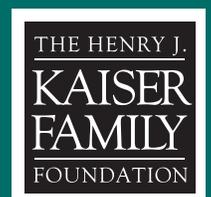


# Follow the Pill:

## Understanding the U.S. Commercial Pharmaceutical Supply Chain

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## I. Executive Summary

The pharmaceutical supply chain is the means through which prescription medicines are delivered to patients. Pharmaceuticals originate in manufacturing sites; are transferred to wholesale distributors; stocked at retail, mail-order, and other types of pharmacies; subject to price negotiations and processed through quality and utilization management screens by pharmacy benefit management companies (PBMs); dispensed by pharmacies; and ultimately delivered to and taken by patients. There are many variations on this basic structure, as the players in the supply chain are constantly evolving, and commercial relationships vary considerably by geography, type of medication, and other factors.

The intent of this paper is to demystify the U.S. pharmaceutical supply chain. The first section of the paper describes each of the key players (i.e., industry segments) involved in the process of supplying prescription drugs to consumers. The section begins with a discussion of what each player does and the role that it plays in the flow of pharmaceuticals from manufacturer to patient. The second section of the paper describes the financial relationships between each of these key players and how the dollars flow between and among the segments, including the consumer.

Highlights from this paper about the key players and their financial relationships include:

### *Pharmaceutical Manufacturers:*

- A relatively few large, multinational firms comprise the bulk of the brand pharmaceutical manufacturing industry today – the 10 largest pharmaceutical corporations, as measured by U.S. sales, accounted for almost 60 percent of total U.S. sales in 2004.
- Pharmaceutical manufacturers have the most influence over pharmaceutical prices, assessing expected demand, future competition, and projected marketing costs to establish the wholesale acquisition cost (WAC), which is the baseline price at which wholesale distributors purchase drug products. Discounts and rebates may be applied, based on market share, volume, and prompt payment.

### *Wholesale Distributors:*

- The wholesale distribution industry has consolidated in the last 30 years, with the number of wholesale distributors in the U.S. declining from approximately 200 in 1975 to fewer than 50 in 2000. The top 3 wholesale distributors account for almost 90 percent of the wholesale market.
- Wholesale distributors typically sell drugs to pharmacies at WAC plus some negotiated percentage. They may facilitate discounts negotiated between manufacturers and other customers.

### *Pharmacies:*

- Although comprising a small overall percentage of total prescriptions filled (approximately 6.1 percent in 2004), mail-order pharmacy sales were the fastest-growing sector of the U.S. prescription drug retail market in 2004, increasing by 18 percent over the previous year.

- Pharmacies may negotiate with manufacturers or wholesalers for discounts and rebates based on volume sales or market share, and they may negotiate with PBMs for inclusion in their networks and for their reimbursement (drug cost plus dispensing fee).

