

Learning To Love Your Specialty Pharmacy

Perspectives on a New Business Relationship

The key to a smooth relationship lies in understanding the SP's capabilities and determining its role in your organization's success.

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One of the fastest growing — but least understood — segments of the healthcare landscape is the specialty pharmacy (SP). Google the term, and you'll see page after page devoted to the vendors but little to describe real-world experience. If you, like many other payers, are suddenly tasked with managing a new relationship with an SP, your questions should be focused and practical. How will SP services align with and support the payer's goals and initiatives? What level of service should be expected? How can a payer position its use of various SP services as a benefit to its contracted physicians? How much "management" of product utilization should be expected by the payer? By the manufacturer? Both are customers of the SP, and the answers to these questions will differ, but they are critical elements in managing a rapidly growing portion of the healthcare dollar: biologics and high-cost injectables.

HISTORY

The term *specialty pharmacy* describes a diverse marketplace of products and services. Depending on the type of operation, customer base, ownership, and skill sets, SPs exist within a very broad range of service models. As relative newcomers to the SP marketplace, few in the payer community are expert in this area, and even fewer have shared their experiences with colleagues in the managed marketplace. For years, SPs gained traction serving as wholesalers for the physician office, supporting the traditional "buy-and-bill" system. Physicians purchased medications and supplies through these businesses and, in some cases, established a new revenue stream. Now, as commercial reimbursement rates begin to trend downward in line with government fee schedules, opportunities are arising to transition to a more efficient system of administration, using the SP as a contracted service provider.



With the surge in targeted therapies, the specialty pharmacy market has moved in a whole new direction, and shows no signs of slowing down, says Genentech's Stephen Lash, PharmD.

SPs are strategically positioned to manage a group of products that often have moved outside of traditional management programs. Not coincidentally, the need for distribution outlets with special capabilities has increased right along with the many U.S. Food and Drug Administration approvals of new biologic therapies and high-cost injectables. Key components favoring specialty distribution are:

- Products are expensive and difficult to keep in inventory
- Impracticality of trying to keep 60,000 U.S. pharmacies "stocked"
- Coverage criteria (e.g., prior authorization [PA]) is common: few retail pharmacies can readily manage the complex, time-consuming processes
- Most SP therapies are infusions with complex patient management needs
- Patients may require education and round-the-clock clinical support
- Most products require special handling or controlled-temperature shipping
- Abuse and counterfeit potential are real concerns

TABLE

Typical SP service offerings

- Full-service national networks
- Managed care experience
- Patient-assistance programs
- Assignment of benefit programs
- Utilization management data
- First-level claims denial and appeals processing
- Disease management programs
- Wholesaler services
- Compliance management
- Flexible shipping capabilities
- 24-hour clinical care teams (RPh, RN)
- In-office, in-home training capability
- Electronic and paper claims adjudication
- Audit capabilities
- Educational programs (patient, clinician)
- Confidential, HIPAA-compliant financials
- Benefit design, formulary support
- Expertise in benefit investigations, prior authorization, appeals

- Payers and manufacturers have an acute need for utilization data

Surprisingly, the one definition that no one can offer would seem to be the one most basic to establishing the parameters of an SP: What is a specialty drug? Answers vary widely, and often depend more on one's contracts and management goals than on how a drug works. For purposes of this article, we can define a specialty pharmaceutical as an expensive pharmaceutical product, biologic or not, that is not generally available via the retail pharmacy network.

Clearly, efficient and appropriate handling of expensive products is a key component for specialty businesses. Retail pharmacy networks operate efficiently, dealing in fast-moving products and online claims adjudication to support their core business model. However, it is extremely challenging for a retail pharmacy to merge an active specialty business into its daily routine. A visit to a busy SP highlights the complexity — patient eligibility, PA, verification of a suitable home en-

vironment, delivery schedules, patient training, clinical monitoring — in filling a prescription for a specialty product. Space limitations also create a barrier for retail pharmacies, as does the need to offer patient support when problems arise at 2:00 a.m. on a Sunday. Round-the-clock service is critical to optimizing outcomes for patients who need specialty products.

