

Retail Independent Pharmacies

White Paper

Specialty at Retail

Considerations and Opportunities for Independent Pharmacies

Introduction

The number of high-cost specialty drugs is growing rapidly and total spending on specialty drugs is rising dramatically, and this trend is expected to continue. While a significant proportion of these products are currently managed through the PBM-owned specialty pharmacy mail order channel, the rapid growth and evolution in the market present opportunities for retail pharmacies.

For community pharmacies, the challenge is understanding how to participate in this growth area in a way that fits with a pharmacy’s strategy, staffing, operations and general capabilities. In order for retail pharmacies to get into the specialty game they need:

- Access to specialty products
- Access to specialty patients, and
- Access to specialty services, including clinical and operational capabilities

Other issues that must be considered include contracting, certification and training, 24/7/365 staffing, storage and handling, prior authorization and payment, adherence management, and much more.

Multiple options exist for community pharmacies to offer specialty drugs at retail, including:

- Building a specialty pharmacy from scratch (which can be time consuming and expensive),
- Buying a specialty pharmacy (which is not realistic for most community pharmacies), or
- Partnering with an entity that already provides existing access and services (specialty pharmacy, hub model, service entity)

Specialty drugs represent an important and growing part of the future pharmacy business. Currently, specialty drugs account for 30% of total drug spend, which is projected to grow 8–10% per year, reaching 50% of drug spend by 2018.^{1,2,3} With this in mind, independent pharmacy owners can benefit by assessing this growth area and deciding how best to proceed for their business.

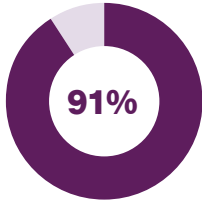
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Specialty drugs are causing significant changes in the pharmacy market, presenting both challenges and opportunities for independent community pharmacies.

This white paper describes:

- 2** What a specialty drug is and how specialty drugs differ from traditional pharmaceuticals
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What Is a Specialty Drug?



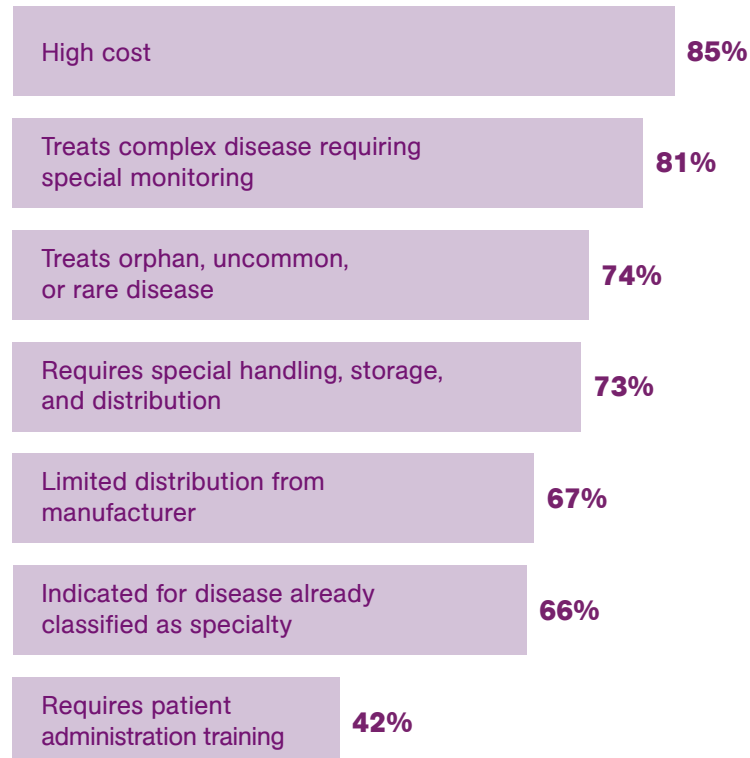
The top 10 specialty drug classes represent 91% of all specialty spending.

There is no standard definition for “specialty pharmaceuticals,” with different stakeholders having different perspectives. For example, the Centers for Medicare and Medicaid Services (CMS) defines specialty drugs as those treatments that cost more than \$600 per month. A working definition provided by PharmaVoice is high-cost, scientifically engineered drugs used to treat complex, chronic conditions. These drugs require special storage, handling and administration, and involve a significant degree of patient education, monitoring and management.⁴

Currently, more than 90% of stakeholders consider drugs in the following categories as specialty: asthma, cystic fibrosis, growth hormone disorders, hemophilia, hepatitis C, human immunodeficiency virus (HIV), multiple sclerosis, pulmonary arterial hypertension, and rheumatoid arthritis/psoriasis.⁵ In 2013, four specialty classes — oncology, autoimmune, HIV antivirals and multiple sclerosis — accounted for 73% of total specialty drug spending, and the top 10 classes represented 91% of all specialty spending.⁶

Compared to traditional pharmaceuticals, specialty drugs differ in many ways.

