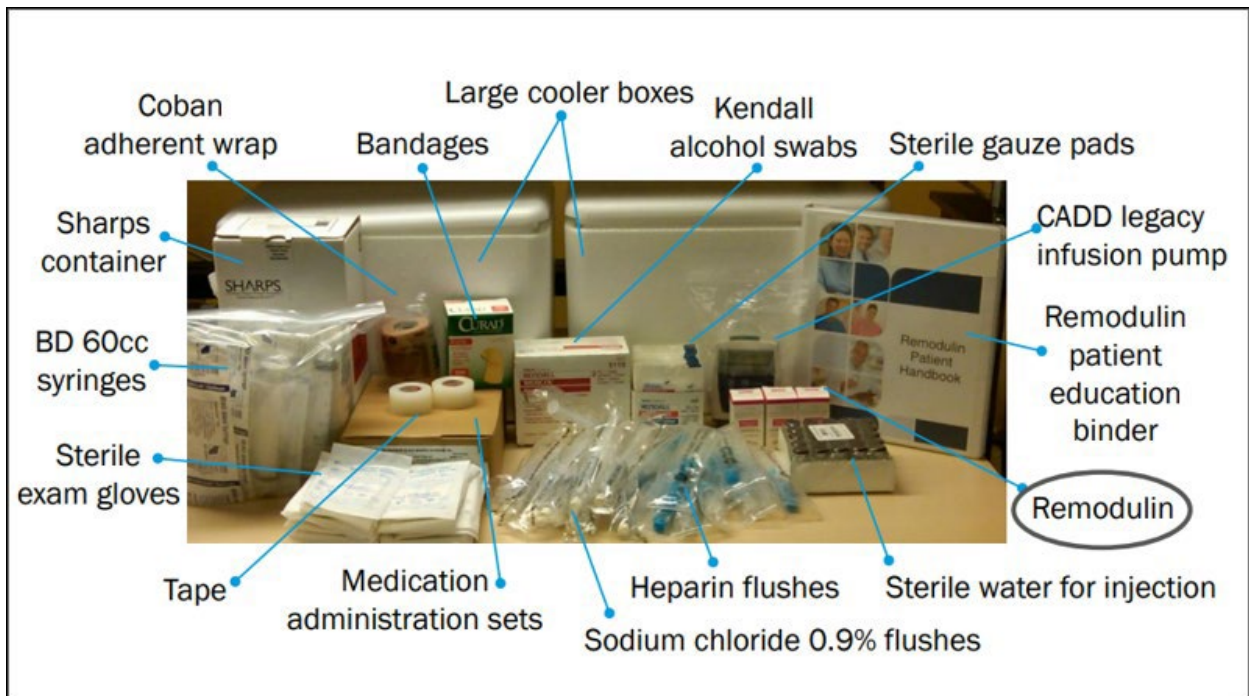
Example 1 - Packing of specialty drug products using Cold Chain Technology to ensure temperature and safety.



Example 2 - Specialty pharmacy access to specialty medications.



Example 3 - A drug shipment for a specialty medication, Remodulin. The pharmacy provides all drug supplies to effectively manage the patient’s treatment.



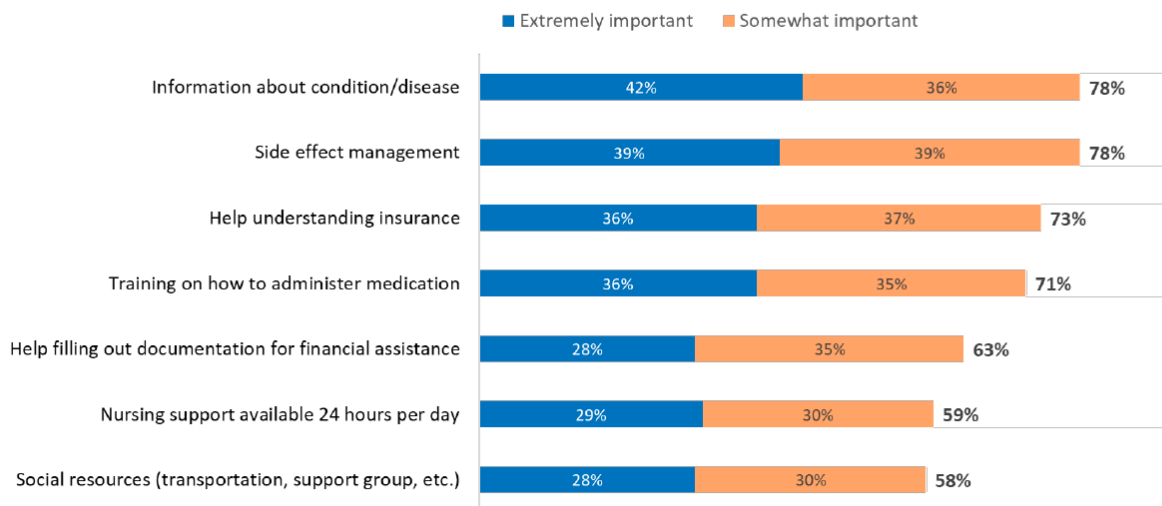
Example 4 - The extra support a specialty pharmacy team provides to a patient that is not offered at a traditional retail pharmacy.

Specialty Pharmacy Team Examples

Rheumatoid Arthritis and Inflammatory	Neurology & Multiple Sclerosis (MS)	HIV
<p>Features:</p> <ul style="list-style-type: none"> • Activities of daily living screenings • Easy-open bottle caps • Clinical contact for individuals with gaps in care • Employed in-home nursing model <p>Example Drug: Humira</p>	<p>Features:</p> <ul style="list-style-type: none"> • Depression screening and physician notification • Engagement with social worker • Clinical Care may include: <ul style="list-style-type: none"> – Clinical interventions (type of intervention, action/follow up, outcome) – Adherence support – MS Flares and Exacerbations (relapse, outcome of relapse, e.g. treatment with steroid) – Quality of Life assessments and/or disability progression <p>Example Drug: Copaxone</p>	<p>Features:</p> <ul style="list-style-type: none"> • Specially credentialed HIV pharmacists • HIV therapy optimization and pill burden reduction • In-home nursing model • Compliance and Adherence monitoring <p>Example Drug: <u>Biktarvy</u></p>

Example 5 - Peer-Review Study demonstrating the importance of specialty pharmacy services in 2020.

Importance of Specialty Pharmacy Services to Patients, 2020



Source: Drug Channels Institute analysis of *Boehringer Ingelheim Pharmacy Satisfaction Pulse Survey*, 2020. Figures show percentage of consumers (n=2,455) who answered the following question: "Now please tell us how important each is to the management of your/your household's illness or condition."

Attachments

(Separate documents from the report)

1. Presentation by Heather Bonome, PharmD, Director of Pharmacy with URAC and Jon Pritchett, PharmD, RPh, BCSCP, Program Director with ACHC
2. Presentation by Dr. Johnny Garcia, PharmD, RPh, Government Affairs Principal and Pharmacist at Prime Therapeutics
3. Presentation by Sheila Arquette, RPh, President & CEO of the National Association of Specialty Pharmacy (NASP)
4. Presentation by Penny Shelton, PharmD, FASCP, Executive Director, North Carolina Association of Pharmacists and Tim Weber, RPH, MBA, System Executive Director, Pharmacy, UNC Health Integrated Pharmacy Supply Chain Management.
5. NASP Definition of a Specialty Pharmacy and Specialty Medications
6. Comments from the America's Health Insurance Plans (AHIP)
7. Comments from Pharmaceutical Care Management Association (PCMA)
8. Recommendation from the North Carolina Association of Pharmacists (NCAP)
9. Comments from the NC Association of Health Insurance Plans, Inc (NCAHP)
10. Comments from the National Association of Specialty Pharmacy (NASP)
11. Specialty Pharmacy Stakeholder Workgroup Recommendations Chart

Specialty Pharmacy Stakeholder Workgroup Recommendations

Workgroup Objective 1: Examine the regulatory, administrative, and financial challenges facing those who wish to gain specialty pharmacy status

Workgroup Objective 2: Recommend a single, unified process to accredit specialty pharmacies in the State

Workgroup Membership: Independent Pharmacies, Pharmacy Service Administrative Organizations (PSAO), Pharmacy Benefit Managers (PBM), Health Benefit Insurers, Hospitals, Accreditation Organizations.

Recommendation	PBM	Insurer	Accreditation Organizations	Hospitals	Independent Pharmacists
To dispense specialty drugs to insured patients of North Carolina, a health plan, payor, or PBM, may require a pharmacy to obtain a current, nationally recognized, independent specialty pharmacy accreditation by one of the following organizations: a. Utilization Review Accreditation Commission (URAC) b. Accrediting Commission for Health Care (ACHC) c. The Joint Commission (TJC)	Oppose	Oppose	Support	Support	Support
To dispense specialty drugs to insured patients of North Carolina, a health plan, payor, or PBM may require a pharmacy to obtain a current, nationally recognized, independent specialty pharmacy accreditation by one of the following organizations: a. Utilization Review Accreditation Commission (URAC) b. Accrediting Commission for Health Care (ACHC) c. The Joint Commission (TJC) d. A combination of these organizations as required by the insurer or employer.	Support	Support	Oppose	Oppose	Oppose
The state of North Carolina shall have the right to evaluate the list of approved specialty pharmacy accreditation organizations when significant organizational or industry changes occur.	Support	Support	Support	Support	Support

Specialty Pharmacy Stakeholder Workgroup Members

Members	Association	Statute category
Jon Pritchett, Pharm.D., RPh., BCSCP	Program Director with Accreditation Commission for Health Care, Inc. (ACHC)	Accreditation

F. Michael James, RPh.	Exec Vice President Association of Community Pharmacists/Pharmacy Owner	Independent
Maribeth Martinez Battarelli, PharmD	Executive Director of Quality and Accreditation at CVS Caremark	PBM
Johnny Garcia, PharmD, RPh	Government Affairs Principal and Pharmacist at Prime Therapeutics	PBM
Rachel Littles	Pharmacy Program Manager, Specialty Program Operations at Blue Cross Blue Shield of North Carolina	Insurer
Mary Dorholt, PharmD	Sr Director, Clinical Practice Lead at CIGNA	Insurer
Heather Bonome, PharmD	URAC Director of Pharmacy/ previous practicing pharmacist	Accreditation
Toni Giglio	VP Accelerate Specialty Network at Amerisource	PSAO
Joey McLaughlin, RPh.	Pharmacy Owner at Realo Discount Pharmacy	Independent
J. Todd Jackson, PharmD, MHA	Director, Ancillary Services ECU Physicians, Brody School of Medicine - East Carolina University ECU · Department of Medicine	Hospital
Drew Huggins, PharmD, RPh	CEO at DrugCo Pharmacy	Independent
Tim Weber (replaced)	System Executive Director, Pharmacy UNC Health Hospital- Integrated Pharmacy Supply Chain Management	Hospital

Jeff Reichard, PharmD, MS, BCOP (effective 2/18/22)	System Executive Director, Retail and Specialty Pharmacy Services at UNC Health	Hospital
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Specialty Pharmacy Accreditation

Dr Johnny Garcia, PharmD, RPh
Government Affairs Principal and Pharmacist

January 13, 2022

Commissions charge and presentation outline

Commissions Charge: The workgroup shall examine at least the regulatory, administrative, and financial challenges facing those who wish to gain specialty pharmacy status.

Agenda:

- i. Explain a specialty pharmacy dispensing processes, including coordination with MD offices, drug storage and shipment
- ii. Demonstrate the extra standards for specialty shipments
- iii. Demonstrate specialty training for specific drug diseases
- iv. Discuss the difference of a Board of Pharmacy inspection in NC vs accreditation
- v. Explain patient safety and standards of care tracking in specialty pharmacies

What is a Specialty Pharmacy?

What is a Specialty Drug?

Caution: Innovation Happening at Warp Speed

Specialty drugs may possess any number of these common attributes:

- Prescribed for a person with a complex or chronic medical condition
- Treats rare or orphan diseases
- Requires advanced patient education, adherence, and support
- Is oral, injectable, inhalable, or infusible
- Has a high monthly cost
- Has unique storage, shipment, or administration requirements
- Is not stocked at a majority of retail pharmacies



Definitions unable to predict or account for warp speed innovation

- Car T-cell therapy
- Gene Therapy

The Prescription Drug Market

Prescription Volume vs. Prescription Dollars

Generics	Brands	Specialty
85% of Rx Volume	13% of Rx Volume	3% of Rx Volume
15% of Rx Dollars	35% of Rx Dollars	50% of Rx Dollars

One month supply (prices from multiple pharmacies)

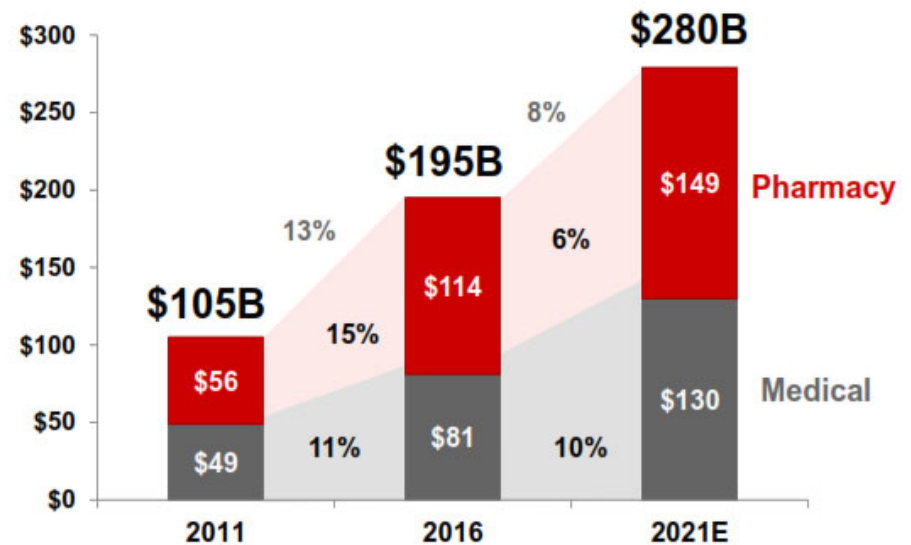
Generics	Brands	Specialty
Atorvastatin 40mg #30	Lipitor 40mg #30	Humira (2 Pens)
\$10.29- \$30.26	\$515.06- \$518.77	\$5808.72- \$6305

What has changed in Specialty?

