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Specialty Pharmacy: Why Your Organization Can't Afford to Sit on the Sidelines

Introduction

“Financial incentives for cancer programs have never been under more scrutiny and pressure.”

We've all heard similar grumbings. Reimbursement and regulatory changes over the last few years are negatively impacting the bottom lines of cancer programs everywhere. Whether it's site neutrality or reimbursement cuts to 340B programs, cancer providers are being forced to do more with less.

But what if most cancer providers aren't looking in the right places? What if they could find an untapped revenue stream to offset the financial corrosion their cancer programs have experienced in recent years?

This article will explore one of those untapped opportunities: Specialty Pharmacy. The specialty pharmacy market is exploding and now represents nearly *half* of all drug expenditures in the United States.¹ Yet most healthcare providers are still sitting on the sidelines, largely because they don't fully grasp the full value that specialty pharmacy represents.

The burgeoning specialty pharmacy market represents both an opportunity and a threat to cancer providers. Providers that don't offer specialty pharmacy services in-house will increasingly lose volume and revenues from limited-distribution specialty drugs to other avenues. Evolving oncology care models (e.g., migration from infusion to oral chemotherapeutics) will significantly elevate the strategic and financial importance of specialty pharmacy for health system. Those that act on specialty pharmacy now can create a profitable new revenue stream and be well-positioned to participate in an accountable care environment.

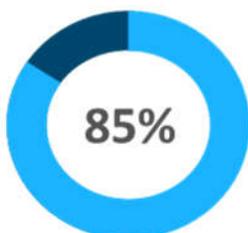
What is Specialty Pharmacy?

Specialty pharmacy is a loosely defined concept. As a general definition adopted from Vizient, specialty pharmacy is the “medication management of patients with rare or chronic diseases who use high-cost medications, generally around \$1,000 per month or more.”¹

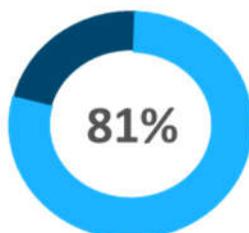
In defining a specialty pharmaceutical, there are two main factors: cost and complexity.

1. **Cost:** CMS categorizes a specialty drug as one with a minimum monthly cost of \$600 with respect to the Part D drug benefit. Other organizations utilize a higher cost threshold for specialty classification that may be as much as double that of CMS (add source).
2. **Complexity:** Specialty pharmacy drugs typically have a complex risk profile, meaning they have substantial side effects, special handling instructions and/or require intensive patient management.

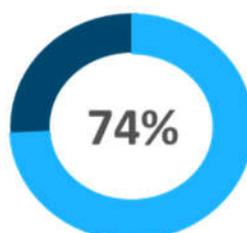
Health Plans Define Specialty Pharmacy by These Factors:



