

PBM Specialty Pharmacies Improve Patient Outcomes and Reduce Costs



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SOLUTIONS IN AN ERA OF RISING DRUG COSTS

As the prices of specialty drugs continue to rise in the United States, patients, healthcare providers, employers, unions, and government programs are searching for ways to make these medications more affordable.

With specialty drug costs averaging more than \$4,500 per prescription,¹ patients and payers do not have the long-term capacity to pay for unmanaged drug costs. Spending on specialty drugs reached \$121 billion in 2015, up more than 15% from 2014.²

At a time when rising specialty healthcare costs are otherwise uncontested, Pharmacy Benefit Managers (PBMs) play a crucial role in working with specialty pharmacies to manage drug benefits, lower costs, and improve the quality of healthcare.

PBMs partner with specialty pharmacies to reduce prescription drug costs and improve quality for patients, employers, unions, and government programs by:

- ▶ Engaging patients to make better health decisions and maximize the use of their benefits
- ▶ Supporting healthcare providers through evidence-based care support
- ▶ Improving patient adherence to their treatment plans and supporting patient safety
- ▶ Assisting physicians in managing increasingly complex medication regimens and patient populations
- ▶ Focusing on clinical outcomes, their corresponding economic savings, and value-based pricing
- ▶ Offering lower cost pharmacy plans that offer convenient access and extra discounts at certain pharmacies
- ▶ Offering lower cost home delivery of medications for patients with chronic conditions
- ▶ Negotiating rebates and discounts from drug manufacturers and drugstores
- ▶ Leveraging competition to reduce the cost of specialty medications and improve adherence
- ▶ Encouraging the use of generics, biosimilars, and more affordable brand medications
- ▶ Managing specialty medications billed under both the pharmacy and the medical benefits

INCREASING COMPLEXITY LEADS TO WASTE IF NOT PROPERLY MANAGED

Given the complexity of specialty drugs, patients require active clinical management, considerable education, and sophisticated logistical support for administering and optimizing the therapeutic outcomes of these drugs. Specialty and other high-cost medications are often misused and underutilized without PBM and specialty pharmacy management programs, support systems, and monitoring tools in place.

Specialty drug benefit management goes beyond price negotiations and plays an important role in improving health outcomes.

It is critical for payers to stay current with evolving benefit management strategies and marketplace conditions that impact specialty medication utilization and spend. Employers, unions, and other healthcare payers therefore rely on PBMs and specialty pharmacies to offer a range of customizable

clinical and operational services that enhance the safety, quality, and affordability of care for patients using specialty drugs.

PBMs and specialty pharmacies utilize teams of specialty-trained pharmacists, nurses, social workers, and insurance coordinators to provide tailored services to help patients achieve the best possible outcomes from specialty therapies. These teams work to:

- ▶ Make medications available to patients — in terms of accessibility and affordability
- ▶ Enable patients access to the right drug at the right time and place
- ▶ Improve care and health outcomes
- ▶ Lower overall treatment costs
- ▶ Utilize data, technology, and leadership across the healthcare system to deliver value

BILLIONS CAN BE SAVED THROUGH BETTER DRUG BENEFIT MANAGEMENT

Pharmacy waste costs the healthcare system billions of dollars each year. Better drug choices, pharmacy selection, and care decisions are needed to achieve healthier patient outcomes and lower costs for patients, employers, and taxpayers.

- ▶ \$37 billion could be saved if patients used the most cost-effective and highest quality pharmacies³
- ▶ \$53 billion is spent annually on higher-priced medications when more affordable, clinically equivalent alternatives are available³
- ▶ 80% of patients taking a specialty drug have at least one other chronic condition⁴
- ▶ 50% of people taking a specialty drug with other chronic diseases fail to take their medication as directed⁴
- ▶ \$337 billion is wasted annually on avoidable medical and pharmacy expenses as a result of patients' non-adherence to medications³

NOT ALL PHARMACIES PROVIDE SUPERIOR SPECIALTY CARE

Pharmacies across the nation provide varying levels of clinical care and product support. States do not legally differentiate specialty pharmacies from traditional pharmacies, so any licensed pharmacy can market itself as a specialty pharmacy. Of the 64,000 pharmacies in the United States, few are considered a specialty pharmacy.