In a survey as part of the 2014 EMD Serono Specialty Digest, shown below, industry stakeholders identified several characteristics as common to specialty drugs.



Source: EMD Serono Specialty Digest™, 10th Edition, 2014, p. 10

Traditional vs. Specialty Drugs

	Traditional	Specialty
Administration	Oral, topical	Oral, injectable, infused
Patient education	Some regarding administration and storage	Robust counseling regarding administration and storage
Education frequency	Counseling occurs at baseline and as needed throughout therapy	High-touch and frequent counseling sessions supported by adherence and disease-specific surveys
Adverse events	Infrequent and less severe	More common and severe; proactive counseling sessions occur focusing on mitigation strategies
Impact to patient routine	Typically does not require changes	Many factors may require changes to daily routine (administration)
Adherence impact	Poor adherence may not have immediate consequences	Poor adherence may have immediate consequences (e.g., resistance)



Specialty patients take, on average, an additional 3–11 associated prescriptions.

Sources: Carmen Fontanez, Rosemary McDermott, Deborah Whitehead, "2004 Specialty Pharmacy Management Guide & Trend Report," CuraScript Pharmacy, June 2005, p. 15. Accessed Jan. 14, 2014 at www.drugtrendreport.com/docs/DTR-2004-Specialty.pdf.

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How Are Specialty Drugs Disrupting the Pharmacy Market?

Specialty drugs represent ~1% of Rx volume today yet ~30% of overall drug spend and are projected to be 50% of spend by 2018.

Specialty drugs represent the fastest-growing segment of drug spending. Reports show that fewer than 4% of individuals use specialty medications⁷ and these medications represent just 2.3% of prescriptions,⁸ but they represent more than 30% of all drug spending, which is projected to increase to 50% by 2018 (see chart below). This is driven by multiple factors:

- **Growth in the number of specialty drugs.** In 1990 there were a mere 10 specialty drugs, but in 2012 there were more than 300.⁹ Further, in 2013, 70% of the new drugs approved by the FDA were specialty products.¹⁰ In addition, there are hundreds more specialty drugs in the development pipeline. Per the CVS Caremark publication Insights 2014: Advancing the Science of Pharmacy Care, “While the pipelines for generics and traditional brands are thin, the specialty pipeline continues to be robust, promising to dominate FDA approvals for years to come.”¹¹

In particular, many of the new specialty drugs coming to market are for “orphan” conditions, defined by the FDA as a disease or disorder affecting fewer than 200,000 people.¹² These drugs for orphan diseases are for very limited populations, which is very different than drugs for conditions like high blood pressure or cholesterol that affect millions of people.

- **Growth in the cost of specialty drugs.** While the utilization of specialty drugs increased 3.2% in 2013, total spending increased by 15.6%, driven by the high prices for these drugs.¹³ An often-cited example is Sovaldi, a treatment for hepatitis C approved by the FDA in December of 2013. Priced at \$84,000 for 12 weeks of treatment, Sovaldi has already generated billions in sales for its manufacturer (Gilead) while sparking controversy surrounding the high prices of specialty drugs.¹⁴ Other areas where new specialty drugs have been launched include oral oncolytics, drugs for HIV and MS treatments
- **Growth in specialty’s gross trend.** The Insights 2014 Report showed that the overall trend for non-specialty drugs was -3.8% in 2012 and 0.8% in 2013. In contrast, the overall trend for specialty drugs during this time was 18.3% in 2012 and 15.6% in 2013. Looking ahead, spending on traditional, non-specialty drugs is projected to be relatively flat, with specialty drugs being the primary driver for drug spending growth. Within just three years specialty drugs are projected to account for 50% of total drug spend.

Specialty Market Projections

	2012	2014	2016	2018
Total industry specialty spend	\$92B	\$127B	\$179B	\$235B
Annual growth rate	18%	17%	17%	17%
Percent of total drug spend	30%	38%	45%	50%

Source: Insights 2014: Advancing the Science of Pharmacy Care; CVS/Caremark

Specialty Drug Ecosystem

Since specialty drugs are very expensive (usually without comparable generic alternatives) and often require special handling, manufacturers and payers have been more focused on how to effectively manage distribution channels, clinical benefits and patient adherence. As a result, specialty drugs do not easily fit into the traditional pharmaceutical distribution model. To help control the patient experience, receive dispensing data from dispensing partners and manage overall costs, manufacturers and payers exert significant influence on the distribution channels used. The result is a complex ecosystem with multiple participants.

