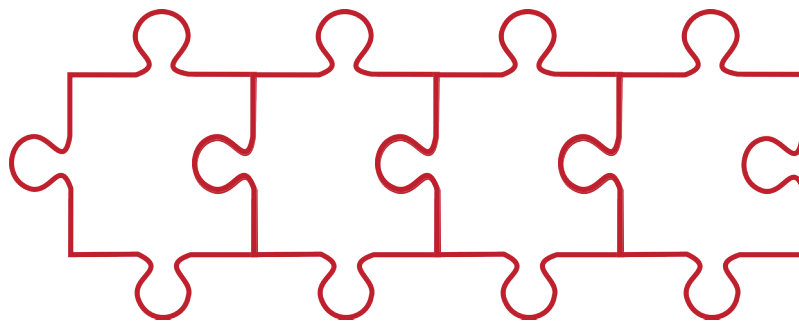


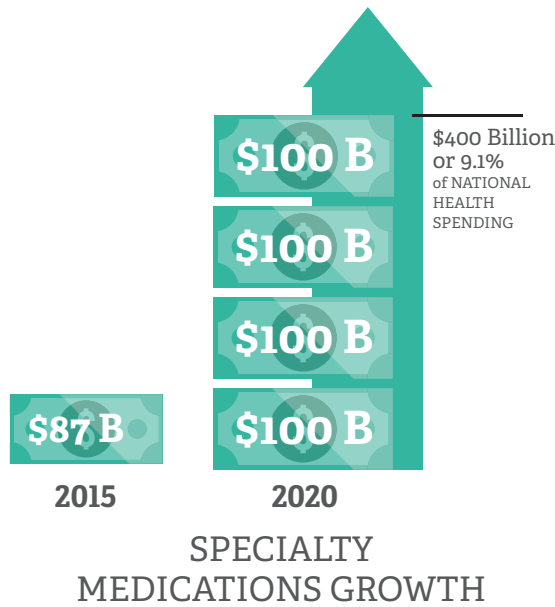


# Challenges & Opportunities in the Specialty Pharmacy Space



## Challenges & Opportunities in the Specialty Pharmacy Space

# Introduction



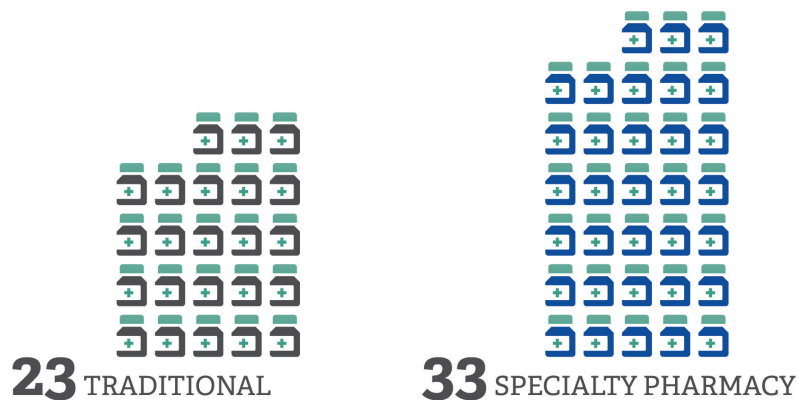
Sales of specialty pharmaceutical drugs continue to escalate, and are expected to quadruple by 2020 with revenues of \$400 billion annually, representing 9.1% of national health sales.<sup>[1]</sup> Over the last five years, the majority of FDA approvals have been specialty pharmaceutical drugs, with 2015 a blockbuster year for drug approvals by the FDA granted in one year.

Of the 56 pharmaceutical drugs approved, 33 were specialty pharmaceutical drugs and 23 traditional drugs.<sup>[2]</sup> The trend continues into 2016, with specialty drugs representing three out of every five drugs approved by the FDA.

This growing market opens the door to tremendous opportunities but simultaneously creates many hurdles for the stakeholders. All must rise and work together to meet current and emerging challenges to optimize the promise of this market.

To gain strategic insight into the Specialty Pharmacy space, DMD interviewed leading executives of Specialty Pharmacy Providers (SPPs) and Specialty Pharmaceutical Manufacturers (SPMs). The report that follows is the 3rd in a series of three white papers which explores the unique opportunities and challenges faced by stakeholders.