Therefore, PBMs actively work with payers to identify specialty pharmacies that best serve patient and healthcare provider needs. Specialty pharmacies must meet payers' terms and conditions in order to be included in preferred pharmacy networks. These terms and conditions focus on quality clinical care, performance, and cost-saving criteria. Qualified specialty pharmacies must meet payer reimbursement rates to be included in these networks.

Additional Pharmacy Types

Traditional retail pharmacies and pharmacies affiliated with pharmaceutical manufacturers are not typically equipped to manage the full range of products and services that payers and PBMs require for the distribution and active management of specialty drugs.

In contrast to traditional retail and manufacturer-affiliated pharmacies, specialty pharmacies in partnership with PBMs offer a full range of personalized clinical and operational services to enhance the safety, quality, and affordability of care for patients using specialty drugs.

Not all pharmacies provide the same level of comprehensive clinical care and product support...Therefore, PBMs actively work with payers to identify specialty pharmacies that best serve patient and healthcare provider needs.

Traditional Pharmacies

Since any pharmacy can market itself as a specialty pharmacy, it is challenging for patients and payers to assess the quality and depth of care being delivered by a pharmacy. Traditional pharmacies do not have the time, systems, and resources necessary to provide the degree of care needed to ensure the optimal use of specialty medications.

Whereas consultations in traditional retail pharmacies only last an average of 2 minutes, specialty pharmacy clinical consultations average 15 to 18 minutes for patients with serious diseases, such as rheumatoid arthritis, hepatitis C, and cancer.⁵

Without dedicated specialized pharmacists available to patients around the clock and access to comprehensive patient claims data, traditional pharmacies cannot fully support patients and healthcare providers seeking optimal clinical outcomes.

PHYSICIANS PREFER SPECIALTY PHARMACIES OVER TRADITIONAL PHARMACIES

A survey of 400 physicians* who prescribe specialty medications shows high levels of specialty pharmacy usage and satisfaction.⁶

- ▶ Two-thirds of physicians who work with specialty pharmacies believe that few traditional drug stores have the expertise to provide the range of services needed to provide optimal clinical support to patients using specialty medications.
- ▶ 70% of the specialists in these fields who prescribe specialty medications work with specialty pharmacies.
- ▶ Only 2% of the specialists who work with specialty pharmacies believe that all traditional drug stores “have the expertise and capability to provide the different types of specialty medications to patients.”
- ▶ Specialists are satisfied with the specialty pharmacy services by an 89 to 9 percent margin.

**Representing cardiology, neurology, gastroenterology, endocrinology, rheumatology, nephrology, infectious disease, oncology, pulmonary, and hematology specialties*

Manufacturer-Aligned Pharmacies

Not all pharmacies serve in the best interest of patients. Manufacturer-aligned pharmacies frequently market themselves as specialty pharmacies, but in reality they prioritize the needs of pharmaceutical companies over those of patients, healthcare providers, and payers.

This practice is best highlighted by the former relationship between Valeant Pharmaceuticals, a large drug manufacturing company, and Philidor Rx, a self-designated “specialty pharmacy.” In order to improve the sales of their high-priced medications, Valeant offered Philidor Rx significant financial incentives to evade payer drug benefit design. Following a congressional investigation, Philidor Rx was found to have altered doctors’ orders to extract more reimbursements out of payers, changed codes on prescriptions to give the appearance that physicians required patients to be on Valeant’s brand-name drugs instead of less expensive generic

versions, and submitted claims under different pharmacy identification numbers to increase the likelihood of payer approval.⁷

Philidor Rx’s misrepresentation as a specialty pharmacy reflected negatively on legitimate specialty pharmacies across the industry. Rather than serving as a true patient-centered pharmacy, Philidor Rx instead acted on Valeant’s behalf to use questionable business practices to circumvent payer drug benefit design.



PBMs proactively identify pharmacies with limited capacities or mixed motives and remove them from their preferred quality networks. This increased level of scrutiny protects patients and payers from inappropriate medication use and wasteful drug spending.⁸

THE VALUE OF PBM PARTNERSHIPS WITH SPECIALTY PHARMACIES

Prioritizing Patient Care

Patients, healthcare providers, and payers expect specialty pharmacies to offer a range of customizable clinical and operational services that enhance the safety, quality, and affordability of care for patients using specialty drugs. PBMs manage pharmacy networks and work with payers to assess a wide variety of performance and cost-saving criteria to determine each pharmacy's true capabilities and services before entrusting their patients to their care.

