



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

Specialty Pharmacy in Community Pharmacy:

The Time Is Now—and How!

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Executive Summary

Specialty pharmaceuticals represent the fastest growing segment of the prescription drug market in the U.S. Industry projections have the growth rate at 20% per year. Typically, these products are used to treat chronic and/or rare diseases, are high-cost, and can be administered by injection, infusion inhalation, or orally. Given the complexities of therapies—which require close supervision and monitoring of the patient, special handling, and administrative processes—as well as the costs, the delivery of specialty pharmaceuticals over the years has migrated toward managed care.

The provisions of continuity of care and access to specialty or biotechnology pharmaceuticals through community pharmacy have an important relevance to the entire retail pharmacy industry. As the utilization of biopharmaceuticals is projected to climb significantly and highly specialized patient care services demand more attention, community pharmacy, to avoid further carve-out by managed care organizations and payers in general, must become proactive and seize the opportunity to find ways to participate in this marketplace. If it chooses not to become an integral component of the specialty pharmaceuticals distribution process, these products will be moved entirely to mail-order facilities, and specialty pharmacy will become a major threat to community pharmacy's business and, worse, its survival. Additionally, the adoption of specialty pharmacy services further demonstrates, and can justify, community pharmacy's role as a health care provider versus a dispenser of product.

To assist community pharmacy in becoming a major provider of biopharmaceutical products and related services, and to address this strategic issue for the whole industry, the National Association of Chain Drug Stores' (NACDS) Pharmacy Industry Council¹ partnered with VCG & Associates² to undertake a research project, which was based on the following premise:

The development of a deliverable plan and strategic road map on how community pharmacy can be best positioned to participate in the dispensing and management of specialty pharmaceuticals and the impact on community pharmacy.

VCG & Associates developed a market/situational analysis to understand the complexity of the biopharmaceutical marketplace and the positions of stakeholders; researched solutions for community pharmacy; built alliances with specialty manufacturers and managed care organizations; and educated various

¹ The NACDS Pharmacy Industry Council was formed in 2004 and provides a forum and mechanism for chain retailers and pharmaceutical suppliers to have an ongoing process to identify and address industry issues, with the potential for significant impact on the strategic objectives of community pharmacy industry stakeholders.

² VCG & Associates is a consulting firm with expertise in developing strategic health care marketing initiatives that address the challenges surrounding product entry into the U.S. pharmaceutical market.

stakeholders about the role of community pharmacy, with the ultimate goal of developing a business plan for community pharmacy.

Research findings are outlined in this white paper. It addresses some of the differences between a traditional drug and a specialty drug, as well as services provided through a traditional pharmacy and a specialty pharmacy. The paper provides a historical background of specialty pharmacy, its evolution and emerging trends, and pipeline. It examines some of the key players and consolidation processes within this sector, as well as recent government actions that created many opportunities for community pharmacy to participate in specialty pharmacy business.

The paper identifies some operational challenges that community pharmacy needs to address in order to provide competitive specialty pharmacy services. It provides a detailed account of implementation steps community pharmacy must undertake to succeed in this business, including product selection, infrastructure, staffing, store design, customer service and order management, marketing plan, and competitive analysis, as well as the offering of several clinical programs.

Additionally, elaborate qualitative and quantitative research was conducted to include:

- A comprehensive survey questionnaire with the participation of key representatives from the payer community (i.e., managed care organizations and employers), specialty pharmaceuticals manufacturers, specialty pharmacy, and community pharmacy;
- Insight into many questions community pharmacy may have as it faces the challenge of either entering or expanding the daunting business of specialty pharmacy; and
- A detailed checklist of implementation steps to be taken into consideration as community pharmacy engages in specialty pharmacy business.

Overall, the paper provides key concepts and deliverables to assist any community pharmacy operation, whether chain or independent, in evaluating the opportunities within the specialty pharmacy segment. The ultimate goal is to provide guidance on developing a business plan for community pharmacy to be able to participate in the delivery of products and services related to specialty pharmaceuticals on either a small or large scale.

Defining Specialty Pharmaceuticals

Specialty pharmaceuticals are generally defined as products used to treat chronic, high-cost, or rare diseases and can be injectable, infusible, oral, or inhaled medications. Specialty pharmaceuticals tend to be more complex to maintain, administer, and monitor than traditional drugs; therefore they require closer supervision and monitoring of a patient's overall therapy. Key characteristics are as follows:

- Frequent dosage adjustments
- Dosage administration of injectable and infusible
- More-severe side effects than traditional drugs
- Special storage, handling, and/or administration
- Narrow therapeutic range
- Periodic laboratory or diagnostic testing
- Higher costs than "traditional" products (\$10,000–\$100,000 annually)
- Target small numbers of patients (5,000–100,000)
- Patient registration
- Patient training and clinical call center
- Compliance management
- Clinical data reporting and analysis

Often, specialty pharmaceuticals can be broken down into four distinct categories and are commonly defined and/or classified by the method of administration:

- Office-administered injectable products
- Self-administered injectable products
- Clinic/office administered infusible products
- Select oral agents

Defining Specialty Pharmacy

Specialty pharmacy is defined as the service created to manage the handling and service requirements of specialty pharmaceuticals, including dispensing, distribution, reimbursement, case management, and other services specific to patients with rare and/or chronic diseases. Specialty pharmacy, therefore, is a service that endeavors to provide two key deliverables:

- A mechanism to manage the cost of specialty pharmaceuticals for the patient; and
- An opportunity to save money for the benefit sponsor as compared to traditional models in which products are delivered through less efficient means, primarily hospital or physician's office. (Note: Within this white paper, benefit sponsor may represent third-party payer, insurer, self-insured, managed care, or other entity that is ultimately responsible for the payment of an individual patient's pharmacy benefit.)

Specialty pharmacy is centered on products used to treat specific disease states. The focus on appropriate drug utilization in conjunction with the ongoing monitoring of patient care provides an opportunity for payers to realize immediate savings working with those patients who use rare, highly expensive medications. The ability to enable and measure short-term and long-term savings has been the primary reason why managed care organizations (MCOs), pharmacy benefit managers (PBMs), and employer groups have responded to specialty pharmacy program offerings. Examples of the types of diseases addressed within the scope of specialty pharmacy services include:

- Cancer
- Crohn's disease
- Gaucher's disease
- Growth hormone deficiency
- Hemophilia
- Hepatitis C
- HIV/AIDS
- Immune disorders
- Infertility
- Multiple sclerosis
- Pulmonary hypertension
- Rheumatoid arthritis

Relevance for Community Pharmacy

The challenge for community pharmacy is the impending mix change from treatment with traditional pharmaceuticals to more specialty products, based on a number of market factors, including:

- Continued growth of generics;
- Anticipated slowdown in the growth of traditional branded products; and
- Projected growth in approvals for specialty products.

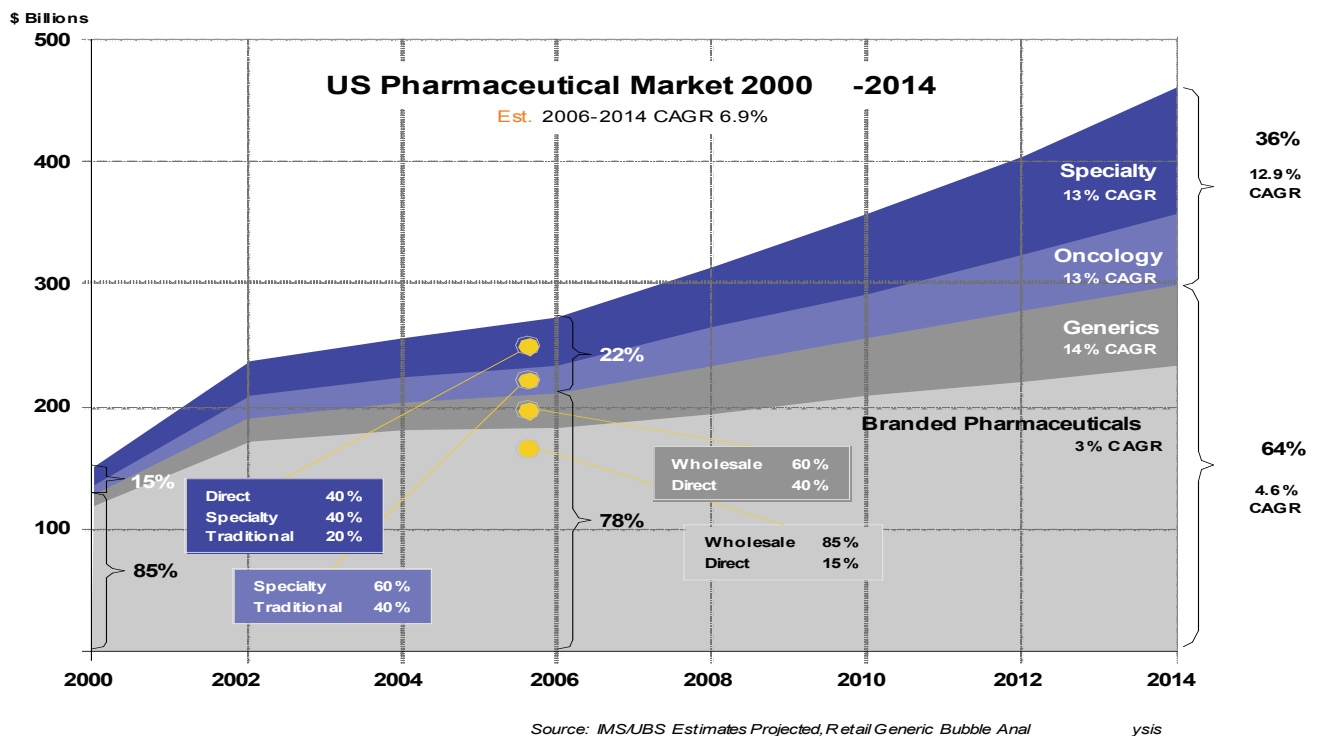
The implications of this product-mix shift within the pharmaceutical industry will impact all stakeholders, including manufacturers, distributors, and community pharmacy. As depicted in Figure 1, the compound annual growth rate (CAGR) for specialty pharmaceuticals from 2000 through 2014 is projected at 12.9%. The growth rate from 2006 to 2014 is even more pronounced. Conversely, the CAGR for oral solids, including branded pharmaceuticals and generics, is only 4.6%.

An extrapolation of the data in Figure 1 demonstrates that the result in dollar share of the combined pharmaceutical market represented by specialty pharmaceuticals, including oncology, will go from 22% market share in 2006 to an estimated 36% market share in 2014, a growth of more than 63% or a CAGR of almost 14%. At the same time, the portion of the market represented by

branded pharmaceuticals and generics is projected to go from 78% to 64%, a decline of 18%. Although this is a decline in market share, it represents real dollar growth, from an estimated \$220B to a projected \$300B during the same time frame. However, the specialty pharmaceutical sector grows from an estimated \$48B to a projected \$162B.

For community pharmacy, continued dependence on oral solids and generics will represent a relatively small growth opportunity for the foreseeable future. The real growth opportunity for community pharmacy will be driven by taking advantage of those products that are driving growth in the overall market.

Figure 1



Evolution of Specialty Pharmacy

History

Specialty pharmacy began with pockets of independent pharmacies attempting to fill key voids in traditional pharmacy practice, such as the management of complex disease states, treatment regimens, and challenging reimbursement scenarios. Initially, the “customer” was simply the patient whose disease state required the use of specialized medications. However, as specialty pharmacy has evolved, the “customer” has also evolved to include not only the patient but also the manufacturer and has attracted the attention of MCOs, PBMs,

employers, community pharmacy, distributors, and others seeking to manage costs or offer enhanced drug management services while providing an acceptable standard of care.

