New Channels for Drug Distribution and Reimbursement

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Date: 2007-12-09

Evolving business practices among healthcare providers and healthcare payors will impact both how and what pharmaceuticals are marketed in the near future

No person doubts that we are experiencing significant change in U.S. healthcare financing and service delivery. These changes are being driven by actions or responses from government (CMS), by commercial employer payors executed through PBMs and by integrated health plans as intermediate payors. The unifying element to product coverage decisions or benefit plan design is economics, but not just cost. Employers, CMS and other payors are seeking value [a measurable benefit from the expense incurred] from their healthcare spend, including pharmaceuticals. This search for value has moved from just talk to action through benefit design changes.

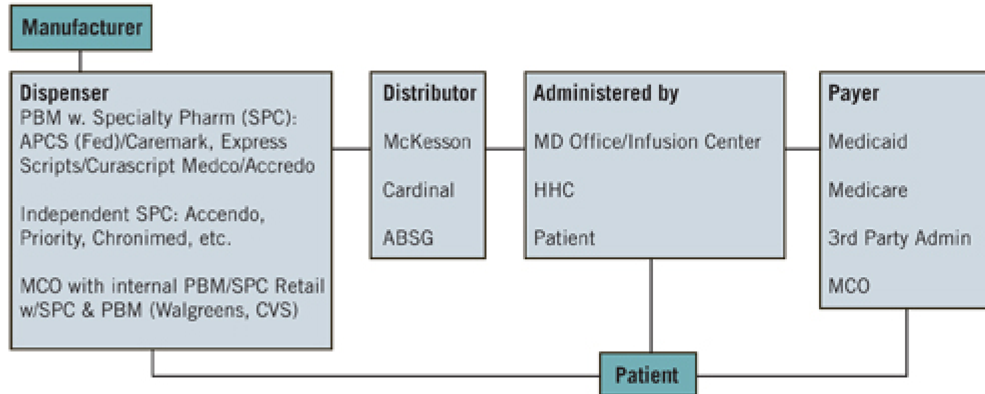
In a survey of over 500 managed-care organizations (MCOs), employers, and pharmacy providers, a soon-to-be-released 2007 Wyeth Prescription Drug Benefit Design Report indicates a change in payor strategy. A stronger emphasis on wellness and prevention begets heightened scrutiny among employers as to whether their prescription drug benefit is delivering value. Survey respondents generally agreed that they would have to take more control over their prescription drug plan formulary to ensure that products are chosen for overall value rather than to maximize rebates.

While a majority of employers did report using generic incentives today as their organization's primary benefit design strategy, a stronger majority of respondents said their pharmacy benefit cost-management strategy over the next three years would focus on preventive measures and fostering a culture of wellness and personal responsibility among employees. The implication to manufacturers is in how the value of health benefits and pharmaceuticals will be measured over time.

Employers as commercial purchasers of healthcare increasingly view value through more of a contribution to their enterprise-wide bottom line then just a silo cost. In an approach known as a value-based health strategy, employers are initiating self-funded healthcare coverage plans that mirror their strategic goals, employees' demographics and medical conditions, and opportunity for real savings beyond just the health plan cost.

As a result, manufacturers and others in the pharmaceutical value chain need to have an understanding of the needs of their ultimate customers—not those who may just purchase products. Those customers (patients, employers or trust fund payors) are exerting more decision-making authority, which changes the nature of relationships with other third parties (health plans, PBMs) who have been the more recent payor, contracting agent, or decisionmaker for the utilization of pharmaceutical products.

The Market View of Value: Who Controls the Drug?



Pharmaceutical distribution has undergone many changes in the past few decades, such as increased throughput via wholesale versus direct sales to retail or hospital channels, but has remained fundamentally a product-distribution focused business. Today that business is undergoing significant change within the complex U.S. healthcare market system that itself is changing.

New technologies force new channels

Centralized pharmacy operations and pharmacist-controlled or remote-dispensing from wholesalers (e.g., McKesson and Cardinal) for hospitals or pharmacies to Federally Qualified Health Centers and nursing homes are changing channel information flow and product movement. Professional and care site regulations are being updated to allow for practice changes that can improve access while lowering cost with no change in care quality. Upstream and downstream IT enhancements to facilitate a better value proposition are driving both professional practice changes and business channel integration to a greater level than in the past.

Retailers/wholesalers evolving as alternate direct channels of medication distribution for both traditional drugs and biotechnology products. Recently, the vaccines distributor, FFF Enterprises, has linked vaccine products to provider and patients. FFF reports that their 2006 integrated flu-vaccine program delivered product on-time for more than 98% of the requested scheduled administrations.

Change in the definition of specialty pharmacy products and services that can be delivered to patients has expanded the number of products distributed through specialty pharmacy versus PBM-dominated mail-order facilities. In addition, there is an overall increase the number of new biotechnology-based products or tests and the number of oral-administered biotechnology formulations. This has resulted in a decrease in specialty products available in retail pharmacies overall—another channel shift. For manufacturers, this means an increase in new stakeholders, regulatory changes as well as alternate distribution and utilization channels for newer biotech versus the traditional products.

