

SPECIALTY PHARMACY

A UNIQUE AND GROWING
INDUSTRY



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SPECIALTY PHARMACY: A UNIQUE AND GROWING INDUSTRY

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INTRODUCTION

Specialty drugs are occupying an increasing percentage of the pharmaceutical industry in the US, with more than 400 specialty drugs¹ now available in the market. This is a result of continued research into rare (~7000 diseases collectively affecting 25 – 30 million Americans¹), chronic, or complex diseases (such as cancer and inflammatory conditions).

The federal government has prioritized research to help patient populations with these diseases through the Food and Drug Administration (FDA)

approval incentives (e.g., fast track, priority review, breakthrough therapy designation, accelerated approval) provided in regulations such as the Orphan Drug Act, FDA Modernization Act, and FDA Safety and Innovation Act.¹ Specialty drugs are also a big focus area for pharmaceutical R&D, with 9 of the top 10 launches in 2018 being specialty drugs.²

Furthermore, pharmacies that can provide the specialized services that go along with these drugs – and the disease states they treat – have also gained prominence.

In the 1990s, there were fewer than 30 specialty drugs available at large retail pharmacy chains (for diseases such as hemophilia and Gaucher disease).¹ A limited number of patients were served with these high-cost, low-volume, and high-maintenance drugs. A distinct centralized specialty pharmacy model did not exist at this point. Retail stores had to balance between inventory carrying costs for these expensive drugs while trying to stay in stock to serve a small number of patients receiving these drugs.



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8.403.98E-09	2.51E-06	0.715	0.715
8.801.58E-09	6.31E-06	0.863	0.863
9.001.00E-09	1.00E-05	0.909	0.909
9.403.98E-10	2.51E-05	0.962	0.962

There are no universally accepted definitions for the terms ‘specialty drug’ and ‘specialty pharmacy’, although the descriptions that do exist have some consistent themes.

SPECIALTY DRUG DEFINED

A specialty drug can possess any of the following attributes: a high-cost prescription drug used to treat individuals with chronic, complex, and rare diseases; complex to manufacture; often biologically derived; requiring special handling, storage, or delivery; difficult to administer injectable, infused product, oral agent, or inhaled drug; requiring close supervision and monitoring; administered at home, MD office, infusion center, or outpatient hospital; and available through exclusive, restricted, or limited distribution.

SPECIALTY PHARMACY DEFINED

- The specialty pharmacy practice encompasses the provision of specialty pharmaceuticals, which typically require unique fulfillment and patient care support services such as:
 - **Access to Care Services** includes health care provider (such as pharmacists, nurses, and clinicians) access, physician consultations, and disease and drug-specific patient care management services.
 - **Clinical Outcome Services** includes tracking clinical outcomes, patient adherence programs, risk evaluation and mitigation strategies (REMS) programs, and data management of technical and clinical patient care services.
 - **Drug Affordability Services** include insurance navigation, (investigating benefits, prior authorization, and utilization management processes to expedite access to therapy), patient assistance, and plan optimization.
 - **Operational Services** include supply chain management, collaboration with patients’ physicians, logistical coordination, and convenient delivery.
- Specialty pharmacies in the US should be accredited by independent third parties such as the Utilization Review Accreditation Commission (URAC), the Accreditation Commission for Health Care (ACHC), the Center for Pharmacy Practice Accreditation (CPPA), and The Joint Commission (TJC), to ensure consistent quality of care.

As more specialty drugs became available, paperwork and treatment costs posed a challenge for patients who received these prescriptions from retail pharmacy chains. These chains identified an opportunity to centralize specialty pharmacy distribution to drive not only efficiency in the supply chain but also to grow a lucrative specialized pharmacy delivery model.

As the specialty pharmacy component of the total pharmacy spend grew, insurers and PBMs increasingly started managing specialty drugs as a separate category. Pharmacies started differentiating themselves by specializing in specific disease areas, private equity firms began investing in specialty pharmacies, and health plans showed increasing interest in owning the specialty pharmacy asset.

Also, as insurers sought to manage access and expenses for patients with chronic, complex, and rare conditions, specialty pharmacies increasingly started focusing on patient care. They started designing comprehensive, coordinated patient care management programs to ensure optimal therapeutic and cost-effective outcomes for patients.