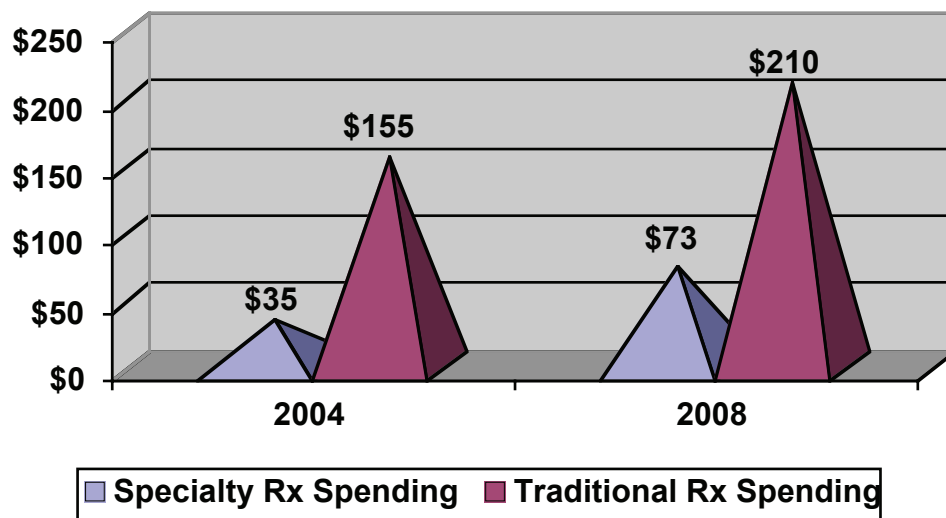
As a result, benefit sponsors have taken steps to “carve out” specialty products from their standard formulary offerings and treat them as stand-alone product lines in order to create specific alternatives to cut, or at the very least manage, these costs.

Growth

Estimates of the size of the specialty pharmacy market depend on the definition and continue to vary dramatically based on the source. However, it is generally accepted that the percentage of people on specialty medications is about 3%; on average, these patients account for 25% to 30%³ of a benefit sponsor’s overall medical costs. Current spending on specialty pharmaceutical products is estimated at \$35B. Growth, however, is very strong and, as depicted in Figure 2, is projected to grow at an estimated 20% per annum from 2004 to 2008. It is anticipated that by the year 2008, specialty pharmacy spending will be more than 34% of all drug costs, at more than \$73B in total dollars.

Figure 2

Projected Spending for Specialty Drugs, 2004 vs. 2008 (In Billions)



Sources: IMS data 2004; Wall Street Equity.

³ Pharmaceutical Care Management Association.

Consolidation

Similar to other consolidations in the pharmaceutical industry, the specialty pharmacy area is also experiencing consolidation. Consolidation within the specialty pharmacy sector is driven primarily by the following factors:

- Market share
- Scope of services
- Complexity of services
- Access to patients

The following table illustrates recent changes within the specialty pharmacy industry.

Table 1

Acquirer	Acquired Company	Year Completed
Express Scripts	Priority Healthcare	2005
Express Scripts	CuraScript PBM Services	2004
MIM (now BioScrip)	ChroniMed	2005
Medco	Accredo	2005
Omnicare	Neighborcare	2005
National Medical Health Card Systems	Pharmaceutical Care Network	2005
National Medical Health Card Systems	Inteq	2004
WellPoint	Anthem	2004
Caremark Rx	Advance PCS	2004
Cardinal Health	Alaris Medical Systems	2004
Aetna	Priority Healthcare	2004
AmerisourceBergen	US Bioservices	2003

Source: U.S. Securities and Exchange Commission, various company filings.

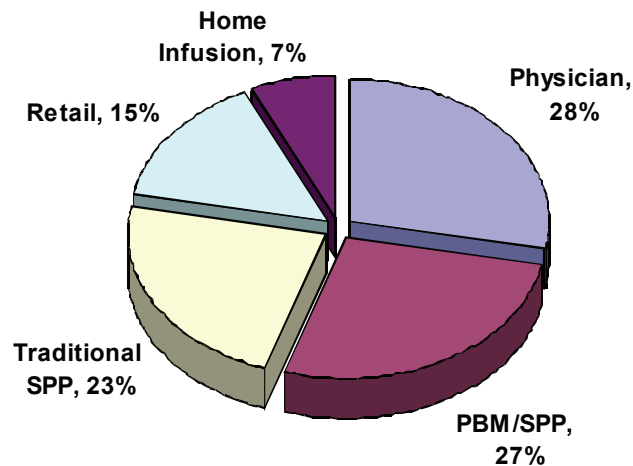
These examples validate the significance of specialty pharmacy and the tremendous impact specialty pharmaceuticals have on the lives of patients as well as on the budgets of health care benefit sponsors.

Key Players

Specialty pharmaceuticals continue to be very fragmented in terms of delivery channels and number of providers. In fact, while there has been significant consolidation in the sector, specialty pharmaceuticals continue to be delivered through a variety of outlets throughout the U.S. Figure 3 depicts the diversity of delivery channels utilized for specialty pharmaceuticals.

Figure 3

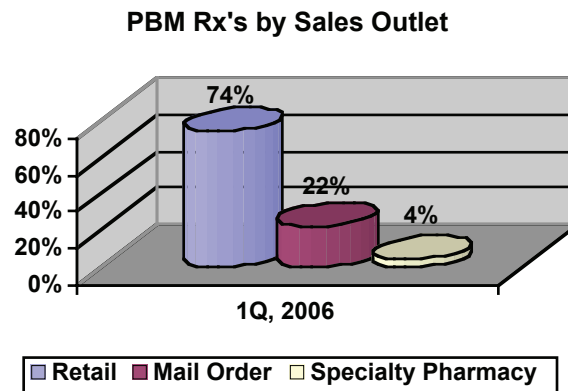
Specialty Product Purchases to Provider Channel (Including Oncology)



Source: *Specialty Pharmacy News*, October 2005.

As of the first quarter of 2006, *Specialty Pharmacy News* reported that more than 142 million specialty pharmaceutical prescriptions were being filled annually. Included in this number is fulfillment via retail, mail, specialty pharmacy, or specialty infusion, as well as products administered in physicians' offices. According to Figure 4, by volume, specialty pharmacy scripts now represent 4.64% of total prescriptions.

Figure 4



Source: *Atlantic Information Services 1Q, 2006 Quarterly Survey*.

While there are many delivery outlets, there are clearly entities that have achieved significant volume in both dollar volume and units shipped, as well as market presence, within the delivery of specialty pharmaceuticals.

The following is a list of some of the large, higher-volume providers:

- Accredo Health Inc. (Medco)
- AdvancePCS (Caremark Rx Inc.)
- U.S. Bioservices Corp. (AmerisourceBergen Corp.)
- Option Care Inc.
- Priority Healthcare Corp. and CuraScript Pharmacy Inc. (Express Scripts)
- Pharmicare, a subsidiary of Massachusetts-based CVS Corp.
- Bioscrip
- Walgreens Health Initiatives⁴

Emerging Trends

Some small independent community pharmacies represent an emerging trend in the delivery of specialty pharmaceuticals. They concentrate on the delivery of medications within a subset of specialty pharmaceuticals. These pharmacies are also delivering significant value to the benefit sponsor and the patient by concentrating on the holistic delivery of both specialty pharmaceuticals and traditional pharmaceuticals, and in some cases devices specific to select disease states. This trend could continue to develop as a subspecialty sector within the delivery of specialty pharmaceuticals. As an example, the types of disease states that have been successfully addressed by select community pharmacies include cystic fibrosis, hemophilia, Alpha-1 antitrypsin deficiency, immune disorders, growth hormone deficiency, and infertility.

FDA Pipeline Implications

Within the pharmaceutical industry, research and development drive the discovery of new pharmaceutical products, which in turn drives growth. While the Food and Drug Administration (FDA) approval process is not perfectly predictable, the reported pipeline of drugs currently under review indicates, by sheer numbers, that growth within the specialty pharmaceutical sector will significantly drive the overall growth of the pharmaceutical market. Specifically, as reported by Express Scripts in its February 2006 report, there are more than 800 products in the FDA pipeline that qualify under the definition of specialty pharmaceuticals. The majority of these products fall into the following categories:

⁴ Atlantic Information Services Inc., "Specialty Pharmacy 2005: Stakeholders, Strategies and Markets."

- Rheumatoid arthritis
- Multiple sclerosis
- Hepatitis C
- Psoriasis
- Oncology
- Pulmonary arterial hypertension

Specialty pharmaceuticals within the above disease states are expected to have an average retail selling price in excess of \$1,000 per month, compared with a traditional oral product, which sells at an average of \$87 per month, or a generic, which sells at an average of \$45 per month.⁵ Many of these products are injectable, which is important because, historically, injectable products such as human growth hormone have been delivered mostly through the community pharmacy channel.

Comparing historic delivery models with future drug indications suggests that specialty pharmaceuticals within the FDA pipeline represent a volume and profitability growth opportunity for community pharmacy.

Key Distinctions Between Specialty Pharmacy and Community Pharmacy

As set forth above, specialty pharmaceuticals are a segment of the prescription drug market primarily set apart by their use in the treatment of high-cost, chronic, and/or relatively rare disease states. For community pharmacy to become a participant in specialty pharmacy, it is important to summarize some of the differences that currently exist between the two. The comparison below demonstrates the difference between traditional drug management and specialty drug management. The key takeaway is the fact that traditional community pharmacy care is provided via a one-time event, with very little ongoing follow-up. Specialty medications, however, require ongoing professional services to ensure appropriate patient care.

⁵ VCG & Associates internal research.

Table 2

Management of Specialty Pharmaceuticals	Management of Community Pharmaceuticals
High level of patient training required and enlightenment regarding usage and proper handling.	Patient training required and enlightenment regarding usage and proper handling other than traditional counseling.
High and continued patient interactions beyond the initial dispensing process.	Generally a one-time patient counseling session on first fill and availability to respond to questions as needed.
Drug therapy may result in a higher frequency of side effects that are potentially more severe.	Potential drug therapy side effects are less frequent and not as potentially debilitating.
Dosage administration, side effects, storage condition, and other factors may require altering daily patterns.	Drug therapy generally does not require significant alteration to patient's daily patterns.
Patient noncompliance has potential for significant impact on expected improvements from therapy and can increase related costs.	Lack of patient compliance may have modest impact and may likely be a progressive rather than immediate negative consequence.
Rigorous patient education is required, often provided by nursing or pharmacist staff together with monitoring to ensure optimal outcomes.	Patient compliance education is generally limited to counseling and labeling of the product and distribution of Consumer Medicine Information (CMI).

Challenges to Dispensing Specialty Pharmaceuticals

One important aspect of specialty medications is how the products are administered to the patient. The dominant routes of administration include an oral solid tablet/capsule, which is swallowed; an injectable, which is administered by the patient or the physician; or an intravenous product, which is infused into the patient using a gravity flow or infusion pump system.

The complexity of the routes of administration in combination with the comfort level, time commitment, and space requirements will determine each individual pharmacy's capacity to participate in the delivery of specialty pharmaceuticals. The good news, however, as referenced within the FDA pipeline section, is that the majority of the specialty pharmaceuticals are in fact injectibles, which have traditionally been easier for community pharmacy to deliver.

In addition, a key differentiator between specialty pharmacy and community pharmacy has been the specialty pharmacy's ability to provide expert and focused therapy management and related services. Therapy management services have been a true value-added sell for specialty pharmacy, but have really been focused on compliance and persistency. The types of services include:

- 24/7 pharmacy hotline
- Physician practice counseling
- Reimbursement support
- Patient education
- Administration support
- Side effects counseling
- Home health coordination
- Patient outreach for prescription renewal
- Patient monitoring and capturing of select clinical criteria
- Payer/manufacturer reporting

One key element will be for the community pharmacy to provide ancillary support services similar to what is currently offered through specialty pharmacy providers. A venue to provide these services is to have a contracted or owned entity able to provide those services not currently provided within community pharmacy. A contracted venue, of course, is only applicable for those entities that are unable to make either the financial or structural commitment to provide these services internally.

Given that the revenue streams for specialty pharmacy services are segmented by key activities, a structure that shares responsibility for a patient should also be able to share revenue based on the fair market value of the services provided. This would allow the community pharmacy to be compensated for the distribution of the product, while the ancillary service entity would be compensated for reimbursement support, home health coordination, and other activities not handled by the community pharmacy. While the bundling of services may also be considered, uncoupling these services allows community pharmacy to bill for all services provided to a given patient population. Given that the service levels may vary dramatically from one patient population to another, charging on a service fee basis will allow community pharmacies to maximize revenue opportunities where legal and appropriate.

