

# THE RISE AND ROLE OF SPECIALTY PHARMACY

Over the last 30 years, specialty pharmacy has grown from a notion to a cottage industry to being on the cusp of becoming a major force in healthcare delivery.

BY DAVID SUCHANEK, RPh

Specialty pharmacies (SP) offer services for providers and insurers by streamlining the delivery process and smoothing out the challenges in healthcare delivery and financing. Given that more than three fourths of health plans now use SPs (Baker 2005), they clearly are trying to manage costs and are doing much outsourcing. This article addresses the use of SPs, why certain products fall under their domain, and how this channel came about.

Though SP lines of business vary

greatly, their services generally have come to include access to, and support for, most pharmaceutical and biologic products that have high acquisition costs, are difficult to manage, and present reimbursement challenges. These include most injectables (also those administered at home) and adjuvant therapies. With the implementation of the Medicare Prescription Drug Improvement, and Modernization Act of 2003, we expect to see an increase in the number and scope of products that SPs handle.

Overall, these products tend to present challenges to physicians, patients, payers, pharmacies, and manufacturers. They necessitate a high level of support for patients, many have special data and handling requirements, and often, they require strict inventory control. As newer therapies come to market, SP's role continues to become more refined (Table 1, page 32).

## SP'S NICHE

The increase in SP's importance relates to new financial and third-party payment challenges that healthcare organizations face. Table 1 gives a historical overview of the prescription drug billing challenges that led to the SP industry's growth.

Specialty products pose myriad challenges, for which SP offers solutions (Table 2, page 34). For patients, two key considerations are cost and access. The retail pharmacy has the challenges of inventory, product knowledge, and ad-

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ministration tools. Physicians must deal with issues of inventory, sourcing, and slow reimbursement, while MCOs have some unusual administrative challenges, related primarily to the tracking of claims.

SP has come a long way in the past five years, and technology is a driving component of that. As products become more mature,

clinical markers are established, allowing for more complete data collection and better outcome measurement. We are now testing software that will give physicians access to a database with information about all their patients who are prescribed a particular therapeutic regimen. This information can include a variety of valuable data,

such as prescription information, current prescription processing status, reimbursement information, and patient-adherence information.

This is an example of how technology can help a physician manage patient care in the office. Take the beginning of any benefit year, for instance — a difficult time for a physician and the office staff. Some

**TABLE 1** Overview of prescription billing

Early 1970s	1975–1985	1986–1999	2000–today
<b>Conventional drugs</b>			
<ul style="list-style-type: none"> <li>Traditional indemnity insurance dominates core health care markets</li> <li>All prescription claims submitted on paper</li> <li>Prescriptions represent 40% of healthcare claims</li> <li>Pharmacy costs represent &lt;5% of total healthcare costs</li> <li>ANPR=AWP+30% or “usual and customary”</li> </ul>	<ul style="list-style-type: none"> <li>Managed care begins to proliferate</li> <li>Third-party “plastic card” adjudication processors emerging</li> <li>Online pharmacy benefit, eligibility, and claim processing standardized via NCPDP</li> <li>Basic copayment model: \$5 brand name \$1 generic</li> <li>Mail order pharmacies enter market, offering 30% savings to payers</li> <li>Pharmacy costs represent 7% of healthcare costs</li> <li>ANPR=AWP+\$4 dispensing fee</li> </ul>	<ul style="list-style-type: none"> <li>Managed care firmly supplants indemnity insurers</li> <li>Third-party “plastic card” adjudication processors increase to 70% of all claims</li> <li>Drug manufacturers introduce rebates to gain market share</li> <li>Prior authorization and formularies affect 30% of all pharmacy claims</li> <li>Pharmacy equals 12–16% of healthcare costs</li> <li>ANPR=AWP minus 13%</li> <li>Mail order providers aggressively compete against retail channel; offer AWP minus 18%</li> </ul>	<ul style="list-style-type: none"> <li>Chronic disease dominates global healthcare costs</li> <li>Chronic disease patients represent about 3–5% of total population and about 55–65% of total pharmacy costs</li> <li>Annual biotech R&amp;D of &gt;\$24 billion in 2004 driving more than 300 drugs in phases 1, 2, and 3</li> <li>Trend toward outpatient and/or self-administered therapies results in lower control</li> <li>Biotechnology drug sales projected to exceed \$80 billion by 2008</li> </ul>
<b>Specialty drugs</b>			
<ul style="list-style-type: none"> <li>Injectables not covered under pharmacy benefit</li> </ul>	<ul style="list-style-type: none"> <li>Injectable use grows; coverage is through major medical insurance</li> </ul>	<ul style="list-style-type: none"> <li>Injectable use continues to grow; most benefits are still under major medical insurance</li> </ul>	<ul style="list-style-type: none"> <li>Payers looking for increased control; MCOs shift selected injectables to drug benefit with increased guideline management and risk focus</li> </ul>