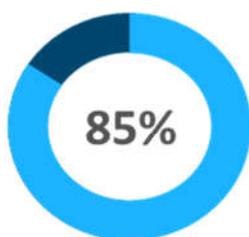
High Cost



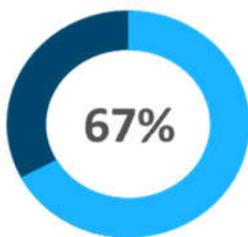
Complex Disease



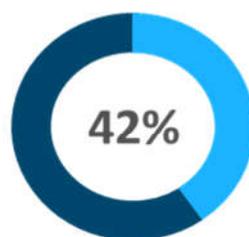
Orphan, Uncommon,
or Rare Disease



Special Handling
Required



Limited
Distribution



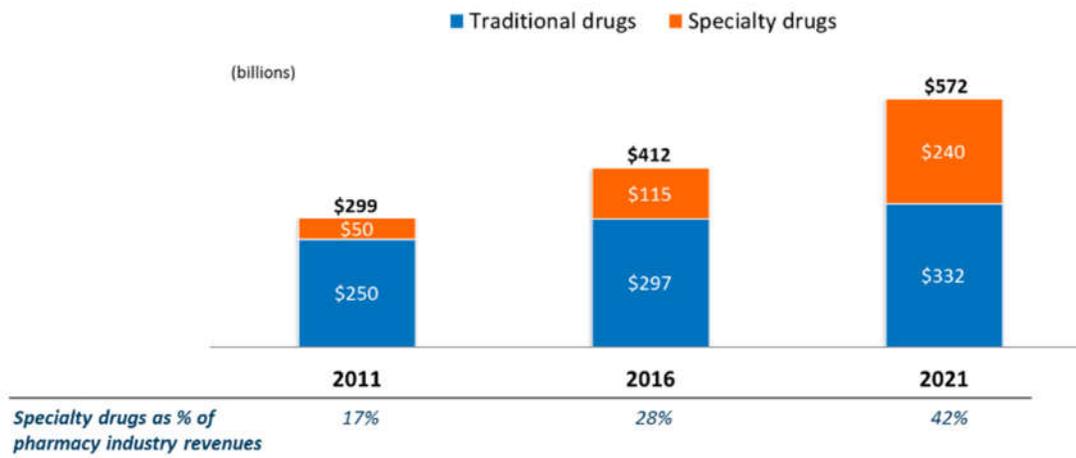
Patient Must Be
Trained to Administer

² Infographic: <https://www.urac.org/blog/infographic-specialty-pharmacy-growth-trend-hospital-systems>

Why is Specialty Pharmacy generating so much attention?

Not only are specialty pharmacy drugs extremely expensive, but they also account for a large and growing portion of the drug development pipeline – up to 50% by some estimates.² Pharmaceutical costs are now the fastest growing portion of total healthcare spending, and specialty drugs are the primary source piloting this trend.

Pharmacy Industry Prescription Revenues, Traditional vs. Specialty Drugs, 2011-2021



Figures in billions. Data include retail, mail, long-term care, and specialty pharmacies. Totals may not sum due to rounding.
 Source: *The 2017 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Drug Channels Institute, 2017, Exhibit 66.

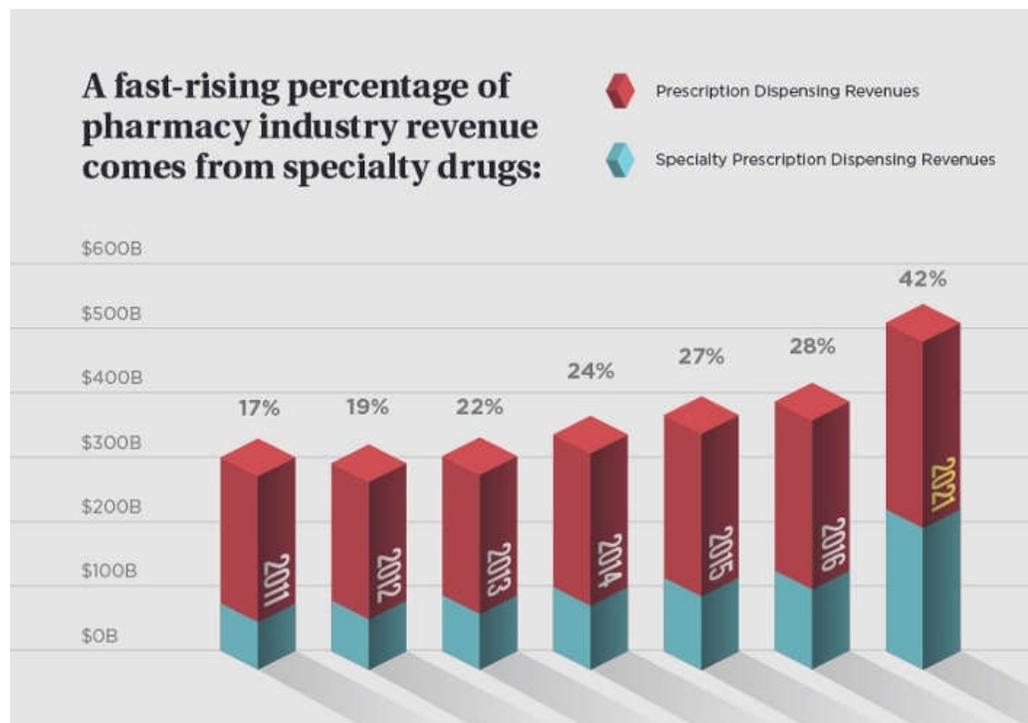
Published on *Drug Channels* (www.DrugChannels.net) on April 11, 2017.