Recent Government Actions Create Opportunities for Community Pharmacy

Medicare Modernization Act

The Medicare Modernization Act (Medicare Prescription Drug Improvement and Modernization Act of 2003; MMA) stands to be the most significant change to the health care system since the inception of Medicare in 1965. It also brought about a number of opportunities for community pharmacy in terms of the ability to provide highly specialized services and be compensated for performing certain professional activities defined as medication therapy management (described below).

Another key opportunity for community pharmacy is the federal government's impact on leveling the competitive playing field. It was initially anticipated that the

MMA might shift more pharmacy volume to restricted providers of pharmacy services. However, in June 2006, the Centers for Medicare & Medicaid Services (CMS) decided Part D plans may not restrict access to certain Part D drugs to specialty pharmacies within their Part D network in such a manner as to contravene the convenient access protections of specific sections of the Social Security Act. Specifically, Part D plans may not restrict access to Part D drugs by limiting distribution through a subset of network pharmacies. They can do so, however, when it is necessary to meet FDA limited distribution requirements or ensure the appropriate dispensing of Part D drugs (i.e., when the drug requires extraordinary special handling, provider coordination, or patient education when such extraordinary requirements cannot be met by a network pharmacy). Therefore, Part D plans may not restrict access based solely on the placement of a Part D drug in a specialty/high-cost tier. This is not indicative of any special requirements associated with such a drug.

As a result of the MMA, patients have been given coverage previously nonexistent for medication therapy, and as such, utilization has and will continue to increase. As volume for specialty medications continues to increase, benefit providers will look to the market for assistance in managing those patients receiving specialty medication. This creates an opportunity for community pharmacy, if properly positioned to participate in providing a market-based solution. The current position of the CMS opens the door to nonrestrictive opportunities for community pharmacy and, more important, removes the risk factor of being carved out of networks in the near future specific to a Part D patient population.

Medication Therapy Management

As outlined by the CMS, medication therapy management (MTM) encompasses a broad range of professional activities and responsibilities within the licensed pharmacist's or other qualified health care provider's scope of practice. These services, all of which are nice enhancements to an expansion of the current specialty pharmacy environment and based upon the individual needs of the patient, include, but are not limited to, the following:

- Performing or obtaining necessary assessments of patient's health status;
- Formulating a medication treatment plan;
- Selecting, initiating, modifying, or administering medication therapy;
- Monitoring and evaluating patient's response to therapy, including safety and effectiveness;
- Performing a comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events;
- Documenting care delivered and communicating essential information to the patient's other primary care providers;
- Providing verbal education and training designed to enhance patient understanding and appropriate use of his/her medications;

- Providing information, support services, and resources designed to enhance patient adherence with his/her therapeutic regimens; and
- Coordinating and integrating medication therapy management services within the broader health care management services being provided to the patient.

As outlined by the CMS, a program providing coverage for MTM services shall include:

- Patient-specific and individualized services or sets of services provided directly by a pharmacist to the patient. These services are distinct from formulary development and use generalized patient education and information activities and other population-focused quality assurance measures for medication use.
- Face-to-face (or telephonic) interaction between the patient and the pharmacist as the preferred method of delivery. When patient-specific barriers to face-to-face communication exist, patients shall have equal access to appropriate alternative delivery methods.
- MTM programs shall include structures supporting the establishment and maintenance of the patient-pharmacist relationship.
- Opportunities for pharmacists and other qualified health care providers to identify patients who should receive medication therapy management services.
- Payment for MTM services consistent with contemporary provider payment rates that are based on the time, clinical intensity, and resources required to provide services (e.g., Medicare Part A and/or Part B for Resource-Based Relative Value Scale⁶).
- Processes to improve continuity of care, outcomes, and outcome measures.

In relation to specialty pharmacy services, payment for the support of specific MTM activities performed will now be available to all pharmacies that perform specific duties for those eligible patients. For those qualified pharmacies (those who have agreed to follow MTM guidelines), the pharmacist's activities are now compensated for specific patient services. Payment for these services will be contingent on the pharmacy having obtained the appropriate authorization from the board of pharmacy or other authorizing agency. The pharmacy will need to contract with the appropriate plans in their market area to provide services to the manage care plan's members.

This compensation model will enable community pharmacies to compete and receive compensation for the delivery of specialty pharmaceuticals

⁶ Resource-Based Relative Value Scale (RBRVS): A physician reimbursement scale defined by the CMS. RBRVS is the model referenced by the CMS to enable pharmacies/pharmacists to attain reimbursement for clinical patient services.

and the surrounding services without the financial demand or aggregating significantly large volume.

Key Success Factors

There are many potential disease states that can be managed within a specialty pharmacy environment. The following are several key operational challenges that community pharmacy has to address in order to provide competitive specialty pharmacy services currently in practice:

- Pharmacy adjudication
- Benefit sponsor contracting
- Manufacturer services
- Hub services

Pharmacy Adjudication

Reimbursement is key to any business and no less important to a pharmacy dispensing products costing thousands of dollars per month. The key to community pharmacy involvement with specialty pharmaceuticals is to concentrate activities on those products that can be adjudicated through the existing pharmacy billing systems. The list of pharmaceuticals that allow for adjudication through the pharmacy billing system can be accessed through standard industry listing agencies such as Medi-Span and First Data Bank. As mentioned under the MMA and Medicare Part D, the number of these products and patients with access to them will only continue to grow.

Fortunately, the trend for the past two to four years has been for payers to move self-injectable products from the medical benefit to the pharmacy benefit. This trend has provided very positive benefits to the payer, including the bundling of contracting for a variety of medications, the tracking of compliance and persistency, and the ability to monitor pricing across expensive disease states. Community pharmacy can take advantage of this trend by offering competitive services on products billed through the standard pharmacy billing systems.

Examples of specialty pharmacy product categories that can, in whole or in part, be adjudicated using standard pharmacy billing systems include rheumatoid arthritis, multiple sclerosis, growth hormone deficiency, infertility, psoriasis, hepatitis, as well as some of the more complicated products in the hemophilia and intravenous immunoglobulin (IVIG) sectors. These are all products initially only available to the medical billing side of health care. However, largely as a result of specialty pharmacy providers working with benefit sponsors in recognizing cost saving opportunities, access to specialty pharmaceuticals has increased as products have shifted to the pharmacy side of benefits.

Due to the success relative to cost control and efficient electronic billing, the trend for specialty pharmaceuticals to be billed through the pharmacy billing

systems will continue to accelerate. The result is that this access provides an ongoing and growing opportunity for community pharmacy to participate in specialty pharmacy services and distribution.

Benefit Sponsor Contracting

One of the key drivers of growth within specialty pharmacy has been the ability of specialty pharmacy to aggregate services on behalf of multiple manufacturers and offer payers discounted rates across a multitude of disease states. Simply put, specialty pharmacy has built the tools to perform the activities and has actively asked for the business. It is that single focus toward getting the business and making it easy and efficient for both benefit sponsors and manufacturers that has made the difference and allowed for the success of specialty pharmacy.

Community pharmacy will need to actively promote its capabilities to contract with benefit sponsors to be included as a specialty pharmacy provider.

While specialty pharmacy can offer many benefits in aggregate including multiple delivery locations, it will be very difficult for any one pharmacy to solicit contracts for multiple MCOs. It should be considered then by any community pharmacy wanting to get into specialty pharmacy to take one of the following three strategies:

Start local

Any given community pharmacy may have a greater degree of success if it starts payer contracting with a local entity. If a local employer has significant patient concentration around the community pharmacy location, this may create an opportunity for the community pharmacy to provide specialty pharmacy services, if only on a select set of disease states.

Partner with local physicians

A community pharmacy may find opportunities if there is a physician's practice in the vicinity that specializes in select disease states. As an example, growth disorders, infertility, and autoimmune disorders have been categories where local community pharmacies have entered the specialty pharmacy market by serving the needs of a local physician group.

National contracting

A network of community pharmacies may want to enter the specialty pharmacy market by aggressively seeking contracts with regional or national benefit sponsors. In the event that community pharmacy chooses this direction, they will need to put contracting experts in place to negotiate with plan sponsors. This can be done via hiring internal managed care sales or outsourcing this function until such time as a measurable return on investment (ROI) is realized on this effort.

National contracting will need to focus on MCOs. The managed care market has evolved into a marketplace with relatively few players dominating the landscape. In selected markets, the managed care model, in which decisions are made based on evidence-based outcomes, means that the authority for the decisions around which products will be used has shifted from individual prescribers to formulary and medical committees.

Manufacturer Services

In order to successfully compete with existing specialty pharmacies, community pharmacy will need to develop relationships with specialty pharmaceutical manufacturers. This will enable community pharmacy to purchase specialty pharmacy products at attractive discounts and to receive payment from manufacturers for services provided to patients on behalf of a manufacturer's product. Examples of some of these services include:

- Reimbursement support
- Therapy management
- Patient counseling
- 24/7 clinical support
- Patient registration
- Clinical tracking
- Reporting

In order to engage in meaningful manufacturer negotiations, community pharmacy should make sure to consider the following issues:

- Identify the key disease states in which they would like to initiate contracts;
- Identify the specific manufacturer with which they would like to contract; and
- Research existing discounts and services for which these specific manufacturers are willing to pay.

The community pharmacy can share the benefit of their experience with the targeted patient population and also can help the manufacturer with pre-launch planning and ongoing decision-making. The potential for providing baseline data about the patient population, use of current therapies, and information on prescribers offers keen insight.

By having access to the patient's entire drug history, the community pharmacy may provide, to the extent allowed by applicable privacy regulations, the manufacturer partner with utilization and outcomes data to help develop present and future products. This data is not readily available to the manufacturer community outside of the community pharmacy involvement and thus creates an opportunity for community pharmacy not available to specialty pharmacies that use mail order delivery. A further advantage for community pharmacy is the

ability to target small or hard-to-identify patient populations. This is unique to community pharmacy and not available to specialty pharmacies that use mail-order delivery.

Hub Services

A key challenge to provide specialty pharmacy services is to determine the delivery model for those services that typically reside outside of traditional community pharmacy. Some of those services, which have been previously referenced, include:

- Reimbursement support
- Therapy management
- Patient counseling
- 24/7 clinical support
- Patient registration
- Clinical tracking
- Reporting

While in the long term these services can generate some level of revenue, they may represent a costly barrier to entry when initially endeavoring to provide specialty pharmacy services. One potential solution is to provide these services for many individual community pharmacies via one “hub” provider.

The hub provider, whether owned or contracted, will enable multiple community pharmacies to provide services comparable to existing specialty pharmacy providers. Furthermore, the hub provider can be used for a central fill specialty pharmacy to supply those products that any individual community pharmacy may not want to stock.

Utilizing the hub concept enables the community pharmacy to enter the specialty pharmacy arena with a lower investment in design, structure, manpower, technology, cost of services, and products. Depending on the scale of a community pharmacy company, those costs can be adequately distributed across a significant base of pharmacies, thereby creating cost efficiencies. Sharing a common platform (or one that is interfaced) leads to an efficient structure in providing broad specialty pharmacy services.

Key Community Pharmacy Advantages

A key advantage for community pharmacy is to address issues for patients with multiple conditions. Patients treated with specialty products generally have multiple disease conditions. A disease-management approach that addresses all the needs of a given patient supported by hub services would both enhance care and provide important management tools for both the manufacturer and the plan sponsor. Examples of services that can be differentiated using community pharmacy include:

- A combination of community pharmacy dispensing and central distribution of pharmacy order fulfillment for specialty medications within targeted disease states;
- Clinical programs that will positively impact appropriateness and utilization and ensure proper compliance and persistency to prescribed therapies;
- Disease-management programs, as applicable;
- Reimbursement support transparent to the community operation;
- Options for the traditional “buy and bill” model;
- Ability to accept assignment of benefits for physicians and the payer;
- Disease specific programs as applicable and appropriate;
- Benefit design and formulary consulting as appropriate; and
- Ability to provide immediate drug access to the patient.

For the local community operation, access to not only the clinical services but the myriad other products and services that could be made available to the patient, provides great advantages. Examples might include home health care equipment, diabetic supplies, blood pressure monitoring, and others.

Steps to Implementation

A key to success for community pharmacy is to understand the key decision points required to provide a competitive offering for specialty pharmacy services. Below is an overview of the key components to building a successful community pharmacy specialty program. To best facilitate the process, the authors have created a “Checklist to Specialty Pharmacy Implementation” plan (Attachment C).