Specialty drug prices are increasing dramatically:

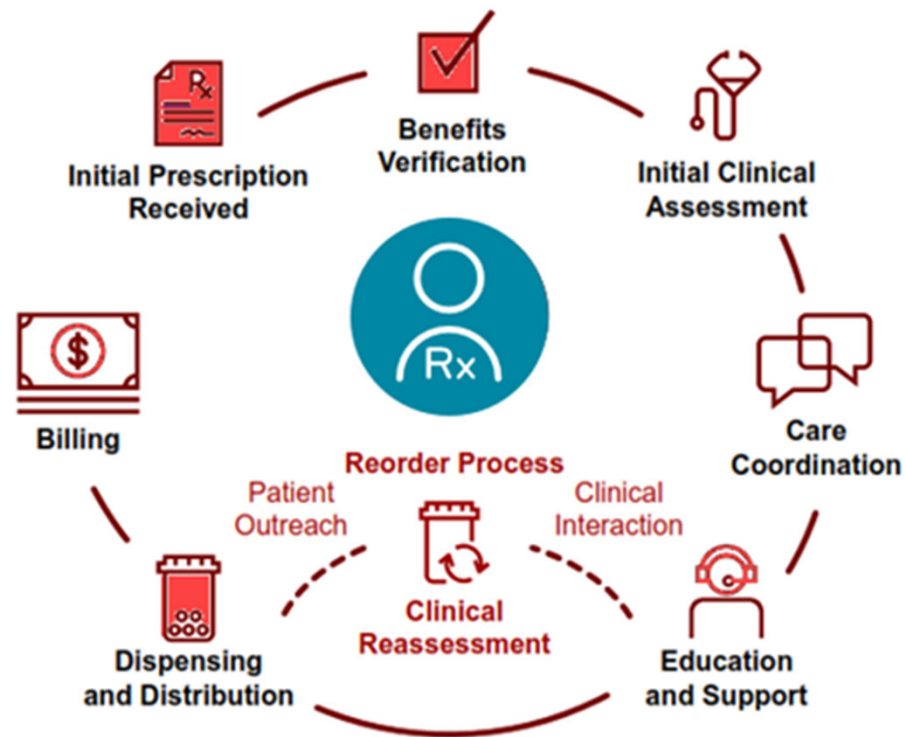
- Example Sovaldi
 - Used to be dispensed in pharmacy
 - \$81K per treatment (over 3 months)
 - Pharmacy purchase: \$27,300 per month
 - Retail price (no insurance): \$29,571 per month

- Staying on outlined therapy is critical
 - Specialty drugs require close monitoring
 - In example above, if the patient misses a dose, they must start the program from start.
 - Insurance companies needed tighter control of specialty drugs to reduce drug spend for unnecessary therapy adherence



Specialty Pharmacy Process

An Individualized Patient Care Approach



Occurs at every refill

Specialty Pharmacy: Above and Beyond

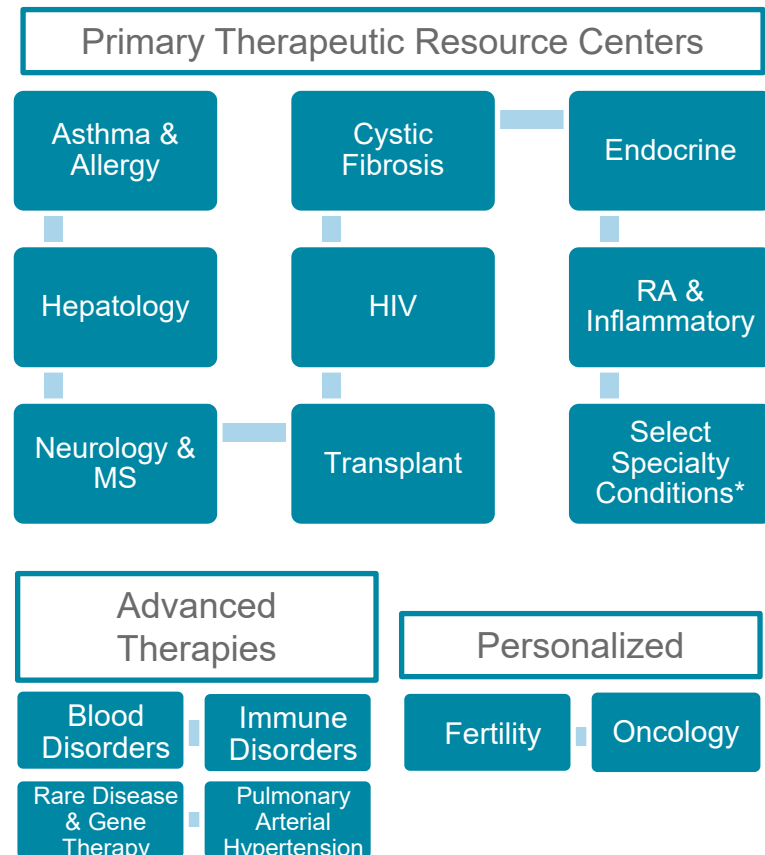
Ensuring patient safety and driving better patient outcomes

High-Touch Engagement	Financial Assistance (aka Benefits Verification)	Medication Management	Care Coordination
<ul style="list-style-type: none">• 24/7 access to a <u>specialized</u> health care provider• Physician consultation• In-depth patient education• Proactive outreach for refills and care	<ul style="list-style-type: none">• Medical and Prescription benefit navigation• Prior authorization assistance• Plan optimization• Patient financial assistance programs	<ul style="list-style-type: none">• Staying on the drug (adherence)• Supply chain management• Coordinating administration services• Monitoring safety and efficacy	<ul style="list-style-type: none">• Communication & care coordination with entire healthcare team• Medical & pharmacy benefits claims data• Quality control measures• Payer and/or manufacturer reporting• Improved health outcomes

Specialty Pharmacy Design

Clinical care for all patients

- Specialty-trained technicians, pharmacists, and nurses
- Disease and drug-specific teams to improve patient outcomes
- Programs customized for each individual



Specialty Pharmacy Team Examples

Rheumatoid Arthritis and Inflammatory

Features:

- Activities of daily living screenings
- Easy-open bottle caps
- Clinical contact for individuals with gaps in care
- Employed in-home nursing model

Example Drug: Humira

Neurology & MS

Features:

- Adherence support
- Depression screening and physician notification
- Engagement with social worker

Example Drug: Copaxone

HIV

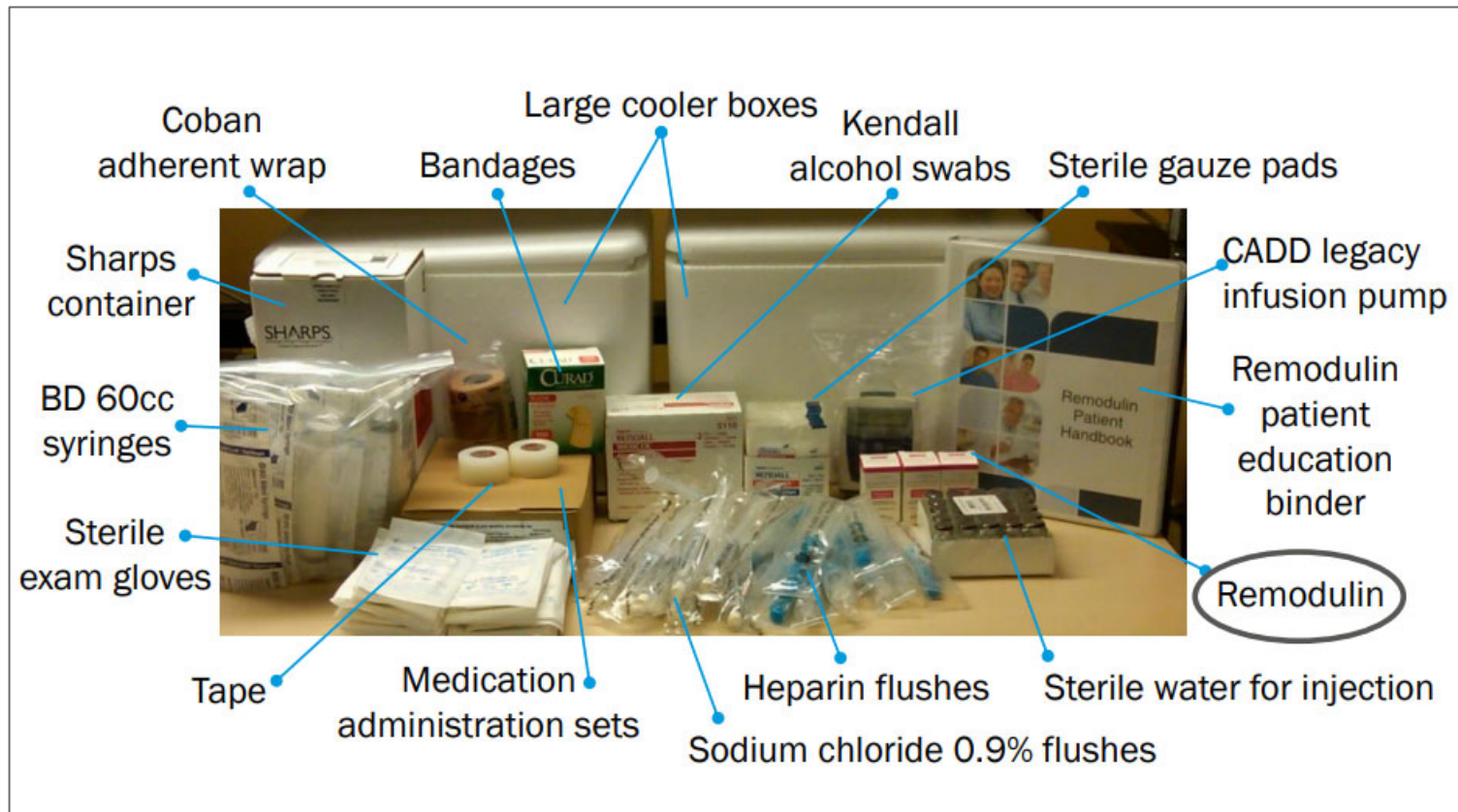
Features:

- Specially credentialed HIV pharmacists
- HIV therapy optimization and pill burden reduction
- In-home nursing model
- Compliance and Adherence monitoring

Example Drug: Biktarvy

What's So Different About Specialty Drugs?

Details matter for each medication



What's So Different About How Food is Delivered?

Example of steak shipment from Kansas to Florida

Simple packing:

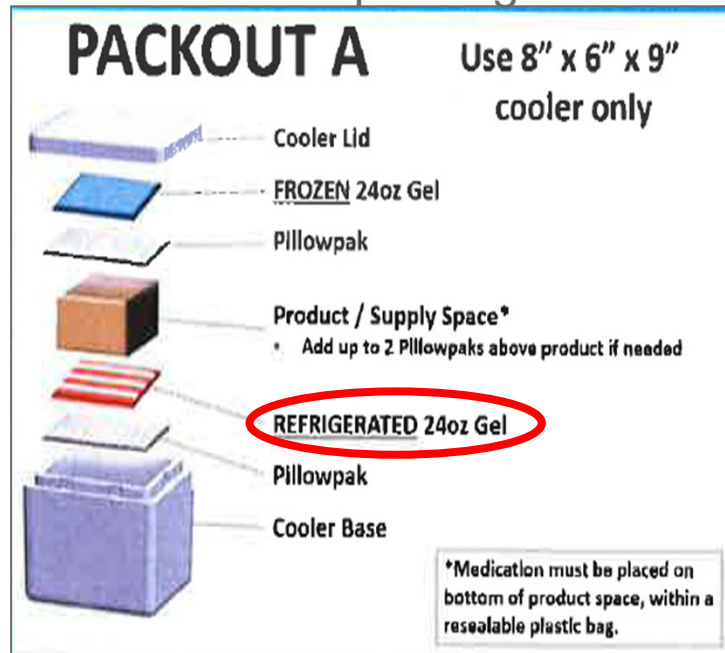
- Styrofoam cooler wrapped in plastic
- Cooler with dry ice and food product in cardboard box
- No buffering layers to protect food or monitor temperatures
- Is this packing tested?



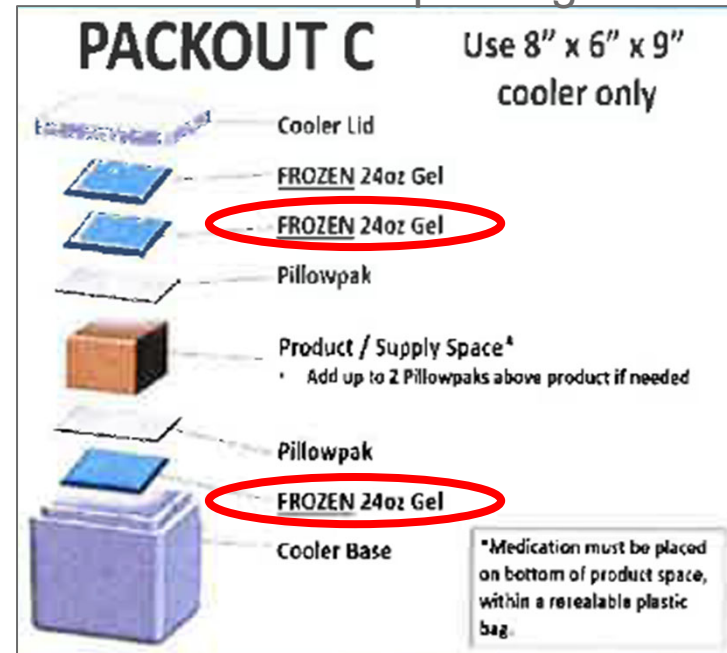
Specialty pharmacies use Cold Chain Technology

Specialty drugs use sophisticated shipping processes

Winter packing



Summer packing



- Sophisticated systems determine the “packout” based on temperatures at delivery location.
- Accreditation requires that the shipping is tested by an independent third party, and medications arrive safely within temperature requirements
 - Standards require policies and processes for delayed shipments from weather or other circumstances
- COVID-19 resulted in a 20% increase to mail order and accreditation ensures a standard of care to our patients

Why accreditation matters:

A North Carolina pharmacy license suspension

Apex Family Pharmacy

- Licensed pharmacy located in North Carolina
- Shipped unsafe drug products into Arizona
- AZ Board of Pharmacy partnered with NC Board of Pharmacy to investigate, issuing a sister discipline
- Accreditation would have identified gaps in this process
- These drugs are “waste” and increase the cost to payors and consumers, and potentially harming patients

BEFORE THE NORTH CAROLINA BOARD OF PHARMACY	
In the Matter of:) APEX FAMILY PHARMACY, INC. d/b/a) BLUE RIDGE PHARMACY) (Permit No. 9471))	CONSENT ORDER
<p>3. Between November 13, 2010 and April 17, 2015, the Pharmacy engaged in approximately three hundred (300) wholesale shipments into the state of Arizona, without having the required non-resident permits. In addition, the Pharmacy shipped some of these drugs in opened, partial packages, which was not permitted by Arizona law. The Pharmacy made these shipments by using services provided by MatchRx to pair interested buying and selling pharmacies for overstocked prescription drugs. Similar services are provided by other companies, including RxCherryPick, RxTrade and ExchangeMeds. In using the MatchRx service, the Pharmacy relied upon representations that the Pharmacy could lawfully ship to other states using the service. The Pharmacy's representatives acknowledged that they should have researched permitting requirements in other states before shipping there, rather than relying upon MatchRx's representations. Although the Board finds that it was not reasonable for the Pharmacy to rely on the representations of a third-party with a profit motive to cause the Pharmacy to use the service, rather than researching legal requirements on its own, the Board finds that the Pharmacy acted in good faith in its reliance.</p>	

