



Redefining the Role of Health Systems as a Specialty Pharmacy Solution for Drug Manufacturers

SPECIALTY SNAPSHOT



Specialty drugs now account for more than 55% of net revenue for drug manufacturers.



Among hospitals with 600 or more staffed beds, 89% have a specialty pharmacy, up from about 47% in 2015.



Forty percent of accredited specialty pharmacy locations are owned by healthcare providers, and this constitutes the fastest-growing category of accredited specialty pharmacies.

KEY CONCEPTS

- The ideal care model for complex patients is a model in which the entire health care team is made up of experts in the specific disease state being treated. Integrated health care systems and major academic medical centers provide this level of expertise and coordination.
- Lack of access to specialty drugs, specialty pharmacy benefit carve-outs, and other structural issues can complicate the care of complex patients, often resulting in a disjointed experience that can negatively impact clinical outcomes and total cost of care.
- Shields Health Solutions supports health systems in offering efficient, high-quality patient-centered specialty pharmacy solutions.
- The Shields Performance Platform for Drug Manufacturers provides drug manufacturers with a single point of access to high-performing health system specialty pharmacies across the country.
- One aggregated data feed with robust, real-world data from Shields health systems supplies valuable insights for drug manufacturers.

INTRODUCTION

Innovative specialty pharmacy medications continue to transform patient care and disrupt the prescription drug marketplace. Payers, health care providers (HCPs), manufacturers, and patients are evolving to meet the challenges presented by these transformative drugs. Manufacturers now have complex and unique business requirements, including selecting and managing the appropriate channels for limited distribution drugs (LDDs), while health systems are assuming more of the risk for outcomes and total cost of care through Accountable Care Organization (ACO) payment models.

To improve clinical outcomes and address rising costs, many health systems have developed proactive, integrated, and coordinated efforts to address the needs of complex patients within specific disease states. As one element of this approach, more than half of integrated health systems, and nearly all of the larger systems, have established or expanded their own specialty pharmacy operations. These owned specialty pharmacies provide point-of-care connectivity to the care team: local, hands-on patient monitoring supported by state-of-the-art care protocols, integration with the electronic medical records (EMR), seamless access to lab values and other data.

THE HEALTH SYSTEM CONUNDRUM

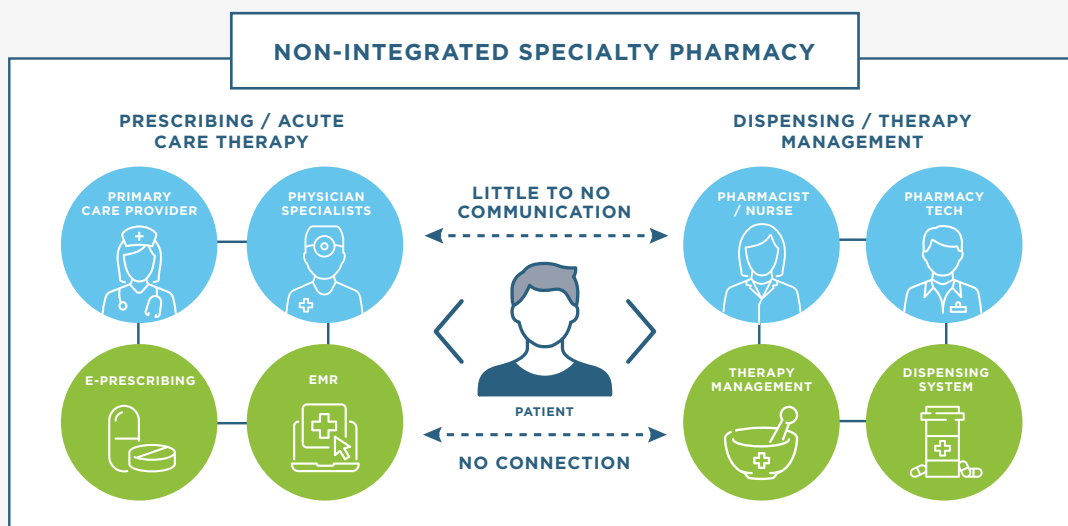
Patients who require specialty pharmacy services usually receive their care through integrated health systems. Specialists and relevant clinical programs attract these complex patients, who are likely to have several chronic diseases and to be taking multiple medications. Specialists at these hospitals and health systems conduct clinical trials, develop treatment protocols, and prescribe specialty medications. This critical mass of patients and specialists, in a coordinated, local context, produces a concentration of expertise and high quality of care.

The conundrum: Drug manufacturers sometimes dismiss health systems when developing a brand strategy for specialty medications — and this can appear to be a rational business decision. Certainly, building relationships with health systems across the country, one at a time, represents a major investment in time, effort and expertise. Thus, despite the concentration of expertise and high quality of care that health systems provide, they are often not able to access any given patient’s prescribed specialty drug product. This limits the

ability to provide fully integrated care that would maximize clinical outcomes and deliver the best possible patient experience.