INDUSTRY STRUCTURE

A diverse set of organizations, own specialty pharmacies. While some specialty pharmacies are independent, others are owned by PBMs/insurers, retail chains, wholesalers, and healthcare providers (includes hospitals, health systems, physician practices, and providers' group purchasing organizations), with PBMs and insurers dominating specialty drugs dispensing channels.³ The concentration of specialty dispensing revenues, among PBMs and insurers, results mostly from the strategies used by PBMs, insurers, and pharmaceutical companies to narrow specialty pharmacy networks. Pharmaceutical companies limit the specialty pharmacies eligible to dispense specialty drugs to maintain product integrity, control drug flow, and cost as well as collect distribution and patient-use data. PBMs and health plans can further limit the number of specialty pharmacies selected by the pharmaceutical company

ROLE OF PHARMACY BENEFIT MANAGERS (PBMS)

PBMs operate as corporate "middlemen" in the pharmaceutical supply chain. These companies manage prescription medication benefits on behalf of health insurers, Medicare Part D drug plans, large employers, and other payers. By negotiating with pharmaceutical companies and pharmacies to control medication spending, PBMs have a significant impact in determining total drug costs for insurers, shaping patients' access to drugs, and determining how much pharmacies are paid. Their role includes:

- Developing and maintaining formularies, of covered medicines on behalf of health insurers, which influences the drugs individuals use and determines out-of-pocket costs
- Utilizing their purchasing power to negotiate rebates and discounts from pharmaceutical companies
- Contracting directly with individual pharmacies to reimburse for medicines dispensed to beneficiaries

Earnings of PBMs are mainly driven by rebates negotiated with pharmaceutical companies to have their drugs listed on PBMs' formularies and the price difference (also referred to as spread pricing) that PBMs get from what they pay to specialty pharmacy providers versus what they get paid by plan sponsors (a plan sponsor is an employer or organization that offers a group health plan to its employees or members).

by requiring patients to use the specialty pharmacy owned and operated by the plan or PBM.

The top four specialty pharmacies, account for more than 70% market share and are part of integrated health systems.⁴The specialty pharmacy industry has seen a tremendous amount of consolidation over the last few years, where the top four pharmacies have captured market share primarily through acquisitions. Some prominent acquisitions announced during 2018-19 included⁵:

- CVS Health acquired five specialty pharmacies (Apothecary By Design, Central Drugs, EncompassRx, EntrustRx, & SimplicityRx) in 2018 and two in 2019 (Commcare and MsRx).
- In 2019, UnitedHealth Group's OptumRx announced its acquisition of Diplomat Pharmacy, the largest publicly traded specialty pharmacy and infusion services business at that time. The transaction was finalized in February 2020.
- Walgreens Boots Alliance and the private equity firm, Welsh, Carson, Anderson & Stowe acquired Shields Health Solutions, a company that develops and manages specialty pharmacies for hospitals.
- In 2019, Cigna's Express Scripts business acquired Verity Solutions, a private-equity funded provider of 340B software and services.

FIGURE 1: PRESCRIPTION REVENUES AND MARKET SHARE FROM SPECIALTY PHARMACEUTICALS, BY COMPANY, 2019

Pharmacy Name	Parent Organization	Estimated 2019 U.S. Prescription Revenues from Specialty Drugs (\$ billions)	Change in Revenues vs. 2018	Share of Prescription Revenues from Specialty Drugs
CVS Specialty	CVS Health	\$43.9	+19%	27%
Accredo / Freedom Fertility	Cigna (Express Scripts)	\$32.1	+5%	20%
AllianceRx Walgreens Prime / Walgreens stores	Walgreens Boots Alliance	\$21.2	+8%	13%
Optum Specialty Pharmacy	UnitedHealth Group (OptumRx)	\$17.8	+6%	11%
Diplomat Pharmacy	n/a	\$4.5	-6%	3%
Humana Specialty Pharmacy	Humana	\$3.6	+11%	2%
Kroger Specialty Pharmacy / Kroger stores	Kroger	\$3.4	+21%	2%
Specialty Pharmacy Solutions	McKesson	\$1.7	+8%	1%
US Bioservices	Amerisource Bergen	\$1.5	+9%	1%
AHF Pharmacy	AIDS Healthcare Foundation	\$1.2	+10	1%
PANTHERx Rare	n/a	\$1.2	+65%	1%
Walmart Specialty Pharmacy	Walmart Stores	\$1.1	+5%	1%
SenderraRx	n/a	\$0.9	+15%	1%
BioPlus Specialty Pharmacy Services	n/a	\$0.7	+4%	0%
Onco360 / CareMed	BrightSpring Health Services	\$0.7	+8%	0%
All other retail, mail, long-term care, and specialty pharmacies	n/a	\$25.7	n.a.	16%
Total		\$161.1	+9%	100%