Payers expect specialty pharmacy services to include:⁹

Clinical Services

- ▶ **Healthcare provider access:** Provides around the clock access to specially trained pharmacists, nurses, and clinicians who offer patients guidance and insight on disease states, as well as the use and management of specialty drugs
- ▶ **Physician consultations:** Consults directly with physicians to address patient side effects, adverse drug reactions, non-compliance, and other patient concerns
- ▶ **Care management:** Performs disease and drug-specific patient care management services that meet the unique needs of each patient and incorporate multiple safeguards when dispensing and delivering the drug to ensure patient safety
- ▶ **Clinical outcome measures:** Collects data and tracks outcomes for specific patients

- ▶ **Patient adherence programs:** Manages patient adherence and persistency of drug regimens
- ▶ **Patient care quality measures:** Integrates defined quality measures into all aspects of patient care, providing staff with ongoing training, monitoring, and remediation when necessary
- ▶ **REMS programs:** Manages care for manufacturer Risk Evaluation and Mitigation Strategies (REMS) program requirements, including REMS reporting, Phase IV trials, the dispensing of FDA trial drugs under strict protocols, and related clinical and cognitive counseling

Operational Services

- ▶ **Supply chain management:** Adheres to rigorous storage, shipping, and handling standards to meet product label shipping requirements, such as temperature control and the timely delivery of products in optimal conditions
- ▶ **Quality control measures:** Uses enhanced quality control, electronic imaging, drug utilization reviews, and final quality assurance checks when dispensing medications
- ▶ **Care coordination:** Offers coordinating services with other healthcare providers, including those providing skilled nursing services, custodial care, infusion administration, and direct-to-physician distribution
- ▶ **Insurance navigation:** Expedites access to therapy by working directly with insurers and navigating their benefits, utilization management, and prior authorization processes

- ▶ **Patient assistance:** Facilitates eligible patients' enrollment in patient assistance programs and access to charitable resources
- ▶ **Plan optimization:** Aligns economic incentives across medical and pharmacy benefits while helping patients navigate the complexity of sometimes-siloed benefit structures

Leveraging Data & Technology

Specialty pharmacies further differentiate themselves from other pharmacies by leveraging data and technology to ensure the most clinically appropriate use and administration of specialty and high cost drugs, while simultaneously producing savings for healthcare payers.

Specialty pharmacies employ sophisticated data collection systems to generate information that allows payers and PBMs to guide patient care and demonstrate how clinical services and programs lower overall healthcare expenses.

Patients and healthcare providers benefit greatly from pharmacies' use of payer-generated data, which includes information regarding patient medication histories, adherence rates, hospital admissions, and related medical and pharmacy benefit claims data.

Improving Adherence

Adherence to high-cost specialty medications is critical to better outcomes and lower total costs. Costs to the U.S. healthcare system continue to climb each year as a result of medication non-adherence. Rather than treating patients as passive recipients of adherence messaging, specialty pharmacies actively engage patients in strategies that improve adherence and health outcomes. This results in significantly higher rates of patient medication adherence and lower overall medical costs.^{10, 11}

PBMs and payers utilize programs that integrate patient-specific medical, pharmacy, and lab data to identify patients at highest risk for non-adherence.¹² Specialty pharmacy teams harness this data to provide at-risk patients with highly personalized interventions to increase medication adherence

and achieve improved clinical outcomes. By working with patients and incorporating this information into individualized patient care plans, specialty pharmacists are able to provide a superior array of services that address patients' clinical and logistical needs.