<http://www.ncbop.org/Disciplinary%20Actions%20-%20PHARMACIES/ApexFamilyPharmacydbaBlueRidgePharmacy09471.pdf>

New England Meningitis Outbreak

- Injectable drugs were compounded unsafely by an unaccredited pharmacy and sent to 23 states
 - Resulted in 260 patients contracting fungal meningitis
 - 2 patients were in North Carolina
 - 7 states were protected from outbreak due to recalls issued by FDA
- Accreditation agencies review techniques, equipment, policies and training for pharmacies who provide these services.
 - Review consists of **demonstration**
 - Review the recall process for drug product at the pharmacy and patient level

Accreditation adds protection and safety

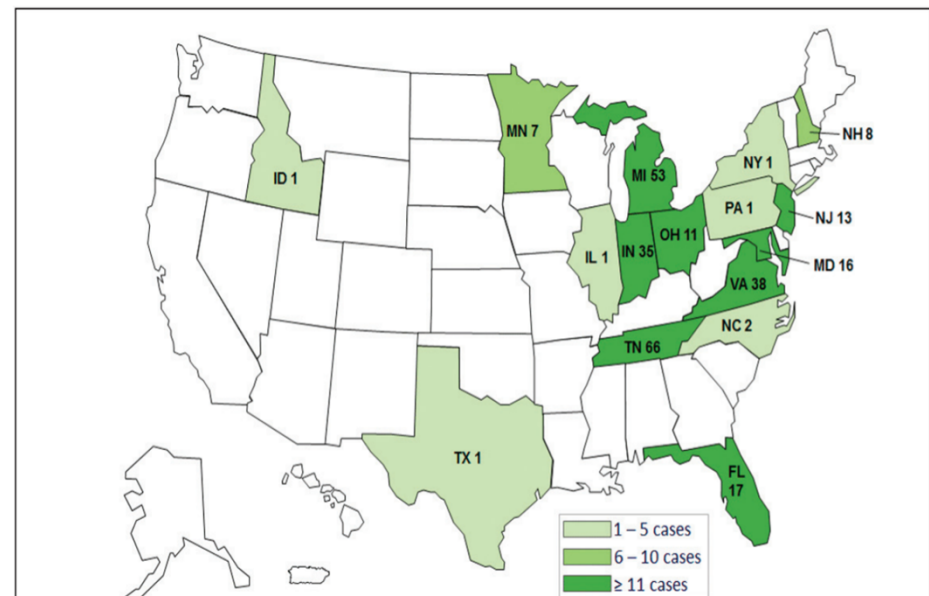


Figure 1. Cases of meningitis reported in the U.S. as of October 19, 2012.

Accreditation vs Board of Pharmacy Inspection

Drug Supply Chain Oversight

Federal

- US Food and Drug Administration
- US Pharmacopeia

Other

- International Safe Transit Association Certification
 - Packing materials
 - Packing methods
- Accreditation

State of North Carolina

- **Medication requirements for pharmacies**
 - 10A NCAC 27G.0209
- **Pharmacist-Manager Responsibilities**
 - 21 NCAC 46.1411 and 21 NCAC 46.2502
- **Applicability to out-of-state operations**
 - § 90-85.21A
- **Patient counseling**
 - 21 NCAC 46.2504

Specialty Pharmacy

Licensure, Credentialing, Accreditation... are NOT the same

Licensure

States do not differentiate specialty pharmacy licensure from retail/community pharmacies

- There is no “Specialty Pharmacy License”
 - Some self-identify their services (e.g., sterile compounding or specialty)

Boards of Pharmacy do not have statutory authority to credential or accredit pharmacies

Credentialing

Process used to obtain, verify, and assess a pharmacy’s basic qualifications to provide patient care.

Evidence typically required may include:

- Description of pharmacy services
- State licensure
- Current federal DEA license
- Current pharmacy malpractice insurance
- Electronic claims processing and electronic prescribing capacity
- Credit worthiness
- Use of licensed wholesalers

Accreditation

Independent, national quality entities accredit specialty pharmacies: URAC, ACHC, Joint Commission

- Certifies high standards of service and uniformity of care
- Demonstrates the pharmacy’s commitment to quality, cost containment, and proper utilization of services
- Goes beyond Board of Pharmacy’s scope of public health and safety
- PBMs and payers should be able to dictate the terms and conditions for joining their networks

NC Inspection vs Accreditation

NC BOP Inspection Report

- Inspections are conducted every 4 years, or as part of an investigation or complaint ¹
- Does not include separate specialty inspection
- Does not include safety check for storage of any drugs (including specialty or mailed)
- Simple Yes/No questions
- Asks “does pharmacy ship into other states? (if yes, document permits)” ²
- Inspections include label requirements, physical pharmacy requirements, record requirements, pharmacy access, inventory, control substance requirements, compounding requirements

¹ <http://www.ncbop.org/Forms%20and%20Applications%20-%20Pharmacies/NCBOPInspectionPolicy.pdf>

² <http://www.ncbop.org/Forms%20and%20Applications%20-%20Pharmacies/PharmacyInspectionReportNov2016.pdf>

Accreditation

- Valid for 2-3 years
- Ensures a standard of healthcare and quality
- Not simply a “yes/no” question, but demonstration of process
- Specialty Pharmacy:
 - Ongoing review of quality procedures, including a quality committee
 - Ensures development and maintenance of written policies and procedures
 - Staff qualifications, credentialing, and oversight requirements of qualified staff for certain functions
 - Development, delivery and expectations of drug utilization management programs
 - Scope of appeals considerations, or procedures in place for how an appeals process works

Patient Safety and Specialty Drug Monitoring

Specialty drug safety is more complicated

FDA Adverse Event Reporting System (FAERS)

- FAERS is a database that contains adverse event reports, medication error reports and product quality complaints.
- FAERS is a useful tool for FDA for activities such as looking for **new** safety concerns that might be related to a **newly marketed product**.
 - **Note: New drugs to market are specialty drugs. Community pharmacies will be required to adhere to these strict requirements.**

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Healthcare professionals, consumers, and manufacturers submit reports to FAERS. FDA receives reports directly from healthcare professionals (such as physicians, **pharmacists**, nurses and others) and consumers.

<https://www.fda.gov/drugs/surveillance/questions-and-answers-fdas-adverse-event-reporting-system-faers>

Recap and Questions

Accreditation Take-Aways

Accreditation is necessary to ensure standards of care and safety exist for patients using pharmacies who provide the same service

Specialty pharmacies look and act differently than retail/community pharmacies

Specialty pharmacies provide a full range of personalized clinical and operational services beyond the capabilities of traditional retail/community pharmacy

- Active clinical management, considerable education, sophisticated logistical support, and programs to optimize therapeutic outcomes
- Teams of specialty-trained health care professionals
- Expertise, technology, and infrastructure to provide quality care

It's not as simple as counting pills and putting a label on a bottle.

Our purpose:

To help people get the medicine they need
to feel better and live well

Thank you!

Dr Johnny Garcia, PharmD, RPh
Government Affairs Principal and Pharmacist
(505) 610-8110
JGarciajr@primetherapeutics.com



NORTH CAROLINA ASSOCIATION OF PHARMACISTS SPECIALTY PHARMACY ACCREDITATION

**PENNY SHELTON, PHARMD, FASCP | EXECUTIVE DIRECTOR
NORTH CAROLINA ASSOCIATION OF PHARMACISTS**

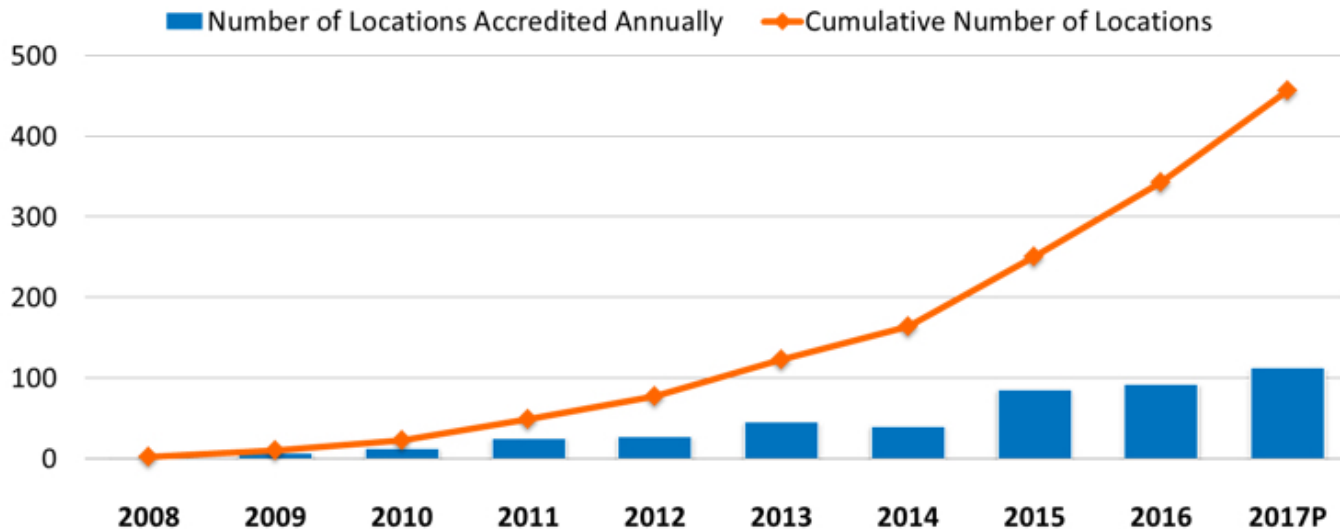
**TIM WEBER, RPH, MBA | SYSTEM EXECUTIVE DIRECTOR, PHARMACY
UNC HEALTH INTEGRATED PHARMACY SUPPLY CHAIN MANAGEMENT**

JANUARY 27, 2022

OUR POSITION

- ▶ Specialty pharmacy accreditation
 - ▶ Has an important role
 - ▶ For medications that are ‘truly’ special and not just expensive, accreditation helps to ensure patient safety, optimal patient outcomes, and quality care
 - ▶ BUT, many aspects of specialty pharmacy accreditation, and more so the entities that are driving required multiple accreditations are out of control

Locations With URAC Specialty Pharmacy Accreditation, 2008-2017



Source: [The 2017 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers](#), Drug Channels Institute, 2017, Exhibit 41.
Data show number of locations accredited at end of year.

Published on Drug Channels (www.DrugChannels.net) on April 13, 2017.



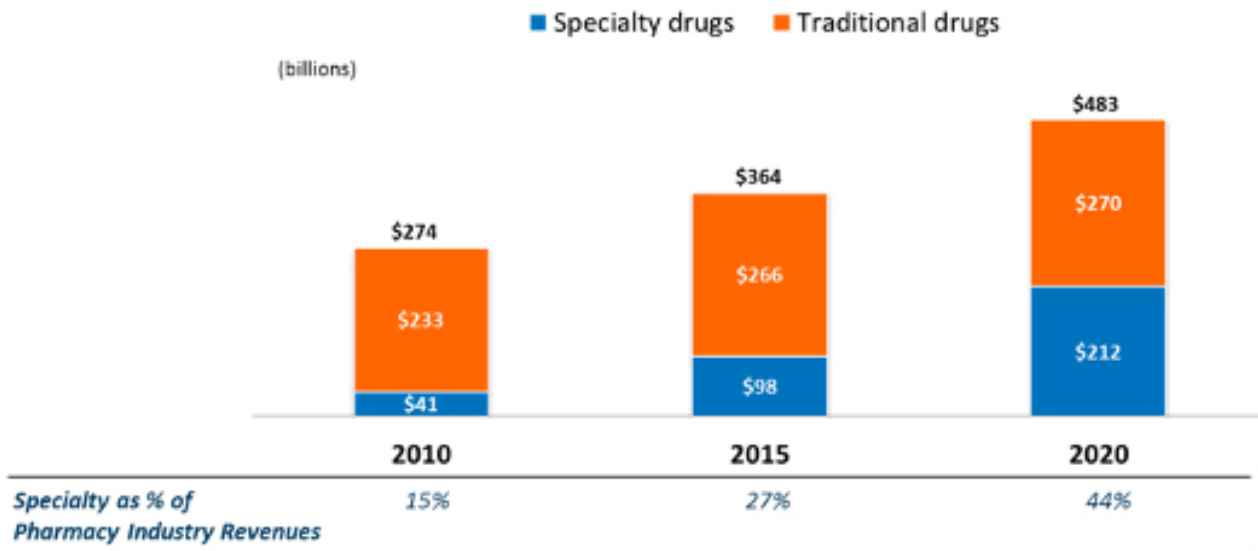
DRUG CHANNELS
INSTITUTE



THE RISE OF SPECIALTY PHARMACY

- ▶ The emergence and (some of the) rising trajectory for the number of specialty drugs and therefore the number of specialty pharmacies closely aligns with the past decade's rise in the number of expensive orphan and biologic drugs approved by the FDA.
 - ▶ Orphan drugs are treatments for very rare diseases.
 - ▶ Biologics are used to diagnose, prevent, treat, and cure diseases and medical conditions; and are generally large, complex molecules produced in a living system, such as a microorganism, plant cell, or animal cell. Examples: monoclonal antibodies and vaccines.

Pharmacy Industry Revenues, Traditional vs. Specialty Drugs, 2010-2020



Figures in billions

Source: Pembroke Consulting estimates

This table appears as Exhibit 34 in: Fein, Adam J., *The 2016 Economic Report on Retail, Mail, and Specialty Pharmacies*, Drug Channels Institute, January 2016. Available at http://drugchannelsinstitute.com/products/industry_report/pharmacy/

SPECIALTY DRUG DEFINITION

- ▶ Varies across organizations, ever-evolving, but should require attributes besides a 'high cost' to classify a drug as 'specialty'

Complex or chronic medical condition that left untreated can be debilitating or fatal

Treats a rare or orphan disease

Requires complex or additional patient ed, adherence, and support beyond traditional pharmacy

Are typically biologic (oral, injectable, infusion) medications, that may also have biomarker tests

Has unique storage or handling requirements such as refrigeration

Is not stocked at a majority of retail pharmacies

May be defined by payers as specialty pharmaceutical

WHO DETERMINES IF A MEDICATION IS A SPECIALTY DRUG?

- ▶ Not the FDA
- ▶ Not pharmacies
- ▶ Sometimes it's the pharmaceutical manufacturer
- ▶ Often it is the health plans, PBMs or 3rd party administrators, as a part of their formulary management, for cost reasons

Each of you has health insurance, the health plan that you have publishes a drug list that lists the medications covered by your health plan. The list is generally divided into tiers. The lower the tier number the lower your copay for medications in that tier. The drug list also includes a designation for any medications covered that the plan classifies as 'specialty' drugs.