Ecosystem Participant	Description
Patients	Fewer than 4% of patients use specialty drugs, but these patients often have rare, chronic conditions. They may receive co-pay assistance and need help with reimbursement as well as clinical education.
Manufacturers	Depending on the therapeutic class and the addressable market, the product teams at manufacturers determine the optimal channel(s), which may be “open” for some large markets, or “closed” or “limited” for conditions that are more rare.
Payers	Because of the high costs of specialty drugs, payers play an extremely important role in the specialty market and can influence (and at times dictate) where a patient gets their specialty prescription from. This is further causing networks to narrow to a more limited-dispense model.
Distributors	Both traditional distributors and specialty distributors receive specialty drugs from the manufacturer and then provide fulfillment as directed by the manufacturer. Many specialty products will typically not be channeled through “open access” or traditional wholesale models. Manufacturers may prefer regionalized or even exclusive distribution solutions.
Hospitals and clinics	Some specialty treatments, such as certain cancer medications or intravenous drugs for chronic diseases such as MS, are often shipped to and administered in hospitals, clinics and physicians’ offices.
Specialty pharmacies	These are unique types of pharmacies that work with manufacturers to get access to specialty drugs, and manage the handling and service requirements of these drugs, which can include dispensing, distribution, reimbursement, case management, and other high-touch services unique to patients with rare and/or chronic diseases. Many specialty pharmacies are independently accredited by organizations like URAC or the Center for Pharmacy Practice Accreditation (CPPA) to develop and verify their specialty capabilities to manufacturers and payers.
Retail pharmacies	For specialty drugs that don’t need to be delivered in a hospital, clinic or physician’s office, retail pharmacies can be an important channel. However, many drugs are being moved away from this channel to more sophisticated pharmacies that can handle all patient and access services required by key stakeholders such as the manufacturer or payer.
“Hub and spoke”	In this model, the prescription is transmitted to a central hub (run by a distributor, specialty pharmacy, or on its own), which assesses the prescription and matches the patient with the best delivery and payment option, which might be receipt at a physician’s office or clinic, or fulfillment by a retail pharmacy or via mail order.

Hospitals and clinics often provide specialty drugs that are infused. Oral or injectable specialty drugs are often distributed via retail channels, including community pharmacies and mail order. Currently, 5 of the top 10 specialty classes generate more than 50% of their sales from retail and mail order channels.¹⁶

Five out of the top 10 specialty classes have more than 50% of sales from retail and mail order channels

Specialty Class	Retail and Mail Share of Total	Mail Share of Retail and Mail	Retail Share of Retail and Mail	Chain Share of Retail and Mail	Ind. Share of Retail	Food Share of Retail and Mail
Autoimmune diseases	66.8	74.0	26.0	56.1	27.5	16.4
HIV antivirals	77.6	44.7	55.3	61.0	32.9	6.1
Multiple sclerosis	88.6	89.1	10.9	58.6	24.9	16.5
immunosuppressants for organ transplants	69.4	44.1	55.9	69.8	20.7	9.5
Antivirals, excl. anti-HIV	84.4	66.5	33.5	42.7	50.9	6.4

Source: IMS Health, National Sales Perspectives, June 2013

Unique Capabilities Required to Dispense Specialty Pharmaceuticals

Dispensing specialty drugs is not simply a matter of stocking these drugs. Compared to traditional pharmacy, offering specialty drugs requires unique clinical and operational capabilities, and significant investment.

Retail pharmacies need to understand the unique requirements of dispensing specialty drugs before deciding how to enter the market.



Clinical Capabilities

Because of the unique conditions of those taking specialty drugs, pharmacies providing specialty drugs must have available a broad range of clinical capabilities including:

- 24-hour patient access to pharmacists with disease-state expertise
- Patient education and intensive, disease-specific patient counseling
- Support and monitoring for side effects, and safety and efficacy
- Medication therapy management (MTM) case management and adherence programs



Operational Capabilities

Compared with traditional pharmacies, pharmacies providing specialty drugs need additional operational assets and capabilities. These include:

- The ability to store and handle specialty drugs
- Providing refill coordination and prescription renewal
- Reimbursement assistance, which includes being able to navigate the process of securing prior authorization
- Benefits investigation and support for patient assistance programs
- Initial communication with physicians and ongoing follow-up
- Data systems for tracking and reporting patient adherence and outcomes
- Execution and reporting of Risk Evaluation and Mitigation Strategy (REMS) programs, and reporting of adverse events

Why Do Specialty Drugs Matter to Independent Community Pharmacies?