## 2015 FDA APPROVED SPECIALTY PHARMACEUTICAL DRUGS



While SPPs have made tremendous strides in meeting the needs of this expanding arena, there are clear opportunities for enhancing services. This paper covers these opportunities, as well as inconsistencies in service provision issues concerning the coordination of care and services among stakeholders, as well as market dynamics.

Opportunities to enhance patient adherence, data tracking, and crafting value-based agreements will also be reviewed. Additionally, we will provide analysis of potential benefits of focusing on key niche areas such as orphan diseases or other areas.

# I.

## Challenges in Specialty Pharmacy

### *Processes and Technology*

As discussed more in-depth in DMD's March 2016 white paper "Specialty Pharmacy Programs and Services: Core, Enhanced and Future Considerations", SPPs are indispensable in a myriad of roles: providing education and training on the disease or condition, dose administration, procurement, communicating therapy goals and providing cost and financial assistance options. In addition, SPPs are tasked with facilitating communication with physicians, payers, health plans, hubs and manufacturers.

SPM executives in this study noted the following inconsistencies in SPP services:

- Benefit verification process, and how quickly prior authorization is processed
- Shipping pharmaceuticals in a timely, cost-effective way
- Timeliness of one-time outreach after onboarding

Another challenge, and perhaps an opportunity, for specialty pharmacies is related to appropriate nursing care. Nurses with expertise and willingness to administer a first dose of specialty medicines, and/or to manage the care appropriately in the patient's home are not easy to find and recruit at present.

Additionally, meeting regulatory requirements is a challenge for some specialty pharmacies.

*"Pharmacy is a largely compliant industry, with lots of regulations. Not only around state board of pharmacy regulations, but also DEA regulations. We also have contractual obligations to the payers, Stark issues and anti-kickback issues."*

**-President & COO**  
(Specialty Pharmacy Provider)

## Communication and Coordination Among Stakeholders

Deeper analysis into the inconsistencies with onboarding new patients and other services highlights a communication overload among stakeholders, as well as a lack of coordination, sometimes involving duplication of efforts. This includes communications from the perspective of the patient, and interactions between specialty pharmacies, physicians, payers, and hubs. Poor communication affects SPPs and SPMs who manage bottlenecks and redundancy between one another. According to executives in SPPs, hubs and SPPs have competing priorities, which can also impede communication.

A number of areas related to onboarding pose a challenge due to outmoded communication tools and inherent complexities in onboarding steps. Complications can arise for SPPs while acquiring prior authorizations, during discussions with physicians, when negotiating with payers, and in attempting to educate patients.

From the patient's perspective, they are bombarded by communication from multiple stakeholders: SPPs, payers, possibly payer case management, the physician's office, and possibly by case management for the physician's office. Many executives in SPPs express concern that patients on more than one specialty-care therapeutic from multiple SPPs may lack continuity of care.

*"Continuity of care and therapy management is a challenge when patients are on multiple specialty-type therapies."*

**-President & COO**  
(Specialty Pharmacy Provider)

There is the burden of overly complex number of interactions among SPPs, patients, payers, physicians, and hubs for the services needed. For example, patients may find themselves dealing with multiple SPPs, and multiple hubs and payers, all involved in acquiring financial assistance and gaining prior authorization for the pharmaceutical drugs required for a single patient.

## Access to Care

There can be many hurdles and roadblocks in gaining access to care, caused in part by poor communication and/or coordination by stakeholders, and other reasons.

### Complexities in Prior Authorization

With generally no oversight, payers determine their own criteria to limit coverage for certain pharmaceuticals, leading to unnecessary roadblocks. For example, prior authorization may be based only on FDA-approved indications, despite medical evidence that off-label use of a drug is more effective than approved alternatives. <sup>[3]</sup>

Many SPPs report hurdles in gaining prior authorization approval as physicians face complex, time-consuming, and time intensive documentation procedures. An American Medical Society survey found that physicians' offices devote an astounding 20 hours per week to prior authorization activities. <sup>[4]</sup>

There are also difficulties in communication between the physician, SPP, payer and patient during the prior authorization process. SPPs attempt to expedite the process, but opportunities for improvement remain large.