Nucala®
(Eosinophilic
Asthma)
Aetna—No
BCBS—Yes
Cigna—No
United—Yes

Inconsistencies among
health plans as to
whether a medication
is classified as
specialty or not

Biktarvy®
(HIV/AIDS)
Aetna—No
BCBS—Yes
United—No
Cigna—Yes

Sovaldi®
(HEP C)
Aetna—No
BCBS—Yes
United—No
Cigna—Yes

Health plans, PBMs or
3rd party
administrators require
or prefer dual
accreditation

Most recognize
URAC & ACHC

Inconsistencies
in recognition/
preference for
other accrediting
bodies—some
recognize CPPA,
NABP specialty
or joint
commission
specialty, others
may not

Health plans and/or
PBMs have created
their own specialty
pharmacies to steer
even require
beneficiaries to use

State Employees
Health Plan
PBM—
CVS/Caremark
CVS Specialty

United
Healthcare
Optum Specialty

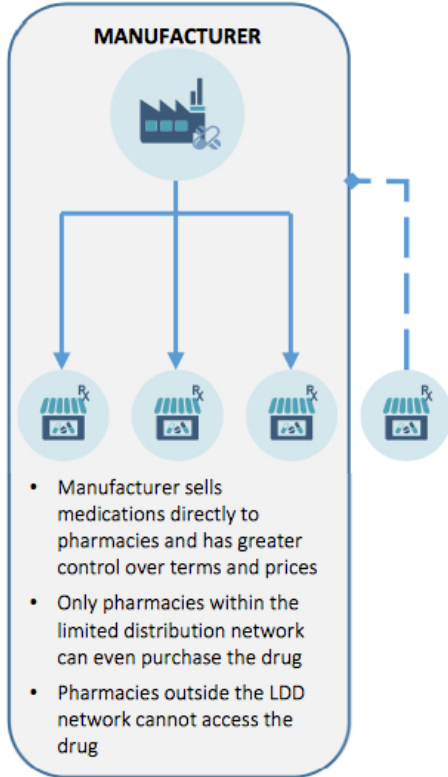
OTHER INCONSISTENCIES

- ▶ Pharmacies are told that if they acquire dual accreditation it is looked upon more favorably for inclusion in-network, but there are no guarantees
 - ▶ Lack of transparency regarding how inclusion or exclusion from network is determined.
- ▶ Specialty drugs are not always about ‘special care’ but rather convenience in the moment and cost—as examples:
 - ▶ For many chronic condition specialty medications a non-accredited pharmacy/patient is permitted or granted first fill approval, but then ongoing refills to be provided by preferred specialty pharmacy—typically the payer/PBM specialty mail order
 - ▶ When the heart failure drug Entresto® first became available it was classified by a number of plans as specialty, solely because of cost. Today, some plans have it as a preferred brand, others in a non-preferred tier, some as prior authorization, but it is no longer classified as specialty.

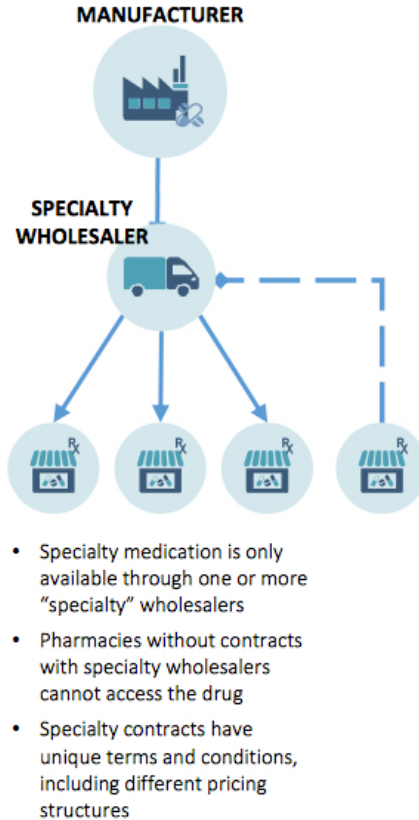
ACCREDITATION IS NOT A CHOICE

- ▶ Accreditation is not about what best fits your pharmacy
 - ▶ If pharmacies want to care for their patients, in their institution or community, and if those patients need medications that are deemed by a health plan to be specialty, then the pharmacy has to get accredited as a specialty pharmacy
 - ▶ The reason the # of specialty pharmacies has grown exponentially in the past 10 years is because more and more medications, particularly newer, and therefore more expensive medications, are being classified as specialty by health plans/PBMs.
 - ▶ Pharmacies care for patients who have a variety of health plans, which means multiple specialty pharmacy accreditations

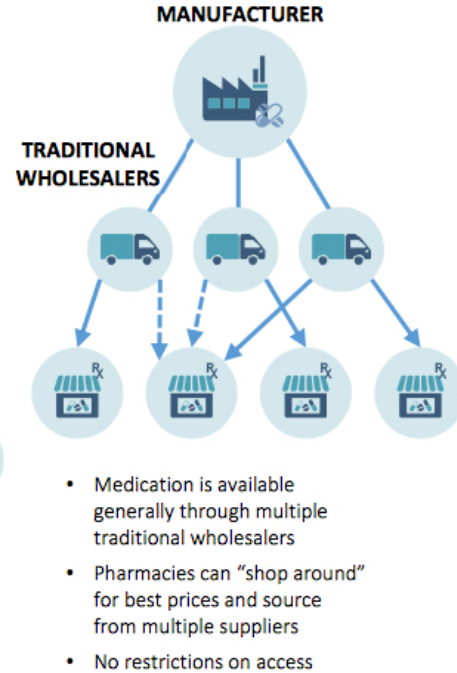
Limited Distribution Drug Model



Specialty Contract Distribution Model



Traditional Drug Distribution Model



ACCREDITATION IS EXPENSIVE & LABOR INTENSIVE

- ▶ Accreditation is expensive and administratively burdensome
 - ▶ What are the fees, for accreditation, reaccreditation: URAC \$30,000 / ACHC \$10,000 / CPPA(ASHP) depends on size (Rx volume) \$8,000 - \$28,000 / Joint Commission Specialty \$10,000
 - ▶ Keep in mind many of the accreditation fulfillment elements are requirements for which the pharmacy has no means of payment or reimbursement. (later slide highlights many of these elements)
 - ▶ Each of the accrediting bodies have standards that fall under 4 categories:
 - ▶ Organizational Infrastructure
 - ▶ Access to Medications
 - ▶ Clinical & Patient Management Services
 - ▶ Quality Improvement

Each category has a a number of standards and within each standard a number of guidance items/ components to be addressed. In some categories 200+ items to address. Some have additional standards related to disease states.

ACCREDITATION STANDARDS

- ▶ Why multiple accreditations? Are there substantive differences in the accreditation standards, as they apply to pharmacy operations and safe/quality of care for patients?

COMPARISON: CPPA TO URAC

- ▶ Clinical & Patient Management Services Category
 - ▶ Standard 3.5a The specialty pharmacy practice provides patient-centered consultation and education regarding expectations of therapy.

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Through review of social and patient medical information, pharmacy staff provides medication consultation and patient education in a patient-centered fashion. Information is provided at a literacy, health literacy and education level appropriate for the patient based on staff assessment, and addresses the communication needs of the patient or caregiver, including languages and cultural influences, and disabilities, such as blindness or deafness. In addition to specialty pharmacy staff, other patient education resources are available including websites (links to medication information, for example), email, print, text messaging, live web chats, etc.). References or medication information are available to the patient or caregiver during business hours and after hours (include website information or links).

The organization provides information to consumers in multiple (i.e., at least two) formats and media (e.g., Internet, print, live oral presentation, audio, video, e-mail, telephonic, and interactive) such that all consumers have access to relevant information (as per contract). Then there are subsections with specific guidance for health literacy and culturally appropriate communication; as well as guidance that the education materials are to reflect the learning needs of the target population; reflect current best practices for patient management; when provided to individual patients are to be documented in the care plan; reviewed at least annually; describe potential health benefits and limitations of participating in a patient management program; include instructions on how to contact the pharmacy's patient management program; and provide opt-out opportunities.

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COMPARISON: CPPA TO ACHC

- ▶ Clinical & Patient Management Services Category
 - ▶ Standard 3.7 The specialty pharmacy practice modifies patient case management based on patient-specific factors when needed.

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Specialty pharmacy care is dynamic and is inclusive of patient-centric assessment. Specialty pharmacy practices have the ability to take an individualized approach to every patient and assess the patient-specific metrics, which increase the likelihood of non-adherence, lack of follow-up, or drug interactions. However, pharmacy staff must be able to make modifications to the standardized patient management protocol pursuant to patient assessment. These modifications may drive more frequent follow-up or patient assessment if a reason exists to do so.

The organization shows evidence of the client/patient participation in the plan of care/service. There is evidence of changes in the plan of care based on reassessment data. Changes are noted on the plan of care and/or in the progress notes based on: client/patient's requests; client/patient's condition; client/patient's response to therapy; and/or when physician orders indicate changes. There is evidence of communication to the physician regarding the client/patient's condition. If new or revised client/patient or treatment goals are indicated, they must be reflected in a revised plan of care. Revised plans of care shall be approved by the client's/patient's physician.

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ACCREDITATION: TIME & MANPOWER

- ▶ What does it take to prepare for accreditation/reaccreditation?
 - ▶ 3-4 months of intensive focus (Depending on the size of specialty pharmacy 1-3 employees solely devoted to accreditation related work)
 - ▶ Each year that reaccreditation due, activities occur 8-9 months of that year
 - ▶ Implementing, assessing, updating policies and procedures in alignment with ever-changing standards
 - ▶ Report generation, review and submission
 - ▶ Data validation
 - ▶ Multiple accreditations (pharmacies try to cycle in alternate years)—but constantly working on some aspect of accreditation processes
 - ▶ Pharmacies often have multiple employees dedicated to meeting/maintaining accreditation standards & guidelines

Definitions for Specialty Pharmacy and Specialty Pharmaceutical

Specialty pharmacy practice encompasses the provision of specialty pharmaceuticals, which typically require unique fulfillment and patient care support services.

Unique fulfillment elements may include:

- Coordination of care and facilitating drug access to limited distribution specialty pharmaceuticals
- Facilitating mail-order delivery logistics
- Negotiating payer contracts
- Maintaining cold-chain distribution
- Dispensing and tracking a significant number of products requiring REMS
- Accounts receivable support/management
- Program accreditation management and development of program marketing materials

Technical and clinical patient care support services will include:

- Benefits investigation, prior authorization, and patient assistance program (PAP) management
- Call-center development, staffing, and monitoring
- Case management, which may include development of protocols and disease state management at a minimum

- Product device training
- Data management of technical and clinical patient care services

Specialty pharmaceuticals have at least some of the following characteristics:⁴

- High cost
- Involve complex treatment regimens that require ongoing clinical monitoring and patient education
- Have special handling, storage, or delivery requirements
- Are generally biologically derived and available in injectable, infusion, or oral form; biologics may also have companion genetic biomarker tests
- Increased potential for limited or exclusive product availability and distribution
- Are dispensed to treat individuals with rare diseases
- Treat diseases or conditions marked by long-term or severe symptoms, side effects, or increased fatality
- May be defined by payers as a specialty pharmaceutical

REMS = Risk Evaluation and Mitigation Strategies

Clinical services passed on (pushed off) to pharmacy with no ability for the pharmacy to be paid for these 'super important specialty drug' required patient care services

Because if the care coordination, patient education, device training, and ongoing patient monitoring were done by a physician or physician office's staff, there would be payment

SPECIALTY COST OF CARE

- ▶ A NC Health System Specialty Pharmacy has calculated the cost to fill a specialty prescription based on all of the specialty fulfillment requirements associated with accreditation at approximately \$65-\$85/prescription
- ▶ In many cases the margin on the product dispensed is \$0 or less than cost of acquisition, which means the pharmacy takes a loss each time they fill one of these prescriptions.

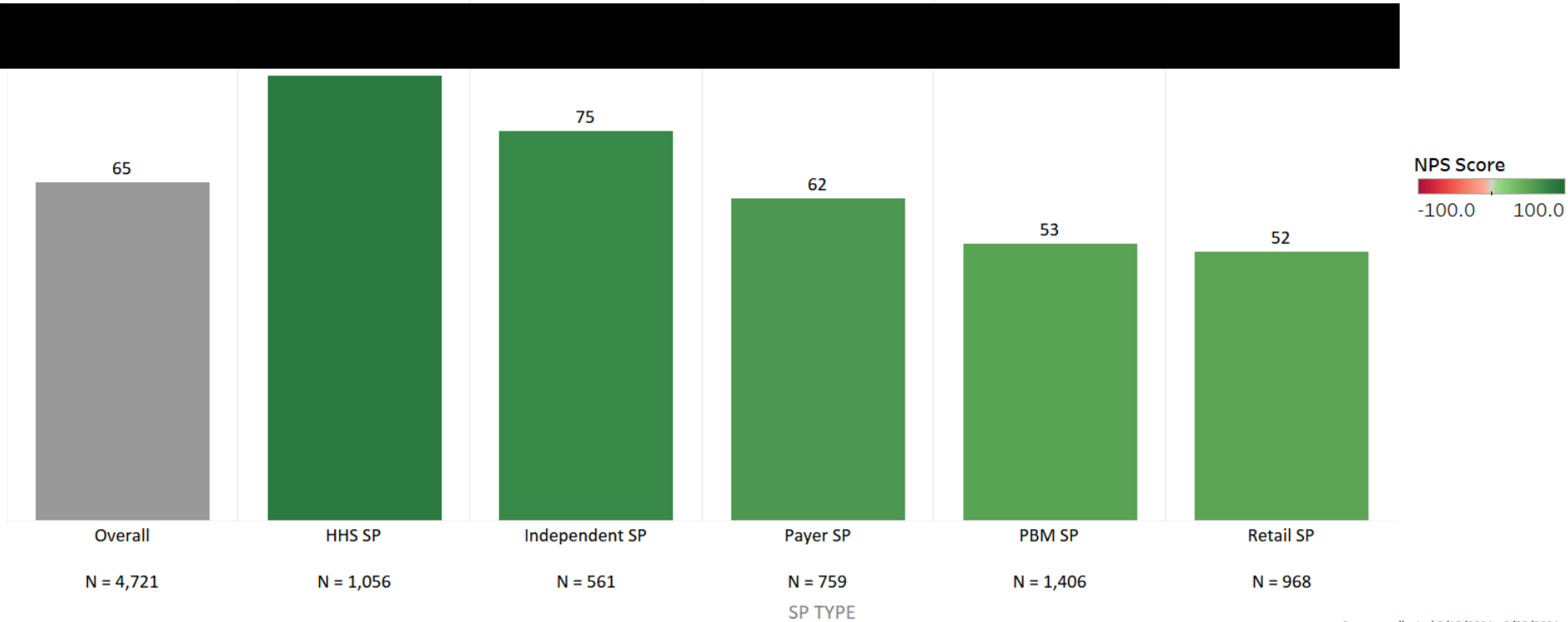
MULTIPLE ACCREDITATION: BARRIER TO CARE

- ▶ In how 'specialty' drugs are currently defined, and in an earlier presentation before this workgroup, you have heard that “payers should be able to dictate the terms required for participating in network”—this is what has led to explosive # of specialty drugs AND required multiple accreditations for pharmacies (left unchecked both continue to drive business to the payer/PBM’s own specialty pharmacy).
- ▶ In the context of safe and optimal patient care, there is no meaningful difference between the various specialty pharmacy accreditations; therefore there is no real purpose for multiple accreditations; other than, it creates barriers to care because pharmacies, on extremely narrow margins, cannot afford all of the costs that go into maintaining multiple accreditations just to maybe be allowed in network.