As fewer blockbuster drugs are able to be developed, Big Pharma increasingly has moved to biotechnology, and in some cases such as Roche, has recast its entire business model to the discovery and commercialization of biotech products. Midsize and small pharma companies (biotech included) have become the new research laboratories and partners to the marketing prowess of Big Pharma. For the day-to-day professional in a given specific channel area, confusion among the players and their role in the product chain has led to an indifferent commoditization response to-date in dealing with market changes amongst the channel players. This commoditization is evidenced by CMS reimbursement changes for physician-administered products, home healthcare and durable medical equipment. The consolidation or elimination of select healthcare-delivery

channels can be disruptive to manufacturers or at least marginalize their control over the distribution channel.

Evolving business models
The future of PBMs over the next 5-10 years has become increasingly uncertain. CMS incentives for beneficiaries to join integrated medical and pharmacy plans versus stand-alone PBM-like plans may indicate a requisite change in the PBM business model. That, along with convenient care clinic implications from Walgreens' acquisition of Take Care and the CVS/Caremark merger (which includes the Minute Clinic franchise) has led Wall Street analysts and industry observers alike to wonder how consumer health and purchasing behaviors may shift. A disruption in the care delivery channels, and the shape of new benefit administration intermediaries, should cause manufacturers to watch how health system changes will affect their product utilization as well as profitability.

As a wholesale channel distributor of various products, AmerisourceBergen created an integrated organization, AmerisourceBergen Specialty Group, that offers end-to-end channel services to deal with the myriad reimbursement and product access issues for manufacturers, patients and providers. Medication Therapy Management (MTM), as demonstrated in the Asheville program pharmacist intervention model, has begun to impact employer decision making in many local communities as increasing numbers of pharmacists offer those services. (The Asheville Project, developed by the American Pharmacists Association Foundation, has demonstrated the value of pharmacist-managed medication services that improved patient outcomes [diabetes, cardiovascular disease, asthma] and lowered health claims cost for the City of Asheville, NC over an initial five-year period.) Congress and CMS have endorsed MTM since 2005, but CMS has yet to fully fund those services in the Part D program.

TIPS FOR SUCCESS

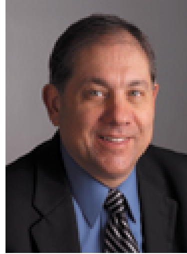
Think big: be aware of the entire market landscape not just contiguous or your own channel segment
Focus on the end user: understand emerging economics and reimbursement trends for products in the healthcare system
Do not overlook the change factor: recognize or anticipate channel movement and change in order to take advantage of a timely response to changing business conditions

Potential medication class changes
Changes in service channels and a deconstruction of the many functional silos within the healthcare industry today require manufacturers to be more knowledgeable about what goes on in their neighboring silos—looking throughout the channels of distribution.

Consider the potential of "behind the counter" (BTC) drugs. Fallout from pediatric cough & cold re-evaluations, psuedoephedrine restrictions, and the potential for statin medications such as Mevacor to be moved from prescription status to join other formerly prescription only products, including emergency contraception, are among the disruptions leading to renewed interest in BTC products to be "prescribed" and dispensed by a pharmacist. FDA held a public meeting in November on the topic, and may consider new prescribing practices. BTC would affect product reimbursement since it is neither a prescription covered by a drug benefit or an OTC product that is paid for as an out-of-pocket expense by patients. In addition, high deductible plans and consumer-driven plans would be affected since allowed medication expenses need to be determined by the IRS. This is another example of how a seemingly simple change in access to medications results in a series of regulatory and coverage actions that result in channel shifting events for manufacturers.

The end game for all these changes is unknown. The biopharma industry is struggling with new types of medications and combined medication and diagnostics (consider, for example, the implications of personalized medicine, tailored to individual patients).

Economics is forcing the traditional drug-discovery-to-market process to undergo a transformation to not only a focus on biotechnology, but creating a parallel economic value proposition beyond clinical safety or efficacy. Distribution of medications along with the mode, location and restrictions on prescribers who may distribute these products will have profound effects. PC



About the Author

Randy is a co-founder of EPS LLC (Cranston, RI; tel: 781-307-6247), which supports clients in the pharmaceutical, biotechnology and medical device industries in creating business strategies and interventions for self-insured employers. Dr. Vogenberg is a nationally recognized leader in pharmacoeconomics, health outcomes, and the promotion of value-based health plan principles. His specific expertise is strategic benefit consulting and pharmacy benefit design.

Prior to EPS, he was Senior Vice President for Aon Consulting. He holds an academic appointment in pharmacy management at the University of Rhode Island College of Pharmacy, Kingston, RI, and appointed a Senior Scholar for the Department of Health Policy, Jefferson Medical College, Philadelphia. Dr. Vogenberg is Chairperson for the Working Group on Employers/Insurers, International Society for Pharmacoeconomics and Outcomes Research, and served two terms as Chairperson, APhA STAT Committee on Payment & Empowerment.

Pharmaceutical Commerce. January 2008.