Picking the Right Products

As discussed herein, there are a number of avenues a specialty pharmacy can take. In planning for the future, it is critical that forecasts of which products the market anticipates will be approved is essential. Table 3 includes an analysis based on information compiled from MedEquity and other industry analysts.⁷

⁷ MedEquity Capital LLC is a private equity firm investing in mid- to late-stage health care service and product companies. Data based on MedEquity estimated, compiled using data from AIS, Raymond James, SG Cowen, Bear Stearns, IMS HEALTH, and other company documents.

Table 3

U.S. Market Size and Growth of Selected Specialty Pharmacy Categories

Category	U.S. Market (\$MM)	Estimated Growth	Delivery Method
Cancer	\$1,800	20%	IV infusion, subcutaneous (SC) injection
Crohn's	\$500	25%	IV infusion
Gaucher's	\$450	10%	Injection
Growth hormone	\$350	5%	Injection, SC injection
Hemophilia	\$2,000	10%	Injection
Hepatitis	\$2,000	30%	SC and intramuscular (IM) injection, oral
Hereditary emphysema	\$1,025	N/A	IV infusion
HIV	\$3,500	10%	Oral
Immune disorders	\$1,200	30%	IV infusion
Infertility	\$600	20%	Injection
Multiple sclerosis	\$3,000	15%	IM injection
Pulmonary hypertension	\$500	30%	IV infusion, SC injection
RSV	\$900	15%	IM injection
Rheumatoid arthritis	\$3,000	20%	IV infusion, SC injection
Transplant	\$2,100	N/A	N/A
Total	\$22,925	19%	

A prudent approach would be to define which categories of products are specific in the demographic profile of patients served. While many disease states are inherent in various geographic areas, there are several centers of excellence for treating specific diseases or key opinion leader specialists that may tend to skew the demographics of patients served. Designing a series of “marker” products would enable the community pharmacy to identify what disease areas have greater potential than others as well as evaluating who the higher prescribers are in each of the potential locations. In addition, this would allow the community pharmacy to investigate and identify the key specialty areas of the surrounding physician community. One of the best potential sources of information is pharmacies’ current patients.

Infrastructure

A key aspect of providing services for specialty pharmacy product is to ensure that the individual pharmacy has the appropriate infrastructure to support current and future services. This infrastructure needs to both enable delivery of specialty pharmaceuticals and incorporate the services that are required by both the payers and the manufacturers in the delivery of these products. The infrastructure to consider incorporating into community pharmacy includes but is not limited to:

- Cold storage
- Trained pharmacist/staff
- Data capturing and reporting
- Medical claims billing
- Coordination of infusion services
- Reimbursement support
- 24/7 on-call pharmacist

Staffing

Does the current pharmacy staff have the aptitude and fundamental skill sets to support a specialty pharmacy operation? The level of pharmaceutical care needed goes beyond the traditional dispensing and counseling process, and the community pharmacy needs to ensure that its staffing and training meet these requirements.

Store Design

If the community pharmacy is to participate in specialty pharmacy at any level, the design of the store has to be conducive to additional privacy standards above those encountered in today's "average" community pharmacy environment.

A store-design expert should consider which areas of disease specialization the pharmacy would like to have in its practice. Knowing which disease state a pharmacy will focus on should drive what resources and tools it will need to perform patient care. Knowing the appropriate disease areas will also play a role in what ancillary products the store may want to stock and recommend.

The local store pharmacist should be able to list out all of the products, services, and equipment needs—such as computers, fax machines, answering machines, blood pressure units, TVs and VCRs, and monitoring devices—that need to be integrated into the design. Also important are any patient-educational materials such as videos, books, brochures, magazines, and take-home aides. If the location has a home health care section, consideration should be given to how the counseling area is integrated into the overall design.

Customer Service and Order Management

Customer service in a specialty pharmacy environment requires that several criteria be met. First, all individuals (i.e., pharmacist, pharmacy technician, and customer service) interfacing with the patient and other providers should have in-depth training and knowledge of the specific disease state. An educated and enrolled patient who trusts his specialty pharmacy operation is critical to ensuring that those individuals have confidence in the message.

Second, customer service may need to take place at the community pharmacy level, with both professional counseling through the pharmacist and potential patient interface with customer service or pharmacy support personnel. In

addition, patient support may also be provided using access to the hub service model discussed earlier.

Third, communication may take place with multiple individuals involved in the patient's care, including physician, nurse, caregiver, nursing home/hospice staff, payer, and, of course, the patient.

These requirements call for appropriate systems to ensure tracking and reporting includes information from various constituents. Such systems, including those by Creehan & Co., OmniSYS, and CPR+, might be evaluated to assist community pharmacies in the tracking and reporting of services related to this endeavor.

Marketing

Marketing of community specialty pharmacy services should take place on several levels. Payers, which include PBMs, health plans, and employers, are critical audiences directing where the patient may receive therapy. A focused strategy is critical, if the community specialty pharmacy network can actively participate.

SWOT Plan

Many business leaders recommend the execution of a strengths, weaknesses, opportunities, and threats (SWOT) analysis when developing a business plan. Strengths and weaknesses are internal forces in their practice, while opportunities and threats are external forces that must be identified. The weaknesses and threats need to be overcome to achieve success in the specialty pharmacy practice setting.

- **Internal Strengths**

What types of services is a community pharmacy performing successfully today, and what other services, such as specialty, can be built upon this successful model?

- **Internal Weaknesses**

What are the practice areas that support specialty pharmacy that the pharmacies need to improve or build to be successful in the future?

- **External Opportunities**

Based on a community pharmacy's strengths, what types of opportunities can be built upon them to enhance its new specialty practice?

- **External Threats**

Based on competitive factors, how does the pharmacy need to adapt its specialty services so as to not directly compete or, more important, differentiate a community pharmacy's offering of services?

Competitive Analysis

In today's competitive specialty pharmacy environment, community pharmacy sees competition from a variety of stakeholders. First is the traditional specialty pharmacy that has contracted with benefit sponsors to provide specialty pharmaceutical services. Second are large MCOs (e.g., Aetna, Cigna), which have developed their own specialty pharmacy delivery models. Third and most dominant are the PBMs, which have developed mechanisms for the delivery of specialty pharmaceuticals that allow the benefit sponsors to push selected specialty pharmaceuticals away from community pharmacy to a select number of specialty pharmacy providers. This PBM/specialty pharmacy relationship makes it difficult for individual benefit sponsors to have real choice when selecting a distribution methodology relative to their specialty medications.

As part of the competitive due diligence relative to this white paper, several payer surveys (see Attachment A) were conducted, which reveal that a community-based delivery model would be positively received within the payer market. The positive response by the managed care markets indicates a willingness to accept new channel options and a real opportunity for community pharmacy to engage in the delivery of specialty pharmaceuticals.

Marketing Plan

Individual pharmacies should develop a document that details the action plans designed to accomplish the overall strategic objectives of their community/specialty pharmacy network. The marketing plan gives the pharmacy direction and focus for day-to-day operations and future activities. The marketing plan forces the community pharmacy to focus on the most immediate opportunities available and identifies the most achievable and profitable market segments.

Any marketing plan should evaluate the opportunity to access either national or regional MCOs. It should be noted that many times, large national plans have regional divisions that have some level of decision-making autonomy. A listing of the largest MCOs and the estimated number of lives managed is contained in Tables 4 and 5.

Table 4

Top 10 U.S. Managed Care Health Plans

Managed Care Plan	Lives Managed Under Pharmacy Benefit
Wellpoint/Anthem	34,000,000
United Healthcare/Pacificare	13,000,000/3,000,000
Aetna	10,000,000
Prescription Solutions	7,000,000
HealthNet	6,500,000
Coventry	6,500,000
Kaiser Foundation Health Plan	6,500,000
Cigna	6,300,000
Humana	6,200,000

Source: VCG & Associates data.

Table 5

Top 10 U.S. Blue Cross Blue Shield Plans

Blue Cross Blue Shield Plan	Lives Covered
Blue Cross of CA	7,600,000
Blue Cross Blue Shield of MI	4,700,000
Empire Blue Cross Blue Shield	4,500,000
Blue Cross Blue Shield of IL	3,700,000
Blue Cross Blue Shield of TX	3,600,000
Blue Cross Blue Shield of GA	3,100,000
Blue Cross Blue Shield of AL	3,100,000
HealthNow: Blue Cross – Buffalo	3,000,000
Independence Blue Cross	2,800,000
Blue Shield of CA	2,700,000

Source: VCG & Associates data.

Clinical Programs

Another opportunity for community pharmacy is to offer a number of disease-management programs for targeted disease states. These programs will be developed by licensed pharmacists with the assistance of other medical professionals and will address appropriate use, utilization, and access for designated drug classes.

One goal of the disease-management programs is to attain cost savings, ensuring that specialty pharmaceuticals used for these therapies are used appropriately and effectively. Therapeutic targets may include but are not limited to drug treatment for rheumatoid arthritis, multiple sclerosis, hepatitis C, intravenous immune globulin, Crohn's disease, and Infertility. These disease states have been identified within the industry as being high-cost and difficult to manage. Concentration in these potential therapies should provide market opportunities with sustainable short-term and long-term growth potential.

According to the Disease Management Association of America,⁸ critical components of a disease-management program should include the following services:

- The use of treatment guidelines including therapeutic interchange and formulary management
- Coordination of physician and support providers
- Patient education and support
- Outcomes measurements
- Routine reporting and feedback
- Medication self-administration oversight
- Clinical assessment and patient monitoring
- Side-effect management
- Physician consultation
- Drug utilization evaluation and poly-pharmacy review
- Care coordination with other health care providers
- Psychosocial support
- Community resourcing

In addition, disease management frequently extends beyond the pharmacy and the physician's office, since patients will often require home health care services to support in-home injection training or ongoing infusion services. Therefore, specialty pharmacies should be able to provide coordination of nursing services in the home setting. Many times, the need for nursing care may be a one-time education and training home visit, not a long-term need. Separating drug delivery from nursing care often decreases costs by limiting higher-than-necessary levels of care.

Disease management can often be provided by telephone, reducing the need for acute in-home services. Thus, specialty pharmacies have the potential to use a multidisciplinary team of experienced registered nurses/social workers, in addition to trained pharmacists, to support the complex management requirements of chronically ill patients receiving specialty medications.

These services bring the added value of disease-management concepts to specialty pharmacy throughout the patient's treatment to optimize clinical outcomes. Ongoing, objective measurement of clinical outcomes indicators specific to the disease and its treatment is paramount to quantifying the success of care management strategies and thus the critical need to ensure that data is appropriately integrated into the overall system. This integrated approach will contribute toward the validation of pharmacy's role in controlling costs while improving patient outcomes.

⁸ The Disease Management Association of America is a nonprofit, voluntary membership organization founded in March 1999 that represents all aspects of the disease-management community.

Community specialty pharmacies should initially consider three types of prescription and care management programs:

Prior authorization

Prior authorization requires additional clinical information besides a valid prescription in order to ensure that patients meet clinically acceptable guidelines for the use of the drug. Prior authorization has immediate applicability to the aforementioned therapies. Strategies regarding prior authorization will vary by plan, and a complete profile on each payer's methodology will be important.

Step therapy

Step therapy requires the use of less costly appropriate therapies before approving more-expensive drugs. Step therapy has immediate applicability to certain number of disease states such as rheumatoid arthritis and Crohn's disease and their therapies. Each of these disease areas has well-established and accepted treatment protocols driven by physician peer groups.

Adherence/education

Adherence and education programs will be designed to educate and monitor compliance with long term therapies thus ensuring the maximum benefit from each given therapy. In some cases, this may entail arranging in-home support for administration or teaching. There are several applicable to high-cost therapies such as IVIG and multiple sclerosis.