So do the Payer/PBM specialty pharmacies do a better job?



NET PROMOTER SCORE: I WOULD RECOMMEND A FRIEND/FAMILY MEMBER TO THIS PHARMACY
Net Promoter Score = Promoters - Detractors



Surveys collected 8/12/2021 - 9/30/2021

OUR RECOMMENDATIONS

- ▶ Eliminating unnecessary, costly and burdensome multiple accreditations (Accrediting bodies then have to earn the business of pharmacies, and not that of specific health plans or PBMs.)
 - ▶ Competitive market discipline—that could help further streamline processes to those that are important and necessary for safe/optimal care, rein in the cost for obtaining/maintaining accreditation, and reduce related administrative burdens.
- ▶ As long as a pharmacy is accredited by one specialty accrediting body (as recognized by the NC DOI) then a pharmacy cannot be required to obtain a different accreditation in order to be able to dispense specialty meds, in network, to patients.
- ▶ Health plans, PBMs should not be allowed to exclude pharmacies that have obtained a specialty pharmacy accreditation from being in network for specialty medications

CAUTION / DO NOT RECOMMEND

- ▶ Any form of language that refers to local pharmacies having to meet same criteria as a health plan's or PBM's own specialty pharmacy—in New Jersey this has kept some independent's from being included in some specialty networks because, unlike the PBM specialty like CVS specialty, the local pharmacies are not licensed for care in all states, but this has excluded them from caring for specialty patients in their own state.

Penny Shelton, PharmD, FASCP
Executive Director
(984) 439-1646 x 225
penny@ncpharmacists.org



Specialty Pharmacy Accreditation

SPECIALTY PHARMACY STAKEHOLDER WORKGROUP

JANUARY 13, 2022

HEATHER BONOME, PHARMD, URAC DIRECTOR OF PHARMACY

JON PRITCHETT, PHARMD, RPH, BCSCP, ACHC PROGRAM DIRECTOR

Agenda

Introduction to Specialty Pharmacy

- Specialty Drugs
- Specialty Pharmacy Services
- Market trends
- Specialty Pharmacy Models

Accreditation in Specialty Pharmacy

- Standards
- Review Process
- Requirements

Questions

What is a Specialty Pharmacy?

Defined by the **medications** that are dispensed → **self-administered specialty medications**

Defined by the **health conditions** the pharmacy services → **chronic, complex disease states**

Defined by **the services** that are provided → **comprehensive patient care services**

Defined by the **quality standards** that are met → **specialty pharmacy accreditation**

Specialty Drugs

Common Drug Categories

- Cancer
- Cystic Fibrosis
- Hemophilia
- Hepatitis
- HIV/AIDS
- Human Growth Hormone
- Inflammatory Conditions
- Multiple Sclerosis
- Transplant

Common Factors

- Complex Treatment Protocols
- High Cost
- Injectable
- Patient Monitoring Required
- Significant Adverse Effects
- Special Handling Requirements
- Temperature Sensitive

Specialty Pharmacy Services

Patient Therapy Management

- Disease specific patient education
- Refill reminders to ensure adherence to therapy
- Clinical monitoring to ensure progressing to therapy goals
- Counseling to manage adverse effects
- Ready telephone access to pharmacist or nurse

Product Handling, Storage, Distribution

- Temperature requirements
- Hazardous material management
- Distribution logistics

Coordination of Care

- Coordinating with all members of the healthcare team
- Managing payment by supporting prior authorizations and copay assistance
- Providing manufacturers with de-identified patient data

Who provides these services?

Pharmacists, Nurses, Pharmacy Technicians, Patient Care Coordinators, etc.

Specialty Pharmacy Services Example: Hepatitis C

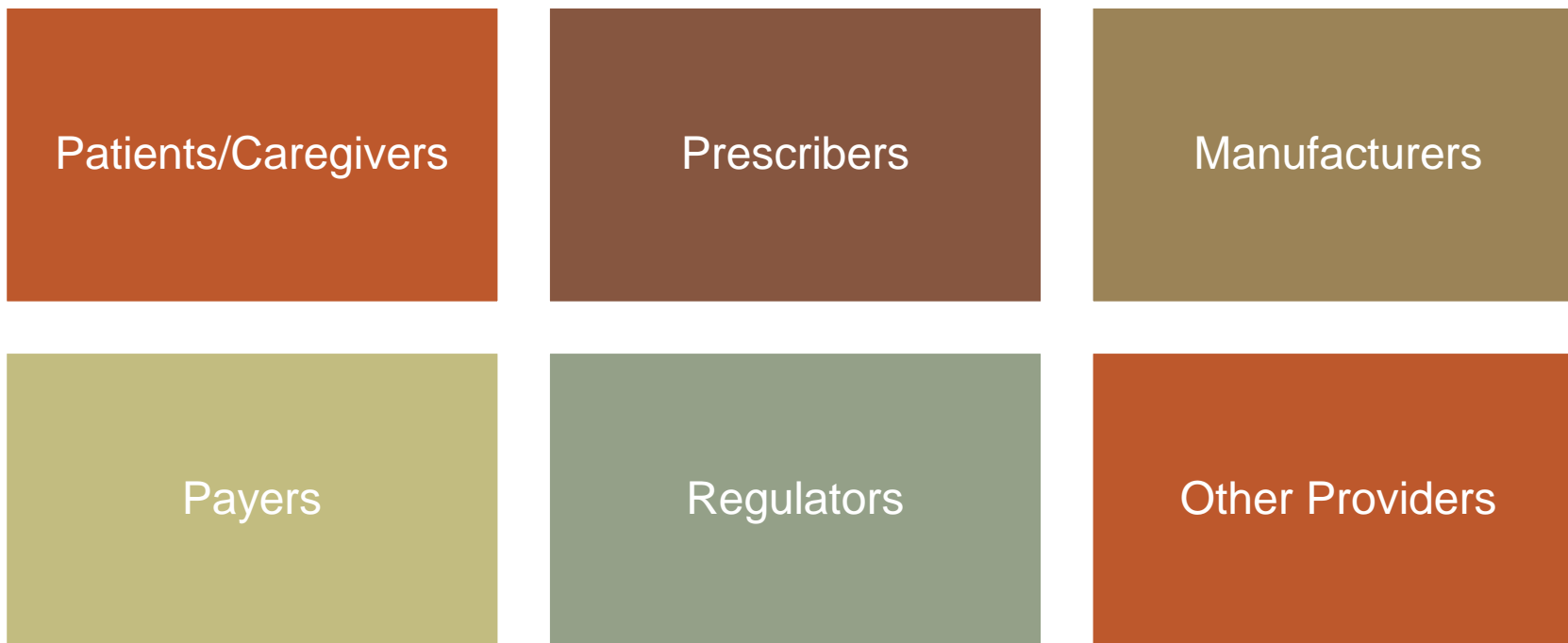
Hepatitis C Therapy

- In 2014, the treatment of Hepatitis C changed dramatically with the approval of the first oral Direct Acting Antiviral (DAA) for Hepatitis C
- DAAs:
 - Have a much higher cure rate than previous therapies with fewer side effects
 - Are oral tablets that are taken daily for either 8 or 12 weeks
 - Are expensive. Sticker price can be ~\$85,000 and copays with insurance can still be several thousands of dollars
- A Hepatitis C cure can prevent a future liver transplant (over \$500K)
- Strict adherence to regimen is required for treatment success

The Role of the Specialty Pharmacy

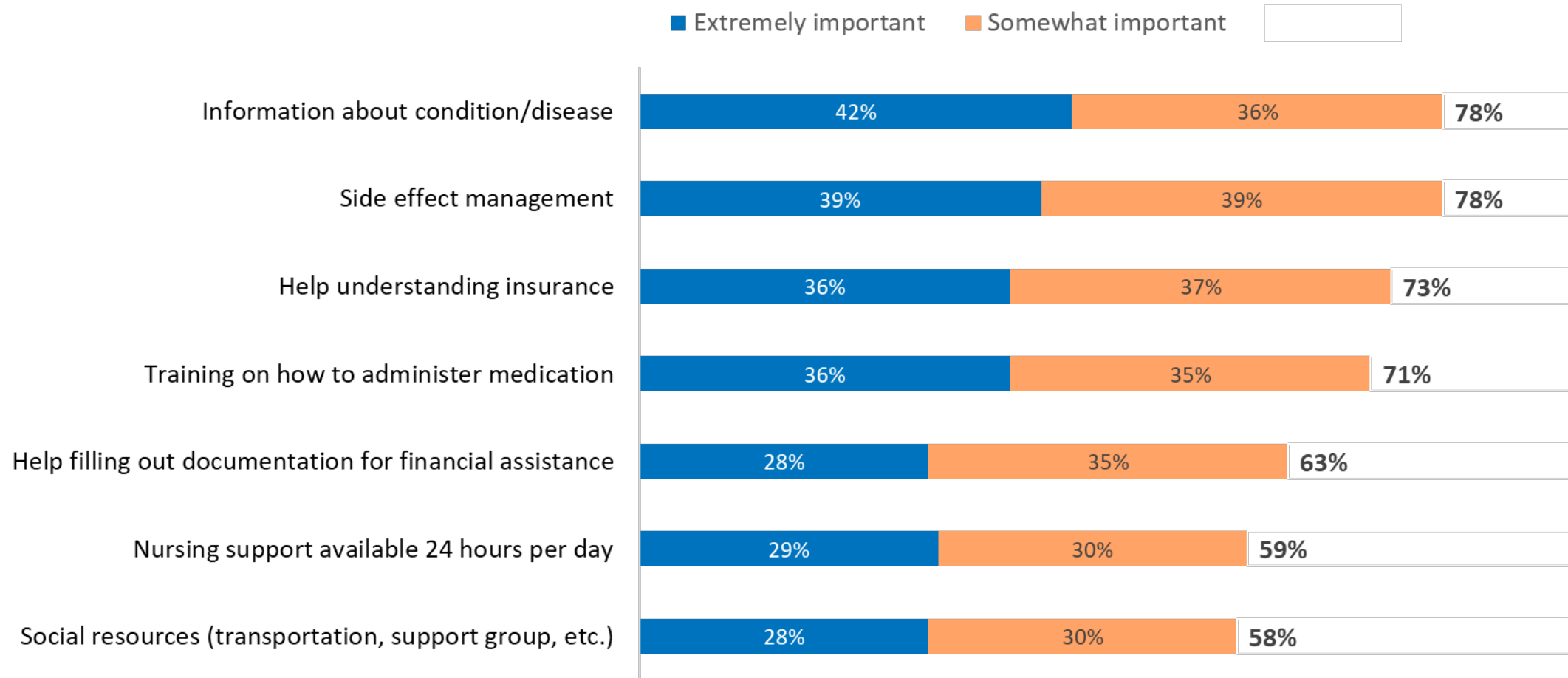
- Confirm appropriate therapy selection considering medical history, current medication list, and viral genotype
- Coordinate insurance coverage and co-pay assistance
- Coordinate lab screenings with medical team
- Manage specific drug-drug interactions
- Address stigma of patients with Hep C
- Address social determinants of health
- Evaluate ability to adhere to therapy
- Monitor adherence closely
- Track treatment success (viral load)

Value of Specialty Pharmacy Services



Many stakeholders value the services specialty pharmacies provide.

Importance of Specialty Pharmacy Services to Patients, 2020



Source: Drug Channels Institute analysis of *Boehringer Ingelheim Pharmacy Satisfaction Pulse Survey*, 2020. Figures show percentage of consumers (n=2,455) who answered the following question: "Now please tell us how important each is to the management of your/your household's illness or condition."

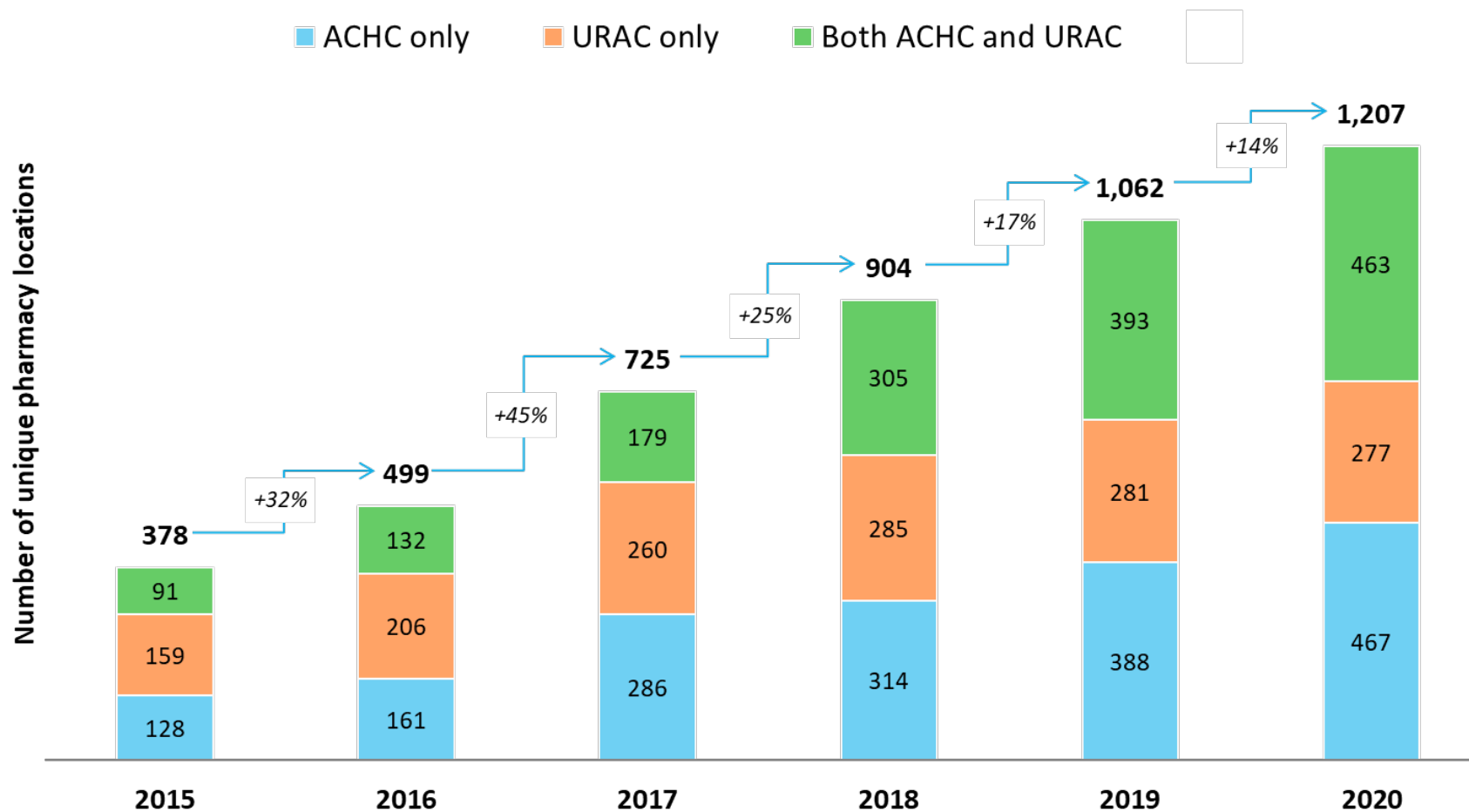
Stakeholder Value of Specialty Pharmacy Services

- Peer-reviewed studies have shown specialty pharmacies and the services they provide increase patient adherence to therapy
- Payers value specialty pharmacies capabilities over traditional pharmacies and establish limited networks for dispensing specialty drugs
- Manufacturers recognize specialty pharmacy services and value the data they can provide and may limit the pharmacies allowed to dispense their medications
- Payers and manufacturers utilize accreditation as a way to validate compliance to quality standards for specialty pharmacy services for inclusion in their networks
- Regulators utilize accreditation to assist in ensuring quality care

Growth & Trends

- Specialty drug market share has grown significantly from 24% of total prescription drug cost in 2014 to 38% in 2020.
- Specialty drugs represented 2.3% of outpatient prescriptions in 2020.
- Over the past decade, the number of specialty drugs available has increased dramatically.
- Over the past decade, the number of specialty pharmacies has increased dramatically.
- Several models of specialty pharmacies have evolved. The fastest growing segment is within hospital systems, followed by community pharmacies.