Source: Drug Channels Institute⁴ research and estimates. Includes revenues from retail, specialty, and mail pharmacies. Includes specialty revenues from retail locations, where relevant. Excludes revenues from network pharmacies of PBM-owned specialty pharmacies and infusion services covered by medical benefit. Totals may not sum due to rounding.

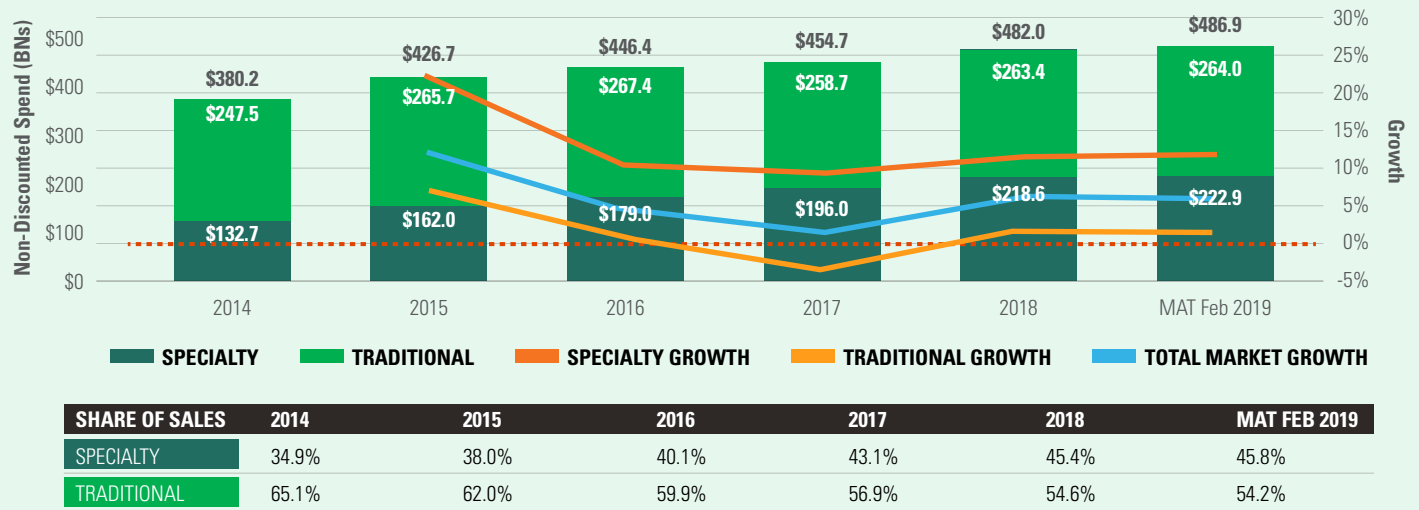
TRENDS IN SPECIALTY DRUG SPENDING

Spending on specialty drugs is growing and constituted about 46% of total non-discounted spend in MAT Feb 2019. Furthermore, growth in spending on specialty drugs is outpacing growth in

spending on traditional drugs. During MAT Feb 2019, spending on specialty drugs grew at 11.7%, whereas, spending on traditional drugs remained relatively flat at 1.8%.² This growth in spending on specialty drugs is driven by higher utilization, aided by newer

treatments entering the market (with few or no competing medicines to drive down prices), indication expansions, and the declining share of traditional drugs as growth has slowed due to patent expiries.⁶

FIGURE 2: SPECIALTY SPEND VS. TRADITIONAL SPEND, US \$BN (2014-18)



