Specialty Pharmacy At a Crossroad

Consolidation of the specialty pharmacy business indicates a repositioning to buy new market channels, reduce costs, and compete in a burgeoning market. The challenge for SP is to prove its value to payers. Some companies are doing that on the basis of price or by offering care management services. Here's a look at a business in transition as it redefines itself for the biologics era.

BY KATHERINE T. ADAMS, *Senior Editor*

Warren Buffet, the famed Nebraskan investor, observed that in business, the rearview mirror is always clearer than the windshield. That's true in the specialty pharmacy (SP) market, where a wave of consolidation has left many SP companies in the hands of pharmacy benefit managers, drug distributors and retailers, and MCOs. SP consolidation shares traits that have become commonplace across the economy: larger players buying smaller ones, a scattered market becoming more concentrated and coherent, and relentless cost cutting to maintain margins.

Medicare Part D, which will restructure the drug market in ways as yet unknown in coming years, is also a mover in SP consolidation. Already, infusion and injectable therapy companies that provide at-home services to the elderly are being acquired rapidly by pharmacy benefit managers, distributors, and retailers.

WHAT IS THE SP BUSINESS?

Before any view of the road ahead for SP can emerge, those driving the business will have to decide which road they want to take. Up to now, SP has been about managing and distributing high-maintenance biologics and other high-cost medications. That may no longer suffice as payer expectations grow. Attempts to move into care management — a term that lacks a standard definition when it comes to SP — face steep hurdles, among them: defining the boundaries of care management and persuading customers that SPs are better equipped to provide those services than are others.

Serious dollars are at stake. Specialty pharmacy represents a $40 billion market that could approach $75 billion by 2008, according to Knowledge Source, a market research company in Trumbull, Conn. Consolidation has reached the point where eight vendors control more than half a segment that represents about 5 percent of overall pharmacy spending.

SP costs are rising faster than other pharmacy benefits, according to Aon's Spring 2005 Health Care Trend Survey of 79 medical, dental, pharmacy, and vision vendors. Aon forecasts that SP expenditures will increase by 22.5 percent over the next year, whereas general pharmacy spending will increase by only 13.1 percent.

ONE-STOP SHOPPING

Stand-alone SP companies of any scale have become a rarity, though smaller, local niche providers remain. "At this point, you certainly do not have any large SPs in the public or private marketplace," says Andrew Speller, a senior analyst at A.G. Edwards. "They all have been gobbled up — either by PBMs or by retailers. Everyone else who competes in the SP marketplace basically does it on a local basis."

PBMs bring broad expertise to the SP market, says Steve Russek, vice president of Medco Specialty Pharmacy Services. "Biologics are expensive; with the pipeline as robust as it is, there's a lot of financial pressure on payers." Consolidation, he says, brings the market clout that is needed to negotiate lower prices with manufacturers and to provide coordinated care for patients.

This consolidation has been dri-

ven by employers and health plans seeking one-stop shopping for all pharmacy coverage. Buyers, says Speller, want to get away from "a fragmented marketplace with different constituents having to go to multiple providers to get health benefits." The country's four largest PBMs — Medco Health Solutions, Caremark Rx, Express Scripts, and PharmaCare — manage drug benefits for close to 90 percent of Americans with commercial pharmacy coverage. Over the past several years, the four have bought SPs or formed strategic alliances. Medco acquired Accredo Health, previously the nation's largest publicly traded SP vendor; Caremark Rx merged with AdvancePCS; Express Scripts bought CuraScript and Priority Healthcare; and PharmaCare bought several independents, including Stadtlanders.

"PBM/SP combinations have economies of scale and can get better purchasing agreements that, for many health plans, will mean better pricing and national distribution coverage," says Debi Reissman, PharmD, a managed care consultant and president of Rxperts, in Irvine, Calif. "As the consolidated companies streamline management, they should be able to manage profitability better and improve margins — which, in the stand-alone SP business, is becoming a struggle."

SP is "an extremely fragmented market — with different companies using different strategies," says Brooks O'Neil, a senior analyst at Dougherty & Co. "In retail, for instance, which is an important component in distribution, you have dedicated SP pharmacies like Wal-Mart, and then you have the retailers such as Walgreen and CVS. Though

"We believe in an integration approach," says James E. Hartert, MD, of Prime Therapeutics, "and in the value of holding the pieces of medical, pharmacy, and specialty in a common management structure."