“Any pharmacy that is not trying to position for the specialty pharmacy business is setting itself up for failure.”

— Adam Fein, Ph.D.

Independent pharmacy owners may find the challenges associated with specialty at retail to be intimidating or overwhelming, but simply dismissing the specialty opportunity could be a costly mistake. Adam Fein, Ph.D., president of Pembroke Consulting, CEO of the Drug Channels Institute, and an expert on specialty drugs, has said, “Any pharmacy that is not trying to position for the specialty pharmacy business is setting itself up for failure.”¹⁷

Specialty at retail represents a significant opportunity for community pharmacies for the following reasons:

- **Specialty drugs represent an emerging revenue stream with significant potential growth.** While the market for traditional, non-specialty drugs is growing at a steady state, the market for specialty drugs is exploding. As a new category for many community pharmacies, specialty drugs represent a new revenue stream that complements the core business of community pharmacy. Fein characterized this opportunity by saying, “We are in the middle of a specialty pharmacy gold rush.”¹⁸
- **Specialty drugs can provide attractive profits.** The margins on specialty drugs may be lower than on traditional drugs on a percentage basis, but because the prices of specialty drugs are so high, the profit dollars can be significant.
- **Specialty patients are extremely valuable.** Patients needing specialty drugs often have multiple prescriptions. An internal study conducted by McKesson has found that patients taking specialty medications typically have 3 to 11 additional prescriptions, making them valuable patients. By having the ability to fill specialty prescriptions, independent pharmacies are less at risk for losing a specialty patient to another pharmacy.
- **Specialty services are a good fit for independent community pharmacies.** Known for personalized care and customer service, independent pharmacies are primed to offer the high-touch specialty services required. If community pharmacies invest in understanding the needs of specialty patients and building the capabilities to serve them, they can be successful in retaining and growing their business.

Keys to Success in Specialty at Retail

While the opportunity presented by specialty drugs is significant, so too are the challenges associated with providing specialty at retail. Among the most important considerations in offering specialty drugs at retail and the keys to success are:

- **Access to specialty drugs.** If a retail pharmacy wants to continue with their core business while also distributing specialty products through the retail channel, it can do this, as some specialty products are available via open networks and can be dispensed through retail pharmacies.

Additionally, a pharmacy owner can work directly with manufacturers to try to gain access to specialty drugs at favorable prices via contracts to limited distribution drugs.

- **Access to specialty patients.** As with access to specialty drugs, if a pharmacy wants to continue with their core business of dispensing those specialty drugs that are available through the retail channel, they can serve specialty patients in this way. Alternatively, for pharmacy owners that want to seriously pursue the specialty opportunity, they can access new lives and reimbursement by participating in specialty contracts with PBMs and health plans.
- **Access to specialty services.** The types of services that must be provided to offer specialty at retail include storage and handling; education and counseling; adherence management; adverse event reporting management and REMS; renewal management and refill coordination; and assistance for patients on payment issues, including benefit investigation, prior authorization and enrolling patients in financial assistance programs.

Providing this range of specialty services is not simple or easy. It can involve significant investments in staff and technology for various clinical and operational capabilities, and requires a business transformation. Keys to success include having qualified staff, obtaining necessary certification and training, and having an appropriate technology infrastructure.

In addition to the necessary clinical and operational considerations, retail pharmacies must develop plans to market their clinical capabilities to prescribers (health systems and physicians), as well as to patients.

The bottom line is that the opportunity presented by specialty pharmacy is significant. The keys to success are access to drugs, access to lives and access to services.

Three Paths to Offering Specialty at Retail

Making the right decision for your pharmacy requires careful consideration and analysis of today's options for entering the specialty at retail market.

The first step in being successful in providing specialty drugs at retail is gaining access to specialty services. Once a pharmacy has these services, they will have the ability to pull data and begin conversations with manufacturers and payers about new access to lives and drugs.

