Specialty Pharmacy: Status and Future Direction

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When talking about specialty pharmacy, I am reminded of the famous words of Supreme Court Justice Potter Stewart as he ruled on a 1964 obscenity case. Justice Stewart wrote in his short concurrence that hard-core *pornography* was hard to define, but that "*I know it when I see it*." The same may be said for specialty pharmacy.

Generally, specialty pharmacy programs are designed to address drugs and biologics that are high in cost and difficult to manage, and have challenging reimbursement issues. These products often are problematic from all perspectives, including those of manufacturers, prescribers, patients, pharmacies, and payers. Specialty pharmacy programs evolved to address these issues by focusing on improving the access, delivery, disease state management, and financial support associated with these agents. Originally, specialty pharmacy could best be defined as a "cottage industry" that sprang up to support pharmacy benefit managers (PBMs) as they struggled with the management of increasingly high-cost agents. However, over the past 20 years, specialty pharmacy has grown significantly and many observers feel that it now is "the next big thing."

Speaking about the future of specialty pharmacy, Zach Gerger, PharmD, DO, President, The Pharmacy & Therapeutics Society, noted that "traditional methods of reimbursement and clinical decision making around specialty health products are not working, and together we need to define the new way forward" (Personal communication). Figures from the *Employee Benefit News* indicate that in 2003 the specialty pharmacy industry had $40 billion in overall drug spending, which rose to $78 billion in 2008.[1] That is a 95% growth rate in just 5 years, which is not surprising given the numbers and types of drugs and biologics coming into the marketplace. Currently, approximately 50% of all drugs approved by the US Food and Drug Administration fall into the specialty category, and the biologics' share of the pharmaceutical market has moved from approximately 15% in 2005 to more than 21% in 2010. This growth also has been subject to a confluence of other market factors such as declining reimbursement rates, shifts in coverage from the medical to the pharmacy benefit, increasingly complex monitoring requirements, and much greater emphasis on cost control. These factors have contributed to the evolution of specialty pharmacy as a way to better manage these high-cost drugs.

The trend in specialty pharmacy is to include virtually any drugs/disease states that are high cost, with the current focus on management of high-cost disease states such as cancer, HIV/AIDS, rheumatoid arthritis, multiple sclerosis, hepatitis C, infertility, solid organ transplant, growth hormone deficiency, and Crohn's disease.

The provision of specialty pharmacy programs is currently dominated by the PBM industry, with much of the business provided by their own specialty operations. However, with the rapid growth of specialty pharmacy, opportunities are available for other players to enter the market. Many large hospital organizations are successfully moving into this market. As integrated service delivery networks, many organizations provide home and clinic infusion services, retail pharmacy services, and extensive clinical pharmacist support for targeted disease state management initiatives. In addition, many hospitals now are exploring the opportunity to get into the insurance/PBM business themselves. Integration creates a comprehensive portfolio that allows effective delivery of specialty pharmacy services.

Mike Flagstad, RPh, MS, Chief Executive Officer of Visante Inc, an organization that provides consulting services to both the PBM and hospital markets, observes

that "there is certainly a lot of growth and change in the specialty market, but more importantly, a lot of opportunity. We (Visante) are seeing increasing interest from hospitals in creating specialty pharmacy service lines, and our consultants have already helped hospitals to successfully do this in Michigan, Nebraska, Tennessee, Massachusetts, Utah, Indiana, and Mississippi. One of the primary areas where hospitals interested in entering this market need support is in the management of billing and reimbursement associated with specialty pharmacy. Although hospitals may be well positioned in terms of service delivery and disease state management, they typically are not providing the financial infrastructure to effectively support a full-scale specialty pharmacy program" (Personal communication).

Retail pharmacies also are becoming increasingly interested in expanding their specialty market presence. They have traditionally been very good at product distribution and control. The primary barrier to a successful specialty program has been the lack of clinical expertise to manage the patient and the disease state, which is not an insurmountable obstacle. There are excellent examples of retail pharmacies that started out with a focus on specific disease states that they could manage and then expanded their expertise to support patients with other diseases. Diplomat Specialty Pharmacy in Michigan, for example, started out with a limited focus but gradually built up the required expertise so that they now offer a wide array of specialty programs in multiple states. The larger retail chains also have been successful in providing specialty pharmacy programs. For example, CVS/Caremark provides support for multiple disease states and provides specialty pharmacy solutions from personalized patient support services to medication management programs for health plans.

At the same time, some trends point in the opposite direction. Many health plans have or are examining exclusive arrangements in their contracting for specialty pharmacy and are creating arrangements with a single specialty provider, effectively locking other potential service providers out of that market. Manufacturers also are driving consolidation for some drugs/disease states. They are concerned about contracting with a wide variety of providers as they strive to create more service continuity nationally, which limits access to some smaller service providers. Limited distribution networks for specialty products are particularly frustrating to hospital and retail providers. In an attempt to control both inventory and data, manufacturers may opt for a closed distribution system. The advent of programs such as risk evaluation and mitigation strategies, often associated with high-risk/high-cost drugs, has created the need for extra data collection. From the point of view of the manufacturers, limiting the distribution of drugs increases compliance and the consistency of data collection.

However you define specialty pharmacy, this market segment is rapidly expanding. There is tremendous change both in and around the market (ie, new drugs), particularly in oncology, personalized medicine and genomics, a more integrated approach to patient care with medical home and accountable care organizations, and integrated patient care facilitated by electronic health records. All this growth and change mean opportunity for players in the market such as hospitals/health systems, retail chains and community pharmacy providers, PBMs, and health plans. Specialty pharmacy is a microcosm of the entire American healthcare system. It is evolving and changing, and we will be reinventing it in the next 5 to 10 years. For anyone interested in specialty pharmacy, this is *not* a good time to be on the sidelines. Now is a good time to get in the game.

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Reference

1. Hawes J. The specialty pharmacy revolution. *Employee Benefit News*; June 15, 2008. ajpb