PHOTOGRAPH BY STEVE WOIT

the major PBMs and distributors control about 50 percent of the pharmacy business, that's far from complete consolidation." O'Neil sees opportunities for big and small SP players for some time to come.

"Consolidation is inevitable in the life cycle of any industry — and it is good, because it means the industry is entering a more mature stage and the strongest vendors will continue to prosper," says Kerr Holbrook, vice president of marketing for McKesson Specialty, a division of McKesson Corp., one of the top three U.S drug distributors, with Cardinal Health and AmerisourceBergen. In 2004, McKesson's SP business had revenue of $800 million, about 3 percent of the SP market.

"For payers, the benefit of consolidation is more competitive and consistent pricing across SP drugs, and elimination of redundant operations, which detract from service efficiency," says Holbrook. "Having six SPs to choose from is better than having 66 to choose from."

Becky Cherney, president and CEO of the Florida Health Care Coalition, which represents employers that provide health benefits to over 1 million Floridians, could

Specialty pharmacy consolidation: 10 largest acquisitions

Acquirer	Acquired company	Year completed	Price	Impact on market
Medco Health Solutions	Accredo Health	2005	$2.3 billion	Creates nation's largest specialty pharmacy with about 20% of market share
Express Scripts	Priority Healthcare	4th quarter 2005 *(expected)*	$1.3 billion	Priority owns 60% of Aetna specialty pharmacy through a joint venture and is exclusive manager of Wal-Mart's specialty pharmacy. Acquired SpectraCare's specialty infusion pharmacies in June 2005
Express Scripts	CuraScript Pharmacy and CuraScript PBM Services	2004	$335 million	Expands market share for hepatitis and multiple sclerosis injectables; care management component
PharmaCare	Stadtlanders	2001	$225 million	Several smaller acquisitions. Only major PBM with national mail and local service
Amerisource-Bergen	U.S. Bioservices	2003	$160 million	Specialty pharmacy distribution; reimbursement consulting; D.C.-area presence
MIM Corp., now BioScrip	ChroniMed	2005	Not disclosed	Broadens chronic disease coverage and retail/mail distribution services
National Medical Health Card Systems (NMHCRx)	Inteq	2004	$31.5 million	Latest in several acquisitions since 2002: Entered market with Portland Professional Pharmacy; information technology firm Integrail; Pharmacy Care Network; regional PBMs in Midwest. With Inteq, moves into Texas and Southwest
McKesson	D&K Healthcare Resources	Tender offer made 2005	$208 million	Footprint in Midwest and South; information technology expansion
Omnicare	Neighborcare RxCrossroads	2005 2005	$1.55 billion $235 million	Expansion into infusion therapies and Medicare drug market
Caremark Rx	Advance PCS	2004	$6 billion	Merger of two of the largest PBMs, both with specialty units; Caremark Specialty Pharmacy Services targets 13 diseases
Cardinal Health	Alaris Medical Systems	2004	$1.6 billion	Alaris provides infusion therapy and home-care management services

— With reporting by Tony Berberabe, MPH

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not disagree more. SP consolidation is "bad news for employers, payers, and consumers, because an issue with health care is the lack of competition across the system." A decade of consolidation among health plans, hospital systems, and drug companies has left purchasers with less negotiating leverage. "Ten years ago, we had 36 pharmaceutical companies on our vendor list; today there are 7. If we don't have a choice of going from one SP to another — one that might agree with our value proposition — then we don't have a value proposition."

Reissman doubts that SP consolidation will kill competition, noting: "Almost every major PBM now owns an SP — and there is no lack of competition on the PBM side."

In the short term, SPs and the companies that are buying them are streamlining the distribution of biologics. "SP has a variety of distribution vehicles, including home health care agencies and physician offices — and, increasingly, employers, plan sponsors, and insurers are asking PBMs to manage that continuum of distribution," says James E. Hartert, MD, chief medical officer of Prime Therapeutics.