In contemplating how to gain access to these services, retail pharmacies have multiple options to consider:

- **Build.** This entails creating all of the capabilities to offer specialty from scratch. Doing so gives a pharmacy owner ultimate control over all aspects of specialty operations. It can provide a pharmacy access to a new patient base, a new revenue stream, and possibly different prices as a new class of trade. Pharmacies pursuing this option may choose to focus on a particular therapeutic area and build expertise in that niche. Challenges associated with building a specialty pharmacy are that this approach can be slow, difficult and expensive. Payers typically require that specialty pharmacies in their networks become accredited, which can be time consuming and costly. Staff training and technology investments can also be significant, which for many independent community pharmacies may be prohibitive. If successful in building a specialty pharmacy, there are many benefits to be had. Owners capture all the proceeds (in comparison to the partnership model) and position themselves as a more clinically inclined pharmacy that is moving beyond a transactional relationship with their patients.
- **Buy.** Acquisitions of specialty pharmacies are taking place, as specialty pharmacy is a rapidly consolidating market. As with building a specialty pharmacy, buying one can provide access to a new base of patients and a new revenue stream, and can leverage some existing operational capabilities more broadly in a new class of trade. Beyond trying to finance an acquisition, buying a specialty pharmacy requires being able to manage elements of a different type of operation and requires having the specific capabilities to offer specialty services, and for most independent community pharmacies isn't a viable option.
- **Partner.** For many community pharmacies, the most realistic option in offering specialty at retail — as well as the fastest, least expensive and lowest-risk option — is to partner. The ideal partner is an existing specialty pharmacy, hub or service entity that is willing to partner and is operationally able to support a retail partnership model. Supporting a retail partner requires having the expertise, capabilities and focus to deliver the types of specialty services that retail pharmacies need. In a partnership, the benefits will be shared between the specialty pharmacy and the retail pharmacy, which doesn't need to develop the core competencies of a specialty pharmacy.

Through partnership, a community pharmacy can gain access to the full portfolio of clinical and operational capabilities needed to offer specialty drugs and compete for specialty business. This is a practical option that is increasingly being pursued by many independent retail pharmacies.

Making the Right Decision

The trend is clear: specialty drugs will be a major area of growth for years to come. And, many specialty drugs can be provided at retail by community pharmacies that gain access to specialty drugs, patients and services. But pharmacies will have to complement their existing capabilities with new contracts, services and technologies.

As pharmacy owners evaluate the different ways to participate in this market — and not be left behind — important questions to be answered include:

- What are the trade-offs associated with acting now or waiting?
- Which option — build, buy or partner — fits best with your pharmacy’s strategy, plans, resources and capabilities?
- If you decide to partner, how do you decide who is the best partner for your business?
- What is the best way to gain access to specialty drugs and patients who need them?
- How do you create and operationalize the services to provide specialty at retail?
- What types of staffing and technology are required?
- Should you focus on a limited set of diseases and treatments, and if so, which ones?
- How do you market your pharmacy’s specialty capabilities to physicians and patients?

To think through the options and to make the best decision for your pharmacy, additional information about specialty at retail is available from resources such as:

- [National Association of Specialty Pharmacy \(NASP\)](#)
- [Specialty Pharma Journal](#)
- [CPO \(Chief Pharmacy Officer\)](#)
- [Specialty Pharmacy Certification Board \(SPCB\)](#)
- Also, see the following articles:
 - [Community Specialty Pharmacy: The Time Is Now!](#) *Specialty Pharmacy Times*, August 19, 2014
 - [Pathways to Specialty Pharmacy: How to Gain a Foothold in a Field Dominated by ESRX, CVS, WAG](#), *Drug Topics*, July 10, 2014

Specialty Solutions from McKesson for Independent Pharmacies

McKesson can help independent retail pharmacies compete in the growing specialty market through our partnership with Diplomat, the nation's largest independent specialty pharmacy. Together, we help coordinate high-touch patient access and reimbursement services on the pharmacy's behalf, including:

- Prior authorization
- Benefits investigation
- Patient assistance programs
- Clinical support and education on product, administration and side effects
- Refill coordination
- 24/7 pharmacist support

In addition, McKesson and Health Mart® provide tools to help independent pharmacies proactively promote their specialty services to prescribers and patients with customizable marketing support to:

- Educate prescribers on your specialty capabilities
- Attract all of a patient's scripts to your pharmacy (specialty, brand, generic)
- Improve patient retention, adherence and satisfaction

To learn more about McKesson Integrated Specialty Solutions and Health Mart Specialty Solutions, call 800.212.2606 or email SpecialtySolutions@emg3.com.

McKesson Integrated Specialty Solutions

McKesson Corporation

One Post Street
San Francisco, CA 94104

SpecialtySolutions@emg3.com

800.212.2606

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