When distribution of a specialty drug is limited to a handful of the largest specialty pharmacies, health systems must cede control of the medication management and delivery component of care to an organization whose capabilities, customer service, and geographical proximity may be suboptimal for meeting the needs of specialty patients. This situation disconnects drug dispensing and therapy management from the care itself.

At times, hospitals and health systems that have been providing a specialty drug to patients during a clinical trial find themselves “locked out” of distribution once the drug becomes commercially available. Institutions and clinicians who were once very connected to a patient’s care, with access to all necessary information, are suddenly missing vital updates regarding drug therapy. The care of vulnerable, complex patients becomes fragmented, potentially compromising effective clinical outcomes and increasing the total cost of care. Lockouts can also increase time to therapy.



When it is mandated that specialty pharmacy services be obtained from a non-integrated third party, critical information about these complex patients is at risk between different companies that do not talk to one another.

SOLVING THE CONUNDRUM OF A HEALTH SYSTEM-BASED STRATEGY FOR MANUFACTURERS

For drug manufacturers, these health system specialty pharmacies offer the opportunity to distribute their drugs through the most expert channels, in the most patient-centered possible way. Yet, while health systems are the ideal providers of specialty pharmacy services, any given health system alone might not have enough patients to be able to access LDDs, and, as noted previously, manufacturers may find it impractical to develop relationships with numerous individual specialty pharmacies.

The solution: Drug manufacturers must find a way to access the expertise of health systems and their specialty pharmacies through a single point of contact.

HIGH PERFORMANCE, AT SCALE, WITH A SINGLE POINT OF ACCESS

Shields and its health system partners exemplify the potential of integrated specialty pharmacy. Through the Shields Performance Platform for Drug Manufacturers, drug manufacturers can connect to this distribution channel and exceptional level of performance through a single point of access.

Shields health system partners have a full array of capabilities to meet and exceed manufacturer requirements, offering a better solution than the all-too-common non-integrated specialty pharmacy model. A consistent, cutting-edge data platform meets the critical data needs of drug manufacturers, as well as of payers and the health systems themselves. A single point of contact for contracting eliminates the need for a manufacturer to negotiate and manage multiple contracts with health systems, while offering access to a large number of patients. This model also has the power to hold health system partners to the rigorous standards required by LDD contracts, removing this burden from the manufacturer.

A pioneer in helping health systems integrate specialty pharmacy into their operations and work more seamlessly with manufacturers, Shields now has a national footprint encompassing more than 75 health systems, including 850 hospitals, that represent more than 1.5 million patient lives, providing national reach for LDDs. Through its combination of centralized



Shields average time to therapy.

A single point of contact for contracting eliminates the need for a manufacturer to negotiate and manage multiple contracts with health systems.

management and localized patient care, Shields and its health system partners meet and exceed manufacturers' specifications and expectations, including:

- Robust and accurate data capture and reporting capabilities
- Consistent operating standards
- Comprehensive adverse event reporting
- Experienced REMS implementation and management
- Team approach to breaking down barriers to initiation of therapy
- Innovative adherence and therapy management programs, supported by TelemetryRx® technology
- A team dedicated to studying and improving clinical outcomes
- Strong, consultative payer relationships

Shields' integrated care model focuses on access to better quality care for more patients through a dedicated team of specialty pharmacy experts, a proven collaborative care model which includes pharmacists, pharmacy liaisons and patient advocates, and integrated technology solutions.

Shields health system partners meet and exceed manufacturers' requirements, including adverse event reporting and REMS implementation and management.

COMPREHENSIVE ADVERSE EVENT REPORTING

A commitment to patient safety aligns with manufacturers' goals of assuring patient safety through monitoring to identify post-launch trends. For Shields health system partners, adverse event (AE) capture and reporting is a priority, including ongoing training on product-specific AE documentation requirements. Standard operating procedures ensure that information received from all patient touchpoints is captured and reported in a timely manner. Audits of patient encounters are performed regularly.

EXPERIENCED REMS IMPLEMENTATION AND MANAGEMENT

Shields health system partners implement REMS programs of all complexities with tight operational control and strict adherence to documentation requirements. Because the integrated specialty pharmacy is engaged at the point of care, REMS requirements are an important part of the treatment protocol rather than simply items on a checklist. Shields provides a dedicated team that helps build, manage, and support REMS programs, as well as audit compliance.

TEAM APPROACH TO INITIATION OF THERAPY

The Shields model breaks down barriers to initiating specialty therapy, which are quite frequently economic barriers. The onsite pharmacy liaison and centralized support staff work to expedite the prior authorization process and find creative solutions to financial obstacles. They identify patient assistance programs (PAPs), grants, copay cards, and other sources of financial assistance more quickly than patients and their family caregivers can, if they are even aware of the programs. With this help, patients can begin therapy quickly.

If a manufacturer uses a hub, the health system partner's dedicated pharmacy liaison proactively contacts the hub to get the product to the patient as quickly as possible. When a manufacturer does not use a hub, full medical and pharmacy benefits investigation and prior authorization (PA) coordination are provided. Proximity to physicians and routine access to the EMR enable health system specialty pharmacies to access information for successfully gaining approvals for reimbursement appeals, as do solid payer relationships.