Conclusion

Currently, community pharmacy has a strategic advantage because it already has the broadest network of pharmacy outlets in the U.S. market today, and consumers generally know and trust their community pharmacist. In a recent citation:

WilsonRx^{®9} Reports published in late 2005, shows that community pharmacies continue to be the most commonly used type of pharmacy, followed by Mail, Food Store, Mass Merchant, Independent and Clinics. However, for the first time in four years, the percentage of households using Mail declined versus the previous year. Among those who use Mail, 72% probably or definitely would use their local pharmacy if the amount and price were identical. Fifty-six percent (56%) of household consumers report that they use more than one pharmacy to fill prescriptions. Eighty-two percent of consumers claim that their pharmacist is a source of information on medications and health conditions, however, very few

⁹ WilsonRx[®] is an independent, privately owned health care consumer research company that provides unique insight into pharmacy, pharmacy benefit, health insurance, and treatment satisfaction. WilsonRx[®] provides annual industry reports encompassing chain pharmacy, independent pharmacy, insurer, wholesaler, and other industry segments.

consumers report that they have a close relationship with their pharmacist and are on a first name basis.

It stands to reason that when given the choice of maintaining a professional relationship with their local pharmacist on specialty products, community pharmacy is the choice patients will make over other providers.

The brand recognition of community pharmacy in each marketplace cannot be easily replicated by other providers. Community pharmacy already has the advantage of:

- Being patient-management based, with a focus on professional services;
- Local relationships with the patient and physician community;
- Key relationships with the manufacturer for purchasing power;
- Reporting capability by capturing data currently lost within medical benefit; and
- Potential tie-in of financial management services.

In closing, the advent of MTM, the dynamic growth of specialty pharmaceuticals, and the relatively slow growth of the branded and generic oral solid markets makes it a unique time for community pharmacy to evaluate opportunities related to specialty pharmaceuticals. Although the hurdles may be difficult, involvement in the delivery and/or services related to specialty pharmaceuticals will ensure significant growth opportunities in the foreseeable future.

Attachment A

Community Pharmacy: Market Survey Results, June 2006

A confidential survey was conducted as a part of the research for this document. The respondents included payers (managed care and employer groups), specialty manufacturers (large and midsize biotech manufacturers), and specialty pharmacy providers and community pharmacy providers (chain and independent). The following represents an overview of the responses provided.

Overview of Market Survey Results

Payers

Payers today (defined as either MCO or employer groups) have some variations on the definition of specialty but generally categorize it as the following:

- High-cost injectable/infusible biologic specialty;
- Requiring a high level of patient education to ensure requirements;
- Unique or hard-to-manage specialty categories, such as pulmonary arterial hypertension, transplant, and oncology; and
- Those products that are expensive and also require refrigerated shipment or other specialty handling/delivery considerations.

Payers are very concerned about the burgeoning pipeline and anticipated growth of biotech products. This growth in the specialty sector brings perceived challenges to payer's budgets, distribution models, and patient care. As payers struggle to find a cost-effective, patient-friendly way to deliver specialty pharmaceuticals, community pharmacy represents a potential channel for payers to access a positive, direct relationship with the patient.

Payers are also looking for new distribution models to address concerns around capacity and services they believe cannot be delivered with a limited number of distribution providers. With many new medications available, payers believe in the need for more distribution outlets. Of particular concern is the recognition that the current industry infrastructure will be challenged to provide for infusion delivery capacity over the next five to 10 years. In effect, payers are looking for the market to evolve and somewhat redefine the distribution environment. In today's landscape, an efficient channel is defined by cost; in tomorrow's environment, the most efficient channel will be defined by outcomes.

Payers see reimbursement driven by route of administration. They inherently understand that using the pharmacy benefit provides the most efficient methodology to affect payment, manage discounts, and monitor overall usage. However, given the dosing requirements and services (e.g., compounding) that

may be required, payers see the pharmacy benefit as not always matching the needs of a given therapy. Second, driving payment that currently resides in the medical benefit through an electronic medical billing system is another way to streamline payment processing and reduce a payer's internal administrative costs.

Payers also see a larger percentage of payment responsibility being shifted to the patient. The opinion of the surveyed payers is that patients need to have more responsibility in the overall cost of their care as well as the fact that the plan cannot bear the overall cost of the drug. The use of health savings accounts may be an important tool in balancing the payer-patient cost exposure.

Finally, payers see convenience for beneficiaries as a major advantage for community pharmacy. The ability to attain a broad range of services across multiple specialty disease areas while enhancing therapy specific education using an individual pharmacist-patient relationship is a unique opportunity for community pharmacy. The key is to provide competitive services (i.e., competitive with current specialty pharmacy offerings) in a cost-competitive manner utilizing the opportunity to have a direct relationship with both the patient and the physician. Payers see community pharmacy with well-trained pharmacists as a unique opportunity to drive compliance and extend the delivery of quality health care services.

Specialty Manufacturer

A major key to community pharmacy's success in the delivery of specialty pharmaceuticals will be its relationship with the manufacturing community. Community pharmacy needs a vehicle to allow for the collection and aggregation of data and provide the data in a flexible Health Insurance Portability and Accountability Act (HIPAA)-compliant manner. The ability to provide data on services, compliance, and other disease-specific information will be an absolute requirement for inclusion in the delivery of specialty pharmaceuticals. As payers and the FDA drive health care to outcomes-based delivery, providing manufacturers key information on patient data will be a lynchpin in participating in specialty pharmacy delivery.

Specialty Pharmacies

Specialty pharmacies see three contributing factors to significant opportunities in the next five to 10 years:

- Ongoing growth in the specialty sector
- Alignment with PBMs to assist in the contracting of lives
- An increasing elderly population

Specialty pharmacies today are working to position themselves to provide far-reaching services, including the delivery and administration of infusible medications. Further, specialty pharmacies that have had long-standing

relationships with specialty manufacturers are working even harder to ensure favorable manufacturer relationships.

Community Pharmacy

The first requirement for community pharmacy to aggressively participate in the delivery of specialty pharmaceuticals is to incorporate the appropriate infrastructure. This infrastructure needs to both enable delivery of specialty pharmaceuticals and incorporate the services that are required by both the payers and the manufacturers in the delivery of these products. The infrastructure needed to be incorporated into community pharmacy includes, but is not limited to:

- Cold storage
- Trained pharmacist/staff
- Data capturing and reporting
- Medical claims billing
- Coordination of infusion services
- Reimbursement support
- 24/7 on-call pharmacist

In the immediate timeframe, community pharmacy can quickly be positioned to compete in the self-injectable and high-cost oral solid market. Competing in these markets may include some additional data capturing capability but otherwise can be delivered using the current community pharmacy infrastructure.

The other key piece for community pharmacy relates to contracting with MCOs. To date, MCOs have indicated that they would consider community pharmacy as a delivery channel if community pharmacy came to the table with a competitive offering.

Payer Questions

The payer participants included representatives of both large and small organizations. Some participants had a national scope, while others were more regionally focused.

1. How does your organization define specialty pharmaceutical business?

The payer community defines the specialty pharmaceutical business using a combination of definitions. First, the specialty pharmaceutical category is defined as high-cost injectable/infusible biologic specialty therapies inclusive of transplant and oncology. A further definition includes high-cost medications (defined as greater than \$500 per month), including both infusible and injectable medications requiring a high level of patient education to ensure proper utilization.

2. How does your organization see the mix of specialty products coming to market within the next five years (i.e., oral solid, injectable, infusible)?

All payers surveyed agree that the specialty pharmaceuticals market, regardless of definition, will grow dramatically in the next five years. In some cases, this growth is defined as infusion, injectable, and specialty oral solid medications specifically within the oncology sector. In addition to growth in new therapies, payers demonstrated concern over the ongoing growth of existing therapies and existing products that are expanding to new therapies.

3. How will the mix of products change the dynamics of your organization's distribution and delivery channels?

Large payers see the growth in specialty products as an opportunity to develop internal specialty capabilities or to develop an "in-house" specialty pharmacy delivery model. In either case, the larger players see the growth in specialty pharmacy as a potential revenue stream within their organization. Further, payers see the need to create cost incentives that drive the delivery of specialty pharmaceuticals to the most efficient channel. In today's environment, the most efficient channel is largely defined by cost; in tomorrow's channel, the payers are looking to define efficiency by outcomes. Payers also see more infusion activities shift to infusion clinic and home infusion environments, thereby driving infusion away from the physician's office. Finally, payers are looking for new models to emerge because they are very concerned about accelerated growth in the most expensive therapy segments.

4. Will the mix of products change the dynamics of the mechanism and/or location of patient services (i.e., specialty pharmacy, physician office, infusion clinic, home)?

Payers see additional growth in specialty pharmacy, infusion clinic, and home infusion segments. Payers believe that given historic physician markup, the payers will use the advent of *ASP* + 6% for office infusions through CMS as an opportunity to drive infusion away from the physician office location. Payers see the need for the market to grow the infusion-delivery portion of the business to respond to the growth in infusion product delivery.

5. What percentage of your client's business would your organization say is defined as "specialty" today?

The payers demonstrated a wide variance in what they determined "specialty" as a part of their business. Depending on the client mix (i.e., higher self-funded), the regional mix, and the inclusion of oncology, the view of specialty can be vastly different from one payer to another. In general, for specialty business not including oncology, the payers perceived approximately 10% in dollar volume and 2% in units shipped as falling into specialty pharmaceuticals.

6. Do you see your operation moving closer toward managing a specialty product portfolio through an "in-house" offering?

As outlined in the response to question 3, the opportunity to provide an "in-house" specialty offering was confined to those payers that are the larger payers in the market. This is due to the fact that the larger payer can define a measurable ROI on this market sector, even given the capital cost required to create an "owned" specialty pharmaceutical offering.

7. What percentage of your organization's managed care volume would you anticipate being "specialty" in five years?

All participants are concerned about the dramatic growth of the specialty category. Answers varied from a low of 10% of dollar value in five years to as high as 25%. This growing percentage represents a double concern for the payers due to the fact that they see this as a larger percentage of a pie that is growing mainly due to specialty pharmaceuticals.

8. How does your organization see reimbursement changing with the shift in the product mix toward specialty?

Payers see reimbursement largely driven by the route of administration. This being said, all payers talked of continued efforts to drive reimbursement to the most efficient reimbursement structure. The most efficient structure recognized today is to run coverage through the pharmacy benefit. The pharmacy benefit represents a most efficient methodology to affect payment, manage discounts and monitor overall usage. A secondary methodology was

to drive payment residing within the medical benefit through an electronic medical billing system, to streamline payment and reduce internal administrative costs. A third reimbursement change is an ongoing shift from the payer to the patients. Payers see the patient as having to share the burden of high-cost specialty pharmaceuticals.

9. In your opinion, should community pharmacy invest in specialty pharmacy distribution and support services?

Payers recognize that community pharmacy is already involved with the distribution of many specialty distribution products. However, the trend seems to continue to move distribution away from community to the most cost-effective distribution model, primarily identified as specialty pharmacy (i.e., a pharmacy designed to handle the unique needs associated with specialty pharmaceuticals). Payer outlook is that while community may represent a good delivery model, community does not appear to be competitive with either price or services in comparison to other distribution options. The result is that the payer community sees value in community pharmacy's investment in specialty pharmacy distribution and support services only if community pharmacy can be competitive with other distribution options.

10. Should community pharmacy move more toward a specialty offering, what services would you recommend that they participate in to differentiate themselves from the "pure play" specialty pharmacy providers?

The one key differentiator for community pharmacy to differentiate themselves relative to a specialty offering is in the potential relationship between the pharmacist and the patient. Payers have indicated that this relationship may have value if it drives additional education, compliance, and outcomes for the patient. According to payers, the key for community pharmacy to compete in this sector is to be able to use their local relationships as a differentiator and to provide tracking that allows payers to measure potential outcomes. This can separate community pharmacy from specialty and mail-order segments.

Employer Group Questions

The employer participants included primarily larger self-funded employer groups. The answers were very similar to the payers, with a greater concern around emerging costs.

1. How does your organization define specialty pharmaceutical business?

The employer groups defined the specialty pharmaceutical business, largely like the payer community, based primarily on cost and complexity to manage specialty pharmaceuticals. Some of the definitions provided by employer groups included:

- High-cost injectable/infusible biologic specialty;
- Requiring a high level of patient education to ensure requirements;
- Unique or hard to manage specialty categories such as pulmonary arterial hypertension, transplant, and oncology; and
- Those products that are expensive and also require refrigerated shipment or other specialty handling/delivery considerations.

2. How does your organization see the mix of specialty products coming to market within the next five years (i.e., oral solid, injectable, infusible)?

