

PBMs Provide Clinical Value to Patients, Doctors and Other Healthcare Providers



Contents

Introduction	1
Vital Services for an Evolving Marketplace	2
Essential Patient Services.....	3
Payer Expectations and Challenges	4
Critical PBM Functions that Physicians Rely On	5
Ensuring Clinical Outcomes and Reducing Healthcare Waste.....	7
Conclusion.....	8
References.....	8

INTRODUCTION

Pharmacy Benefit Managers (PBMs) are critical to the delivery of high-quality, cost-effective healthcare. PBMs have long been recognized for their ability to create savings through providing clinical utilization management programs, offering more affordable pharmacy channels, negotiating discounts with drug manufacturers and retail drugstores, and encouraging the use of low cost generics and affordable brands.¹

In today's marketplace, the increased drug spend and utilization of high-cost specialty medications are creating an even greater need for the comprehensive services offered exclusively by PBMs.²

PBMs 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 and improving patient adherence to their treatment plans
- ▶ Assisting physicians in managing increasingly complex medication regimens and patient populations
- ▶ Partnering with specialty pharmacies to support patient safety, reduce errors, and improve the lives of patients
- ▶ 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 and more affordable brand medications
- ▶ Managing specialty medications billed under both the pharmacy and the medical benefits

VITAL SERVICES FOR AN EVOLVING MARKETPLACE

PBMs were created to meet specific needs in the healthcare marketplace. Today, the industry has a 40+ year track record of clinical and cost management innovation. In the late 1970s, the first PBMs focused on claims processing, mail order pharmacy services, and retail pharmacy network management. As the drug benefit marketplace matured, payers asked for additional services. PBMs began to offer formulary design and management services, negotiate on behalf of payers with pharmaceutical manufacturers for rebates, carry out utilization analyses, distribute specialty drugs, and provide patient-focused services such as adherence programs, patient education, and counseling services.

The services PBMs have always provided — processing pharmacy claims, creating and maintaining retail pharmacy networks, using volume purchasing power to negotiate favorable unit cost savings, managing drug mix to encourage generics and preferred brands, reducing inappropriate use, and improving patient adherence — continue to be relevant in today's marketplace. PBMs have evolved over time to meet the needs of payers, improve patient health outcomes, support healthcare providers, ensure high quality care, and manage costs.

Cost management is a primary concern for healthcare payers. PBMs deliver tremendous value to public and private payers. PBMs collaborate with payers and healthcare providers to ensure that patient needs are balanced with payer fiduciary responsibilities.³ A recent analysis by Visante found that PBMs save payers and patients 40–50% on their annual drug and related medical costs compared to what they would have spent without PBMs.⁴ This equates to a per capita annual savings of approximately \$941.

Beyond cost management, PBMs provide pharmacy expertise, innovative clinical patient engagement programs, and integrated specialty care management programs. To meet the needs of today's complex healthcare market, payers ask PBMs to innovate rapidly to manage drug costs, ensure clinical appropriateness, and provide support for patients and physicians. This enables payers to make better value-based decisions, promote medication adherence, and provide differentiated services to the wide variety of patients and consumers.

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ESSENTIAL PATIENT SERVICES

Specialty medications and biologics raise hopes for healthier, longer patient lives, yet pose new challenges for the healthcare system. Specialty medications have moved beyond treating only rare and orphan diseases to treating chronic conditions such as rheumatoid arthritis, multiple sclerosis, and high cholesterol. While specialty medications provide patients with significant benefits, these drugs can be difficult to administer, store, and monitor.

PBMs provide patient-centered services that specialty patients and their healthcare providers have come to rely on. These services help ensure that medications are taken safely and effectively.

PBMs help patients manage costs, access clinical experts around the clock, and be engaged in their own care by taking advantage of tools and programs that support them as they manage their health. This is particularly important as healthcare benefit plans encourage patients to be more engaged in value-based care decisions.