LOW

Emphasis on cost and control

HIGH

LOW

Impact of technology

HIGH

HIGH

Reimbursement rates

LOW

ANPR=Average network provider reimbursement, AWP=average wholesale price, NCPDP=National Council for Prescription Drug Programs.

SOURCE: AUTHOR ANALYSIS, UNPUBLISHED MATERIAL

**TABLE 2** Challenges stakeholders face with specialty drugs

Traditional pharmacy	Prescriber	Patient	Payer
High cost of inventory Inability to have same/next-day delivery Special storage and delivery capabilities Reimbursement: pharmacy or medical, inability to bill major medical Pharmacist knowledge of injectables Patient counseling and support limitations: compliance, injection training Unwillingness to break package sizes Administration tools not included (needles, syringe, alcohol swabs, sharps)	Ability to gain access to products: sources constantly changing Multiple vendors Decreasing reimbursement by payers Formulary approval delays/billing risks Personnel required to oversee prescription ordering Increasing cost of labor/nursing shortages High cost of inventory, if held by physician Accounts receivable drain cash; uncertain collections Support of patients' demands increasing: reimbursement, training Compliance monitoring challenges	Access to products from traditional pharmacies Delays/interruptions in therapy created from uncommitted supply channels Varied coverage: medical and pharmacy benefit Prior authorization processes Higher out-of-pocket expenses/copayments/deductibles Difficult coordination of deliveries to treatment settings Product safety: storage and stability issues Counseling and support needed around the clock Compliance monitoring needed to improve outcomes and decrease global healthcare costs to plan and patient (lifetime maximums)	Member dissatisfaction Prescriber dissatisfaction Major medical "usual and customary" payment vs. managed care pricing Lack of national consensus guidelines/formulary controls Hidden billing codes ("miscellaneous" J3490s) Prior authorization and approval-criteria processes and associated labor Collection of proper copayments, co-insurance, deductibles Tracking and auditing utilization, showing return on investment of control programs Multiple plan designs can add confusion to process Multiple providers and in-network pharmacies create confusion

SOURCE: AUTHOR ANALYSIS, UNPUBLISHED MATERIAL

Medicare patients obtain therapy in the office via Part B, while others, next year, might obtain a biologic drug through Part D. Still another group might be in a Medicaid plan that has a buy-and-bill requirement for a certain product, while more are in commercial plans with varying copayments and access restrictions. SPs have to sort through these requirements to help physicians and their office staffs manage reimbursement challenges.

SP's goal is to provide a centralized point in the process. We have made great progress in helping clients streamline this process — yet, there is still a long way to go, as

multiple platforms and processes are used in the industry today.

**INDUSTRY TRENDS**

**MCO contracting.** A growing percentage of our agreements are exclusive arrangements in which health plans contract with a single SP. From year to year, we see an approximately 15 percent increase in use of exclusive arrangements between a health plan and an SP.