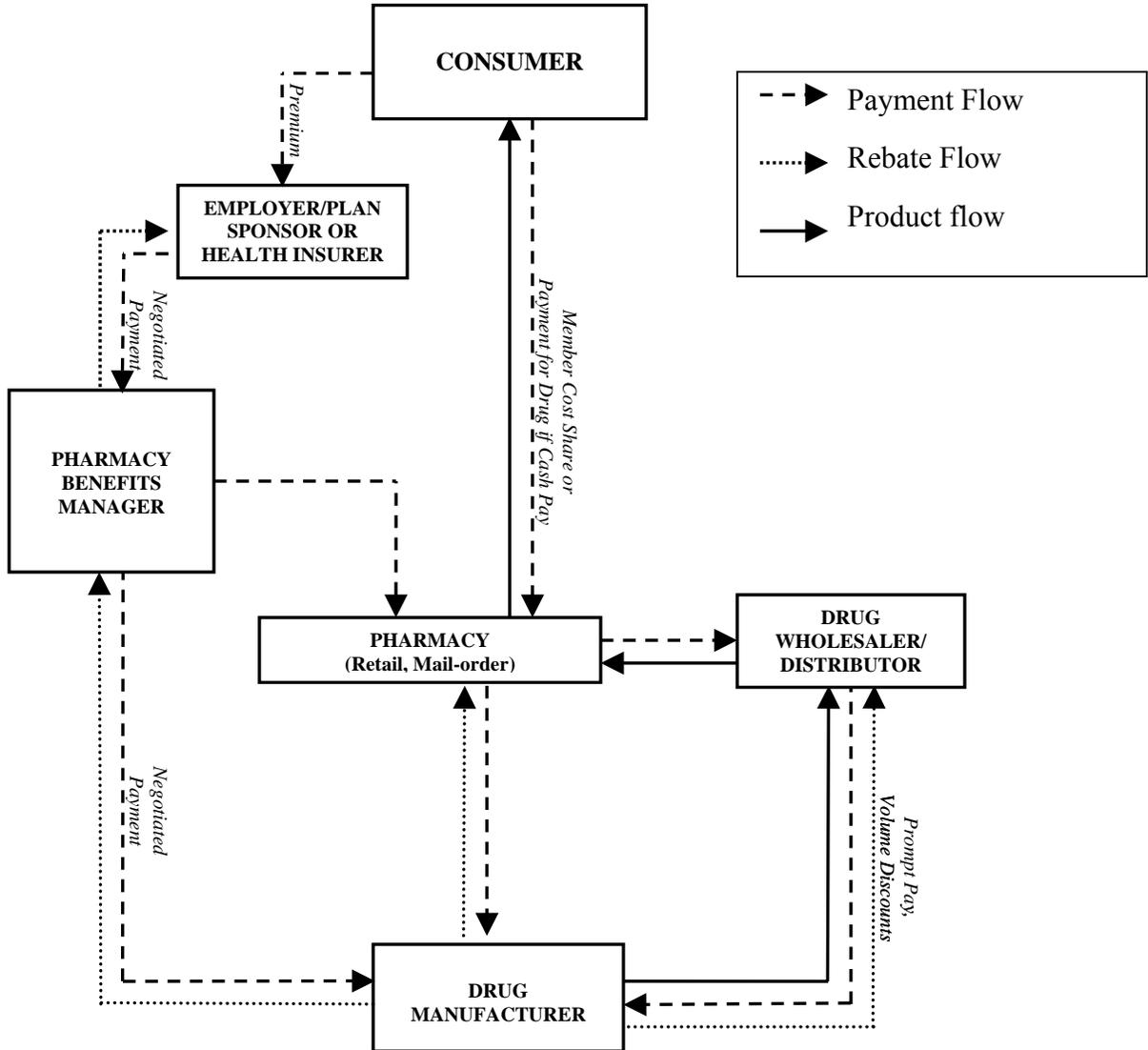
*Pharmacy Benefit Managers (PBMs):*

- Approximately two-thirds of all prescriptions written in the U.S. are processed by a PBM.
- PBMs may achieve savings for their customers by negotiating discounts and through cost containment programs, including use of formularies and cost sharing.

The Appendix briefly describes: (A) special pricing rules applicable to Medicaid and some other federal programs, and (B) the roles physicians, large employers, and health plans have in the pharmaceutical supply chain.

The pharmaceutical supply system is complex, and involves multiple organizations that play differing but sometimes overlapping roles in drug distribution and contracting. This complexity results in considerable price variability across different types of consumers, and the supply chain is not well understood by patients or policymakers. Increased understanding of these issues on the part of policymakers should assist in making rational policy decisions for the Medicare and Medicaid programs.

**Exhibit 1. Flow of Goods and Financial Transactions Among Players in the U.S. Commercial Pharmaceutical Supply Chain**



Source: The Health Strategies Consultancy LLC

## **II. The Flow of Goods from Manufacturers to Consumers in the U.S. Pharmaceutical Supply Chain**

### *Pharmaceutical Manufacturers*

Manufacturers are the source of the prescription drugs in the pharmaceutical supply chain. The pharmaceutical manufacturing industry is composed of two distinct business models: manufacturers of brand-name drugs (e.g., Pfizer, Merck, and Novartis) and manufacturers of generic drugs (e.g., Mylan, Roxane, and Barr). There are a few pharmaceutical companies that participate in both the branded and generic parts of the industry, and both models focus on the manufacturing and packaging of pharmaceutical products, but there are other important differences. Most brand manufacturers devote a portion of their expenses to the scientific research and development of new drug therapies. Generic drug manufacturers typically do not develop new drug therapies, but instead manufacture generic compounds that compete directly with the original branded version of a drug once the brand product's patent protection has expired.

Manufacturers manage the actual distribution of drugs from manufacturing facilities to drug wholesalers, and in some cases, directly to retail pharmacy chains, mail-order and specialty pharmacies, hospital chains, and some health plans. Manufacturers may also distribute products directly to government purchasers, such as the Veterans Administration, AIDS Drug Assistance Programs (ADAPs), and Vaccines for Children (VFC), which typically receive the largest price discounts. In a few rare cases, a manufacturer may distribute drugs directly to a self-insured employer with an on-site pharmacy, but the typical employer-sponsored plan does not follow this path. Wholesale distributors are the manufacturers' largest purchasers. Very few drugs are distributed directly to consumers.

