Identifying & Overcoming Gaps in the Specialty-Pharmacy Ecosystem

By effectively monitoring specialty pharmacies at different stages of drug approval and understanding the challenges patients face, manufacturers can accelerate the delivery of these complex medications.

Executive Summary

U.S. specialty pharmacies are becoming big business. In 2014, consumers increased their spending on specialty medications by an unprecedented 31% from 2013. Moreover, three specialty classes—nflammatory conditions, multiple sclerosis, and cancer—accounted for 60% of total specialty spending in 2013. This upsurge is due in part to U.S. healthcare reform, which generated new models for delivering and paying for care, and underscored the pivotal role that specialty pharmacies now play.

In this climate, specifications for handling, delivering, storing, preparing and distributing specialty drugs prior to administration can challenge manufacturers, who must become adept at identifying and overcoming gaps in their existing care-delivery model. If not addressed, shortcomings in areas like administration, training at the sales and pharmacy levels, and drug utilization management can significantly affect a company’s operations.

Moreover, the many channels involved in specialty drug disbursement underscore the need for organized, systematic improvements in how this process is managed.

Considering these issues, as well as the pharmaceuticals industry’s dynamic landscape, it is imperative for players large and small to ensure they achieve the highest levels of efficiency throughout the stages of delivering complex care. Doing so will serve the two-pronged objectives of today’s pharmaceuticals companies:

- To provide patients with critical life-saving drugs as seamlessly and cost-effectively as possible.
- To improve the company’s bottom line by enhancing operational efficiencies.

This white paper examines the typical stages of a patient’s journey across the specialty pharmacy system, the points that can stall the delivery of essential medication, and the crucial role played by managed market players. We also outline a range of descriptive analytics that can help identify and reduce major bottlenecks, as well as potential solutions for addressing these challenges.

Defining a Specialty Pharmacy

A specialty pharmacy provides critical health services, with an emphasis on high-priced
medication therapies that require close pharmacist/patient relationships and involve numerous customers within various therapy areas. The diseases covered by specialty pharmacies range from critical illness such as cancer, to rare genetic conditions. Specialty pharmaceuticals can be injected, infused, administered orally or inhaled.

Specialty pharmacists practice in a variety of environments that focus on specialty medications. Specialty pharmacies support patients in a number of areas: dispensing medication, administering medication therapy, patient advocacy, and treatment compliance, among others. Pharmacists who work in more traditional retail settings concentrate on certain specialty disease states at their practice sites, or work with an affiliated specialty pharmacy to dispense these complex treatments.

Specialty pharmaceuticals, which are used to treat high-cost, chronic and/or life-threatening diseases, can be injected, infused, administered orally or inhaled.

Though often challenging to stock, manage and monitor, specialty pharmaceuticals are at the forefront of cutting-edge medical care. They can be effective in treating formerly incurable diseases and reducing the pain and suffering associated with certain chronic illnesses.

The Increase in Specialty Pharmaceuticals
There is ample evidence that specialty pharmaceuticals are big business:

- Specialty drug expenditures comprised 31.8% of the overall U.S. drug spend in 2014, up from 27% in 2013. Since 1990, the number of specialty pharmaceuticals approved by the FDA has doubled approximately every five years, with almost 200 drugs currently in use and more than 1000 in development.
- Specialty pharmaceuticals expenditures in the U.S. approached $100 billion in 2010, and are expected to increase at a rate of 12% to 15% annually.
- While only representing 1% of all U.S. prescriptions in 2013, specialty drugs accounted for more than one quarter (27.7%) of the nation’s total pharmacy spend.

- New breakthrough products expected over the next few years include drugs for hepatitis C, multiple sclerosis, cystic fibrosis and a number of cancers.
- New pharmacy models and data requirements are beginning to emerge from the macro changes occurring in the healthcare arena.
- Healthcare reform has accelerated efforts to create new care-delivery and payment models. Together, these trends are forcing manufacturers to rethink and readjust how they interact with the healthcare system - a shift that will create major opportunities as well as significant challenges.

Recent Trends in the Specialty Pharmaceuticals Industry
According to Drug Trend, while pharmaceuticals manufacturers continue to bring new ground-breaking products to market, their efforts are being undermined by the prices charged to cash-strapped managed market payers and patients. Hence, manufacturers and specialty pharmacies typically forge agreements to make these drugs more affordable to payers and more accessible to patients.

