THE SPECIALTY PHARMACY & MANUFACTURER RELATIONSHIP

A Study in Symbiosis

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Existing and evolving business processes between Specialty Pharmacies (SPs) and the pharmaceutical manufacturer require the exchange of data ("real world evidence") that demonstrates mutual value for all parties. Optimizing these flows is now a critical success factor to realizing the anticipated benefit for both sides.
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Specialty Growth is a Critical Trend. IMS Health notes that drugs largely dispensed through Specialty Pharmacies (SPs) will continue to be a major factor in the U.S. market for the foreseeable future. The powerhouse analytics and data company concludes that the specialty drug market grew nearly 27% in 2014; others project that more than 50% of drug costs by 2018 will fall in the specialty category for rare or specialty conditions. SPs represent a crucial distribution pathway for manufacturers to effectively serve the patient in need of their specialty products across varied geographies and payer markets. SPs are operated by many different entities including pharmacy benefit managers, health plans, retail chains, pharmaceutical wholesalers and some hospital systems.

SPs & Pharma companies already engage in collaborative agreements that involve the SP’s service delivery, purchase discounts, a manufacturer’s product discount or service or data fee and data & information exchange between a SP and pharma companies. Because there are not standards in place currently, each SP-Pharma contract comes with its own idiosyncrasies. The parties on either side thus administer these critical agreements using a disorganized process, often leading to a considerable operational and financial burden on both organizations.

Each SP is a source for unique information and certainly has an impact on the care and specific therapy of the individual patient. The organization and delivery of related data to manufacturers is currently highly variable in terms of formats and fields, often manually created or extracted from the SP’s dispensing system reports. Some of the current processes are inefficient, prone to error, and costly to both sides in terms of organizational time and effectiveness.

Via a specialized task group, NCPDP’s Work Group Seven (Manufacturer and Associated Trading Partner Transaction Standards) is working to develop a specialty pharmacy data standard that would support the primary business needs of the manufacturer and SP regarding the exchange of information between the SP and/or hubs that provide service to the SP.

**Mutual Need between Parties.** The parties each must work in a collaborative manner. Most recognize that the SP is much more than a simple distributor, providing services that are uniquely tailored to a specific high-need often, high-cost patient. The rapid growth of SP pharmacies has not occurred without challenge and controversy, however, their value in pharmacovigilance is generally well-recognized.4

The SP clinical and technical staffs interact with the patient, the prescriber, and the payer at the point of first dispensing and over the course of managing the patient’s disease. The work done by the SP with each of these parties is also important to the manufacturer. For that reason, agreements between the SP and manufacturer govern specialty product dispensing activities, offering assurances that product inventory and handling methods are honored. These agreements may also provide for “fair market value” payments for data and/or patient support services as well as pricing discounts based on the terms agreed to by both parties.

As both sides better understand the other’s perspective in managing patient needs and safety issues, alignment based on patient clinical outcomes is realized. Specialty pharmacies have access to key patient data by nature of their business that contributes to tracking safety and outcomes. As manufacturers include specialty pharmacies in their training activities (as a critical business partner), they enable “best practices” for patient management at each SP. This ultimately enhances safety and optimizes outcomes for the patient, prescriber and payer.

Among the contractual goals of the manufacturer-SP relationship are the following:

1) Minimizing each side’s operational burden
2) Fostering a collaborative environment
3) Optimizing patient outcomes
4) Managing cost and price expectations for all parties involved.

**Understanding the Challenges.** The SP can provide pharma with access to critical information and insights regarding the access to and adoption of product alternatives. SPs provide an efficient and effective way to distribute high-cost/high-impact products for limited populations. While the manufacturer is ultimately an important customer paying for a service rendered by the SP, the relationship between SPs and manufacturers are very complex, requiring a delicate balance and transparent compliance.

Typically, the manufacturer remains the responsible party in the government’s eyes and is subject to pricing, reporting, and discount compliance provisions and penalties and must maintain clarity in terms of

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Fair Market Value payments, discounts, and requirements between the parties during contract negotiation. See the graphic below for the types of services provided by SPs that may be referenced in contracts with pharmaceutical manufacturers:

What’s the Big Deal about the Data? Data, including clinical endpoints from the SP, are unique and thus highly valuable. These data can shine a light on challenges (by geographic area, payer, or other element) for product access, use, uptake, adverse drug reactions, inventory and distribution, and reimbursement.

The use of this Real World Evidence and analysis of patient outcomes from the use of innovative new products in real world settings generates additional perspective on safety and efficacy. The SP data is a high value data source that can identify factors in safety and clinical effectiveness. Used as part of an overall analytics and/or pharmacovigilance program, it can help manufacturers make strategic and tactical decisions pertaining to the Commercial enterprise.

What Should A Manufacturer Do To Optimize SP Contract Effectiveness? At this current time, NCPDP Work Group 7 is crafting a “data standard” that will make the exchange of data & information between the parties more efficient to collect and to receive for both parties. This SP data typically covers a myriad of needs in addition to discount or rebate payments, including facilitating safety recalls, reporting of REMS or Adverse Drug Reactions, patient experience, and competitive effectiveness.

- Get Involved with NCPDP Work Group 7. Manufacturers must identify and delegate team resources that understand the desired data fields and the technical elements before the standard is developed in order to have satisfactory dialogue about the value of RWE to both internal & external audiences.
- Build Solid Ethical Relationships with SPs. Manufacturers must understand the nature and strategic importance of these relationships to objectives for each product and create approaches that meet the goals of the SP as well as the Pharma company.
- When In Doubt, Please Reach Out!
  - Cambria Health Advisory Professionals (and its sister company SME Health Systems) is working with other partners and colleagues to help manufacturers manage the data yielded from these unique pharmacy relationships in a variety of ways.
  - For example, with our colleagues at Pharosity Consulting (www.pharosityconsulting.com), we can help you extract the promised value of the SP data. Your ideal “Data Driven Operation” should include the integration of your Specialty Data, defining pragmatic and effective strategies with the supporting processes and operational capabilities, so that a

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Pharma company can gain the most benefit from your investments / agreements with the SPs.
- Pharma manufacturer leadership should consider how to gather “real world evidence”, whether collected from SPs or other providers, and most effectively understand what the data indicates. Pharma companies can then integrate that new intelligence into a waterproof product value proposition for the payer, the prescriber, the SP, and, most importantly, the patient.

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