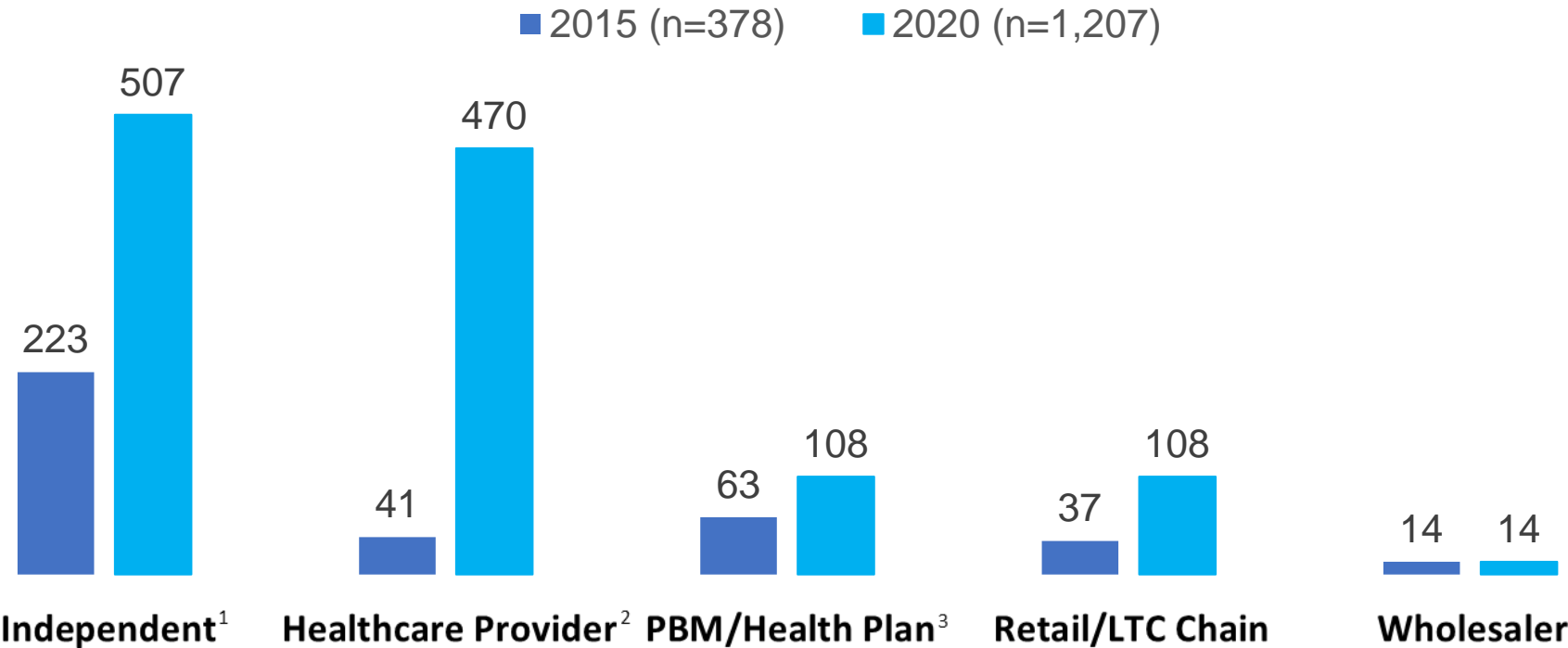
Number of Pharmacy Locations With Specialty Pharmacy Accreditation, by Organization, 2015 to 2020



ACHC = Accreditation Commission for Health Care; URAC = Utilization Review Accreditation Commission

Source: Drug Channels Institute research. Figures show number of unique accredited locations at the end of the year. For comparability, data for ACHC exclude certain accredited pharmacy spoke locations within retail chains. Multiple category includes locations with accreditation from two or three of the accrediting organizations. Figures exclude locations with provisional, conditional, and expected accreditation. Figures differ from previous reports due to the exclusion of Center for Pharmacy Practice Accreditation data.

Pharmacy Locations With Specialty Pharmacy Accreditation, by Corporate Ownership, 2015 vs. 2020

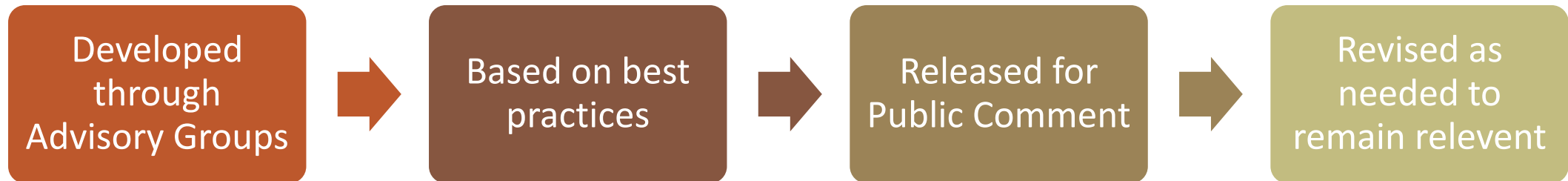


LTC = Long-term care; PBM = pharmacy benefit manager
 1. Includes private independent pharmacies, pharmacies owned by private equity firms, and independently owned franchise locations.
 2. Includes pharmacies owned by hospitals, health systems, physician practices, and providers' group purchasing organizations.
 3. Includes pharmacy locations owned by chain drugstores, grocery chains, and national long-term care pharmacy chains.
 Source: Drug Channels Institute research. Figures show number of unique pharmacy locations accredited by ACHC and URAC at the end of the year. For comparability, data for ACHC exclude certain accredited pharmacy spoke locations within retail chains. Figures exclude locations with provisional, conditional, and expected accreditation. Figures for 2015 differ from previous reports due to the exclusion of Center for Pharmacy Practice Accreditation data.

Specialty Pharmacy Accreditation

- Independent accreditation organizations develop and validate compliance with quality standards
- Accreditation plays a key role in providing quality assurance in the pharmacy supply chain
- Payers, manufacturers and regulators can utilize accreditation to validate compliance to quality standards for specialty pharmacy services

Accreditation Standards



Specialty Pharmacy Accreditation Standard Categories

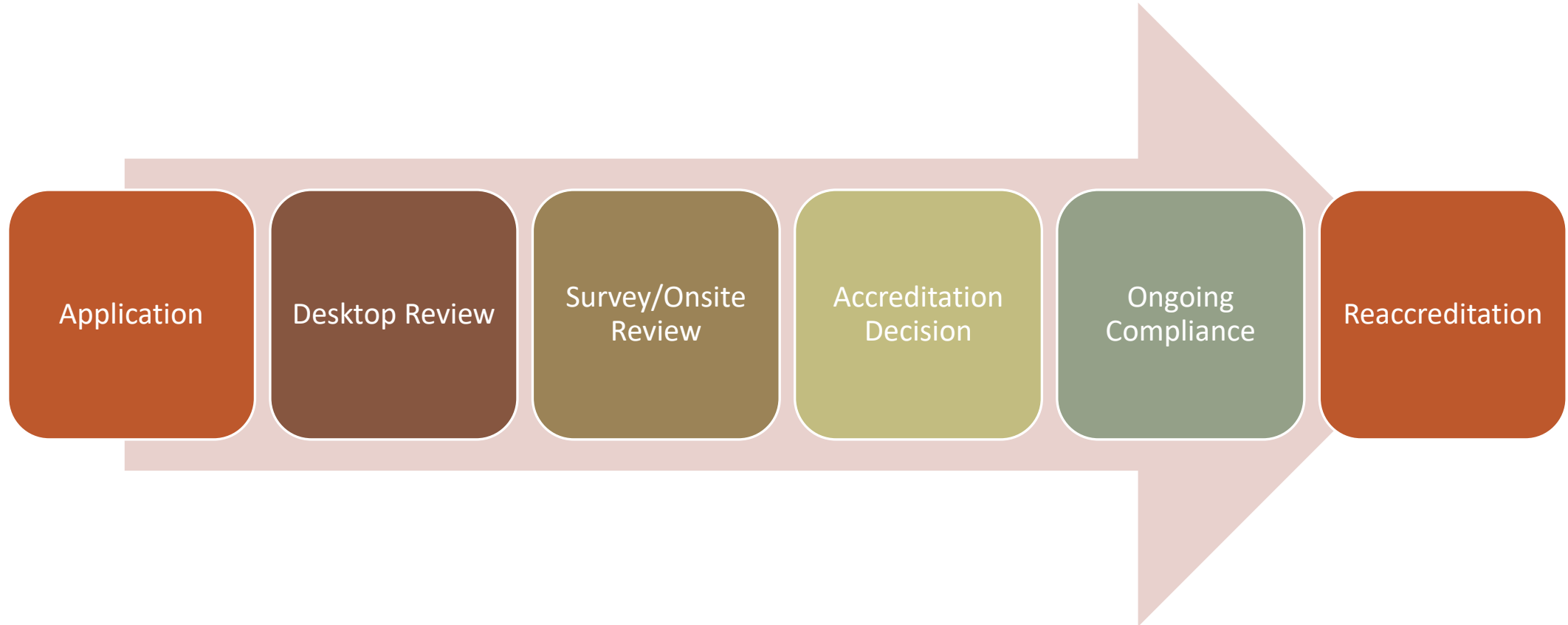
Organization
and
Administration

Pharmacy
Operations

Clinical
Management

Quality Report
and
Improvement

Accreditation Process



Accreditation organizations provide extensive education on the standards and the review process.

Accreditation Requirements

Accreditation Organizations charge a fee for accreditation services

- Fees vary by organization
- Cost will vary by pharmacy size and number of locations

Accreditation typically follows a 3-year cycle

Stakeholders can utilize accreditation to validate quality services

- Should identify which accreditation(s) are accepted
- May accept accreditation from more than one organization
- Should not require more than one accreditation



Upon achieving accreditation,
most organizations express
gratitude for how the
standards have helped to
make them a better
organization

Questions



Specialty Pharmacy Accreditation

Specialty Pharmacy Stakeholder Workgroup

January 27, 2022

Sheila M. Arquette, RPh

President & CEO, National Association of Specialty Pharmacy

National Association of Specialty Pharmacy (NASP)

- The mission of the National Association of Specialty Pharmacy (NASP) is to elevate the practice of specialty pharmacy by developing, delivering and promoting continuing professional education and specialty certification while advocating for public policies that ensure patients have appropriate access to specialty medications in tandem with critical services.

NASP Membership is Diverse

- 150+ corporate members, 2,000+ individual members; includes all specialty pharmacy stakeholders
- Specialty Pharmacy Members include:
 - Chain
 - Grocery
 - Health Plan
 - Hospital / Health System
 - Independent
 - Infusion and Specialty Pharmacy
 - Pharmacy Benefit Manager (PBM)

What is a Specialty Drug?

- A universal definition of a specialty medication has yet to be accepted

NASP Definition of 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

Condition it is used to treat

Patient financial hardship

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

Specialty Pharmacy Staffing Differs from Retail or Mail Order Pharmacy

Intake / Enrollment

Insurance and Billing

Patient Financial Assistance

Patient Care Specialists

Call Center

Specialty Pharmacists

Specialty Pharmacy Technicians

Nurses

Dietitians (at some specialty pharmacies)

Conditions Historically Managed by a Specialty Pharmacy

- Crohn's Disease
- Cystic Fibrosis
- Hemophilia and other Bleeding Disorders
- Hepatitis C virus
- HIV/AIDS
- Human Growth Hormone Deficiency
- Multiple Sclerosis
- Oncology (cancer)
- Organ Transplantation
- Psoriatic Arthritis
- Psoriasis
- Rare and Orphan Diseases
- Rheumatoid Arthritis

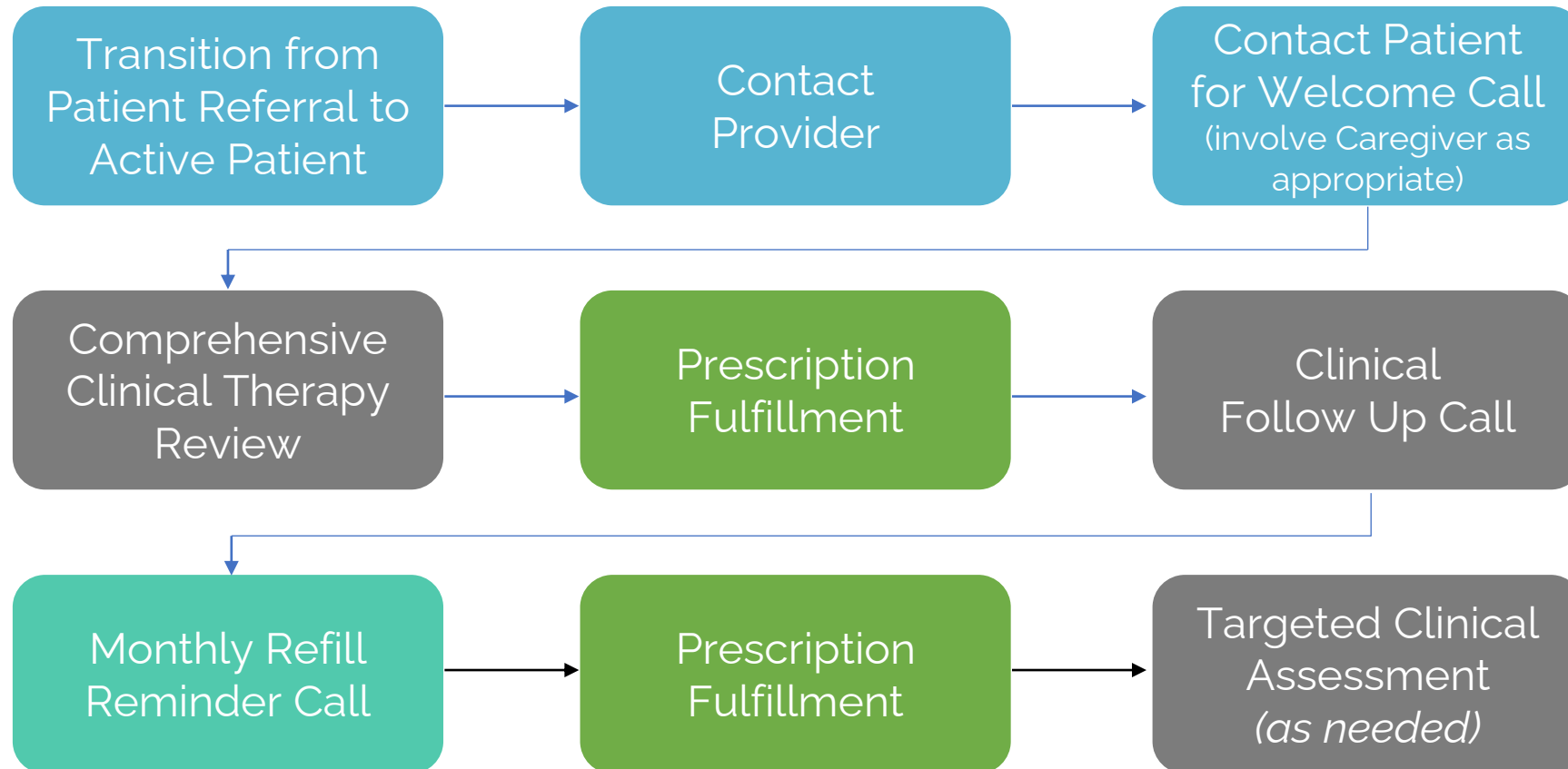
Goals of Specialty Pharmacies

- Ensure appropriate and safe use of medications
- Maximize drug adherence
- Enhance patient satisfaction through direct interaction with healthcare professionals
- Minimize cost impact to patients
- Optimize pharmaceutical outcomes and delivery of information