**Consolidation.** As reported in this issue of BIOTECHNOLOGY HEALTHCARE, there is a trend toward consolidation within SP. This is similar to what happened in recent years among pharmacy benefit man-

agers; today, just three PBMs — Caremark (which merged with AdvancePCS), Express Scripts, and Medco — manage the prescription drug benefit for the vast majority of covered lives in the United States.

This development has both advantages and disadvantages. It eliminates some competition, while also streamlining the process. Many smaller regional SPs are finding it more difficult to compete. Manufacturers are not eager to contract with them, as they seek continuity of services across health plans nationwide. In time, the SP industry will consolidate to a few national players, niche players, and some

managed care hybrids (MCO with a PBM and/or SP).

**Limited distribution networks.** It can be perplexing to try to understand how specialty pharmaceuticals are distributed. One product can be distributed through an *open channel*, meaning that the manufacturer has preferred arrangements with a few SPs. A second product can be placed in circulation through a *controlled distribution system* — say, three SPs and maybe a wholesaler. A third could be channeled through another model that is a hybrid or variation of these two.

Some channels are extremely restrictive; others are more open. Healthcare providers often have difficulty understanding why distribution systems exist or why they vary. Manufacturers put them in place for different reasons.

One common reason is to control inventory. If a product was made freely available throughout the United States, there would be huge inventory to manage. This comes with inherent difficulties. Potentially, a manufacturer would have to produce more inventory at a higher cost, with the risk to the buyer that some of this costly product — particularly if it has a short shelf life — could be wasted.

Further, obtaining data on inventory in stock and using that information to predict manufacturing needs can be a challenge. Years ago, one manufacturer was unable to meet demand for a specific biologic product, and a registry had to be established. Learning from that, some manufacturers have decided to limit distribution to control and manage inventory more easily.

Another factor behind the emergence of limited distribution net-

## Specialty pharmacy's role in managing disease

**S**upport services specifically for patients with specific diagnoses are numerous and varied — prior authorization and other utilization management services, data reporting, appeals processing, delivering medications and ancillary supplies (needles, syringes, alcohol swabs) to patients' homes, and around-the-clock access to a healthcare professional, to name a few.

In addition, we coordinate with manufacturers' external reimbursement programs and not-for-profit financial assistance foundations, we have enrolled patients in the Medicare Replacement Drug Demonstration, and we coordinate at-home-injection training support when appropriate.

The result of all this is to streamline the drug-distribution, delivery, and management processes in ways that engage patients in their care, help payers to understand their return on investment in specialty drugs, and assist manufacturers with inventory challenges and relationships with MCOs.

works is data. With certain products, manufacturers require SPs to gather the same types of information that PBMs do; in this case, the manufacturer obtains consistent data to help define prescribing patterns and to forecast demand.

Several other factors support tightening the distribution of biologic therapies. The data obtained through managing specialty drug distribution allow for greater consistency in delivering services to patients. The need to track utilization in the wake of multiple billing systems — sometimes a specialty drug is billed under the medical benefit, sometimes it's under the pharmacy benefit, and sometimes it's under both — also drives the proliferation of limited networks. So, too, does access to MCOs, which is important to manufacturers when a new product reaches the market. If we have, for instance, a relationship with a health plan, we would know with

whom to speak about how to handle this new drug. A temporary contract is put in a place until the product comes before the pharmacy and therapeutics committee. This helps health plans to manage new products as they come to market.

The need for case management support and advocacy, as well as issues related to disease management, also have given rise to limited distribution networks. If a patient needs copayment assistance, for instance, we review that patient's case: *Is the patient's benefit through pharmacy or medical? Is it retail or mail order?* We will triage the distribution of the product through a channel where the copayment is the least expensive or we will find alternative coverage. It could be, for instance, that a person is eligible for Medicaid but did not know this; in such a scenario, we would help to educate the patient about Medicaid and manage the benefit accordingly. **BH**