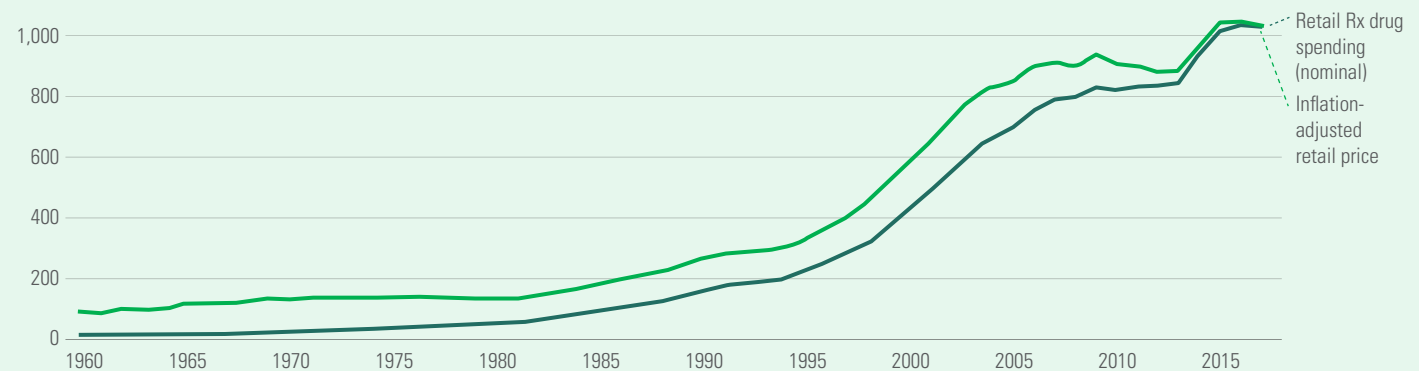
Moving Annual Total (MAT): Period considering the last 12 months from the available period, values at MAT level are rolling yearly sum.
Source: MedImpact²

Furthermore, while the overall drug prices have remained stable over the last few years (Figure 3), specialty drug prices have grown rapidly. For example, among commonly used specialty drugs, branded drug prices have increased by 57% during 2014 – 2018.⁷

High costs are affecting more patients as their out-of-pocket costs are increasing. The proportion of patient costs paid through deductibles and coinsurance has grown since 2013.² With higher cost-sharing comes greater abandonment of medication, affecting patients with deductibles, coinsurance,

and specialty copays. Therefore, policymakers are attempting to improve drug price transparency for PBMs and other parts of the supply chain at the state and federal level, as part of their efforts to address high drug prices.

FIGURE 3: NOMINAL AND INFLATION-ADJUSTED PER CAPITA SPENDING ON RETAIL PRESCRIPTION DRUGS, 1960-2017



Source: Peterson Center on Healthcare and KFF (Kaiser Family Foundation)¹²

At the same time, health plans and PBMs are also formulating strategies to address soaring costs, as elucidated below:

- **Access:** Until recently, specialty drugs were covered under the pharmacy benefit, the medical benefit, or both depending on the benefit design of the insurer. Almost 50% of all specialty drugs were billed through the medical benefit, which lacked the visibility, cost-control strategies, and oversight of the pharmacy benefit.⁸ However, the industry is now seeing a higher orchestration between PBMs and health plans, and the trend to move drugs from medical benefit to pharmacy benefit to rein in costs, is becoming stronger. Additionally, specialty pharmacy networks are becoming more closed, and specialty drug formularies are becoming tiered to promote affordability.
- **Patient Support:** Copay accumulator programs are a utilization management tool implemented by health plans and PBMs. These programs, where applied, block the copay coupons pharmaceutical companies offer for some medicines from being applied to deductibles and out-of-pocket maximums. The programs are implemented to encourage patients to use cheaper alternatives such as generics or other substitutes as well as to pressurize pharmaceutical companies to lower prices. Insurance companies and PBMs perceive copay cards as a way for pharmaceutical companies to keep patients on expensive drugs,

What started as an inventory and supply chain management solution (specialty pharmacy) for expensive drugs, has become a major value driver:

- Cost driver for healthcare budget owners (such as employers for employer-sponsored health insurance coverage and the Centers for Medicare & Medicaid Services for Medicare and Medicaid programs)
- Major value driver for profit and loss owners at PBMs and pharmacies
- A big area of focus for pharma R&D
- Significant driver for an overall increase in pharmacy spending
- Focus area for risk management for most health plans and insurers

circumventing their efforts in reducing costs.⁹ Another essential tool for controlling costs is called site-of-care management. Health plans, in conjunction with PBMs, have begun implementing site-of-care programs that redirect patients and drugs to the most clinically appropriate and cost-effective sites of care, such as at-home, infusion centers, and physician offices, and can save up to \$1.7 billion a year.⁸ Even among these sites of care, at-home and infusion centers, turn out to be more cost-effective, as compared to the physicians' offices in a buy-and-bill model (a healthcare

provider purchases, stores, and then administers the product to a patient). Some health plans and PBMs also use mechanisms such as white bagging (i.e., the drug is purchased through a preferred network specialty pharmacy and shipped to the provider's office for administration) and brown-bagging (wherein the drug is purchased through a preferred specialty pharmacy and shipped directly to the patient, who takes it to the provider's office for administration) to retain greater control of drug costs. Looking ahead, health plans and PBMs may start designing those types of distribution requirements that drive drug administration to the lowest site-of-care setting.

- **Utilization:** PBMs owned by health plans are working towards reducing utilization instead of increasing the transaction volume. Due to the high cost and complexity of specialty drugs, about 9 out of 10 specialty drugs require prior authorization (PA) to ensure appropriate utilization.¹⁰ Another cost-control tool is encouraging the substitution of specialty drugs with non-specialty drugs or biosimilars. Many states have implemented policies to regulate a pharmacist's substitution of such products, anticipating that the FDA is likely to approve interchangeable biosimilars in the future.¹¹
- **Pricing:** Health plans and PBMs are pushing pharmaceutical companies to provide rebates on more transactions with coverage moving towards pharmacy benefits.

VERTICAL CONSOLIDATION

The largest insurers, PBMs, specialty pharmacies, and healthcare providers, have combined into vertically integrated organizations to manage the increasing pharmacy and medical costs. When PBMs administered pharmacy benefits before the integration, they were

volume and utilization driven and were focused on driving the overall pharmacy cost down. However, vertical integration provides insurers the opportunity to focus on the total cost of care impact. Hence, it creates the perfect driver for the adoption of outcome-based or value-based contracting.

Below is an illustration of the major vertical business relationships among the largest companies: UnitedHealth Group (UHG), CVS Health, Cigna, Anthem, Humana, and Prime Therapeutics.¹²

FIGURE 4: LET'S GET VERTICAL: INSURER + PBM + SPECIALTY PHARMACY + PROVIDER

INSURER						
PBM						
SPECIALTY PHARMACY						
PROVIDER SERVICES		 		 	 	

These insurer/PBM/specialty pharmacy/provider organizations are poised to transform the US drug value chain by

exerting greater control over patient access, sites of care/dispensing, and

pricing with the following implications for pharmaceutical companies:

VALUE-BASED CONTRACTING

- With insurers insourcing pharmacy benefits management, risk is transferred to them
- Health plans are seeking more value demonstration from pharmaceutical companies

BENEFITS MANAGEMENT

- More financial burden on health plan insurers
- Push to shift more specialty drugs from medical to pharmacy benefit

PRESCRIBER BEHAVIOUR

- Physician behavior is expected to change since they are working directly with health plans
- Physicians who are employed by the insurer may steer patients to their network specialty pharmacies



REIMBURSEMENT STRATEGY

- Brown-bagging for drugs that are administered by healthcare providers
- Drug costs will be covered by pharmacy benefit and medication administration costs will be covered by medical benefit

PRESCRIPTION STEERAGE

- PBMs steer prescriptions from within their network, to own specialty and mail-order pharmacies
- Networks are becoming more closed for specialty drugs

Source: Atria Inc.



PHARMACEUTICAL COMPANY AND SPECIALTY PHARMACY SERVICES

Both pharmaceutical companies and specialty pharmacies are increasingly adopting new care delivery strategies to manage critical challenges associated with drug access and patient support services. These include:

HUB SERVICES FOR DRUG ACCESS AND PATIENT SUPPORT

Hub services are one of the mechanisms through which pharmaceutical companies can ensure medicine access and support services, while keeping a grip on the marketplace. Hub services sponsored by pharmaceutical companies encompass the full range of services to assist in getting patients on therapy and keeping them adherent in disease states that require chronic care. Some pharmaceutical companies retain some or all the patient support services, but

the trend has been to engage with outsourced vendors that specialize in the practice.