Optimizing Doses

The cost of treating highly complex diseases continues to rise and has led to increased payer interest in improving drug management strategies. PBMs rely on the expertise of specialty pharmacists and data-driven utilization management programs to ensure that patients take the optimal doses of their medications. Recent PBM specialty pilot programs resulted in 11% overall savings for patients with hemophilia¹³ and 8% savings for patients using immunoglobulin drugs.¹⁴

Increasing Value

Value-based payments have the potential to reduce excessive and wasteful spending while simultaneously creating incentives for innovation. Specialty pharmacies support payers' moves to tie reimbursements for prescription drugs to drug efficacy measures by collecting and analyzing patient outcomes data.¹⁵

PBMs are well-positioned to address deficiencies in the current system that impede progress toward improved adherence, optimized dosing, and increased value. Thus, payers depend on PBMs to identify the specialty pharmacies that will provide patients with the highest level of specialty clinical and operational care available in the industry. By integrating the use of these specialty pharmacies with other drug utilization management tools, PBMs and payers provide patients with access to holistic specialty care that optimizes the value of medications used to treat complicated diseases.

PREFERRED SPECIALTY PHARMACY QUALITY NETWORKS

PBMs collaborate with specialty pharmacies to provide patients, healthcare providers, and payers with complex clinical care that is guided by value-based principles. When specialty pharmacies meet clear service, performance, and cost-saving goals, they are eligible for inclusion in PBM and payer quality-focused preferred networks. These specialty pharmacies provide patients with cost-efficient delivery options, care coordination programs, and insurance benefit navigation.

Preferred pharmacy quality networks positively impact patient clinical outcomes and medication adherence. These pharmacy networks encourage patients with chronic and complex diseases to establish a pharmacy home where they receive coordinated care and effective medication adherence support.¹⁶

Specialty Network Inclusion Criteria

Payers rely on PBMs to develop criteria for identifying the highest-quality and most cost-efficient specialty pharmacies in the industry.

PBMs consider specialty pharmacy accreditation as a baseline key indicator in assessing a pharmacy's commitment to quality and safety. The three most prominent accreditation bodies in the U.S. are URAC, The Accreditation Commission for Health Care (ACHC), and The Center for Pharmacy Practice Accreditation (CPPA).

Because securing accreditation from one of these organizations does not provide assurance that a pharmacy can, or will, carry out specialty drug benefit plan design or implement cost-saving tools, PBMs' preferred specialty network criteria pick up where accreditation organizations leave off in terms of fulfilling payer and plan sponsor requirements for specialty benefit plan design.

SUCCESS OF PREFERRED NETWORKS IN MEDICARE PART D

Approximately 36 million seniors and disabled individuals are enrolled in Medicare Part D prescription drug plans. Satisfaction with these drug plans averages about 90 to 95 percent.¹⁷ These drug plans vigorously compete for seniors' patronage. Under the Medicare Modernization Act of 2003, the plans use a variety of techniques to keep premiums affordable, including tiered formularies, preferred pharmacy networks, and mail-order drug suppliers. PBMs negotiate prices with drug manufacturers and distributors, and contract with pharmacy network providers to secure for seniors the lowest possible drug prices.

The use of tiered pharmacy networks has grown rapidly in recent years and is now standard in Prescription Drug Plans (PDPs). The share of stand-alone PDPs with tiered pharmacy networks grew from 7% in 2011 to 85% in 2016. These plans have 96% of PDP enrollees.¹⁸

Though subsidized by Medicare, the premiums seniors pay are a function of the plan they choose — and ultimately of total program expenditures. Premiums have remained relatively stable because competition among drug plans has kept spending far lower than projected. Nearly a decade ago, the Medicare Trustees projected the per capita cost of Medicare drug benefits would be \$1,971 in 2006, rising to \$3,047 by 2013. However, the actual per capita cost in 2013 was only \$1,773 — nearly 42 percent lower than initial projections.¹⁷

Preferred network standards and metrics provide payers with insight on the differences that exist along the spectrum of pharmacy business models, service offerings, and use of data to inform patient care. Through preferred specialty pharmacy networks, patients and providers are provided with access to reliable and robust patient-centered care.