Consequently, specialty drugs are generating a lot of attention and concern across the healthcare landscape. As providers, payers, and employers alike look to rein in healthcare costs in an accountable care environment, the rapid proliferation of the specialty market is garnering significant attention.

Other data points underscoring the continued rise of specialty pharmacy include:

- Specialty drug spend as percent of total annual drug spend will grow from 17% in 2011 to a projected 42% by 2021.³
- Specialty drug spend is growing at a rate of 20% per year while traditional drug spend is flat.⁴
- Three conditions alone – cancer, inflammatory conditions, and MS – make up nearly 60% of the Specialty Market.³ All these conditions are experiencing a rapid growth in incidence worldwide.⁴



Who are the key players across the Specialty Pharmacy landscape?

Historically, only a handful of players have controlled the specialty pharmacy market, including CVS Health, Walgreens, and ExpressScripts.⁵ As of 2012, these 3 companies generated 65% of the revenues from pharmacy-dispensed specialty drugs.⁶

While these “non-provider” organizations have a strong grasp on the specialty pharmacy industry, the competitive landscape is starting to shift as more hospital and health system providers establish their own in-house specialty pharmacies. In fact, there are now more than 2,500 accredited specialty pharmacies in the United States, and health system providers are the fastest growing segment.³

While health systems are driving much of the growth in specialty pharmacy services, it is still only present in a minority of hospitals. According to the American Society of Health-System Pharmacists, only 8.7 percent of hospitals have a specialty pharmacy operation. Not surprisingly, larger hospitals are more likely than smaller ones to be in the specialty pharmacy business. Thirty percent of hospital systems with 400 to 599 beds and forty-seven percent of systems with 600 or more beds now have specialty pharmacies.⁷

While the provider sector has clearly been a driver of specialty pharmacy growth in recent years, other key entrants are also making significant investments in specialty pharmacy and further fragmenting the competitive landscape. Key developments over the last several years include:

- Large insurers have established their own specialty pharmacy programs – Aetna Specialty, Cigna Specialty Pharmacy, UnitedHealthcare BrivoRx
- Regional and national chains have launched their own specialty programs (Costco, Safeway, Giant Eagle)

- Independent retail community pharmacies have organized into collaborative networks
- In the last decade, many of the independent specialty pharmacies have been among the fastest growing companies in the US. (Diplomat, Avella, MedPro Rx)

Prescription Revenues and Market Share from Specialty Pharmaceuticals, by Company, 2017

Pharmacy Name	Parent Organization	Estimated 2017 Prescription Revenues from Specialty Drugs (\$ billions)	Change in Revenues vs. 2016	Share of Prescription Revenues from Specialty Drugs
CVS Specialty ¹	CVS Health	\$35.0	+9%	25%
Accredo / Freedom Fertility	Express Scripts	\$27.0	+20%	20%
Alliance Rx Walgreens Prime / Walgreens stores ²	Walgreens Boots Alliance	\$16.0	+13%	12%
BriovaRx	UnitedHealth Group (OptumRx)	\$13.0	+27%*	9%
Diplomat Pharmacy ³	n/a	\$4.5	-2%	3%
Humana Specialty Pharmacy	Humana	\$3.1	+5%*	2%
Kroger Specialty Pharmacy ⁴ / Kroger stores	Kroger	\$2.3	+13%*	2%
Cigna Specialty Pharmacy	Cigna	\$1.6	+4%	1%
Avella Specialty Pharmacy	n/a	\$1.4	+6%	1%
Specialty Pharmacy Solutions ⁵	McKesson	\$1.4	+11%	1%
US Bioservices	AmerisourceBergen	\$1.1	+10%*	1%
Walmart Specialty Pharmacy	Walmart Stores	\$1.0	+4%	1%
BioPlus Specialty Pharmacy Services	n/a	\$0.8	-6%	1%
SenderraRx	n/a	\$0.7	0%	1%
PANTHERx	n/a	\$0.5	+88%	0%
All other retail, mail, long-term care, and specialty pharmacies	n/a	\$29.0	-7%*	21%
Total		\$138.2	+9%	100%

Source: Drug Channels Institute research and estimates. Includes revenues from retail, specialty, and mail pharmacies. Excludes revenues from network pharmacies of PBM-owned specialty pharmacies and infusion services covered by medical benefit. Totals may not sum due to rounding.