Early on, the most common products managed through SP networks were hemophilia drugs, human growth hormone, orphan drugs, and other low-volume, high-cost products. With the surge in targeted therapies, the SP market has moved in a whole new direction and shows no signs of slowing down. Recently, some products previously in general distribution have moved into the specialty network for reasons already mentioned — high inventory costs, unique storage and handling requirements, and round-the-clock patient support, to name a few. Payers expect more service when paying for high-cost therapies, and SP networks are in a position to deliver on those needs.

SPs differ, depending on the ser-

vices they offer, products they handle, and patient populations they serve. Although several core services are common across the spectrum, SP capabilities vary widely. Not all organizations will offer the same services, and some may offer programs far beyond the scope of services listed in the Table.

STAKEHOLDER EXPECTATIONS

Managed care organizations.

For payers trying to deal with rising costs of care, efficiently managing office-based injectables and biologic therapies is critical. Tactics range from mandatory application of a formulary (complete with step therapy, PA, clinical tracking, and specialized case management) to distribution systems and minimizing waste. In many cases, market forces will dictate the level of intervention available to the plan. When one payer has a dominant market share and maintains an effective relationship with its network physicians, aggressive management may be possible. Conversely, in certain regions, physician shortages may force health plans to compete for a sufficient number of doctors to

serve their members adequately. In these situations, it would be difficult to force mandatory use of an SP—and a “preferred” SP may instead be the end goal.

One of the biggest hurdles a health plan must overcome is the perception of significant profit to a medical practice through the continued use of the traditional buy-and-bill system. Although there are some specialties that have the volume and expertise to buy and bill efficiently (e.g., oncology, rheumatology), the potential for financial benefit may not be as great for other medical disciplines (e.g., dermatology and pediatrics). The medical practice that purchases products sporadically may lack the required expertise an SP has in this area and will be surprised how often claims go unpaid or are paid at a rate far less than was expected.

Health plans may need to employ creative solutions to help medical groups recoup lost revenues (real or imagined) when implementing an SP program. Health plans have a strong interest in helping their contracted medical practices operate as efficiently and profitably as possible, so that rate negotiations in the next contract will be less contentious.

With this in mind, what characteristics should an MCO demand in an SP partner? A shared vision is critical, yes, but how do you structure a relationship to make this a reality? A few issues to consider:

- Does the SP have experience in helping physician practices convert from a “buy-and-bill” system to a specialty network? The MCO needs a competent partner with excellent com-

munication skills to smooth the transition.

- Can the SP support precertification criteria established by the health plan as well as the plan can? If the SP employs a clinical support team competent to manage such processes, a true partnership can take hold.
- Does the SP offer specific disease management programs that align with the health plan’s priorities? If the payer is planning new programs to meet evolving business needs, will the SP be ready both as a partner and a resource?
- Can the SP manage data requests by the MCO to support utilization management programs (e.g., trends, polypharmacy, appropriate use)?
- Rebates and charge-backs are important, but can be a moving target. They are generally performance-based and can vary significantly. Relationships built primarily on discounts may not always achieve the desired end.
- Can the vendor supply all specialty products? What is its operational plan to obtain products for which it does not have direct access?

Manufacturers. The relationship between an SP and a manufacturer also is based on a partnership, although its foundation is different from that of the SP and third-party payers. Increasingly, biologics and high-cost injectables are distributed through a specialty network, so the SP serves as a key link between the patient and the manufacturer. In a sense, the SP represents the manu-

facturer in several ways. The SP must maintain an adequate stock of the medication to handle “just-in-time” availability and be expert in such distributive functions as storage, shipping, and handling. Thorough product knowledge, including reconstitution and administration, clinical use, potential adverse events, and laboratory monitoring, is critical for the SP. When distribution networks are limited, the SP can be a key data source, often supporting registries that can be used for product tracking, sales trends, clinical trials, and economic models.