The overall amount of money spent on pharmaceuticals increased in 2014 by 13.1% following several years of decline - a situation that was due in part to the high cost of drugs. During the period between 2013-2014, there was a small decline (0.1%) in traditional prescription medication expenditures, despite a 6.5% hike in costs. However, the use of specialty-pharmacy medications rose by 5.8% in spite of a +25.2% increase in cost (see Figure 1, next page).

Between 2013-2014, there was a 30.9% jump in spending for specialty medications - the highest specialty drug trend ever recorded.

Given that specialty pharmacies contribute to major drug spending, accelerating the turnaround time from patient enrollment to eventual drug disbursement will not only help patients, but significantly improve the bottom line for the manufacturers of these drugs.

Tracking Patients on Their Journey
Specialty pharmacies play a vital role throughout a patient’s therapeutic journey - from the time a drug is initiated, to the hand-holding required through the various stages of the insurance process, to ensuring that
the patient receives the drug. Consequently, making this process more efficient will revolve to a large extent around making changes to a pharmacy’s internal and external processes.

First, it is essential to understand the typical stages patients go through before they receive specialty medications (see Figure 2, next page).

- **Stage 1: Physician office.** A patient first visits a specialist, who recommends a specialty drug to treat the patient’s condition. The specialty pharmacy receives the order from the doctor via fax, phone or electronically through the pharmacy’s physician network. A treatment form, created by the drug’s manufacturer, is forwarded by the pharmacy to both the patient and the physician, along with the recommended dose of free (or starter) drugs, to be delivered to the patient ideally by day four. The service center at the specialty pharmacy works with the patient to coordinate how the patient would like to receive information on the benefits of the drug and have their questions answered regarding efficacy and dosage, for example. At this stage, the patient must inform the pharmacy if they will require financial assistance, or if their current medical coverage is sufficient. Following the completion of the necessary forms, the pharmacy ships a starter pack to the patient’s residence.

- **Stage 2: Co-pay assistance.** Patients who require financial aid are routed to financial-assistance organizations, such as CVC or NORD; patients who procure a drug through their commercial medical plans are aided according to their requirements. This stage can take a significant amount of time for patients, given the need to further review their records and their justification for qualifying – a process that can involve investigating benefits and assessing prior authorization, for example.

- **Stage 3: Specialty distribution of paid Rx.** Following benefit assistance and fulfillment, the paid Rx is dispensed by the patient’s specialty pharmacy and delivered to their home. Ongoing nursing support, as well as follow-ups, are provided through the specialty pharmacy service center via e-mail or phone. The pharmaceuticals manufacturer then contracts with the specialty pharmacy to regularly track the patient’s adherence, report any adverse events, and address specific concerns the patient may have.

Focusing on Fulfillment Analysis

Patients who require specialty treatments can only start on a drug through the contracted specialty pharmacy, which has the ability to monitor a patient at all stages – from initiation to product fulfillment. The resulting data can be used to examine and understand each phase of the patient’s treatment.

The aim is to identify major bottlenecks, and see to it that the specialty pharmacy’s management team works with the drug manufacturer to ensure that the time it takes for a patient to complete the treatment cycle is significantly improved.

A comprehensive data analysis can be conducted to track a patient’s progress as they make their way through the specialty pharmacy system (see Figure 3, page 5).
There are specific points where the drug disbursement process can stall. In-depth analytics, which feed into the data-collection contracts that pharmaceutical companies have with specialty pharmacies, can provide deeper insight into these issues.

Once the patient is triaged to the dispensing specialty pharmacy and starts receiving a paid prescription, they finally convert to “active status.” In some cases, patients discontinue the drug, based on their prescriber’s recommendation, their own choice, or due to insurance issues.

A patient’s receipt of specialty drugs can be delayed for numerous reasons. Thus, it is important to identify the exact points (outlined in longitudinal studies) where problems exist, and focus on areas that require improvement:

- **New patients typically encounter problems during the enrollment stage.** These roadblocks can be due to benefits investigation (BI) processing, an incomplete patient treatment form, or pending foundation approval. By this time, a majority of patients should have received a free drug to initiate therapy.
- **A patient can opt out of the program for numerous reasons,** such as an adverse event (side effect), lack of efficacy or treatment with alternative medications.
- **A patient has to wait longer for their prescription to be shipped** due to insurance investigations. We call this “pending status.” At this point, the patient could be sent back to the enrollment phase if their paperwork is not in order, or if they encounter other issues, such as an out-of-network prescriber.
Affording Actionable Insights

Pharmaceuticals companies’ marketing teams can benefit greatly by assessing the gap between the number of days from when a patient enrolls for a specialty drug to when their regular supply is delivered.