* Change in revenues based on revised revenue figure for 2016

1. Includes CVS Caremark Specialty Pharmacy and CVS retail pharmacies. Includes Aetna specialty pharmacy volume.

2. North American revenues only. Changes in revenues computed based on pro forma combination with Prime Therapeutics.

3. Includes pro forma full-year revenues from acquisitions completed in 2017

4. Includes specialty revenues from retail locations

5. Includes Biologics Oncology Pharmacy, the Patient Assistance Pharmacy (formerly known as Care Advantage), and RxC | Custom Pharmacy Solutions

This table appears as Exhibit 42 in *The 2018 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Drug Channels Institute. Available at <http://drugch.nl/pharmacy>



The ballooning specialty pharmacy marketplace will continue to draw significant attention and investment from a wide assortment of traditional and non-traditional players across the healthcare sector. The time is now for healthcare providers to take advantage of opportunities associated with specialty pharmacy by leveraging their unique competitive advantage.

More hospital systems are adding specialty pharmacies:

1 in 5

hospital systems have internal specialty pharmacy capabilities.



Nearly **2 in 5**

are considering adding them.



Why should hospitals and health systems consider a Specialty Pharmacy strategy?

The strategic benefit associated with specialty pharmacy for cancer programs is two-fold:

1. **Financial Positioning** – specialty pharmacy represents a new revenue stream for hospitals and health systems in an era where traditional oncology financial incentives are drying up
2. **Value Positioning** – integrating specialty pharmacy services within a provider setting confers an advantage and positions them to compete more successfully in a population health environment

Financial Positioning

In recent years, the traditional financial incentives that generated significant margin for cancer programs have waned. Examples include reduction in average sales price (ASP) reimbursement for Part B drugs, site neutrality cuts for off-campus infusion centers, and reimbursement cuts to 340B providers. In-house specialty pharmacy represents a significant “untapped” revenue stream for hospitals and health systems with thriving oncology programs and a vital strategy for offsetting the financial decline of their cancer programs.

As care models evolve and the delivery of medical oncology increasingly migrates from infusion to oral therapies, we will continue to see the financial opportunity associated with specialty pharmacy proliferate. The financial opportunity associated with specialty pharmacy for hospitals and health systems is largely driven by three factors:

1. **Acquisition Cost:** The procurement cost of specialty pharmacy drugs will impact how much margin a hospital or health system generates off this business. Hospitals with access to 340B can yield significant cost savings on specialty drugs (typically 30-50%), which further enhances their business case for specialty pharmacy. It should be noted that many hospitals have successfully moved into the specialty pharmacy space without 340B, and instead focus on optimizing their negotiated discounts with specialty drug manufacturers and distributors.

2. **Reimbursement:** A hospital-owned specialty pharmacy must be part of a third-party payer’s pharmacy network to receive reimbursement for specialty prescriptions dispensed under a patient’s pharmacy benefit. Reimbursement to hospitals and health systems for specialty drugs is typically based on negotiated prices, which for Medicare Part D reimbursement is usually based on the AWP minus a percentage discount, plus a dispensing fee. These negotiated prices will significantly impact the upside potential associated with the specialty pharmacy business.

3. **Volume:** Ultimately, the total volume of specialty pharmacy prescriptions filled by the hospital or health system will determine the magnitude of the financial opportunity. Hospitals that only care for a small volume of specialty patients may not benefit from a specialty pharmacy strategy, regardless of the strength of their reimbursement contracts and/or access to 340B. It should also be noted that certain PBMs and health plans may limit the number of specialty pharmacies available to a beneficiary and may require patients to use the specialty pharmacy that the plan or PBM owns and operates. To combat this, however, some hospitals negotiate rates that a typical pharmacy can’t meet. For example, a 340B hospital may be able to buy a specialty drug at a 50% discount from the manufacturer’s Wholesale Acquisition Cost (WAC) list price. The hospital could then agree to a prescription reimbursement rate of WAC-30%—a discount far below what any other specialty pharmacy could accept.