Credentialing criteria for preferred specialty pharmacy quality networks may include, but are not limited to:¹⁹

- ▶ **Accreditation:** Specialty pharmacy is accredited by one or more independent specialty pharmacy accreditation organizations
- ▶ **Organizational structure:** Specialty pharmacy has a comprehensive organizational structure in place to support all necessary operations
- ▶ **Pharmacy accessibility:** Clinical staff members are available to speak with patients at all times of the day and night to answer any questions or concerns they have regarding their treatment
- ▶ **Appropriate therapy:** Specialized pharmacists verify the correct medication is being prescribed at the correct dose and frequency
- ▶ **Care coordination:** Specialty pharmacy staff provide patients with all necessary supplies, specialty drug administration training, and support
- ▶ **Adherence management:** Specialty pharmacy staff contact patients before each scheduled fill to arrange the dispensing of their next dose, identify potential adherence barriers, and manage treatment effects
- ▶ **Ancillary supplies:** Patients are provided with all necessary supplies needed to administer their medications
- ▶ **Counseling:** Pharmacists provide patients with relevant information regarding their specialty drug and disease state
- ▶ **Specialty medication fulfillment:** Specialty pharmacies ensure that specialty medications are stocked and readily accessible for timely dispensing to patients

- ▶ **Cold chain management:** Specialty pharmacies have detailed cold chain management procedures that include thorough tracking requirements for drugs that need refrigeration
- ▶ **Specialty clinical protocols:** Pharmacists closely follow all disease state and drug-specific clinical protocols for dispensing, monitoring, and patient follow-up processes
- ▶ **Patient assistance programs:** Patients have access to financial assistance programs provided through drug manufacturers, foundations, and other organizations
- ▶ **Patient education:** Specialty pharmacies ensure multiple languages and methods of education are available to patients

PREFERRED PHARMACY NETWORKS OFFER BETTER PATIENT CARE & LOWER DRUG COSTS

According to the Federal Trade Commission (FTC), cost savings generated by pharmacy networks and selective contracting are passed on to consumers in the form of lower premiums, lower out-of-pocket costs, and better services. In a letter to the Centers for Medicare and Medicaid Services, the FTC wrote:²⁰

“The proposed any willing pharmacy provisions threaten the effectiveness of selective contracting with pharmacies as a tool for lowering costs. Requiring prescription drug plans to contract with any willing pharmacy would reduce the ability of plans to obtain price discounts based on the prospect of increased patient volume and thus impair the ability of prescription drug plans to negotiate the best prices with pharmacies. Evidence suggests that prescription drug prices are likely to rise if Prescription Drug Plans (PDPs) are less able to assemble selective pharmacy networks. The proposed provisions may also hinder the ability of plans to steer beneficiaries to lower cost, preferred pharmacies and preferred mail order vendors through financial incentives or other terms.”

COST SAVINGS

Few pharmacies are able to provide high-touch patient care services while simultaneously delivering cost savings. When specialty pharmacies apply PBM drug benefit design tools to patient care, they have the ability to increase medication adherence rates, reduce hospitalizations, lower patient medical expenses, and save on overall healthcare costs.

Specialty pharmacies consistently outpace other pharmacies' abilities to contain costs and manage complex criteria for patients using specialty drugs. Access to PBM and payer pharmacy, medical, and specialty benefit data allows specialty pharmacies to develop highly customizable programs and services that result in up to a 50% difference in cost trends.²¹

Since other pharmacies have limited capabilities to synthesize and incorporate payer-generated data, payers increasingly rely on PBMs and these specialty

pharmacies to provide high-quality, data-driven interventions while managing short- and long-term costs.

PBMs work with specialty pharmacies to create integrated models that employ clinical solutions to support patients across the continuum of care. Simplifying complex drug treatment regimens for patients through outreach from specialty pharmacists can halve the number of patients who are readmitted to the hospital — improving care and significantly lowering costs to the healthcare system.²²

Over the next ten years, PBMs and specialty pharmacies will save payers and patients an estimated \$250 billion on the cost of specialty medications and related non-drug medical costs when compared to what expenditures would be with limited use of PBMs and specialty pharmacies.²³

PAYERS RELY ON PBMs FOR DRUG COST MANAGEMENT

More patients continue to use complex specialty drugs to treat conditions such as rheumatoid arthritis, multiple sclerosis, hepatitis C, and cancer. PBMs save payers and patients 40-50% on their annual prescription drug and related medical costs compared to what they would have spent without PBMs.²⁴

- ▶ PBMs save payers and patients an average of \$941 per person per year
- ▶ PBMs save the health care system an average of \$6 for every \$1 spent on PBM services
- ▶ Over the next 10 years, PBMs will help prevent 1 billion medication errors
- ▶ Through specialty pharmacy services, PBMs will help extend and improve the quality of life for patients with multiple sclerosis and rheumatoid arthritis by approximately 1 million quality-adjusted life years (QALYs) over 10 years

PRESERVING QUALITY PATIENT CARE

Any Willing Pharmacy Laws

Provisions that enable any willing pharmacy's involvement in PBM networks — including specialty pharmacy networks — jeopardizes the quality of care patients receive, raises costs, and forces payers to use unqualified pharmacies to administer specialty drug therapies.