Hub services are provided through a variety of vendors with affiliations to PBM, specialty pharmacy providers, manufacturers, and distributors, or they can function as freestanding vendors. Services offered by vendors include benefits investigation and verification, prior authorizations, drug delivery, and administration, copay support, financial assistance, patient education, and support programs as well as maintaining the data repository that brings patient data together from hospitals, clinics, labs, and pharmacies.

PHARMACEUTICAL COMPANY SPONSORED COVERAGES TARGET UNINSURED AND UNDERINSURED

Several pharmaceutical companies offer patient assistance programs that provide free drugs to patients who are either uninsured or underinsured.

Uninsured patients include those who may be in a grace period awaiting insurance coverage from a new employer. Underinsured patients include those with Medicare Part D (is a voluntary outpatient prescription drug benefit for people with Medicare, provided through private plans approved by the federal government) and patients with limited specialty pharmacy coverage. Patient assistance programs enforce maximum income requirements and may also necessitate patients to receive treatment from a preferred pharmacy.

340B DRUG PRICING PROGRAM TO SUPPORT CARE FOR LOW-INCOME AND UNINSURED PATIENTS

Offering significant clinical and economic benefits, specialty pharmacies are an essential component of hospital and health-system pharmacy operations. According to the American Society of Health-System Pharmacists (a professional organization that



represents pharmacists who serve as patient care providers in acute and ambulatory care settings), about 50% of hospitals with more than 600 beds operate a specialty pharmacy and purchasing specialty drugs through the 340B program is a crucial element. Hospitals participating in this program can access discounts on drug acquisition costs. These discounts provide significant benefits to the health system by reducing drug spend and improving margins while supporting outreach and care for low-income, uninsured patients. Almost 10% of all specialty prescriptions are dispensed by 340B contract pharmacies.¹³ Enacted by Congress in 1992, the 340B drug pricing program requires that pharmaceutical companies sell outpatient drugs to

certain eligible health care organizations and covered entities at discounted rates. Only those health care providers that serve a large number of uninsured and low-income patients are offered discounts.

PHARMACY SERVICES ADMINISTRATIVE ORGANIZATIONS SUPPORT INDEPENDENT PHARMACIES IN PATIENT CARE

Non-PBM owned pharmacies are exploring alternative revenue sources and are reinventing their business models. Nearly all smaller pharmacies have started participating in pharmacy services administrative organizations (PSAOs), that are owned and operated by pharmaceutical wholesalers. Wholesalers' corporate ownership

provides an advantage for smaller pharmacies in contract negotiations with PBMs and other third-party insurers. The PSAO relationship is crucial for independent pharmacies because they generate more than 90% of their total sales from prescription dispensing.¹⁴ A PSAO provides operational support to these pharmacies by offering services such as handling claims reconciliation and credentialing, negotiating third-party contracts, and providing data-based insights into the pharmacies' clinical performance and productivity. This allows independent pharmacies to focus on providing patients with personalized customer services such as immunizations, blood pressure monitoring, and medication therapy management and adherence.

INDEPENDENT SPECIALTY PHARMACIES TARGET SPECIFIC NICHE OR DISEASE STATES

Independent specialty pharmacies are facing competitive pressures and struggle to gain access to insurer and PBM pharmacy networks. Yet, the number of independent pharmacies specializing in specific niches or disease states (such as cancer, cystic fibrosis, hospice, COPD, and respiratory illness) continues to grow. This allows the pharmacy to gain therapy-specific expertise and build relationships with patients and health care providers.

PATIENT POPULATIONS AND THERAPEUTIC AREAS REGARDED AS 'OPEN ACCESS'

All Medicare patients (patients covered under the national health insurance program in the US) are open access, i.e., all specialty pharmacy providers

can provide services to Medicare beneficiaries assuming they meet Medicare's provider requirements. Additionally, many specialty drugs that treat conditions such as cancer, HIV, and hepatitis C have open access distribution.

