

Specialty pharmacies dispense clinically complex medications used to treat patients with serious and often life-threatening conditions, including but not limited to: cancer, multiple sclerosis, organ transplantation, rare diseases, HIV/AIDS and cystic fibrosis.

The medications a specialty pharmacy dispenses are typically expensive and often have limited generic or biosimilar alternatives. Despite making up approximately 3% of overall prescription volume, specialty medications accounted for over 54% of the U.S. drug spend in 2023. Due to the high cost of specialty drugs, health plans and manufacturers make sure that pharmacies are qualified to appropriately store and manage the transport of the medications, closely manage patients to ensure drug adherence and monitor progress, and protect against loss and waste of medications.

To ensure a pharmacy should be recognized as a specialty pharmacy and can appropriately manage specialty medications and specialty patients, it is important that a pharmacy is accredited as a specialty pharmacy by a nationally recognized independent specialty pharmacy accreditation organization.



## Specialty Pharmacy Model

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Verify and coordinate patient benefits, ensure all prior authorization requirements are met, provide coverage appeals support, and identify and facilitate financial support options to address specialty patient drug costs



Provide patient training on medication use (including injectables/infusions)



Perform comprehensive treatment assessment, close patient engagement and ongoing patient monitoring, including 24/7 call availability for patient guidance and support



Provide side effect management and mitigation



Engage frequent communication and care coordination with caregivers, physicians, and other healthcare providers

## How Are Specialty Pharmacies and Traditional Retail Pharmacies Different?

- There are many types of specialty pharmacies: independent, hospital-based, grocery store- or retail-owned but separately operated, and plan/PBM-owned or affiliated and operated.
- Specialty pharmacies are accredited by a nationally-recognized, independent specialty pharmacy accrediting organization to identify which pharmacies are capable of addressing complex specialty drug and patient management needs to support consistent, safe, quality-focused specialty patient care. This includes:
  - Providing benefits investigation to identify ways to limit patient out of pocket costs. This includes coordinating with physician offices, with multiple insurances, identifying programs that can support drug affordability, supporting benefits and treatment understanding and choices with patients.
  - Coordinating clinical logistics across multiple service providers to manage the delivery of the drug at the patient's site of care (including at home).
  - Ensuring all prior authorization requirements are met, navigating multiple insurance requirements and identifying any and all options to support drug affordability for the patient.
  - Providing 24/7 support through staff clinicians at the specialty pharmacy for patients to address: testing or other pre-treatment arrangements; drug administration and any drug interactions; questions on adherence and side effects; and managing timely physician adjustments to medications and/or therapeutic coordination/reconciliation amongst all of the patient's therapies.
  - Ongoing patient contact and coordination via phone, videoconferencing, text or email.
- A drug manufacturer may stipulate that only certain specialty pharmacies dispense a medication through a limited distribution network if such pharmacies have experience with the small patient base being managed (e.g., cancer); have the clinical capabilities to support the patient from the time when the referral is received at the pharmacy and throughout the patient journey; have the clinical staff to provide interventions based on disease state, drug and patient acuity; can mitigate or immediately intervene in an adverse event; and can measure and document patient adherence rates to support medication-related data.
- Under Medicare Part D, the Any Willing Provider statute and related CMS guidance state that health plans and their PBMs can only limit the size of a pharmacy network to support "limited access drug" (specialty drug) dispensing if: 1) it is necessary to meet FDA REMS requirements; and 2) it is necessary to ensure the pharmacies selected can address complex drug and patient management requirements.