Specialty vs Retail

	Specialty Pharmacy	Traditional Retail Pharmacy
Conditions managed	Chronic, complex, life threatening	Short term illness, maintenance
Patient support	Proactive	Reactive
Drug availability	Carried in stock	Limited
Clinical support/knowledge	Disease state expertise and focus	General
Availability of clinical staff	24/7	Store Hours, some 24/7
Dispensing	High patient interaction	Limited patient interaction
Disease management	Condition specific expertise	General
Insurance process	Primary, secondary, tertiary, etc., coordination of benefits	Primary
Financial assistance / prior authorization	Core service	Limited to none

Specialty Pharmacy Patient Journey is COMPLEX



Accreditation

- In absence of universally accepted definition of SP, accreditation is used to ensure the infrastructure and requirements needed to support critically ill patients are in place
- Accreditation demonstrates a commitment to consistency, quality, safety
- Any standard or process should be fair and used to measure quality, not punitive or intended to decrease competition
- Some payer organizations are establishing requirements that are overly onerous and intended to decrease network participation; restrict patient and provider choice
- Standards should be specific to specialty pharmacy and not so stringent that more time is spent on accreditation than on patient care
- Pharmacy cost and staffing levels required to receive and maintain multiple accreditations are factors that should be considered

Considerations & Recommendations

- Mechanism for oversight in manner that is not overly burdensome
- Workgroup determines specific requirements for accreditation, multiple accreditations to become an approved specialty pharmacy accreditor
- Accreditors submit application to be included on “approved” list
- Specialty pharmacies choose approved accrediting organization

Bottom Line ...

**Ensure the Highest Standards
in Quality and Care for Specialty Patients
and a Fair and Competitive Landscape for
Specialty Pharmacy**



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April 13, 2022

Commissioner Mike Causey
Chairman, Specialty Pharmacy Stakeholder Workgroup
North Carolina Department of Insurance

Dear Commissioner Causey,

America's Health Insurance Plans (AHIP) appreciates the opportunity to provide comments to the Specialty Pharmacy Workgroup related to the legislature's direction in [SB 257](#) (Session Law 2021-161; 2021) that the Department convene the stakeholder workgroup to study and recommend a single unified process to accredit specialty pharmacies in North Carolina. Specialty pharmacies are one of the innovative solutions that health insurance providers have developed to make prescription drugs more affordable. Health insurance providers leverage these lower-cost pharmacies to safely distribute certain drugs when they are confident that the drugs can be safely dispensed and are appropriate for the patient's needs. This strategy saves the patient money and often provides important care coordination support through the patient's continuum of care.

Accreditation is one of the benchmarks employed to ensure patient safety, which is paramount to health insurance providers and our contracted specialty pharmacies. Specialty pharmacies are accredited by nationally recognized accrediting bodies that have specific standards in place to ensure the integrity of the dispensed drug product.

Accreditation Improves Quality of Care. Like traditional pharmacies, specialty pharmacies obtain licensure from state boards of pharmacy which establish the minimum standards with respect to consumer protections. However, states do not differentiate between traditional and specialty pharmacy licensure.

Specialty pharmacies obtain additional accreditation which includes standards that provide key performance benchmarks and raise the bar on quality improvement efforts. Accreditation involves rigorous evaluation and verification of systems, processes, and performance by independent healthcare organizations to ensure their operations are consistent with national regulations and industry best practices.

Independent accreditation and certification organizations, such as URAC and the Accreditation Commission for Health Care, have established standards for specialty pharmacy, which are often requirements to participate in a health plan's pharmacy network. URAC's accreditation standards,

for example, include ensuring access to appropriate drugs, measuring consumer satisfaction, protecting consumer health information, patient adherence programs, and patient care quality measures.¹ These accreditation standards enhance consumer protection and encourage pharmacy programs to improve operations and regulatory compliance activities.

Credentialing Helps Identify High Performing Pharmacies. Additionally, health plans use pharmacy credentialing to identify high quality, cost-effective pharmacies. In the case of specialty pharmacies, credentialing helps to identify those pharmacies that can best serve patients using specialty drugs. Specialty and clinician-administered drugs generally are high priced medications that treat complex, chronic, or rare conditions and can have special handling and/or administration requirements. Many specialty drugs are administered by a clinician intravenously, intramuscularly, under the skin, or via injection. These specialty drugs are given at a variety of sites of care including hospitals, medical provider offices, infusion centers, and by medical professionals during home visits. Both the number and the price of these drugs have rapidly increased in recent years and, as a result, specialty drugs are a leading contributor of drug spending growth.

Credentialing criteria may include patient care and organizational standards such as pharmacy accessibility, appropriate therapy, care coordination, adherence management, counseling, specialty clinical protocols, patient education, cold chain management, and specialty medication fulfillment². Health plans identify specialty pharmacies that meet these high standards for inclusion in preferred networks. Specialty pharmacies in preferred networks provide high-touch services to patients while producing savings for enrollees, employers, and public health programs.

Specialty Pharmacies Are Subject to Government Requirements. In addition to the benchmarks provided through accreditation and credentialing, specialty pharmacies must meet higher quality standards set by federal and state governments. Specialty pharmacies are subject to the same “supply chain safety” requirements as any other dispensing pharmacy under the federal Drug Supply Chain Safety Act (DSCSA) and state licensing laws/regulations. Specialty pharmacies also must meet extra safety requirements for specialty drugs imposed by the FDA, and by drug manufacturers. Further, they must satisfy stringent state and federal requirements for the safe storage, handling, and dispensing of the drugs. Many hospitals and physician groups obtain these medications from the same specialty pharmacies.

¹ URAC, “Specialty Pharmacy Accreditation.” Available at: <https://www.urac.org/accreditation-and-measurement/accreditation-programs/all-programs/specialty-pharmacy/>

² PCMA, “PBM Specialty Pharmacies Improve Patient Outcomes and Reduce Costs,” April 2017. Available at: https://www.spcma.org/wp-content/uploads/2017/04/PBM-Specialty-Pharmacies-Improve-Patient-Outcomes-and-Reduced-Costs_whitepaper_final.pdf

April 13, 2022
Page 3

In summary, accreditation is a critical element in the framework of safety requirements that ensure that specialty pharmacies protect patient safety while improving health care affordability. Thank you very much for your consideration of our comments. AHIP's members plans are eager to continue to work to fight for more affordable medications for the residents of your state and patients, families, and employers across the country.

Sincerely,



Mara C. Osman, J.D.
Senior Regional Director, State Affairs
America's Health Insurance Plans
mosman@ahip.org / (202) 578-8765

cc: Tracy M. Biehn, Senior Deputy Commissioner, North Carolina Department of Insurance
Lu-Ann Perryman, AHIP Retained Counsel

America's Health Insurance Plans (AHIP) is the national association whose members provide coverage for health care and related services to hundreds of millions of Americans every day. Through these offerings, we improve and protect the health and financial security of consumers, families, businesses, communities, and the nation.



NATIONAL ASSOCIATION OF
SPECIALTY PHARMACY

1800 Diagonal Road

Suite 600

Alexandria, VA 22314

www.naspnet.org

NASP Definitions of Specialty Pharmacy and Specialty Medications February 24, 2016

The National Association of Specialty Pharmacy

The following definitions of specialty pharmacy and specialty medications were developed by the National Association of Specialty Pharmacy (NASP). NASP was founded in 2012 to represent the rapidly growing specialty pharmacy industry in the United States. It is projected that specialty drugs will represent 50% of the US drug spend by the year 2019. Currently, NASP is comprised of 84 corporate members and 1,500 individual members, including the nation's leading independent specialty pharmacies, retail chain specialty pharmacies, and health system-based specialty pharmacies. NASP is committed to specialty pharmacist education and certification and strongly invested in the continuing improvement of specialty pharmacy practice as advances in medicine and treatment regimens emerge.

What is a Specialty Pharmacy?

A specialty pharmacy is a state-licensed pharmacy that solely or largely provides only medications for people with serious health conditions requiring complex therapies. These include conditions such as cancer, hepatitis C, rheumatoid arthritis, HIV/AIDS, multiple sclerosis, cystic fibrosis, organ transplantation, human growth hormone deficiencies, and hemophilia and other bleeding disorders. In addition to being state-licensed and regulated, specialty pharmacies should be accredited by independent third parties such as URAC®, the Accreditation Commission for Health Care (ACHC), the Center for Pharmacy Practice Accreditation (CPPA) or the Joint Commission, in order to ensure consistent quality of care.

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 medications have a complex profile that require intensive patient management. Some specialty medications also require special handling. Though some are taken orally, many of these medications need to be injected or infused, some in a doctor's office or hospital. Specialty pharmacies provide services that include training in 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.

What is a Specialty Medication?

Specialty drugs are more complex than most prescription medications and are used to treat patients with serious and often life threatening conditions including cancer, hepatitis C, rheumatoid arthritis, HIV/AIDS, multiple sclerosis, cystic fibrosis, organ transplantation, human growth hormone deficiencies, hemophilia and other bleeding disorders. These medications may be taken orally but often must be injected or infused and may have special administration, storage and delivery requirements. Many of these injectable medications are self-administered in the patient's home. Infused specialty medications are administered in various treatment settings such as a patient's home with the support of a home health care professional, sometimes in a doctor's office or even in a hospital.

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. As a result, patients being treated with specialty medications require comprehensive patient care, clinical management, and product support services.

Specialty prescription medications cannot be routinely dispensed at a typical retail community pharmacy because the therapy typically requires special handling as well as significant patient education regarding appropriate utilization. Typical retail pharmacies are not designed to provide the patient care or other services that specialty medications require.



May 4, 2022

Commissioner Causey
North Carolina Department of Insurance
1201 Mail Service Center
Raleigh NC 27699-1201

RE: National Association of Specialty Pharmacy Recommendations: Considerations for a Specialty Pharmacy Accreditation Process in North Carolina

Dear Commissioner Causey:

I write on behalf of the National Association of Specialty Pharmacy (NASP) to thank the Specialty Pharmacy Stakeholder Workgroup for its effort to consider and propose a unified process for specialty pharmacy accreditation in the state. As the Workgroup continues to finalize its recommendations, NASP would like to provide supplemental feedback to our presentation offered on January 27, 2022 (attached). Again, we offer this perspective as a non-profit trade organization, representing the entire spectrum of specialty pharmacy industry stakeholders, including the nation's leading specialty pharmacies of all types such as independent, hospital-based, mass merchant, grocery store, chain as well as pharmacy benefit managers (PBMs) and others. It is our hope that our diverse membership, and therefore perspective, is of assistance during the Workgroup's concluding deliberations.

NASP believes that accreditation by a nationally-recognized independent third-party accreditation organization as a recommended standard in North Carolina is critically important to ensuring that specialty pharmacies are providing consistent, safe, and quality care to patients. We suggest this as the baseline for the Workgroup's consideration when issuing its formal recommendations. **NASP also believes that when recommending an accreditation standard, it is important that the Workgroup acknowledge in its recommendations the differences in pharmacy models to appropriately identify which pharmacies should receive specialty pharmacy accreditation.** Doing so will ensure that specialty pharmacies are being fairly evaluated against a standard of care that is unique to the services a specialty pharmacy provides.

As I highlighted in NASP's presentation in January, while there is a diversity of pharmacy types within the specialty pharmacy community (hospital system pharmacies, independent pharmacies, grocery store pharmacies, chain pharmacies, etc) one thing all specialty pharmacies have in common that distinguishes them from traditional retail or other pharmacy

types is that they handle and manage clinically complex drugs that must meet facility-specific requirements, and that the pharmacies provide consistent and ongoing patient information and care to treat rare, severe, and life-threatening conditions. The patients supported through a specialty pharmacy are dealing with uniquely complex and serious health conditions that require a high level of care to manage and understand their treatment regimens for conditions like cancer, multiple sclerosis, cystic fibrosis, rheumatoid arthritis, organ transplantation, HIV/AIDS, etc. While all pharmacies provide patient care, the unique knowledge, patient support, and prescription handling that specialty pharmacies provide and the time involved on a per-patient basis is acutely different than how any other pharmacy type operates. It is imperative that North Carolina recognize the unique differences between specialty pharmacy compared to traditional retail and other pharmacy types when working to recommend an accreditation standard that benefits the patients of North Carolina. Failure to do so could risk specialty pharmacies not being held up to a high enough standard when managing life-or-death medications that require pharmacy-level support to ensure patient medication adherence, compliance with medication protocols, and addressing of complex side effects that impact therapy success and management. For example, many oral oncology drugs have complex dosing and administration schedules that are dependent on patient diagnosis, response and tolerability. One such oral oncology drug, Tarceva, which is a specialty drug, can have a complex side effect profile. This particular drug frequently causes significant rashes, which is both a side effect and an indication of the treatment's success. It is imperative the specialty pharmacist has in-depth training and knowledge of the drug itself, the drug schedule, and of the side effects/indications of the treatment's performance to ensure a patient does not deviate from treatment and remains compliant and adherent to the full treatment regimen in order to achieve a maximum therapeutic outcome. The following is a summary list of explained differences between the retail and specialty pharmacy models that illustrate the importance of having a single, independent accreditation standard within the state of NC:

- Drug manufacturers sometimes set up limited distribution networks for specialty drugs, selecting specialty pharmacies with the needed expertise to dispense these drugs, which are not otherwise accessible by other pharmacies.
- Specialty pharmacies have disease-state expertise and clinical management expertise on specific specialty-identified diseases and are frequently staffed with nurses and other health care providers in addition to specialty pharmacists.
- Specialty pharmacies have operations equipped to staff and allow the time for close and frequent communication with patients, including call center operations.
- Specialty pharmacies frequently provide robust data to manufacturers and health plans/PBMs regarding drug performance and concerns.