Proponents Any Willing Pharmacy (AWP) laws claim that requirement to include all willing pharmacies in preferred quality networks will assure convenient access to pharmacies. These laws, however, have several negative consequences:

- ▶ Requiring payers to allow any pharmacy willing to accept its terms and conditions to participate in its networks severely restricts a plan's ability to

achieve higher levels of cost savings and enhance the quality of its pharmacy services for patients

- ▶ Payers must then contract with pharmacies that are inefficient or provide inferior services
- ▶ Opening pharmacy networks to all pharmacies reduces the volume of sales for other network participants, ultimately resulting in smaller discounts and a less competitive marketplace

Requirements to use any willing pharmacy consistently lead to higher drug prices since pharmacies face no threat of lost sales if they are not performing up to standard. They have no incentive to offer their most competitive terms to payers.

CASE STUDY: THE VALUE OF SPECIALTY PHARMACIES

For patients with pulmonary arterial hypertension (PAH) — high blood pressure in the lungs — the transition from infused to oral therapy is safe, yet complex due to frequent dosing adjustments and the need to balance efficacy with common adverse events. The transition process requires a collaboration between specialized clinicians and experienced specialty pharmacists.

Even though clinical guidance proposes that patients should transition to the oral medication in 5 days or less, this specialty pharmacy team found that the average transition time was 47 days. Only 18% of patients transitioned in five days or less.

These specialty pharmacists leveraged their access to electronic medical record (EMR) data to determine that 82% of patients required more time to transition from infused to oral PAH therapy. This insight allowed them to adapt their clinical programs to better fit their patients' needs.²⁵

Due to the complex nature of PAH and the limited experience prescribers have in managing transitions, patients require around the clock access to specially trained pharmacists and nurses.

Specialty pharmacies provide patients with the confidence that clinicians are with them every step of the way. These pharmacies create transition plans tailored to each patient, and offer insights and data to support prescribers. Combined, these resources help patients better manage their conditions and medications, while offering a more personalized pharmacy experience.

THE SOLUTION: GREATER USE OF PROVEN PBM TOOLS

Specialty pharmacies continue to develop innovative capabilities that serve evolving patient needs. PBMs partner with specialty pharmacies to develop strategies to maintain access to high-quality care while ensuring that money spent on specialty drugs is not wasted. Data-driven interventions used by specialty pharmacies enable pharmacists to provide more frequent, targeted patient interventions than traditional and manufacturer-affiliated pharmacy channels provide.

Targeted clinical programs offered through specialty pharmacies improve patient care, lower total drug spending, and reduce inappropriate drug utilization. The continued use of these programs will be essential as PBMs and payers work to manage healthcare expenses and enable access to innovative, life-saving drugs.

State and federal laws and regulations that place restrictions on payers and PBMs' ability to manage specialty drugs and specialty pharmacy preferred networks decreases the quality of care patients receive, while substantially increasing prescription drug and healthcare costs.



Allowing PBMs to work with qualified specialty pharmacies to further develop tools to manage specialty drugs will yield significant value across the healthcare landscape and will create ongoing financial savings for patients, employers, and payers in every state.

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About sPCMA

With the costs and complexity of specialty drug treatments rising, PBMs offer a number of services designed to improve the quality of care for patients across the nation while managing overall costs to the health care system. To encourage complete coordination across the continuum of patient care, payers depend on PBMs' utilization management tools, including the use of specialty pharmacies, to ensure that the value of therapy is optimized, at the most reasonable costs possible. sPCMA was established as a division of PCMA to provide thought leadership to the industry on matters of public policy, industry relations, and the value of specialty pharmacies.



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