Greater patient engagement has the potential to transform value-based healthcare delivery and improve outcomes. However, it is often difficult for physicians to achieve significant patient engagement levels. PBMs therefore rely on expert staff who study and test ways to better engage patients to develop programs that are scientifically proven to build sustained patient engagement.

Beyond encouraging patient engagement, PBM clinical specialists provide numerous additional forms of clinical support for patients. Because specialty medications often require specialized clinical support for patient administration (including complex dosing and injected or infused delivery), PBM specialists help ensure adherence and persistence to medications while monitoring patients for safety issues and possible adverse effects.

PBM clinical experts have a deep knowledge of possible drug side effects and understand ways to mitigate them. These specialists reach out to physicians when patients need additional monitoring or when changes to therapy will reduce side effects, lower patient out-of-pocket costs, or improve efficacy.



PBM tools and specialty clinical programs are patient-centric and make use of advances such as mobile applications, virtual consultations, and algorithms that provide patients with support when, where, and how they need it.

PAYER EXPECTATIONS AND CHALLENGES

Payers are faced with providing valuable drug benefits that optimize clinical care while also managing costs. Specialty drugs in particular create a number of challenges for payers as utilization and costs continue to rise. The U.S. Food and Drug Administration (FDA) has approved hundreds of new specialty drugs, along with new indications for existing specialty drugs. Only 2–5% of patients use specialty drugs, but this minority of patients represents a growing disproportionate share of overall drug and medical costs.⁵

To address these challenges PBMs work with specialty pharmacies to provide patients, physicians, and payers with clinical value by:

- ▶ accurately dispensing complex medications
- ▶ providing ongoing clinical support directly to patients and their caregivers
- ▶ improving patient clinical outcomes
- ▶ managing drug-related side effects, engaging in adherence and persistency support
- ▶ monitoring drug safety through FDA-approved Risk Evaluation and Mitigation Strategy (REMS) programs

PBMs and specialty pharmacies collaborate to develop clinical criteria to ensure the right drug and right dose for each patient. They create strategies that help physicians and patients select the optimal drug, they manage the drug spend across both the pharmacy and medical benefits, and they ensure the most clinically appropriate access to drugs for patients.

Specialty pharmacies provide capabilities that retail pharmacies are not designed to provide. Many specialty drugs require special handling and cold chain storage, requiring patient training or skilled medical personnel to administer. Most large PBMs have developed or acquired in-house specialty

pharmacies that address the unique dispensing needs of drugs requiring special handling, in addition to the needs of patients using these drugs. These pharmacies also help patients and providers navigate the patient's drug benefit.



Payers continue to recognize the significant value that PBMs and specialty pharmacies provide. A recent research survey of payers by the Pharmacy Benefit Management Institute (PBMI) found that payers are 6 times more likely to report that specialty pharmacies provide **better unit prices** than retail pharmacies, and nearly 17 times more likely to report that specialty pharmacies provide **superior clinical programs** when compared to retail pharmacies. Payers were more than twice as likely to report that specialty pharmacies provide patients with **better access to specialty pharmacist services and to copay assistance programs** than do retail pharmacies.⁶

PBMs additionally play a critical role in managing specialty drug costs. PBM tools and utilization management programs developed over the last two decades to control traditional non-specialty drug trend are now being applied successfully to specialty drugs. These tools include formulary management, drug utilization review, prior authorization, step therapy, pharmacy network design, and site of care management programs.^{2, 6, 7} Innovative strategies such as medical claims referencing and use of genomic and other advanced molecular diagnostics are enabling PBMs to ensure that patients receive targeted and cost-effective drug therapies.⁷

PBMs also help payers create value for patients through the use of lower-cost generics and biosimilars. As biosimilars enter the U.S. market, they are creating the opportunity for additional patient and payer savings. As demonstrated by their ability to lower costs through the use of generic drugs, only PBMs are positioned to advance competition in the biosimilars market to reduce costs and create new savings.