The financial opportunity associated with hospital-owned specialty pharmacy is generally lucrative when the volume is present. It is not unheard of for 340B hospitals and health systems to generate 40% – 50% margins on their oncology specialty business. With that said, the degree of profitability can be highly variable depending on the three factors listed above.

The table below highlights the financial experience of three example health systems that have recently implemented specialty pharmacy:

Health System Location	Annual Cancer Program Scale	Specialty Pharmacy Business (Financial Overview)	
Northeast	5,800 Annual New Cancer Cases (Analytic Only)	Oncology SP Fills:	15,600
		Oncology SP Margin:	\$27.3M
		Oncology SP Margin/Fill:	\$2,800
Southeast	1,100 Annual New Cancer Cases (Analytic Only)	Oncology SP Fills:	3,600
		Oncology SP Margin:	\$14.6M
		Oncology SP Margin/Fill:	\$4,100
Midwest	4,100 Annual New Cancer Cases (Analytic Only)	Oncology SP Fills:	15,600
		Oncology SP Margin:	\$20.0M
		Oncology SP Margin/Fill:	\$1,300

Value Positioning

The benefit associated with specialty pharmacy goes well beyond the financial business case and ROI potential. It includes positioning cancer providers for success in a population health environment.

Studies show that about 30% of medications are taken inconsistently. Medication nonadherence is high for specialty pharmaceuticals. The reason is obvious: complexity. A complex disease coupled with

complex medications means patients will have more difficulty adhering to their care protocol – especially if their care journey is shuffled across multiple settings and providers.

When health systems offer in-house specialty pharmacy, they remove the barrier of fragmentation for the patient. The medication dispensing can occur in a setting where the patient’s longitudinal medical record is considered and where a single medical care team is working in unison – ultimately enabling a better clinical outcome. This is especially important as oncology care protocols become more complex and patients receive multi-modality treatment (e.g., infusion, oral medications, radiation therapy, etc.). When the patient’s oncology care pathway is coordinated and integrated into a single setting, health systems are better equipped to reduce readmissions and duplication of services while improving quality.

The transition from fee-for-service to value-based reimbursement will increasingly force cancer providers to contain global costs for individual cancer patients. This is hard to do if a patient gets a prescription for an expensive specialty drug in one setting, but then needs to go elsewhere to fill that prescription. This situation results in cancer providers becoming blinded to information about which pharmacy dispensed the drug, where they dispensed it, when it arrived at the patient’s residence, clinical information, or whether adverse events were reported in a timely manner.

Integrating specialty pharmacy services within the health system setting confers certain advantages not otherwise captured by cancer providers that outsource these services. Health systems typically have the scale, resources, and physician relationships that make them ideally suited to manage complex clinical conditions that drive better performance in key areas such as:

- Decreasing time to initiate therapy and ensuring that prescriptions are filled with bedside delivery⁸
- Preparing patients and their families to transition from inpatient to outpatient care with in-person pharmacist discussions prior to discharge⁸
- Reducing medication abandonment rates and adverse events through frequent monitoring and prompt response to potential problems⁸
- Improving coordination of care and clinical decision-making⁸

Additionally, when specialty pharmacy is integrated in a health system setting, providers and pharmacy staff have access to broader view of a patient’s medical history across multiple departments (lab, radiology, pharmacy, etc.). Access to the patient’s data and history allows for better coordination across multiple providers that are integral to the patient’s care journey. This value proposition is unique to health system organizations and cannot be readily duplicated by standalone specialty pharmacies.

Improving care coordination, reducing duplication of services, and improving patient adherence to care protocols all equate to enhanced value. In an accountable care environment, a health system’s unique positioning to deliver on these outcomes through the implementation of in-house specialty pharmacy will give them an edge when competing for inclusion in specialty distribution networks and broader accountable care networks.