IMPLICATIONS FOR A PHARMACEUTICAL COMPANY'S COMMERCIAL MODEL

The changing dynamics of the specialty pharmacy market has the following implications for pharmaceutical companies in terms of pull-through of referrals as well as sustaining patients through directly observed therapy (DOT):

- **Prescription Steerage:** PBMs might steer prescriptions from within their network, to their own specialty and mail-order pharmacies

- **Brand Loyalty and Switching Risk:**

As out-of-pocket payment levels rise, patients might switch to alternative lower-cost options such as generics and biosimilars

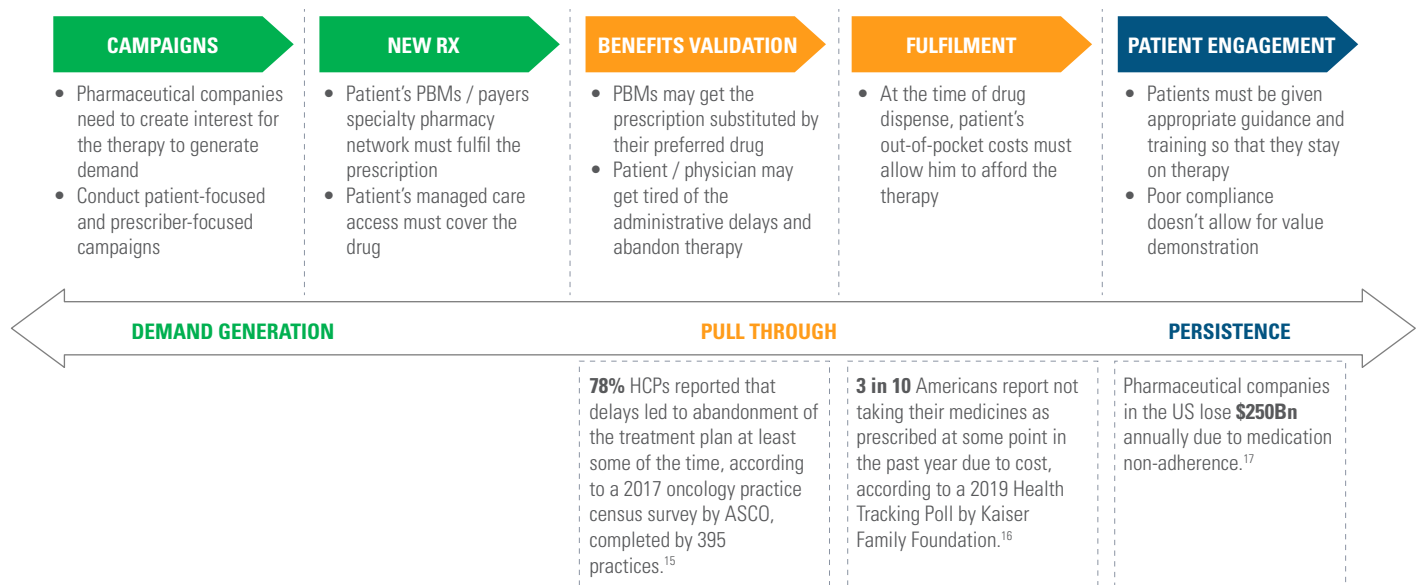
- **Formulary Focus vs. Patient Focus:**

Specialty pharmacies owned by PBMs will focus on driving utilization as per the formulary whereas independent specialty pharmacies will focus on patient needs