Some of the potential challenges pharmaceuticals companies face when dealing with specialty drugs are highlighted in Figure 4 (see next page), along with actions that can help mitigate them.

Looking Forward: Next Steps

Scientific advances and innovations in specialty-pharmacy products will accelerate in the coming years - adding to the arsenal of beneficial cures and treatments. Ensuring that patients receive the right drug in the most appropriate setting will depend on improving the drug distribution process.

Employing descriptive analytics to track patients throughout the specialty pharmacy disbursement process can help identify and diagnose pain points in drug distribution and ensure continuous, seamless patient therapy.

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Effectively analyzing the patient flow at different stages of a patient’s drug treatment allows manufacturers’ marketing teams to increase the effectiveness of marketing programs across physician, patient and pharmacy channels, enhance the company’s brand and boost sales. This is critical, given the expected year-over-year cost increases in specialty pharmaceuticals.

Finally, data analytics enables specialty drug manufacturers to:

- Track patient adherence and reasons for cancellations.
- Improve the processes and management associated with contract pharmacies.
Employ descriptive analytics to enable positive organizational and process changes. Using these tools, pharmaceutical teams can address and understand the intricacies of the rapidly evolving specialty-pharmacy landscape, and rest assured that the processes surrounding specialty treatments are efficient, secure and patient-centered.

**Specialty Pharma’s Special Challenges**

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<th>Product Fulfillment</th>
<th>Challenges</th>
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<tr>
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<td>• High patient cancellation rate.</td>
<td>• Monitor reason codes for cancellation.</td>
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<td>• Low HCP titration rate.</td>
<td>• Introduce nurse support programs to guide patients and caregivers.</td>
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<td>• Specialty pharmacies (SPs) unable to contact HCP for second Rx.</td>
<td>• Patients can be managed by specialty pharmacy service centers until maintenance dose is reached.</td>
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<td></td>
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<td>• SPs can explore new ways to contact HCPs (text, e-mail, web portal, hot lists).</td>
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<th>Financial Assistance</th>
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<td>• Changing Foundation Rules - FPL (Federal Poverty Level), types of coverage.</td>
<td>• Move patients to foundations that accept lower FPL levels.</td>
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<td>• Foundation organizations not efficiently structured.</td>
<td>• Improve patient processing systems at the foundation level.</td>
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<td>• Higher % of prior authorizations.</td>
<td>• Increase SP service center staff.</td>
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<td>• Less disabled patient population with income levels above FPL.</td>
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<th>Treatment Initiation</th>
<th>Challenges</th>
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<td>• Increase in % of filled treatment forms.</td>
<td>• Roll out simplified online versions of treatment forms.</td>
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<td>• Timing of patient visits.</td>
<td>• Provide communication/education for sales reps re: benefits of the SP process.</td>
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<td>• Higher % of prior authorizations.</td>
<td>• Set up a task force to evaluate numerous options for making prescribing easier.</td>
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<td></td>
<td>• Specialty pharmacy system is new for some types of HCPs.</td>
<td>• Create new treatment form.</td>
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Figure 4
Performing a Patient Flow Analysis

Business Situation/Challenge

• A leading manufacturer of a specialty treatment for neurological disorders required a deeper understanding of the patient journey – from enrollment to the time a drug was dispensed.

The Solution

• We conducted a comprehensive data analysis – tracking the entire treatment history for every patient to whom the drug was dispensed.
• The average time it took patients at each point in their treatment/pharmacy cycle was calculated based on historical data.
• A longitudinal study confirmed the areas where the provider needed to work closer with specialty pharmacies to shorten and improve the process.

The Benefits

• The analysis uncovered major areas for process improvements, including product fulfillment, financial assistance programs and treatment initiation.
• The analysis helped the manufacturer make more informed decisions by focusing on specific roadblocks – reducing pharmacy-related performance issues that caused delays in drug delivery.
• Our findings also provided valuable insights to enable the company’s specialty pharmacy management team to better coordinate with pharmacies, and ensure significant improvements in patients’ treatment journeys.
Footnotes


2. Ibid.

3. Ibid.


6. Ibid.

7. Ibid.

8. Ibid.

9. Ibid.

10. Ibid.

11. Ibid.

References

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