Is Specialty Pharmacy Right for All Hospitals?

The investment in in-house specialty pharmacy should align with the health system's broader strategic objectives. For example, is the hospital aiming to take advantage of a new revenue stream linked to a thriving oncology program, or are they attempting to gain tighter control over specialty drug spend and outcomes for patients in an accountable care environment? Without an underlying strategic rationale for the investment, specialty pharmacy is probably not the best use of the organization's precious capital and resources that would be better used to support strategically aligned initiatives.

In developing the underpinning strategic rationale for investment in specialty pharmacy, hospitals should evaluate the feasibility of the investment against a set of evaluation questions/criteria. Key evaluation questions that must be addressed in assessing the viability of specialty pharmacy include, but are certainly not limited to:

- **Scale/Volume and Service Mix:** Does the hospital have access to a thriving population of patients within key services that drive specialty pharmacy referrals (e.g., oncology, rheumatology, neurology)
- **Contracts with Insurers:** Can the hospital obtain access to critical product distribution networks and payer contracts?
- **Access to LDDs:** Can the hospital meet the necessary requirements and accreditations critical for offering access to Limited Distribution Drugs (LDDs)?
- **Collection and reporting of clinical/outcomes data**
- **Staffing Model:** How will the hospital support a staffing model for specialty pharmacy? Will they leverage existing ambulatory pharmacy staff, or will all staffing cost be incremental to baseline? If leveraging existing staff, do they have the required clinical training on specialty disease states?
- **Nursing and Support Resources:** Does the hospital have critical nursing support for self-injectable medication assistance/training? How will the hospital support call center services for the pharmacy? How will case management and patient coordination be deployed across the specialty pharmacy?
- **Adherence Strategy:** Adherence is crucial for patients with all conditions, especially among patients taking costly and complex specialty drugs. Does the hospital have a strategy for optimizing medication adherence?
- **Accreditation:** Can the hospital gain obtain the necessary accreditations? Hospitals that today have access to specialty pharmaceuticals probably have appropriate accreditation from the Utilization Review Accreditation Commission (URAC) and/or the Accreditation Commission for Health Care (ACHC)

Financially, health systems should also be able to construct a thorough business case that supports the investment in specialty pharmacy. This analysis should consider the capital requirements, strength of payer contracts, acquisition costs, staffing, accreditation requirements, and other overhead. It should also demonstrate the cost savings opportunity associated with 340B depending on the hospital's status.

Conclusion

The age of highly individualized and specialized cancer treatments is upon us. Patients can now benefit from complex treatments that are unique to their cancer and genetic characteristics, requiring a more coordinated approach among a range of healthcare providers. Cancer providers that offer in-house specialty pharmacy are better equipped to deliver the highest degree of personalized and coordinated cancer care.

Cancer program executives would therefore be remiss not to investigate how a specialty pharmacy strategy can create value for their organization, improve patient outcomes, and position them for an accountable care environment. As explored in this article, in-house specialty pharmacy represents one of the few opportunities that can succeed in both a fee-for-service and accountable care environment.

Ultimately, the steep growth trajectory of specialty pharmaceuticals means that more cancer patients will be cared for in a specialty pharmacy setting. Hospitals that sit on the sidelines will inevitably witness a deterioration of their cancer program volumes and bottom line.

¹ Vizient: Maximizing Pharmacy Performance, 2018

² <https://www.urac.org/blog/infographic-specialty-pharmacy-growth-trend-hospital-systems>

³ Drug Channels Institute, 2017

⁴ American Society of Health System Pharmacists, "Expansion Opportunities for Health Systems: Where Does Specialty Pharmacy Fit?", 2012

⁵ <https://www.advisory.com/research/care-transformation-center/care-transformation-center-blog/2018/03/specialty-pharmacy>

⁶ <https://www.urac.org/blog/infographic-specialty-pharmacy-growth-trend-hospital-systems>

⁷ <https://academic.oup.com/ajhp/article/74/17/1336/5102661?sso-checked=true>

⁸ <https://newsroom.vizientinc.com/vizient-blog/pharmacy/specialty-pharmacy-revenue-center-disguise>