At the most basic economic level, a pharmaceutical manufacturer supplies a quantity of its products that is equal to the demand for its products from consumers/patients (of course, consumer demand in this market is expressed through the medium of a prescribing physician or other licensed health care provider). Manufacturers also play roles in stimulating demand for drug products through underwriting clinical studies designed to demonstrate the value proposition of pharmaceutical treatments compared to one another or compared to no clinical treatment at all; by engaging in the promotion and marketing of products to health care providers (including health plans and PBMs) and direct-to-consumer advertising; and by administering patient assistance programs that provide the firm's products at nominal cost to low-income consumers.

Manufacturers also play an important role in ensuring the safety of the pharmaceutical supply chain by producing informational labeling for prescribers and consumers that is consistent with the terms and conditions of a drug's approval by the U.S. Food and Drug Administration (FDA), and by using electronic bar-coding technology on drug packaging that may be used to track individual production lots, and to prevent prescribing errors.

## Overview of Pharmaceutical Manufacturing Industry

Pharmaceutical manufacturing is a large global industry. In 2003, worldwide pharmaceutical industry sales totaled \$491.8 billion, an increase in sales volume of 9 percent over the preceding year.<sup>1</sup> The U.S. represents the largest single national market for pharmaceuticals, accounting for 44 percent of global industry sales in 2003, or a total of \$216.4 billion, which was an increase of approximately 12 percent from the previous year's figure.<sup>2</sup>

After a decade of significant mergers and acquisitions by drug companies, a relatively few large, multinational firms comprise the bulk of the brand pharmaceutical manufacturing industry today. The ten largest pharmaceutical corporations, as measured by U.S. sales, accounted for almost 60 percent of total U.S. sales in 2004:

### Exhibit 2. Top 10 Pharmaceutical Corporations by U.S. Sales, 2004

Rank	Corporation	U.S. Sales (\$ Billions)	% Growth Over Previous Year	% Market Share
1	Pfizer	\$30.7	5	13.1
2	GlaxoSmithKline	18.8	1	8.0
3	Johnson & Johnson	16.2	7	6.9
4	Merck & Co.	15.0	8	6.4
5	AstraZeneca	11.3	12	4.8
6	Novartis	10.2	7	4.3
7	Sanofi-Aventis	10.0	13	4.3
8	Amgen	9.5	23	4.1
9	Bristol-Myers Squibb	9.2	-4	3.9
10	Wyeth	8.2	11	3.5
	Total, Top 10	139.1	--	59.3

Source: IMS Health, IMS National Sales Perspectives,<sup>TM</sup> February 2005, accessed 2/28/05 at [http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599\\_49695983\\_69891374,00.html](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695983_69891374,00.html)

<sup>1</sup>IMS Health, "Bruised But Triumphant," *Medical Marketing and Media*, May 2004, accessed at [http://www.imshealth.com/vgn/images/portal/cit\\_40000873/23/12/55250930BruisedTriumphant081804.pdf](http://www.imshealth.com/vgn/images/portal/cit_40000873/23/12/55250930BruisedTriumphant081804.pdf)

<sup>2</sup>IMS Health, "IMS Reports 11.5 Percent Dollar Growth in '03 U.S. Prescription Sales," February 17, 2004, accessed at [http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599\\_3665\\_44771558,00.html](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_3665_44771558,00.html). Prescription sales figures reported by IMS Health represent manufacturer prices.

When measured by prescription volume, the “top 10” list is similar but not identical, as a few generic drug manufacturers appear on the list:

**Exhibit 3. Top 10 Pharmaceutical Corporations by Total U.S. Dispensed Prescriptions, 2004**

Rank	Corporation	U.S. Prescriptions (Millions)	% Growth Over Previous Year	% Market Share
1	Pfizer	360.7	-4	10.2
2	Novartis	225.5	-2	6.4
3	Teva*	221.2	7	6.3
4	Mylan Labs*	215.2	4	6.1
5	Watson*	175.6	7	5.0
6	GlaxoSmithKline	138.8	-13	3.9
7	Merck & Co.	129.5	3	3.7
8	AstraZeneca	100.4	11	2.9
9	Johnson & Johnson	95.6	-9	2.7
10	Abbott	91.5	-4	2.6
	Total, Top 10	1754.0		49.8

\* Generic drug manufacturers

Source: IMS Health, National Prescription Audit™Plus, January 2005, accessed 2/28/05 at [http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599\\_49695974\\_68913574,00.html](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695974_68913574,00.html)

Exhibit 4 provides a description of the generic pharmaceutical market:

**Exhibit 4. Top 10 Generic Manufacturers by Total Global Sales, 2003**

Rank	Corporation	Global Sales (\$ Millions)	% Growth Over Previous Year
1	Sandoz	\$4,004.0	
2	Teva Pharmaceutical Industries Limited	3,276.4	30.1
3	IVAX Corporation	1,420.3	18.6
4	Mylan Laboratories Inc.	1,269.2	15.0
5	Alpharma Inc.	1,297.3	4.8
6	Andrx Corporation	1,046.3	35.7
7	Barr Pharmaceuticals, Inc.	902.9	-24.1
8	Par Pharmaceutical Companies, Inc.	661.7	73.4
9	American Pharmaceutical Partners, Inc.	351.3	26.6
10	Eon Labs, Inc.	329.5	34.9

Source: Hoover’s, Inc. Hoover’s Online, accessed 1/03/2005.