During the initial movement to use generic drugs, PBMs worked with payers to negotiate discounts, promote fair competition, and advise payers on benefit design strategies to promote the use of safe and effective generics. PBMs provided education and research that helped gradually shift patient and physician understanding and acceptance of the safety and efficacy of generic drugs.⁸ As a result,

today 88% of prescriptions filled are for generic drugs.⁹ Industry-wide, this has resulted in an average price reduction of 80–85% when compared to originator brand products, with annual generic drug savings estimated at \$227 billion in 2015.^{9,10}

While savings of this magnitude may not be identical for biosimilars due to the complexity of the manufacturing and drug delivery processes, significant PBM-driven savings are expected.

PBMs are an organizing force pushing for a clearer biosimilar approval pathway and continue to keep the issue from being suppressed by the lobbying efforts of manufacturers who stand to lose billions from biosimilar competition.¹¹ As the primary source of information on specialty drugs, PBMs ensure that payers have access to every possible tool to reduce costs and improve clinical outcomes.⁶

CRITICAL PBM FUNCTIONS THAT PHYSICIANS RELY ON

PBMs serve an often-overlooked role in providing clinical support to physicians in the areas of integrated care delivery, value-based reimbursement, and population health management.

Drug safety is an important component of integrated care delivery. More than 15% of the U.S. population now takes five or more prescription drugs, compared to only 4% in the late 1980s/early 1990s.¹² As more medications are used together, the risk of drug interactions, duplications, and medication contraindications increases. Additional layers of complexity are added as more patients see multiple physicians for their care and use more than one pharmacy (up to 40% in a recent study).¹³

These factors reduce a physician's ability to identify potential problems and errors across their patients' increasingly fragmented care.

Comprehensive Medication Management (CMM) programs are among the most effective approaches to addressing the rising errors and costs associated with fragmented care.¹⁴ CMM programs consist of a formal collaboration between physicians, other members of the patient's healthcare team, and qualified clinical pharmacists who work together to identify and document medication-related problems, leverage evidence-based guidelines, and initiate, monitor, and modify drug therapy as needed to ensure that best practices are followed. Unfortunately, CMM programs are still rare in practice.

Since PBMs have a uniquely comprehensive view of all healthcare providers and pharmacies that patients visit over the course of their care, PBMs perform many of the roles CMMs would otherwise play. This is particularly valuable when patients with multiple conditions are prescribed medications by multiple healthcare providers. PBMs use clinical safety programs like drug utilization review (DUR) to alert pharmacists and physicians that a newly prescribed medication might not be safe, prior authorization (PA) to ensure appropriate use of the medication, and step therapy to guide patients to more effective, lower-cost therapies before escalating therapy, as clinically appropriate.

Critical PBM programs help physicians adhere to clinical guidelines and manage their patient populations. These programs provide a safeguard for patients and physicians by ensuring that clinical criteria are met, leading to safer, more appropriate, and more affordable care.

Value-based reimbursement financially rewards physicians for providing cost-effective, high-quality patient care. While value-based contracts are becoming more prevalent, many physicians lack the necessary information to participate in these creative contracts. Physician electronic health record (EHR) systems are often inadequate and cannot support the data needed for value-based reimbursement.¹⁵ PBM-generated data can lead to higher value- and outcomes-based reimbursement.

Healthcare providers also often lack the time and pharmacological expertise to review the reams of available literature that compare drug efficacy, value, and costs. PBMs, however, prioritize the development of expert-derived clinical guidelines to provide healthcare providers with information and drug formularies that provide safeguards, encourage adherence to guidelines, and support the use of lower-cost, clinically proven drugs. With these PBM tools at their disposal, healthcare providers are more likely to achieve and sustain financial rewards through value-based reimbursement.