### ROADBLOCKS TO ACCESSING CARE



Complexities in Prior Authorization



Copay Assistance Programs



Access to Payer Contracts



Access to Limited Distribution Networks

*“Management of the prior authorization process is a growing challenge. When Electronic Prior Authorization is fully implemented, life will be a lot better.”*

**-VP of Specialty & Home Delivery Pharmacy**  
(Specialty Pharmacy Provider)

Electronic Prior Authorization represents an improvement over the cumbersome, time-consuming methodologies using forms, phone calls and faxes. Newer electronic options help to minimize delays and unnecessary complexity. Third party services provide these platform services.

## **Copay Assistance Programs**

Another example of an overly complex process involves co-pay assistance programs.

Claims are sent to the Pharmacy Benefit Manager, to the co-pay assistance firm, and often to the patient for the balance of the claim. This redundancy and complexity in communication may be addressed by third party platforms designed to connect all key stakeholders. A single platform provides access to electronic consent forms, streamlines prior authorizations and access to co-pay and patient assistance programs. In time, the gap can be closed to reduce current inefficiencies. This topic is discussed more in “Specialty Pharmacy Programs and Services: Core, Enhanced and Future Considerations.” (DMD 2016 Whitepaper)

Co-pay assistance can be critical in making the sale of the pharmaceutical drug. From the standpoint of cost, SPPs need more robust co-pay assistance for manufacturers or PAP programs to minimize lost sales when patients can't afford the drugs.

## **Access to Payer Contracts**

Among the top challenges of many SPPs is qualifying for and gaining access to payer contracts, as payers are narrowing their network of specialty pharmacies, creating a large roadblock for some SPPs in providing service to patients. Payer interaction is the greatest challenge faced by SPPs in terms of how to gain permission or prior authorization for billing and receivables, as well as for data transfer.

There is ample reason for payers and employers to challenge SPPs with careful monitoring and selection. Specialty pharmacy drugs are the fastest growing employee benefit expense. They are high cost and high risk, and usually benefit a small segment of patients. As a result, payers utilize more intense management techniques for specialty drugs. Shrinking profit margins for SPPs have opened a door for payers to demand enhanced services by SPPs in order to improve the total cost to their patients.

By working exclusively with select SPPs who have expertise in particular areas, payers facilitate optimized patient education, create better opportunities for enhanced adherence, and support other cost utilization measures. SPPs provide added value with their clinical expertise, therapy management programs, specialized regional coverage, and information technology medical claim expansion. <sup>[5]</sup>

## **Access to Limited Distribution Networks**

Limited distribution network access is also a highly ranked challenge according to many of the SPP executives we spoke to. For many newer specialty pharmaceutical drugs, SPMs choose to work exclusively with select pharmacies with the highest standards of patient education, clinical expertise, service, and treatment support. The goal of limited distribution drugs is to create high standards for quality outcomes, patient safety, and medication adherence.<sup>[6]</sup> Limited distribution also benefits the selected SPPs and payers, who often share in the volume discounts given by SPMs.<sup>[7]</sup>

Since specialty drugs typically treat rare diseases with fewer patients, limited distribution drugs benefit patients by channeling medications through only a few providers, giving the best opportunities for evidence- and experience-based education and training.<sup>[7]</sup>

## ***Reimbursement/Competition***

### ***Reimbursement***

Several SPPs executives mentioned reimbursement challenges. Through contracts between payers/PBMs and SPPs, SPPs receive reimbursement at the Average Wholesale Price (AWP), less a percentage plus a dispensing fee.

These contracts are increasingly less favorable to SPPs. SPPs can appeal the reimbursement amounts with commercial, Medicare D, or Medicaid plans. However, every SPP has a different price to buy the product, and the payer/PBM is not compelled to respond by changing the reimbursement amount to accommodate the needs of a single SPP.<sup>[8]</sup>

### ***Market Dynamics / Competition***

The explosion of specialty pharmaceutical drug approvals and the movement of SPM portfolios from a primary-care model to the specialty arena creates challenges for SPPs. The rapid change adds further challenge to accommodate and manage the broad number of programs. Additionally, the novelty and complexity of working with specialty pharmacy creates hurdles for physicians new to the space.