"Payers are telling people who manage pharmacy costs to broaden their product lines and to find a way to manage specialty drugs," Hartert says, noting that payer demands and a biologics market that is growing at a 20 percent annual clip drove Prime Therapeutics' decision to develop an SP program. Today, McKesson Specialty is Prime Therapeutics' SP provider.

THE DISTRIBUTION DEBATE

Holbrook thinks that payers and physicians "will look for providers that can span different channels of drug distribution, whether it's SP or specialty distribution. It's likely that they will be looking at those services more like a portfolio, in the sense that you have one provider who can deliver those services."

Expertise in distribution has been the most important component of special pharmacies, given the short shelf life of biotech drugs and need for cold-chain handling — refrigerated warehouses, insulated shipping containers, and strict temperature controls. Whether future biologics will be stored and disseminated in new ways remains to be seen. For now, limited distribution via a single channel to control inventory seems to be the preferred method (see Suchanek article on page 31 for a discussion of this).

The issue of limited distribution is complex and contentious. (Witness the controversy over inventory management agreements [IMAs]).* "I'm concerned that limited distribution networks limit competition," says Hartert. "My preference would be to have manufacturers of specialty medications broaden their distribution vehicles rather than just follow along this consolidation and then align with PBMs for specific products."

Hartert also thinks the narrow distribution model could impede innovation. "I would would like to see the biotech industry explore issues of safety, quality, and inventory, and not be locked into thinking that limited distribution is the only way."

* An IMA is a mechanism for matching product output more closely to actual demand. It limits forward buying in return for a manufacturer's agreement to fees for distribution services.

FIGHT FOR FORMULARIES

Consolidation's greatest impact could be felt in the makeup of formularies. Holbrook thinks payers are just beginning to realize efficiencies by managing SP spending, and he expects payers to gain leverage regarding formulary choices.

The high cost of biologics makes each formulary decision a high-stakes bet. Cherney believes that if payers simply were to put specialty drugs on a formulary without convincing customers of their value, there would be problems: "Once something goes on a formulary, you can't ever take it away. So, given the cost of these drugs, very considerate decisions will have to be made."

Some formulary additions, she thinks, are well worth it — calling, for instance, the $15,000 to $24,000 annual cost of multiple sclerosis injections, "a tremendous value. Patients get their quality of life back, and ancillary costs go down."

The value proposition gets more complicated in other therapeutic areas. "What is the appropriate level of coverage for specialty psoriasis drugs? It's one thing to cover the person who has severe psoriasis and can't work, but should a person who has a patch of psoriasis and wants to go to the beach need the same drug?" says Cherney. "Some specialty drugs are going to come close to being lifestyle drugs."

To address that kind of issue, the coalition has set up a task force to devise a strategy for specialty pharmacy. One result could be private, independent P&T committees to conduct formulary analysis.

ADDING VALUE

Beyond issues of distribution and formularies, a fundamental ques-

"We want pharmacy to get to the point where its information can be integrated easily with total care of the patient," says Becky Cherney, president and CEO of the Florida Health Care Coalition. "We are not looking for pharmacy to take total responsibility for patient care."

tion of definition looms for companies providing SP services, says consultant Peter Boland, PhD, of Boland Healthcare, in Berkeley, Calif.: "What role will SPs play going forward? What value do they add?"

The question is the degree to which drug distributors, PBMs, and specialty pharmacy can play a strategic, as opposed to a tactical, role in cost management and quality assurance. Drug distribution, even at its most efficient, is becoming a low-margin, commodity-based industry. For companies that "go down the commodity-based service path, the future is bleak," Boland says.

To avoid that fate, Boland argues that SPs and other distributors must find a way to add value "that goes above and beyond delivering the right product at the right dosage at the right price and into the realm of patient management."

Care management may be that path, and to be sure, several SPs are moving in that direction — contracting with outside entities to provide care management services to customers. And, say some SP insiders, clinical programs are more robust for it.

O'Neil at Dougherty agrees that value-added services such as care management will differentiate vendors of SP products and services. "More forward-looking companies are looking at the SP market in a way that's similar to how disease management companies looked at their markets. Patients served by SPs are among the higher-cost patients and have complex needs not being met by the current delivery system." That opens a door for SP vendors to use data and offer more sophisticated care-management programs that can help improve patient care and ensure that compliance is according to best available practices.