Employer groups see the growth of specialty medications across all routes of administration including infusion, injectable as well as specialty oral solid medications. Employer groups specifically identified this route of administration mix relative to the oncology sector. Employer groups expressed concern regarding the growth of existing therapies the FDA pipeline in addition to the ongoing investments in personalized medicine.

3. How will the mix of products change the dynamics of your organization's distribution and delivery channels?

Employer groups are continuing to look for new delivery models. They are concerned that given certain union agreements, some groups may not be able to take advantage of lower-cost delivery channels (e.g., specialty mail order), but only have access to specialty products through community channels. While there are many workarounds to this issue, the employer groups expressed concern over both direct access as well as delayed access for their beneficiaries. While employer groups would like to make clear-cut decisions on delivery based on cost effectiveness, they are sensitive to the requirements of existing contracts and convenience to the retiree sector.

4. Will the mix of products change the dynamics of the mechanism and/or location of patient services (i.e., specialty pharmacy, physician office, infusion clinic, home)?

Employers see additional growth in specialty pharmacy, infusion clinic, and home infusion segments. Employers, however, are somewhat limited in their ability to drive coverage to a certain market sector and must provide a certain degree of flexibility for their beneficiaries. Employers are concerned that the advent of ASP + 6% will drive access away from physicians' offices and are currently working on delivery models to address this issue.

5. What percentage of your client's business would your organization say is defined as "specialty" today?

As with the payers, the employer groups demonstrated a wide variance in what they determined as "specialty" as a part of their business. Depending on the client mix, primarily driven by the types of work (i.e., blue collar) and the level of retirees, the estimates for the amount of specialty pharmaceutical spending within their covered lives varied dramatically. In general, the numbers were slightly higher than the payer community, averaging between 5% to 10% in units and 15% to 20% in dollar volume.

6. Do you see your operation moving closer toward managing a specialty product portfolio through an "in-house" offering?

The answer for the employer groups was clearly that they are not significantly considering an in-house offering but would rather see the market define a solution. Further, certain survey participants suggested that a competitive market should be able to provide a more cost effective solution than attempting an in-house offering.

7. What percentage of your organization's volume would you anticipate being "specialty" in five years?

All participants are concerned about the dramatic growth of the specialty category. Answers varied from a low of 15% to a high of 35%. The real concern is that specialty pharmaceuticals not only represent a single growing area of pharmaceuticals but are also driving up the costs of the overall pharmaceutical sector. In addition, employer groups expressed serious concern over the ethical dilemma of providing high-cost medications to patients with limited opportunity for a long-term benefit. One example was how to justify a \$30,000 expense for a 9% chance to extend life for three months. The ethical dilemma of where and how to provide expensive medications to an aging population, within a limited budget, is of major concern to the employer community.

8. How does your organization see reimbursement changing with the shift in the product mix toward specialty?

Employer groups express some limitations on the shift of reimbursement based on the inability to drive beneficiaries to targeted delivery channels. Therefore, employer groups are looking to current delivery models (i.e., physician's office, community pharmacy) to provide products and services that are competitive with the broader market (i.e., PBM, specialty pharmacy). Employer groups see limited opportunity to be market leaders in driving products to the pharmacy benefit, but do see themselves as slowly following the payer community.

9. In your opinion, should community pharmacy invest in specialty pharmacy distribution and support services?

Employer groups see convenience for beneficiaries as a major concern. They see value in attaining more and more services from the neighborhood community pharmacy regardless of chain or independent affiliation. Employer groups see direct value in community pharmacy's investment in specialty pharmaceutical distribution and support services and appear favorable for community pharmacy to be able to compete with other distribution options.

10. Should community pharmacy move more toward a specialty offering, what services would you recommend that they participate in to differentiate themselves from the "pure play" specialty pharmacy providers?

According to the employer groups surveyed, the key differentiator for community pharmacy is in the potential relationship between the pharmacist and the patient. Particular for those employers with a retiree population, they see a well-trained pharmacist as a key to ensuring patient compliance and outcomes, which have a very real impact on employers' health care costs.

Specialty Manufacturer Questions

Both traditional manufacturers with some specialty pipelines and true biotech manufacturers were surveyed. The responses outlined below represent a combination of the answers provided.

1. How many products does your organization believe will enter the “specialty” market within the next five years?

All manufacturers see growth within the specialty sector. However, given the volatility of products going through the clinical trials process and the renewed scrutiny of the FDA approval process, many manufacturers see a relatively small amount of new products coming to market. Of the eight manufacturers surveyed, the estimated number of new specialty pharmaceuticals range from a low of 15–20 to a high of 50–75.

2. What will be the route of administration (oral, injectable, infusible)?

All specialty manufacturers see growth in their infused product lines across a variety of disease states. The infused product lines were mentioned significantly more for new product introductions than other potential routes of administration within the specialty pharmaceuticals category. In addition to infused, however, several players see themselves launching additional injectable products. Finally, a small group within the oncology space sees more expensive “specialty” oral medication being launched within the oncology arena.

3. How many new specialty products do you anticipate launching within the next five years?

The specialty manufacturers surveyed represented a low of two to a high of 10–15 potential specialty pharmaceuticals with the opportunity to be commercialized within the next five years. This number, of course, was tempered with the consideration that many of these products were very early in their clinical trial processes.

4. What is your organization’s preference in regards to injectable or infusible products being administered to patients (physician office, infusion center, and home infusion)?

Pharmaceutical manufacturers had less direct concern on the location of the administration and were most interested in those delivery vehicles that could provide the best market data. To date, specialty pharmacy providers via either direct-to-patient delivery or direct-to-physician delivery were referenced as providing the best market data back to the specialty manufacturer.

5. Is it easier for your organization to get data from one site of care than another?

Similar to question 4, specialty pharmacy providers are looked upon as providing better data and easier to work with to get data, according to pharmaceutical manufacturers. This, of course, is due to the fact that most specialty manufacturers have relationships with existing specialty pharmacy providers and do not have similar relationships to provide data through community pharmacy.

6. What are the types of services that your organization most value (data, services, etc.)?

The types of services mostly valued by specialty pharmaceutical manufacturers relate directly to patient services and data feedback. Pharmaceutical manufacturers need to have data that enable them to respond to market requirements and track some level of patient outcome. The goal of patient data (HIPAA-compliant, of course) is to provide manufacturers with some level of outcomes measurement they can use when negotiating with the payer community. In addition, data shared from specialty providers enables manufacturers to recognize issues with compliance, dosing, and other treatment regimens that need to be addressed before becoming a detrimental issue in the marketplace.

7. How does your organization expect specialty products that are yet to be introduced to potentially change your current distribution strategy?

The majority of manufacturers anticipate having a higher need for infusion services. Specialty manufacturers expressed concern over the number of infusion products coming to market and the number of products on the market today that have the potential for additional indications. As a result of these concerns, manufacturers see the need for additional infusion capabilities including infusion clinic capacity and home infusion capacity. Some specialty manufacturers also see an additional need for exclusive or limited distribution channels. The perceived need for exclusive or limited distribution is driven by products that fall into certain rare chronic disorders (i.e., pulmonary arterial hypertension, cystic fibrosis, and end-stage renal disease) and require an extremely high level of patient education and monitoring for successful therapeutic outcome.

8. What percentage of your organization's products is distributed through specialty distribution today and why?

The percentage of individual manufacturer's products currently distributed through specialty pharmacy varied dramatically by manufacturer. For large (more traditional) manufacturers, the total book of business distributed

through specialty pharmacy was almost negligible. Conversely, true biotech manufacturers stated that a very high (greater than 80%) amount of their product sales was distributed through specialty pharmaceutical distribution. The final amount of any given manufacturer's products going through specialty distribution was based on the manufacturer's overall product line and its historic use of the specialty distribution channel.

9. What, if any, of your organization's current products utilize exclusive or limited distribution?

Specialty manufacturers indicated that some have no products utilizing exclusive or limited distribution, while others have multiple products using limited channels. The majority of manufacturers surveyed indicated that they see value in using exclusive or limited channels for certain product types. Only one manufacturer has no interest in a limited channel, indicating that it sees more-open access as a better vehicle to generate additional sales. In other words, some manufacturers are of the opinion that the more distribution outlets available for a given product, the more sales will be driven for the manufacturer.

Specialty Pharmacy Provider Questions

1. How much growth does your organization see in the specialty marketplace over the next five years?

Specialty pharmacies see dramatic growth within this category. In certain cases, specialty pharmacies anticipate not just more than 20%, but as much as 100%, growth per year for the next five years. Growth drivers include an aging population, a better diagnosis for patients with certain key diseases (e.g., multiple sclerosis, rheumatoid arthritis, psoriasis) and a robust FDA pipeline.

2. Will growth be driven by injectable or infusible products?

Specialty pharmacy providers anticipate growth will be a mixture of the expansion of existing injectable products and the introduction of new infusible products. Note that more than 70% of the products in the FDA pipeline are injectable and infusible products.

3. Will there be a shift in this marketplace based on route of administration (oral solid, injectable, infusible)?

The specialty pharmacy providers see a dramatic shift in the market driven by product type and higher patient needs. The specialty providers anticipate a major shift of infusible distribution and anticipate additional drivers of specialty based on complex care requirements.

4. What disease states and corresponding therapies do you see evolving within your organization in the future?

The most dramatic shift anticipated by specialty manufacturers is driven by the route of administration, not by specific disease states. The opportunity to provide broader infusion capabilities across all disease states, including oncology, is a primary driver for recent investments into infusion capabilities by specialty distributors. Even so, specialty pharmacy providers anticipate continued growth in rheumatoid arthritis, multiple sclerosis oncology, psoriasis, pulmonary arterial hypertension, diabetes, and other specialty disease areas.

Community Pharmacy Provider Questions

1. What type of products would your organization be willing to make infrastructural investments in today?

Community pharmacy sees multiple channels around the infrastructure requirements to distribute specialty medications. At the same time, many community pharmacy participants are either taking steps or reviewing steps to participate in the specialty pharmaceutical market. Some of the key initiatives being considered at this time include:

- Additional cold-storage requirements
- Pharmacist/staff training
- Additional data capturing
- Medical claim billing capabilities

Furthermore, additional space relative to adding physical capacity becomes more challenging due to existing brick-and-mortar limitations with either actual physical space or current leasing arrangements. While no one is ruling out the opportunity to add physical space, this option will likely not be the first step in helping community pharmacy participate in specialty pharmaceutical distribution.

2. What products does your organization see worthy of changing the community pharmacy landscape in the next five years (small molecules, large molecules, personalized medicines)?

Community pharmacy management recognizes that there is a greater opportunity to participate in specialty pharmacy based on the route of administration of the product. Community pharmacy would like to participate in the distribution of specialty products for those products that are self-injectable and can be billed through the pharmacy adjudication system. In addition, community pharmacy feels that it is well equipped to provide additional services such as patient education, as well as compliance data to specialty pharmaceutical manufacturers. Community pharmacy also is interested in providing additional specialty products, such as high-dollar oral solid products. While some feel additional negotiations with either wholesalers or specialty manufacturers will be necessary to manage the potential carrying cost of the products, the products themselves are not seen as a challenge for community pharmacies.

3. Is your organization currently considering investing in specialty pharmacy business?

Community pharmacy today recognizes the need to participate in the specialty pharmaceutical landscape. In fact, every organization surveyed is in

some level of discussion around the distribution and service requirements necessary to compete in the specialty pharmaceutical channel. Community pharmacy sees the value of the specialty pharmaceutical patient relative to both traditional pharmaceutical products and the potential specialty pharmaceuticals these patients may be taking. Thereby, this patient group comprises a very attractive patient sector. Many community pharmacy entities are currently evaluating several opportunities to participate in specialty pharmaceutical distribution, including:

- Driving injectable distribution to existing community pharmacy channels;
 - Building up specialty capability within key stores in designated geographic areas;
 - Potentially building or buying specialty pharmacy capabilities;
 - Adding on infusion capabilities within key large-volume stores; and
 - Providing additional education to existing pharmacist staff to ensure competitive specialty pharmaceutical services.
4. What, if any, current operational capability does your organization have today that might influence the decision to play a larger role in specialty pharmacy?