SPPs need to develop their specialty programs unique to each therapeutic area to meet specific patient needs. A challenge arises as SPPs move into immunotherapy, oncology, and new therapies, with unique requirements leading to unique programs.



Today's market for SPPs provides for more competition and choice regarding which drugs to provide to patients. SPMs partnering with multiple SPPs increase this competition as well.

The challenge for manufacturers is integrating the reality of broad national reach while working with competitor specialty pharmacies at the same time.

SPPs are challenged by payers and manufacturers to provide more and broader services. A major concern of SPP executives we spoke with is the shrinking growth of profit margins due in part to demand by payers.

Limited distribution provides a major competitive advantage to select SPPs, yet the vast majority of SPPs state that access to limited distribution drugs is a big challenge. Limited or exclusive distribution by manufacturers is also impacted as payers restrict the network size of SPPs.

*"Payers are trying to tighten networks for specialties pharmacies, only allowing certain specialty pharmacies in networks. You have this chicken-and-egg problem with the specialty pharmacy needing to get patients in order to convince a manufacturer that they should distribute their drug, but in some cases they can't."*

**- VP Specialty & Home Delivery Pharmacy  
(Specialty Pharmacy)**

## II. Opportunities in Specialty Pharmacy

### *Enhancing Patient Compliance and Adherence*

SPPs and manufacturers face a challenge in enhancing patient adherence. Yet for those who succeed in improving adherence, a clear, marketable opportunity exists to improve patient experience and outcomes. SPPs traditionally demonstrate 10% higher rates of patient adherence compared to the retail pharmacy sector, enhancing the potential for increased revenues. <sup>[1]</sup>

A wide array of options leveraging technology to improve patient drug adherence is discussed in “Specialty Pharmacy Programs and Services: Core, Enhanced and Future Considerations”. (DMD 2016 Whitepaper) Technology options include product packaging, apps with text alerts, and web platforms or portals that enhance communication.

Combined with upgraded adherence measures, technological improvements can lead to more meaningful:

- Patient assistance programs
- Benefits investigation
- Customization of patient experience
- Patient education programs

Some SPPs are challenged to create and implement appropriate patient education programs. Patients need to be well trained on side effects associated with some drugs, so that adherence is maintained throughout treatment. Some SPPs even offer classes to educate patient groups.

*“With Hep C medication, and particularly the first-generation specialty, patients felt miserable when taking it. So we helped them understand what misery might look and feel like so they knew what could happen.”*

**-President & COO**  
(Specialty Pharmacy)

## *Data and Program Improvements*

Because of frequent communication between the SPPs and patients, SPPs have the unique opportunity to compile useful data on the outcomes of patients. While some data is being collected by SPPs, from the SPMs' perspective there is too much inconsistency when it comes to data integration by SPPs. Here are some of the issues that need improvement:

### **Tracking the drug throughout the process.**

Critical information can be gleaned from tracking the whole data flow and data integration process. This may include information on when the patients begin treatment, when they are followed up on, if they are getting the drug on a regular basis, and tracking any roadblocks from a reimbursement and market-access standpoint.

### **Data aggregation to highlight the value of the product, answering: "What was the clinical outcome?"**

Going forward, providing data will be increasingly important for pharma manufacturers to show that products have clinical value.

### **Data aggregation to position SPPs better in promoting their specialty therapeutics to the payers or to employers.**

SPPs must show a model to prove to payers that the combination of product and services, and high touch with patients, can lead to better health outcomes and less hospitalizations.

### **SPMs would also like to have metadata and patient level data collected by SPPs, to gain deeper insight into how their therapeutics are working.**

From a data perspective, SPPs need to connect indications (ICD-9 codes), beyond patient-level data, filling an information gap in therapeutic outcomes.

## Value Based Agreements

Limited distribution plays an important role in the negotiations leading to partnerships between SPPs and SPMs. While clearly a challenge to SPPs, limited distribution provides an opportunity for SPMs to secure better rates and reimbursements from SPPs by negotiating for exclusive or limited distribution with them.

The benefits to SPMs, SPPs and patients are quality outcomes, patient safety and medication adherence, acquiring and retaining customers, and improving revenues.<sup>[6]</sup>

Partnerships between SPPs and payers may also provide a competitive advantage. Opportunities may shift more to payers that have their own specialty pharmacy, leading to stronger, mutually beneficial relationships.