INNOVATIVE ADHERENCE AND THERAPY MANAGEMENT PROGRAMS

A significant differentiator from specialty pharmacies is that Shields health system partners provide innovative therapy management programs that engage the patient's entire care team. This offers significant benefits to patients, payers, and drug manufacturers. Disease-specific therapy management ensures potential problems are detected and resolved, opportunities to keep patients on therapy are identified and acted upon, and quantifiable results are captured and reported. Shields has dedicated clinical teams to support its health system partners across a variety of disease states.

Integrated specialty pharmacies have the ability to assist patients throughout their journey in a multi-faceted way, including screening for mental health, especially for patients on high-risk medications and therapies. Health systems specialty pharmacy teams also provide treatments for conditions that are at high-risk for mental health challenges, such as opioid disorders and multiple sclerosis. Many problems are resolved through these programs.

CONTRAINDICATED DRUG FOR A HEP C PATIENT

At one health system partner, a patient started on Eplclusa® for Hepatitis C. As the therapy management nurse prepared to make her initial call to the patient, she discovered in the electronic health record that the patient had been prescribed omeprazole for acid reflux by a family



Number of disease states supported by Shields, including oncology, auto-immune diseases, rheumatology, and more.

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practice provider in her hometown just six days later. The use of omeprazole is contraindicated with Epclusa and, depending on the dose, can interfere with Epclusa's effectiveness. Therefore, the patient and the hepatology clinic provider were contacted, and the patient stopped taking omeprazole.

GOING ABOVE AND BEYOND FOR AN ARTHRITIC PATIENT

A patient was prescribed a medication for Adult-Onset Still's Disease, a rare type of inflammatory arthritis. The specialty pharmacy liaison completed the prior authorization, and the pharmacist notified the physician of the approval, voicing concern to the physician about the medication's complicated administration instructions. The pharmacist researched nursing programs that would go to the patient's home to reconstitute and inject the medication, selected the Novartis visiting nursing program, and coordinated with the physician's office to fill out the paperwork and enroll the patient in the program. This is the exceptional customer service and patient care that health system-based specialty pharmacy can provide.

STRONG, CONSULTATIVE PAYER RELATIONSHIPS

Payer access is critical to providing specialty products. Shields builds consultative payer relationships and, with aggregate data from its network of health system partners, provides important information not typically available to payers. Information from the HCPs' clinical and practical perspective regarding a specialty product's use makes it possible for the payer to create better policies. The Shields approach also enables payers to demonstrate value to their employer clients by showing improved outcomes for specialty products.

Shields Performance Platform for Drug Manufacturers

Integrated health systems of hospitals, clinics and other health care providers put the patient at the center and are ideally suited to provide specialty pharmacy services to patients.



CONCLUSION

Access to the high-performing specialty pharmacies of leading health systems and academic medical centers provides drug manufacturers an innovative, patient-centered way to build their health system strategy with efficiency, integrity, and rigor. With its platform for facilitating this access, Shields views its manufacturer relationships not simply as contractual obligations, but as strategic, long-term, and mutually beneficial business partnerships.

Shields removes the barriers that prevent drug manufacturers from using integrated health systems as part of their brand strategy. This eliminates unnecessary disruptions in patient treatment and care. In turn, when health systems have access to the specialty drugs required by many complex patients, they can provide high-quality, continuous care that can ultimately result in better health outcomes.

Shields makes it easy for manufacturers to work with health systems by:

- Aggregating data
- Requiring and supporting high performance standards
- Providing analytics and insights on real-world drug usage
- Ensuring patients initiate and stay on therapy

Everyone benefits when health systems and academic medical centers can access specialty drugs and therapies for their patients.

ⁱ IQVIA Institute. The Use of Medicines in the U.S. 2022: Usage and Spending Trends and Outlook to 2026. Accessed 9.20.22.

ⁱⁱ "Hospitals Continue Their Startling Expansion into Specialty Pharmacy." August 18, 2020, Drug Channels Institute. Accessed October 10, 2022.

ⁱⁱⁱ "The Specialty Pharmacy Accreditation Boom Slows." May 18, 2021, Drug Channels Institute. Accessed October 17, 2022.



ABOUT SHIELDS HEALTH SOLUTIONS

Shields Health Solutions is the premier specialty pharmacy accelerator in the country. The Shields Performance Platform, an integrated set of solutions, services and technology, is intentionally designed to elevate payer and drug access for specialty pharmacies, elevate health outcomes for complex patients, and elevate growth throughout the entire health system. As the foremost experts in the health system specialty pharmacy industry, Shields has a proven track record of success including access to over 80 percent of all limited distribution drugs (LDDs) and most (health insurance) payers in the nation; and a clinical model proven to lower total cost of care by 13%. In partnership with more than 75 health systems across the country through national-scale collaboration, Shields has a vested interest in delivering measurable clinical and financial results for health systems.



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