

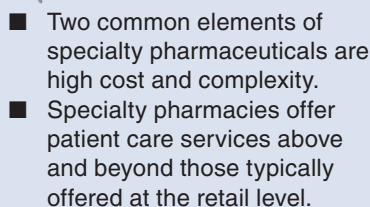
# Specialty pharmacy: A unique and growing industry

Jennifer Hagerman, Stephanie Freed, and Gary Rice

Regardless of your pharmacy practice area, you have likely heard the terms specialty pharmacy and specialty pharmaceuticals. With a rich drug pipeline and innovative programs like specialty-at-retail, specialty pharmacy permeates many areas of the industry. So what exactly do those two terms mean? Although this question is often asked, one accepted, industry-wide definition for either term remains elusive.

In defining a specialty pharmaceutical, there are two main factors: cost and complexity. Using a cost-based approach, CMS categorizes a specialty drug as one with a minimum monthly cost of \$600 with respect to the Part D drug benefit. Other organizations uti-

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- Two common elements of specialty pharmaceuticals are high cost and complexity.
  - Specialty pharmacies offer patient care services above and beyond those typically offered at the retail level.

lize a higher cost threshold for specialty classification that may be as much as double that of CMS. Complexity can encompass a number of factors and affect various groups, including patients, payers, manufacturers, and the pharmacy itself.

A medication considered a specialty pharmaceutical may have some or all of the following key characteristics:

- Treatment of complex, chronic, and/or rare conditions
- High cost, often exceeding \$10,000, with some costing more than \$100,000 annually
- Availability through exclusive, restricted, or limited distribution
- Special storage, handling, and/or administration requirements
- Ongoing monitoring for safety and/or efficacy

## ■ Risk Evaluation Mitigation Strategy

Although this category has historically focused on injectable and infused formulations, a significant number of specialty medications in oral dosage forms have entered the market recently. This trend is only expected to continue, especially among oral oncotics. Due to the complexities associated with specialty pharmaceuticals, patients receiving these medications require a significant degree of continuous patient education, ongoing monitoring, and medication management by well-qualified and skilled specialty pharmacy staff.

The Academy of Managed Care Pharmacy, in its Format for Formulary Submissions, and the Specialty Pharmacy Association of America both recently published definitions of specialty pharmacy. Commonalities seen within the definitions include the distribution of specialty pharmaceuticals and high-touch, patient-centered management that maximally benefits the patient's medication experience. Ideally, this translates into improved care with measurable, positive clinical outcomes.

As part of this patient-focused model, specialty pharmacies offer

services above and beyond those typically offered at the retail level as part of their standard of care. These may include the following:

- 24-hour access to pharmacists
- Adherence management
- Benefits investigation
- Communication and follow-up with the physician
- Dispensing of specialty pharmaceuticals and shipping coordination
- Enrollment in patient assistance programs
- Financial assistance
- Patient education and medication adverse effect counseling
- Patient monitoring for safety and efficacy
- Payer and/or manufacturer reporting
- Proactive patient outreach for prescription refill and renewal
- Prior authorization assistance

Common disease states managed by specialty pharmacies include oncology, multiple sclerosis, rheumatoid arthritis, Crohn disease, HIV/AIDS, hepatitis C, and growth hormone disorders, among others.

Specialty pharmacy, which once occupied only a small niche in the marketplace, has become a burgeoning industry. Pharmacists, regardless of their area of practice, should understand the place of specialty pharmacy within the industry, even though the field may be difficult to define. Collaborations between specialty pharmacies, retail settings, hospitals, and manufacturers are becoming increasingly commonplace. These collaborations can enhance patient access to specialty pharmaceuticals and the high-touch services a specialty pharmacy can provide, thereby improving patient care.

**Jennifer Hagerman, PharmD, AE-C**

Senior Director, Education and Quality

**Stephanie Freed, PharmD**

Clinical Education Coordinator

**Gary Rice, BSpPharm, MS, MBA**

Vice President, Clinical Services

Diplomat Specialty Pharmacy