"Some companies that have bought specialty players — distributors who are in it for the distribution component and PBMs who are coming at this as benefit administrators — are not care managers," O'Neil says. "But some of the SP people I've talked to *do* approach the business with an eye to the clinical component."

Pulling off the transition to care management will prove difficult. "How should SPs charge for care-management services?" Reissman wonders, noting that many SPs that provide some form of care management do not directly charge for it. "Can it be a separate revenue stream for them? I don't know."

WHOSE BUSINESS IS IT?

Then there are the turf issues.

Not surprisingly, given his com-

pany's roots in distribution, McKesson's Holbrook raises the question of how independent an SP vendor that's attached to a PBM can be. Although such a link may have some advantages, a payer could end up with "conflict and discontinuity" if one PBM administers traditional drug spending and another manages specialty drugs. "Independent SP providers can circumvent that conflict," he says.

"Another issue concerns health plans that want to provide pharmacy management services themselves," Reissman says. "They don't want to pay an SP to provide care management services and want SP costs to reflect distribution only."

Aetna resolved its approach to SP by moving the more than $1 billion a year that it spends on specialty drugs to a joint venture with Priority Healthcare called Aetna Specialty Pharmacy. The venture, announced last year, was to be operational by the third quarter of this year. Aetna formed a specialty pharmacy network in 2000 that contracted with multiple providers. Those arrangements will give way to the new exclusive SP venture with Priority.

SP vendors that don't have an arrangement like Priority's with Aetna may have a harder time expanding ties to health plans. "I'm not convinced the insurers want them in," Boland says. To succeed at care management, SPs and PBMs must "work hand-in-glove with MCOs, which have never been accused of doing too much in patient care, and with disease management companies that focus much more on chronic care," he adds. Each of these has certain information that is a valuable part of patient care, he says, but how these parties would work together is a strategic issue that has not yet been resolved.

Cherney doubts that employers will look to PBMs for care management. "I don't think any employer payers are looking at PBMs and thinking they are great at care management or have any reason to believe they are going to be better at it."

The way to overcome such doubts is to appeal to the bottom line, says Russek. "We will demonstrate to payers that there is a return on investment for these costly pharmaceuticals, and that they not only improve quality of life but also produce measurable and tangible reductions in total healthcare cost." That might be called care management, but Russek describes it as a patient-coordination model.

He points to hypertension care as an example. "With the Accredo acquisition, we have nurses all over the country who are visiting with patients under our pulmonary arterial hypertension programs. Our nurses become involved with the patients while they are still in the hospital. That gives us an end-to-end approach to specialty pharmacy. Before consolidation, this kind of care may have been fragmented — there may have been quality, but it was not well coordinated."

INNOVATION COUNTS

Cherney is adamant about the need for payers to leverage their purchasing power to push the consolidated companies into quickly establishing electronic health records. She strongly believes that SPs should not control data. The Centers for Medicare and Medicaid Services, she says, is looking at various pay-for-performance components to try to push data integration, regardless of who is paying for the drug. "It does not matter if Medicare is paying. Ultimately, we have to have a record so we know patients' drug allergies and can coordinate medications. Seniors can have 12 different prescriptions written by six different doctors. That information should be electronically available."

PharmaCare, which covers more than 30 million lives, has pilot projects underway to build care management systems. "That's clearly a direction the industry will take, in part because of the need to assure appropriate, cost-effective care," says Greg Weishar, PharmaCare's president and CEO.

Weishar sees the SP market becoming more, not less, competitive. "In the past, competition was around pricing and obtaining contracts. Pricing will always be key, but survival hinges on innovation — applying new technologies for better products and leveraging relationships with manufacturers to assure payers of cost-effective access to the drugs."

It won't be easy, he adds. "Unless the biologics industry shows a return on investment for these very costly drugs that improve quality of life, it's going to be a hard sell."

Which brings to mind another Buffet observation: "There are three kinds of people in the world: those who can count, and those who can't." With the amount of money at stake in the biologics era, the companies with the sharpest counting skills — those that can deliver specialty products most efficiently — will thrive. BH