Several participants identified the fact that they currently bill medical and durable medical equipment (DME) claims through their community pharmacies, and in fact do provide some level of distribution for specialty pharmaceuticals. Others stated that they have some level of infusion coordination capability within their channel offering. In addition, all surveyed participants felt that they have an advantage in the pharmacist-patient relationship given their local presence. At the same time, many community pharmacy channels feel their pharmacists have the opportunity to build a relationship with local physicians. These relationships would enable the local community pharmacy to potentially have a better level of data that can be provided back to either the payer or the specialty pharmaceutical manufacturer. The primary concern however, was for the individual community pharmacy to have “competitive” specialty pharmaceutical offerings, including 24/7 pharmacist coverage, call center capabilities, reimbursement capabilities, and a repository of tracking data from multiple operational locations. Secondly, the services that may allow community pharmacy to compete with specialty pharmacy are many times not consistent from one store to another, even within a given community pharmacy organization.

5. Would your organization prefer a stand-alone specialty operation or consider an integrated offering of local stores in conjunction with applicable support services?

This question posed many challenges for community pharmacy. While the concept of shared services was very attractive, the functional questions of how to share costs and revenues are of immediate concern. Additionally, for certain large participants a shared offering is not considered a viable option. It is suggested to bring together a consortium of potential participants to explore the opportunity of building an integrated offering.

Attachment B

Key Questions and Answers

The challenges to community pharmacy are significant, and the authors have responded to a number of questions.

- **What will it take to be a profitable active participant in specialty pharmacy?**

There are several critical success factors that must be addressed by community pharmacy. The first step in the process is the commitment and willingness to develop the skills and infrastructure to compete with other specialty pharmacy players in the marketplace. Once the commitment is in place and a reasonable number of transactions are flowing through the operation, from a financial perspective the fixed costs are likely to be covered and the variable costs are truly driven by the number of transactions. Access to products is another key ingredient. The limiting factor for some community pharmacies has been investments in human and physical capital and just “asking for the business” and delivering on the commitment.

- **What are the risk and rewards of being actively engaged in specialty pharmacy?**

As is the case with any new business, there are risks, and, generally speaking, the greater the risk, the greater the reward. However, the authors believe the risks are mitigated by the strength in the relationships the pharmacy has with the patient, in combination with the relationships the pharmacy has the opportunity to create with the payer and the biotech manufacturer. Patients want to continue to have their pharmaceutical needs serviced by their local pharmacist as validated by the WilsonRx study last year. The relationship between patients and their local pharmacist is generally already in place. The services tied to disease states and products need to be developed and implemented. The risks include lost opportunity costs with the equivalent amount of human and real capital. In many cases, much of the physical infrastructure is in place with some enhancements being necessary to fulfill the specifics of specialty pharmacy.

- **Will pharmaceutical manufacturers restrict distribution of specialty drugs to specialty distributors?**

There is a common belief that many products are restricted due to their financial implications. The reality is that their numbers are not overly significant and that many states prohibit restricted access to a pharmacy provider based strictly on financial parameters. It is true that some manufacturers and payers have elected to restrict access to specialty pharmaceuticals through only a handful of

providers; these are generally exceptions to the rule. The key drivers in the decision to create limited availability of products often are lack of professional expertise within pharmacy, limited reporting within information systems (IS), need for patient registries, complexity of shipping and drug administration, and cost/reimbursement of the product, to name a few. All of these drivers must be addressed in some fashion by community pharmacy in order to provide a competitive offering. It will take time, but the current paradigm regarding restricted access to most products will change, and change will come on the heels of community pharmacy making the first move to develop services competitive with existing specialty pharmacies.

- **What drives a manufacturer to restrict distribution through select specialty pharmacies?**

Manufacturers have specific goals in mind when bringing products to market. One of the goals is to offer the provider an understanding of the benefits of their products and why they should be considered as viable therapies for their patients. With specialty products, the market is not necessarily (for larger manufacturers) as significant as other therapies a manufacturer may have. The smaller size of the patient population, coupled with a generally much higher cost, often causes the manufacturer to seek out more “efficient” specialty pharmacy providers willing to provide higher levels of service as described herein. While researching this white paper, many manufacturers pointed out that one-stop shopping or managing a limited network of specialty pharmacies makes their operation more efficient and takes less overall effort, while providing sufficient distribution and control over their product-distribution needs. Until community pharmacy demonstrates a strong commitment and willingness to provide specialty services, the manufacturer will continue to seek efficient alternatives. Please reference the survey in Attachment A regarding insights from payers.

FDA requirements can be key factors impacting restricted distribution. Often with specialty products, a requirement from the FDA might be ongoing drug monitoring that is in part paid for by the manufacturer. In many cases, FDA approval is directly contingent on the manufacturer’s ability to have a defined distribution strategy, which may include a specialty pharmacy or pharmacies directly involved in the distribution of the product and/or the registry of patients engaging in a new therapy. There are several products recently introduced to the market, such as those to treat pulmonary arterial hypertension. These products require monthly or more frequent monitoring to lessen patients’ risks of dangerous adverse effects. Typically, a manufacturer must qualify a network of specialty pharmacy operators to ensure consistency and quality standards that meet FDA mandates. Some manufacturers have taken the path of limiting the specialty pharmacy network to a single provider. History and current trends indicate the networks are driven by a combination of the size of patient population and the care requirements for a given patient base. Other influencers include the provision of adequate access to payers’ preferred networks, which

may lead to the establishment of three to seven national providers. Clearly, a system that provides access through community pharmacy specialty network could be used to ensure adequate patient access.

Realize, for the most part, that specialty products and their volume in units sold are relatively small compared with more-popular chronic therapies for general disease states. With relatively low volume and high-cost products, it is much more difficult for manufacturers to distribute these products across a population of 55,000 community pharmacies in the U.S.

- **What should community pharmacies do differently with the product to be able to more actively participate in the specialty channel?**

Most products need refrigeration of some kind or special handling well beyond what typical community pharmacies have at their facilities. Additionally, compliance and adherence to therapy mandates the timing at which the product gets dispensed. Often, specialty products must be infused or injected at a specific point in time, in a required dose, or at a specific temperature in order to have a beneficial effect and/or minimize potential adverse reactions. Providing the patient and/or provider an adequate storage environment to ensure the drug is delivered to them with appropriate specifications is critical to the success of these therapies. In order to participate, community pharmacy must develop these dispensing capabilities.

It is imperative the pharmacy receives the products within the proper storage conditions, stores them properly, and ships them so they arrive to the ultimate patient/caregiver/provider in proper conditions. It is also imperative that the pharmacy ensures patients understand and are trained on how to appropriately store the product in their home or office. The handling of natural disasters is a good example of the type of protocols necessary to be in place to ensure drugs are received and stored in their proper environment.

Recently, through disasters such as 9/11 and Hurricane Katrina, the business of specialty pharmacy learned some valuable lessons, and extraordinary measures were taken by a number of providers in the health care industry to ensure the medications that were sent were done so in a correct manner. Many of the products are packaged with temperature sensors, and patients and providers are educated about how to read the meters on these packages to ensure product potency. This process is not one typically involved in traditional pharmacy.

- **How can community pharmacy better understand coverage and reimbursement?**

Traditionally, the best source of information has come from the manufacturer, which may either provide education or assist with the training and development of the skills necessary to understand the many aspects of reimbursement and

coverage. There are a number of firms that specialize in supporting providers with education on reimbursement and, most important, working directly with the payers in a collaborative fashion.

In a February 2006 article in *BioExecutive International*, author Patricia Stanfill Edens is quoted:

Payers are struggling to validate efficacy and cost with patient outcomes as rapid advances come to market. Physicians, especially in medical oncology, are facing declines in practice reimbursement of up to 50 percent. Patients are facing increased drug costs, even with the new Medicare drug benefit, and out-of-pocket costs are skyrocketing. For example, only recently did patients receive Medicare reimbursement for oral chemotherapy as most oral preparations were assumed to be the patient's financial responsibility. It is imperative that both biotech and pharma companies consider the impact of their actions; and conversely, providers must study future advances and integration strategies to deliver the highest quality of care to patients.

As discussed throughout this white paper, in order to successfully compete, community pharmacy must meet or exceed the current offerings in the marketplace today. The key challenges are internal to the community operation. A well-developed plan that includes the critical success factors outlined in this paper, coupled with a desire to succeed, is crucial.

Attachment C

Checklist to Specialty Pharmacy Implementation

Done	General	Comments/Tactics
	Assess specialty pharmacy business plan for strategic fit.	Review specialty pharmacy plan versus current strategic operations.
	If a fit, develop a vision and mission for your operation.	Should fit that of current operation.
	Review financial model for return on investment validation relative to current operations.	Are financial ratios acceptable?
	Secure buy-in from senior management.	An enrolled overall organization ensures success.
	Review capital needs to initiate and complete project.	Short-term and long-term investment requirements.
	Assign key business owners and stakeholders to project.	Make sure someone is “on the hook” for the project and can champion it through the organization. Stakeholders should include members from pharmacy operations, information technology, finance, legal, human resources, facilities, managed care, and others.
	Validate which model outline in the white paper works best for your organization.	Decide if your operation will be stand-alone at the store level or regional level, operate a stand-alone call center, or partner with a network of community pharmacies.
	Are strategic partners necessary to secure success?	Evaluate internal competencies and which external relationships need to be developed.
	Staffing	Is there sufficient staffing in your operation to support pharmacy, clinical, nursing, and customer service?
	Select which disease areas work best in your markets.	Chain may want to develop multiple disease centers of excellence depending on store location and patient demographics. Not all locations might be optimal for specific disease areas, and an internal network or hub-and-spoke operation may be advisable.
	Select and develop clinical programs.	The heart of specialty pharmacy is the clinical services tied to the drug distribution components. Selection of the right programs to differentiate your offering is essential.

	Develop disease state management initiatives.	The use of treatment guidelines, therapeutic interchange and formulary management, coordination of physician and support providers, patient education and support, outcomes measurements and routine reporting and feedback, clinical assessment and patient monitoring, side-effect management, physician consultation, drug utilization evaluation and poly-pharmacy review, care coordination with other health care providers, psychosocial support, community resourcing, work with manufacturers, colleges, and boards.
	Investigate manufacturer's needs after reviewing products pending approval.	Offerings may include specialty distribution, specialty pharmacy, reimbursement assistance, hotline assistance, patient registry programs, and patient assistance programs.
	Review peripheral and other needs necessary for manufacturer to commercialize its product.	Plan to purchase and prepare for dispensing additional sterile supplies that need to be included and ensure the final product is ready for administration; assist in the development of clinical guidelines, patient-education materials, and support hotlines for health care providers and patients from a central hub; tightly manage inventory requirements and ensure proper stocking levels are maintained; assist in any necessary market research with payers and reimbursement strategies that should be considered; assist in the design of the final packaging that ensures the product is in the form that best offers optimal outcomes and commercialization success; create alignment among various service providers and payers to ensure that manufacturer's products can be accessed by patients (an example might be coordinating or providing home infusion services); provide total data capture to assist with the continuous monitoring of the utilization of the product, including compliance and adherence; work closely with other care providers to lead or assist with the coordination of care including timely delivery of products to the patient's home or the clinician's office.

Done	Customer Service and Order Management	Comments/Tactics
	Develop order management process.	Entire process flow needs to be developed based on final operation.
	Customer service policies need to be in place.	Procedures and training must be in place to ensure compliance.
	Establish protected health information policy and procedures.	Consistent with other HIPAA policies, it is imperative that the operation have consistent practices in place to ensure compliance with patient-confidentiality practices.
	Establish a central call center.	After reviewing the white paper, community pharmacy companies need to decide how to best manage clinical services, compliance and persistency, reimbursement, and other key processes, centrally, locally, regionally, or through a shared resource.
	If establishing a central call center, plan how key stakeholders interface with which units.	Interaction will take place with physicians, patients, caregivers, managed care, and other pharmacies, to name a few. A decision tree could be established to ensure those inquiries are routed and responded to appropriately.