NASP remains supportive of a single, unified, state accreditation standard for specialty pharmacy. As addressed during our presentation, NASP is concerned that requirements for specialty pharmacies to obtain multiple accreditations creates duplicative, onerous and costly obligations that only seek to threaten network participation for specialty pharmacies. If specialty pharmacies are unable to participate in plan networks as a result of multiple accreditation requirements, then patient access to specialty pharmacies in North Carolina that provide life altering support is threatened. Creating a single process for specialty pharmacy accreditation in North Carolina will ensure that specialty pharmacies are meeting high standards for maintaining quality operations, without imposing financially crippling and duplicative criteria that could ultimately limit specialty pharmacy access for patients in the state.

NASP appreciates the Workgroup's efforts to engage all stakeholders to address this multifaceted and important issue. We also appreciate the effort to consider all perspectives, and we recommend that the Workgroup ultimately address the questions before it through the perspective of a patient living with a specialty health condition. It's imperative that as a pharmacy community, we ensure that a specialty patient has access to the pharmacy that they rely on as a part of their care team to address a life-changing condition; that their pharmacy is meeting the standards required to help them manage their complex condition on an ongoing basis; and that their pharmacy is equipped to deal with the complexity of the injectable, infused, or orally-received specialty medications prescribed. NASP welcomes the opportunity to answer questions or provide any additional information to support the Workgroup's efforts. Please feel free to contact me at 703-842-0122 or sheila.arquette@naspnet.org.

Sincerely,



Sheila Arquette, R.Ph.

President and CEO

CC: Tracy M. Biehn, Senior Deputy Commissioner

April 27, 2022

The Honorable Mike Causey
Commissioner of Insurance
325 N. Salisbury St
Raleigh, NC 27601

REFERENCE: Specialty Pharmacy Workgroup

Dear Commissioner Causey:

I am writing on behalf of the NC Association of Health Insurance Plans, Inc. We have been following the work of the Specialty Pharmacy Workgroup as established by Senate Bill 257. We appreciate the hard work of your staff and the members of the workgroup in dealing with this difficult issue.

The association members have been discussing ways to support the efforts of the group and the recurring theme in our discussions is the importance of accreditation of Specialty Pharmacies in North Carolina and its necessity to ensure patient safety.

The accreditation process is focused on the Specialty Pharmacies' ability to provide the highest possible care for those afflicted with some of the most difficult health issues to treat. While there are several reasons these pharmacies need accreditation, patient safety is paramount.


The drugs Specialty Pharmacies administer are extremely complex formulations and often have very strict regimens. In certain cases, these drugs need to be administered by a trained healthcare professional, stored at a certain temperature, or administered at specific times in a specific way. Patients rely on pharmacists to provide the medicine and instructions to safely administer these drugs.

It cannot be understated how important it is to make sure these professionals are continually trained on the latest techniques and how these drugs can affect patients as well as identify potentially deadly side effects. This process is critical in protecting patients. Accreditation is not about checking a box, it is about life and death and must continue to be a part of the Specialty Pharmacy regulatory process.

The Association of Health Insurance Plans (AHIP) has also provided written comments and we endorse these comments. AHIP is a great resource for the state of North Carolina with a comprehensive understanding of how this issue is being addressed across the country.

Please reach out to me if you have any questions.

Best regards,



Peter T. Daniel
Executive Director
NC Association of Health Plans, Inc
919-302-2064

Attachment



601 Pennsylvania Avenue, NW T 202.778.3200
South Building, Suite 500 F 202.331.7487
Washington, D.C. 20004 ahip.org

April 13, 2022

Commissioner Mike Causey
Chairman, Specialty Pharmacy Stakeholder Workgroup
North Carolina Department of Insurance

Dear Commissioner Causey,

America's Health Insurance Plans (AHIP) appreciates the opportunity to provide comments to the Specialty Pharmacy Workgroup related to the legislature's direction in [SB 257](#) (Session Law 2021-161; 2021) that the Department convene the stakeholder workgroup to study and recommend a single unified process to accredit specialty pharmacies in North Carolina. Specialty pharmacies are one of the innovative solutions that health insurance providers have developed to make prescription drugs more affordable. Health insurance providers leverage these lower-cost pharmacies to safely distribute certain drugs when they are confident that the drugs can be safely dispensed and are appropriate for the patient's needs. This strategy saves the patient money and often provides important care coordination support through the patient's continuum of care.

Accreditation is one of the benchmarks employed to ensure patient safety, which is paramount to health insurance providers and our contracted specialty pharmacies. Specialty pharmacies are accredited by nationally recognized accrediting bodies that have specific standards in place to ensure the integrity of the dispensed drug product.

Accreditation Improves Quality of Care. Like traditional pharmacies, specialty pharmacies obtain licensure from state boards of pharmacy which establish the minimum standards with respect to consumer protections. However, states do not differentiate between traditional and specialty pharmacy licensure.

Specialty pharmacies obtain additional accreditation which includes standards that provide key performance benchmarks and raise the bar on quality improvement efforts. Accreditation involves rigorous evaluation and verification of systems, processes, and performance by independent healthcare organizations to ensure their operations are consistent with national regulations and industry best practices.

Independent accreditation and certification organizations, such as URAC and the Accreditation Commission for Health Care, have established standards for specialty pharmacy, which are often requirements to participate in a health plan's pharmacy network. URAC's accreditation standards,

for example, include ensuring access to appropriate drugs, measuring consumer satisfaction, protecting consumer health information, patient adherence programs, and patient care quality measures.¹ These accreditation standards enhance consumer protection and encourage pharmacy programs to improve operations and regulatory compliance activities.

Credentialing Helps Identify High Performing Pharmacies. Additionally, health plans use pharmacy credentialing to identify high quality, cost-effective pharmacies. In the case of specialty pharmacies, credentialing helps to identify those pharmacies that can best serve patients using specialty drugs. Specialty and clinician-administered drugs generally are high priced medications that treat complex, chronic, or rare conditions and can have special handling and/or administration requirements. Many specialty drugs are administered by a clinician intravenously, intramuscularly, under the skin, or via injection. These specialty drugs are given at a variety of sites of care including hospitals, medical provider offices, infusion centers, and by medical professionals during home visits. Both the number and the price of these drugs have rapidly increased in recent years and, as a result, specialty drugs are a leading contributor of drug spending growth.

Credentialing criteria may include patient care and organizational standards such as pharmacy accessibility, appropriate therapy, care coordination, adherence management, counseling, specialty clinical protocols, patient education, cold chain management, and specialty medication fulfillment². Health plans identify specialty pharmacies that meet these high standards for inclusion in preferred networks. Specialty pharmacies in preferred networks provide high-touch services to patients while producing savings for enrollees, employers, and public health programs.

Specialty Pharmacies Are Subject to Government Requirements. In addition to the benchmarks provided through accreditation and credentialing, specialty pharmacies must meet higher quality standards set by federal and state governments. Specialty pharmacies are subject to the same “supply chain safety” requirements as any other dispensing pharmacy under the federal Drug Supply Chain Safety Act (DSCSA) and state licensing laws/regulations. Specialty pharmacies also must meet extra safety requirements for specialty drugs imposed by the FDA, and by drug manufacturers. Further, they must satisfy stringent state and federal requirements for the safe storage, handling, and dispensing of the drugs. Many hospitals and physician groups obtain these medications from the same specialty pharmacies.


¹ URAC, “Specialty Pharmacy Accreditation.” Available at: <https://www.urac.org/accreditation-and-measurement/accreditation-programs/all-programs/specialty-pharmacy/>

² PCMA, “PBM Specialty Pharmacies Improve Patient Outcomes and Reduce Costs,” April 2017. Available at: https://www.spcma.org/wp-content/uploads/2017/04/PBM-Specialty-Pharmacies-Improve-Patient-Outcomes-and-Reduced-Costs_whitepaper_final.pdf

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In summary, accreditation is a critical element in the framework of safety requirements that ensure that specialty pharmacies protect patient safety while improving health care affordability. Thank you very much for your consideration of our comments. AHIP's members plans are eager to continue to work to fight for more affordable medications for the residents of your state and patients, families, and employers across the country.

Sincerely,



Mara C. Osman, J.D.
Senior Regional Director, State Affairs
America's Health Insurance Plans
mosman@ahip.org / (202) 578-8765

cc: Tracy M. Biehn, Senior Deputy Commissioner, North Carolina Department of Insurance
Lu-Ann Perryman, AHIP Retained Counsel

America's Health Insurance Plans (AHIP) is the national association whose members provide coverage for health care and related services to hundreds of millions of Americans every day. Through these offerings, we improve and protect the health and financial security of consumers, families, businesses, communities, and the nation.



North Carolina Association of Pharmacists.

RECOMMENDATIONS TO THE SPECIALTY PHARMACY WORKGROUP

Based on the presentations and discussions of the specialty pharmacy workgroup thus far, the North Carolina Association of Pharmacists makes the following recommendations. They are similar to those made by the National Association of Specialty Pharmacy in their presentation. We would be happy to draft specific wording for inclusion in the recommendations that the Department of Insurance might make to the General Assembly.

We believe that market discipline will address key problems that were highlighted during the January 2022 presentations and discussion. These key problems include:

- Unnecessary, costly and administratively burdensome multiple accreditations;
- Exclusion of accredited local specialty pharmacies from being in network;
- Requirements that force patients to use specialty pharmacies owned by PBMs or health plans.

The above problems create barriers to care, delays care, and at times mail order delivery systems degrade specific types of medications. To help address these problems we make the following recommendations.

- The workgroup should determine which accreditation types (accrediting organizations) meet standards important for safe quality care.
- Specialty pharmacies should be accredited by ONE accrediting body that is recognized by the NC DOI.
- Other accrediting bodies, health plans, pharmacy benefit managers and third-party administrators would have to recognize, and accept any one of the approved accreditations.
- An accredited specialty pharmacy cannot be required to obtain additional accreditations in order to be included in network for the dispensing of specialty medications to patients.
- Health plans and PBMs should not be allowed to exclude pharmacies that have obtained a specialty pharmacy accreditation from being in their network for specialty medications.

- Prohibit any language that would require local pharmacies to meet the same criteria as a health plan or PBM owned specialty pharmacy, which in other states has prevented local pharmacies from being included in network. [For example: in New Jersey, local pharmacies, accredited for specialty care, licensed for care in New Jersey, have been excluded from being in network, because the health plan/PBM-owned specialty pharmacies are licensed for care in all states. Therefore, the locals do not meet ‘the same’ criteria as the health plan/PBM owned specialty pharmacy.]
- The workgroup should recommend that pharmacies be reimbursed for the many patient care services, required by accreditation standards, for specialty care.

A rule allowing specialty pharmacies to only need to be accredited by ONE accrediting body would mean that these accreditation organizations would have to compete for the specialty pharmacy business. In order to gain the pharmacy business they would, in all likelihood, streamline their accreditation process, lower what they charge to be accredited, and synch frequency and needs related to reaccreditation to items that are most important for safe and effective care.

Presently, the health plans and in particular the pharmacy benefit managers hold a monopolistic position, and the accrediting bodies need only to work to gain the business of a specific PBM or health plan. Together this allows them to force or “dictate” (as it was put) that pharmacies do whatever they require regardless of the cost or burden. They also offload many of the costs associated with proper administration of specialty medications to pharmacies, which pharmacies must comply with, but are not paid for.

We believe the above bulleted recommendations will go far in addressing many of the current issues and problems associated with specialty pharmacy accreditation, without the need for excessive regulatory oversight.

Penny Shelton, PharmD, FASCP
Executive Director
North Carolina Association of Pharmacists
(984) 439-1646 x 225
penny@ncpharmacists.org



March 12th, 2022

The Honorable Mike Causey
Commissioner of Insurance
Albermarle Building
325 N. Salisbury Street
Raleigh, NC 26703-5926

Commissioner Causey,

On behalf of the Pharmaceutical Care Management Association (PCMA), I am writing to provide an additional perspective on the importance and need of accreditation for specialty pharmacies and any potential policy recommendations related to specialty pharmacy accreditation. PCMA is the national trade association representing pharmacy benefit managers (PBMs), which are the entities that administer prescription drug benefits for more than 260 million Americans who receive their health coverage through their employer, insurers, Medicare, or Medicaid.

PCMA appreciates the Department's management of the specialty pharmacy workgroup and the willingness to hear from all stakeholders involved in this process. As the national trade association representing pharmacy benefit managers, we offer the following points to the Department and workgroup for consideration:

- While insurers and other payors require accreditation for specialty pharmacies as a condition for participation in a specific network, it is not the **only** consideration. In addition to accepting certain reimbursement rates, in order to participate in a specialty network, pharmacies may be expected to provide certain patient management services or meet specific performance standards and other clinical requirements.
- Some payors, including employers, utilize preferred pharmacy networks wherein plan enrollees are incentivized to use lower cost, high-quality pharmacies through reduced out-of-pocket costs for patients and lower drug costs for the payor. Any recommendation regarding specialty pharmacy accreditation should not cross over into dictating how plan sponsors design their pharmacy networks and benefit plans. **Plan sponsors and employers should retain the ability to design a plan that best fits the needs of employers and enrollees and find ways to drive down costs.**
- Additionally, the workgroup should avoid mandating any reimbursement systems or payments to pharmacies for services required by the varying accreditation entities. Reimbursements for drug costs and/or services provided are subject to a private contract. In many cases, any clinical or patient management services are provided as a part of the specialty drug's therapy for a given patient. Again, the workgroup should not consider policy recommendations that dictate how and how much pharmacies are paid for the services provided.
- If the workgroup decides to recommend that an insurer or payor must accept accreditation from any accrediting entity approved by the Department and prohibiting an insurer or payor



from requiring multiple accreditations, PCMA would recommend that the standards for approving accrediting entities 1) Include the accrediting entities currently recognized by insurers and PBMs, 2) Allow for the recognition of an accrediting entity that may not yet exist, and 3) Provide flexibility in instances where a certain specialty drug or disease state has specific requirements/services that an accredited specialty pharmacy does not offer or a given accreditation entity may not assess.

- As the workgroup works through finalizing the report and issuing its recommendations, PCMA would offer the following accrediting organizations as a start for those that the Department would recognize: URAC, The Joint Commission, Accreditation Commission for Health Care (ACHC), and the National Committee for Quality Assurance (NCQA).

We appreciate your consideration of our comments and look forward to continuing to work with you and your staff on these issues in the future.

Sincerely,

A handwritten signature in black ink, appearing to read "Connor Rose". The signature is fluid and cursive, written over a light gray horizontal line.

Connor Rose
Director, State Affairs
PCMA