As the marketplace matures and ownership positions change, SPs have evolved toward a patient-centric approach. It, therefore, becomes all the more important that the manufacturer work in concert with the SP to ensure that its products are made available to eligible patients with a minimum amount of paperwork and delay. A partnership between the SP and the manufacturer is important to assure appropriate use of product, timely reimbursement, and optimal patient outcomes.

Physicians. Growth in SP services does not necessarily mean a revenue loss to the medical practice. Allowing an SP to assume risk on reimbursement removes a complex process from the physician’s daily routine and takes with it multiple obligations that the physician practice may not fully appreciate right away—the cost of stocking expensive medications, expanded freezer or refrigerator space, and product loss and/or breakage, for instance.

Moreover, SPs possess billing capabilities and audit services that can prevent financial loss to the prac-

tice resulting from claims rejections. As such, the loss of buy-and-bill revenue may not be as a significant financial loss to the medical practice as might first appear. Removing the purchasing/storage/billing cycle from the practice may even improve efficiency, allowing practices to spend more time on what they do best — serving patient needs.

Patients. An SP's value to a patient is generally underappreciated until the need arises. Patients with medical conditions that require complex treatment regimens are usually poor historians when remembering information given by their doctor at diagnosis. Once a patient hears "cancer" or "multiple sclerosis," they tend to recall little after that point. Introduce the need for treatments that can't be given as a pill or an ointment, and it's easy to understand why memory may falter. In times like these, a patient will appreciate the *healthcare provider* aspect of an SP. By making contact with the patient early in the process, the SP can alleviate stress and get patients focused on what lies ahead. Initially, an intake coordinator assesses the patient's living arrangements, the ability to receive and store medications and supplies, and the level of training necessary for self-management. As has been widely documented in many disease states, patient adherence to a treatment regimen rises in relationship to their understanding of the process. When patients know why they're being treated and what will happen if they don't adhere to their regimen, a better chance exists for an improved outcome. An SP is

equipped to supplement the care and guidance patients receive from a physician's office.

No less important is an SP's assistance in helping patients navigate their payers' benefit coverage. Most patients have heard terms like *non-formulary* or *prior authorization*; in a retail setting, there may be delays or product changes, but the patient generally receives treatment with minimal delay. Coverage criteria for specialty products can be much more complex, and paying out of pocket for therapy may not be an option except for the very wealthy. SPs navigate these waters on behalf of patients.

Besides helping patients deal

As a payer learns to take advantage of the services and expertise offered by its SP, a stronger, more integrated partnership will evolve.

with their insurers, SPs can help with various patient-assistance programs and initiatives offered through charitable organizations.

The importance of an SP's role in monitoring and documenting patients' progress as they undergo specialized treatment regimens cannot be overstated. Their work cannot — and should not — take the place of the primary caregiver; it is a valuable and complementary service that can only improve patient outcomes.

ALIGNING INCENTIVES

Attempts to align incentives between SPs and health plans resemble many of the challenges faced by the payer community and their pharmacy benefit managers. Like a

PBM, the SP is paid only if a claim adjudicates, and, like the PBM, the SP passes product and service costs along to the payer, which holds all risk. Solutions to this Catch-22 evolved, with varying degrees of success, in the PBM environment with the creation of performance-based measurements and trend guarantees. Over time, the PBM industry learned the need to be a good partner with its customers to keep business relations past the initial contract period. The same rationale should hold true for SPs as well. As a payer learns to take advantage of the services and expertise offered by its SP, a stronger, more integrated partnership will evolve, and the payer will ask the SP to handle a broader array of interventions, like PA, to better manage healthcare resource utilization.

LOOKING AHEAD

The use of specialty medications is rising and will continue to do so as new, innovative products enter the marketplace. Demand for these treatments will fuel the need for better delivery systems to ensure proper use and optimize patient care. As the sector continues to grow, SPs will play a larger role, and those that will prosper will understand their customers' needs and deliver on their promises.

The stakes, to put it mildly, are high. **BH**

DISCLAIMER

Stephen Lash, PharmD, is employed by Genentech Inc., as a director in the value-based health department. The views expressed in BIOTECHNOLOGY HEALTHCARE are his own and do not necessarily reflect the views of, nor should they be attributed to, Genentech.