Done	Order Fulfillment and Distribution: Hub vs. Spoke	Comments/Tactics
	Examine distribution capacity for local pharmacy distribution/dispensing.	Does local pharmacy operation have capacity for additional dispensing needs/counseling needs?
	Examine distribution-dispensing capacity for current or future mail-order operation.	Does a community pharmacy company's current mail-order facility have capacity for additional dispensing needs of operation?
	Capacity needs of a central hub operation?	Examine capacity needs of a central hub operation by extrapolating projected volumes from local operations, managed care contracts, and other existing marketing platforms.
	Develop a process for receiving an order and processing a prescription.	Order will come into the system via fax, e-mail, phone, letters, etc. Each will require a specific process and standard operating procedures.
	Is there a requirement for a written prescription?	Review your state pharmacy laws.
	Can a faxed and/or electronic prescription be accepted?	Review your state pharmacy laws.
	What is the standard cutoff time for specific products to be fulfilled?	After determining which products and procedures are necessary to fulfill those procedures for processing a prescription, determine, depending on the product being picked up locally or mailed, what the cutoff times are for processing orders.
	Describe the timeline between the submissions of a request for a medication to the actual delivery of the medication to a patient or provider.	As some products will be going to a physician's clinic, timing of delivery is critical. Determine if the product will be carried in stock or will be ordered just in time or drop-shipped from the manufacturer.
	Develop manual and automated quality assurance steps processes.	Checks and balances need to be integrated into entire supply chain process of order processing, including clinical services, compliance, and reimbursement.
	Develop a detailed workflow diagram of the entire order fulfillment process.	Community pharmacy providers must map out process against specifics of their operation.
	Establish timelines on filling and delivering an order.	Timeliness is critical for meeting service level requirement of manufacturers, payers, prescribers, and patients.
	Design a process for monitoring and filling backorders.	System should have the ability to track backorders that may occur, including notification of staff so assessments of therapeutic alternatives can take place.

	Method of tracking order status throughout the delivery cycle.	Current standard of care is using the web browsers and integrating them into the specialty pharmacy's enterprise resource planning system.
	Automated tracking mechanisms will be utilized to ensure product shipments are delivered as expected.	Using the above, many specialty pharmacy providers request a "proof of delivery" to demonstrate products were received.
	Level of inventory capabilities and capacity in a distribution center/pharmacy for ambient products.	What are the storage capabilities in the licensed areas of store and central pharmacy to handle products that are not refrigerated or frozen?
	Level of inventory capabilities and capacity in a distribution center/pharmacy including refrigeration/frozen.	What is the storage capacity of refrigeration units and freezers? Are there redundant systems?
	Shipping materials and validation processes to ensure that drugs are maintaining the appropriate temperature range throughout the shipping process until received by the patient.	Both the local pharmacy and the central hub pharmacy will need to ensure that any products picked up or distributed to the patient and or provider are kept at the appropriate shipping conditions to ensure quality.
	Develop a process and standard operating procedures for the specialty pharmacy staff to communicate to patients, case managers, and physicians when an order requires coordination of a delivery location.	Suggest the development of "frequently asked questions" for all staff members who may come in contact with outside stakeholders.
	Develop a process for community and central hub staff to coordinate with a third-party administrator (nurse or physician referral) or home health agency (internal and external) that provides the injection in office or home.	Most infused products are either administered in the physician's infusion center or through home health agencies. The specialty pharmacy operation should coordinate its activities to ensure the product is available in a timely manner to meet patient's needs.
	For products that are mailed and/or delivered, identify delivery vendors to ensure refrigerated shipments are kept in compliance.	Both FedEx and UPS have programs designed to ensure products are handled in a manner consistent with package insert and other necessary storage conditions.

	Emergency fill processes for after-hour orders.	The standard of practice for specialty pharmacy mandates that orders that are truly emergencies can be fulfilled. This is particularly critical in times of crisis and if an order gets lost or missed.
	Depending on product and shipping conditions, what is the primary method of delivery, and what is the backup method that might be needed?	Review other products with similar physical/legal characteristics.
	Develop a process for patients to refill prescriptions.	Today many chains have interactive voice response (IVR), e-mail, fax, phone and web-based alternatives. Based on the current and future capabilities, each of these systems should be investigated as opportunities. It has been shown the easier it is to order refills, the better the compliance to therapy and the better the patient outcome.
	Develop a process for communicating information regarding refill prescriptions.	As reviewed in the white paper, compliance and persistency are the cornerstones of specialty pharmacy. Community pharmacy, mail order, and specialty pharmacies have done an excellent job developing strategies to assist patients in staying compliant with their therapy. All methods need to be explored.
	Develop policies on the disposition of the products.	It is foreseeable that patients could return product. Strategies need to be developed to assist with the disposal of these products.
	Develop an understanding of the specialty manufacturer's policies regarding support for picking up the replacement cost for lost, spoiled, or stolen medications.	Review manufacturer's return policies.
	Develop a process and standard operating practices for product recalls and returns procedures and systems used to track this information.	It is essential that the receiving and dispensing processes have the ability to track lot numbers and expiration dates for several purposes.
	Develop a complete process and systems for the delivery and tracking capabilities for distributing patient kits, medical information, and literature fulfillment.	Specialty products are literature-intensive, as the manufacturer generally has materials in several languages and, for self-injected products in particular, ancillary devices/aides to assist with product administration. Often, manufacturers' "programs" become the key source of why their products may get

		dispensed over other therapeutic alternatives.
	Compliance with industry standard Good Manufacturing Practice guidelines.	Some manufacturers that may choose select specialty pharmacy networks may require that products be stored and handled in a manner consistent with good manufacturing practices.
	Should multiple patient classes be necessary to manage, what might the processes be to segregate inventory for traditional dispensing inventory from starter kits, patient assistance programs, and other programs?	Patient assistance programs are prevalent and most frequently offered directly or through a foundation to assist those patients who may not afford a particular therapy either in part or whole. In many cases, the sponsoring manufacturer may choose to have products and other services labeled differently.

Done	Reimbursement Services	Comments/Tactics
	Determine if reimbursement services on specialty products will be handled by the local pharmacy, central hub/call center, and/or be outsourced.	Reimbursement on specialty products is an art, and developing the skill sets and processes in the pharmacy environment often requires highly trained and experienced associates. Many operations may choose to outsource this in total.
	Identify if the manufacturer offers reimbursement services to assist the specialty pharmacy with payment.	Many manufacturers either deploy internal resources to assist with the reimbursement process or offer those services on an outsourced basis as a value add. Additionally, some manufacturers offer extended terms to help defray the cost of money on receivables from payments and, in some cases, if a product does not receive full payment, develop a program to offset the financial exposure.
	Develop the experience necessary for local chain pharmacies to work with separate reimbursement vendors and/or central hub.	The reimbursement process for specialty products is unique and significantly different from that of traditional retail. Having local staff trained on the right questions and processes is essential, as well as having sufficient resources at retail to facilitate the process of ensuring products that are covered can get processed.
	Ensure that credits or reversals to payers are processed and tracked.	It is imperative that any product that must be reversed is accounted for properly, considering high costs.
	Develop the knowledge and experience necessary for a chain-based specialty pharmacy network to be able to take assignment of benefits (AOB)?	A key differentiator of specialty pharmacy from traditional retail is the ability to accept an AOB for patients and prescribers.
	Design a process in which the costly use of resources to manage an AOB can be centrally or regionally supported.	Community pharmacy will need to develop a process for physicians that do not wish to buy and bill for the product.
	How many health plans and PBMs are individual community pharmacy companies contracted with? Would a third-party entity be able to pool resources within their member companies?	Essential to leverage the entire book of business to ensure success in specialty pharmacy.

	Assess how many payers an individual community pharmacy might need to secure and potentially develop a formal contract.	Essential to leverage the entire book of business to ensure success in specialty pharmacy.
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Done	Quality Management	Comments/Tactics
	Assess standards for internal audit and quality control processes including:	
	Claims processing.	Accuracy is a contractual obligation and essential for accounting purposes.
	Provision of client, member, and pharmacy provider services.	In particular for closed or exclusive networks, the proper professional deliverables are essential.
	Report frequency, compliance, and accuracy.	Clients love data.
	Accuracy and timeliness of pharmacy claims payment process and member reimbursement claims processes.	Challenges of accounts receivables and payables have been the downfall of many specialty pharmacy providers.
	Pharmacy auditing.	Access to data in a timely manner is often contracted for service.
	Responsiveness to patient requests and/or complaints.	A key metric in quality measurement for payers is responsiveness to patient needs.
	Clinical programs.	A key measure here is the measurement of patient outcomes.
	Develop procedures for handling corporate, physician, and patient customer complaints and grievances.	A minimal standard for all aspects of specialty.

Done	Patient Education, Provider Education, and Compliance and Persistency Services	Comments/Tactics
	Assess specific programs aimed at patient monitoring for compliance and follow-up.	Review the disease states and product mix that is selected to tie specific programs to ensure best outcomes for patients.
	Provide product use training by internal staff or contracting to a third party.	Manufacturers will generally provide training to specialty pharmacy providers to assist with the patient-education process and materials that should be necessary to properly use their products. In some cases the instruction will take place via DVD or in person with home health care nurses. The key benefit of a retail network is the availability of local pharmacy staff to provide live education.
	Necessity for 24/7 availability of product support services by pharmacists and/or nurses.	Can be managed with those retailers who have 24-hour stores supplemented by central hub.
	Improve the compliance and persistency for patients receiving specialty pharmacy products.	Available local counseling provides the opportunity to develop a more intimate relationship with the patient and thereby heightens the opportunity to improve compliance.
	Develop methods to measure, report, and document patient education.	Processes should be reviewed for ongoing quality and potential for improvement.

Done	Information Technology, Data Management, and Reporting	Comments/Tactics
	Define necessary requirements for data systems (hardware and software).	Interface and integration with individual chain's pharmacy system will be critical with all potential business models in specialty pharmacy.
	Investigate changes to software that may be necessary to provide reimbursement services to the dispensing of specialty products.	
	Take an inventory of all database systems.	Evaluate if systems are adequate to support the new business environment.
	Need for contingency plans and backup systems in place to respond to primary system or utility outages.	Disaster-recovery process for these systems.
	Evaluate if retail pharmacy-based specialty pharmacy will agree to provide detailed reporting to IMS HEALTH or other third-party companies.	If so, define the data fields submitted and frequency of submission.

Done	Sales and Marketing	Comments/Tactics
	Evaluate marketing and sales tools necessary to ensure community pharmacies are represented in contrast to the current state of specialty pharmacy.	What resources would be necessary for community pharmacy participants to secure in-network status for managed care plans?

Attachment D

Additional Resources

- *AIS* quarterly survey
- *BioExecutive International*, 2006
- Center Square Inc.
- CMS Press Release
- creehan & co.
- Express Scripts website
- IMS HEALTH data, 2005
- MedEquity
- NACDS website
- Novartis press release
- *The Pink Sheet* issues
- Securities and Exchange Commission, various company filings
- Wall Street Equity Research, 2004
- WilsonRx® reports

Attachment E

About the Authors

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Strategic Product Development and Distribution

With more than 30 years' experience, Mr. Steiber has served as a practicing pharmacist, store manager, pharmaceutical buyer, clinical services director, and pharmacy marketing leader for one of America's leading chain drug stores. Serving as vice president of marketing, he oversaw all retail programs and was vice president of Branded Rx for AmerisourceBergen (ABC) and general manager of their third-party logistics. Mr. Steiber's expertise stems from his tenure with Eli Lilly and Longs Drug Stores.

Currently, Mr. Steiber focuses on new product launch strategies, formulary and contracting initiatives, compliance and persistency programs, return goods programs, packaging strategies, e-commerce design, supply chain optimization, and other business-development efforts.

Mr. Steiber earned his pharmacy degree from Washington State University and has attended several executive programs at Northwestern and Harvard universities. He is a registered pharmacist in California, Washington, Pennsylvania, and Texas.

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Mr. Erhardt offers nearly 20 years' worth of strategic marketing and management experience across the pharmaceutical and consumer product arenas. His areas of expertise include analysis and development of pharmaceutical support programs, pharmaceutical and consumer product distribution, and specialty pharmaceutical product management. Mr. Erhardt has provided marketing consultation services to pharmaceutical and biotech companies, assisting 14 of the top 20 U.S. pharmaceutical manufacturers in structuring and implementing various aspects of their specialty distribution and product support programs.

Previously, Mr. Erhardt's health care experience spanned several Fortune 500 companies, including Express Scripts, Cardinal Health, and US Healthcare.

Mr. Erhardt has a B.A. in marketing from the University of Oklahoma and an M.B.A. from the Keller Graduate School of Management.

Attachment F

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