- **Patient Follow-Through and Refill Reminders:**

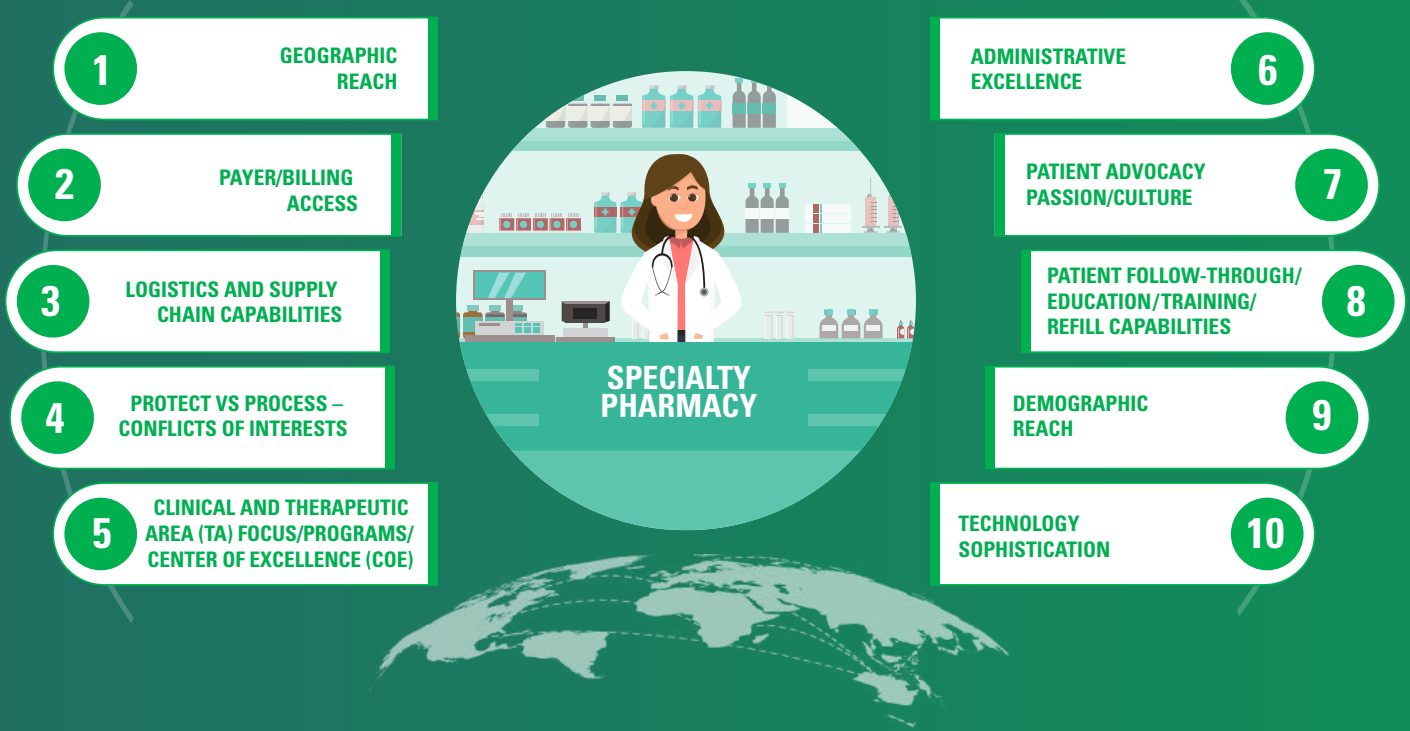
Specialty pharmacies will encourage patient adherence and persistence with the prescribed therapy through refill reminders, patient education, and troubleshooting

As rising out-of-pocket costs and insurer strategies create barriers at each stage of the fulfillment process, pharmaceutical companies should consider the following:



Source: Atria Inc.

Furthermore, to design a patient-centric pharmacy network, pharmaceutical companies need to assess a specialty pharmacy for fit against multiple dimensions such as:



Source: Atria Inc.

Additionally, pharmaceutical companies must evaluate the effectiveness of their current specialty pharmacy network in the context of patient persistence and pull-through, which includes evaluating the following (as illustrated below):

- Data aggregation practices around data ownership, data management, and data consumption
- Performance of their specialty pharmacies and patient hub ecosystem

Attribute	Best Practice	Common Practice	Business Impact
✓ Data Ownership	---	---	---
✓ Data Management	---	---	---
✓ Data Consumption	---	---	---
✓ Network/Hub Management	---	---	---
✓ Network/Hub Performance Guarantees	---	---	---
✓ Patient Funnel Insights	---	---	---
✓ Commercial Model Feedback	---	---	---

Source: Atria Inc.

CONCLUSION

Specialty pharmacies are vital members of a patient's (living with complex, chronic, and rare diseases) health care team and will continue to evolve to provide optimal models of care across a patient's journey, achieve superior clinical and economic outcomes, and expedite their access to care. The size, specialization, and types of specialty pharmacies differ widely. Today, there are several specialty pharmacy solutions

available in the market, owing to the uniqueness of each disease state and motivations of each player in the market to capture revenue from the growing industry. To develop an effective commercial model, pharmaceutical companies need to understand the patient journey for their drugs and assess specialty pharmacies against multiple dimensions to bring in the most suitable specialty pharmacy partners

to fit their unique needs. Hubs and PSAs are essential components of an optimized commercial model to ensure maximum pull-through of demand and drive patient persistence once retained. Data from specialty pharmacies and hubs can provide pharmaceutical companies with valuable insights needed to make key strategic decisions for the successful commercialization of drugs.



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