TOOLS AND PROGRAMS PBMs PROVIDE PHYSICIANS:

- ▶ Drug utilization review (DUR) programs
- ▶ Medication adherence and persistency programs
- ▶ Medication therapy management (MTM)
- ▶ Clinical patient support provided by specially trained pharmacists, nurses, nutritionists, and patient educators
- ▶ Population health information and patient support

PBMs use a multifaceted approach to population health management. This provides significant value to healthcare providers and health plans. For example, PBMs are able to identify patients under a physician's care who meet guidelines for the use of statin medications to lower blood cholesterol but have not been prescribed one of these important medications. PBMs provide the physician with notifications that highlight the potential gaps in care, either directly or via the patient's health plan, thus allowing the physician to make more well-informed patient treatment decisions.

ENSURING CLINICAL OUTCOMES AND REDUCING HEALTHCARE WASTE

PBMs use sophisticated tools and strategies to ensure that patients and payers are receiving the full value of prescription drugs. PBMs improve clinical outcomes and create sustainable pharmacy benefits by reducing waste in the healthcare system through:

- ▶ Clinically appropriate utilization management programs focused on safety and clinical outcomes
- ▶ Indication-based pricing
- ▶ Pay-for-performance contracts
- ▶ Value-based insurance design
- ▶ Drug adherence programs
- ▶ Medical benefit management
- ▶ Oncology management
- ▶ Site-of-care management

PBMs continue to add new technologies to meet continually evolving marketplace demands. Specialty pharmacy programs offered through PBMs help physicians meet the needs of unique patient populations under their care. By providing support for patients who are living with complex diseases, PBMs help patients, healthcare providers, and payers work toward the commonly shared goal of improving clinical outcomes and quality of life.

The results of these programs are quite remarkable, as highlighted by the following case studies:

Organ Transplant Patient Support Program

This comprehensive transplant specialty pharmacy program not only dispenses immunosuppressive medications to prevent rejection of the new organ, but also provides adherence, clinical management, patient education, and counseling services by transplant pharmacology experts. Total healthcare costs for transplant patients in this program were 13% less than in a matched cohort of patients not in the program.¹⁶

Telephonic Medication Therapy Management Program

This pharmacist-led educational telephonic medication therapy management program provides services for Medicare Advantage Prescription Drug plan patients who have at least two chronic conditions that require 8 or more medications. All-cause total healthcare expenditures per participant were an average of \$3,680 lower over a 9-month period when compared to the pre-intervention period.¹⁷

On-Pathway Lung Cancer Treatment Program

One PBM implemented a clinical pathway treatment program to treat patients with non-small cell lung cancer (NSCLC) based on evidence-based guidelines. Over a 12-month period, NSCLC patients who were treated according to the established pathways achieved a 35% average cost of care savings compared to those treated without regard to the treatment pathway. This cost reduction was attributed primarily to the lower costs for chemotherapy and other medications.¹⁸

CONCLUSION

Pharmacy benefit management is one of the most rapidly evolving segments in the healthcare industry. Over the past decade, prescription drug expenditures have grown faster than any other healthcare category and represent an increasing percentage of per capita health spending.

PBMs are responding to these challenges by providing patients and physicians with clinical services and programs that are essential to ensuring the safety, clinical appropriateness, and efficacy of prescription drugs. With a focus on population health and patient support, PBMs are helping healthcare providers and payers improve clinical outcomes, economic savings, and value-based care models.

PBM tools and strategies enable patients to receive the maximum benefit from their medications, while creating a sustainable pharmacy benefit that reduces waste in the healthcare system. As the system strives to deliver on the “Triple Aim”¹⁹ — lower cost, better health, and improved patient experiences — PBMs are playing a more important role than ever before.

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About PCMA

The Pharmaceutical Care Management Association (PCMA) is the national association representing America's pharmacy benefit managers (PBMs). PBMs administer prescription drug plans for more than 266 million Americans who have health insurance from a variety of sponsors including: commercial health plans, self-insured employer plans, union plans, Medicare Part D plans, the Federal Employees Health Benefits Program (FEHBP), state government employee plans, managed Medicaid plans, and others.



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