Many SPMs and payers have expressed interest in risk-sharing agreements (RSAs). While stakeholders are more optimistic about financial-based RSAs as compared to outcomes-based RSAs, there is interest within the U.S. private sector in the latter, especially as data collection systems improve.<sup>[9]</sup>

Some examples of outcomes or performance-based risk-sharing agreements involve:

- Schemes tied to performance metrics such as clinical outcomes, biomarkers, hospitalizations or other metrics
- Schemes tied to patient adherence
- Indications-based schemes



## *Pharmacy Benefit Managers*

Large cost reductions can be made by working through Pharmacy Benefit Managers (PBMs), typically 10-20% savings over limited management plans. Cost reductions also benefit other stakeholders by increasing the number of patients who can afford expensive therapeutics.

PBM tools provide cost reductions to patients insured through commercial plans or through Medicare via several avenues <sup>[10]</sup>:

- Negotiating drug rebates from manufacturers and discounts from drugstores
- Offering more affordable pharmacy channels
- Reducing waste and improving adherence
- Managing high cost specialty pharmaceuticals
- Encouraging use of generics and affordable brands

## *Specialization and Serving Orphan Diseases*

Since the Orphan Drug Act of 1983, 490 new orphan drugs have been approved and more than 3,200 additional investigational drugs have received the orphan designation from the FDA.<sup>[11]</sup> This large market provides yet another area of expanded opportunity for all stakeholders.

By narrowing focus to key niche areas serving orphan diseases or other areas, SPPs are better equipped to provide individualized guidance, coaching, and more high-touch options. They may be better structured to handle requirements of orphan drugs - special handling, refrigeration, and flexibility to meet the special requirements of the manufacturers.

The other advantage of specialization is that SPPs may align themselves with key referral sources.

Today, more pharmaceuticals fit into the specialty pharmacy space rather than the primary-care model, due in part to an increase in injectable drugs and infusions. This creates more opportunities for SPPs.

*“The other bet people are making is that infusion therapy is going to come back in a bigger manner. Some larger players have started to re-engage on the infusion side.”*

**-Executive Director of a Specialty Pharmacy Trade Association**

One factor in the overall expanding patient base is the recent trend in FDA approvals, with 2015 having a greater than average number of approvals. Of 45 new drugs approved in 2015, 60 percent were expedited through clinical trial development or accelerated FDA approval, with fast track, breakthrough, priority review and accelerated approval designations.<sup>[12]</sup>

Other emerging trends creating opportunity are the growing number of patients stemming from the Affordable Healthcare Act and aging baby boomers. Higher numbers of patients with insurance and diagnosed disease have lead to a need for more drugs.

# Summary

SPPs are providing a powerful avenue to streamline drug distribution, delivery and management. They are in the unique position to enhance patient care, assist manufacturers with management challenges, and provide enhanced services that provide payers a return on their investment. The challenges involved in maintaining a balancing act with all of these stakeholders may seem insurmountable, yet there are many opportunities for SPPs who embrace flexibility, new strategies and updated technologies, ultimately providing better resources for all stakeholders. Specialization can be a key point of differentiation for SPPs, especially with large national organizations competing for contracts on new pharmaceutical drugs. With the boom in specialty drugs with orphan drug status entering the market, SPPs representing these drugs will have the advantage.

Other areas that provide a competitive advantage are better communication, enhanced data reporting, a focus on improved patient adherence and improved access to pharmaceutical drugs.

The ultimate focus and center point for any SPP/SPM strategy should be the patient. There are a myriad of hurdles involved in management of care for patients with complex disease states. By focusing on patient outcomes, SPPs and SPMs will stay competitive from the viewpoint of other influential stakeholders as well as patients.



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Delta Marketing Dynamics is a market research consultancy with a long tradition of helping clients “Know More and Connect Better”, especially in the pharmacy space. For over 40 years DMD has offered key insights and deeper understanding of distribution patterns for many large and expensive brands distributed through the specialty channel. With direct access to top specialty pharmacies in the US, DMD offers customized research and syndicated options to help you assess and compare specialty distribution and programs.

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