To convey the size of the pharmaceutical manufacturing industry from the perspective of individual products, the following tables present data on the biggest selling pharmaceutical products in the United States in 2004, measured by prescriptions dispensed and by sales in dollars. Exhibits 5 and 6 are for individual drug products, while Exhibits 7 and 8 are for broader therapeutic classes of drugs.

**Exhibit 5. Top 10 Products by Total U.S. Dispensed Prescriptions, 2004**

Rank	Product	Manufacturer	Prescriptions (Millions)	% Growth Over Previous Year	% Market Share
1	Lipitor	Pfizer	74.8	9	2.1
2	HYCD/APAP	Mallinckrodt	49.5	12	1.4
3	Synthroid	Abbott	47.4	-5	1.3
4	Norvasc	Pfizer	38.3	5	1.1
5	Toprol-XL	AstraZeneca	35.0	18	1.0
6	Zoloft	Pfizer	33.1	1	0.9
7	Zocor	Merck	29.6	1	0.8
8	HYCD/APAP	Watson	29.0	-2	0.8
9	Albuterol	Warrick	26.8	0	0.8
10	Amoxicillin	Teva	26.2	-5	0.7

Source: IMS Health, National Prescription Audit™ Plus, January 2005, accessed 2/28/05 at [http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599\\_49695974\\_68913594,00.html](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695974_68913594,00.html)

**Exhibit 6. Top 10 Products by U.S. Sales, 2004**

Rank	Product	Manufacturer	U.S. Sales (\$ Billions)	% Growth Over Previous Year	% Market Share
1	Lipitor	Pfizer	\$7.7	14	3.3
2	Zocor	Merck	4.6	4	1.9
3	Prevacid	TAP	3.8	-5	1.6
4	Nexium	AstraZeneca	3.8	23	1.6
5	Procrit	Ortho Biotech	3.2	-3	1.4
6	Zoloft	Pfizer	3.1	8	1.3
7	Epogen	Amgen	3.0	-4	1.3
8	Plavix	Sanofi-Synthelabo	3.0	33	1.3
9	Advair Diskus	GlaxoSmithKline	2.9	26	1.2
10	Zyprexa	Eli Lilly	2.8	-10	1.2

Source: IMS Health, IMS National Sales Perspectives,™ February 2005, accessed 2-28-05 at [http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599\\_49695983\\_69890133,00.html](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695983_69890133,00.html)

**Exhibit 7. Top 10 Therapeutic Classes by Total U.S. Dispensed Prescriptions, 2004**

Rank	Therapeutic Class	Total Prescriptions (Millions)	% Growth over Previous Year	% Market Share
1	Codeine	157.6	5	4.5
2	SSRIs/SNRIs	147.4	4	4.2
3	ACE Inhibitors	143.8	5	4.1
4	HMG-COA Reductase Inhibitors (Statins)	139.8	11	4.0
5	Beta Blockers	120.6	7	3.4
6	Proton Pump Inhibitors	93.1	-2	2.6
7	Thyroid Hormone, Synthetic	90.0	6	2.6
8	Calcium Blockers	88.4	0	2.5
9	Seizure Disorders	84.8	7	2.4
10	Oral Contraceptives	82.5	-3	2.3

Source: IMS Health, National Prescription Audit™ Plus, January 2005, accessed 2/28/05 at [http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599\\_49695974\\_68914714,00.html](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695974_68914714,00.html)

## Exhibit 8. Top 10 Therapeutic Classes by U.S. Sales, 2004

Rank	Therapeutic Class	U.S. Sales (\$ Billions)	% Growth Over Previous Year	% Market Share
1	HMG-COA Reductase Inhibitors (Statins)	\$15.5	12	6.6
2	Proton Pump Inhibitors	12.5	-3	5.3
3	SSRIs/SNRIs	11.0	1	4.7
4	Antipsychotics, Other	9.1	12	3.8
5	Seizure Disorders	8.2	19	3.5
6	Erythropoietins	8.0	8	3.4
7	Antiarthritics, COX-2 Inhibitors	5.3	0	2.3
8	Calcium Channel Blockers	4.4	1	1.9
9	Angiotensin II Antagonists	4.4	24	1.9
10	Ace Inhibitors	3.9	-5	1.7

Source: IMS Health, IMS National Sales Perspectives,<sup>TM</sup> February 2005, accessed 2/28/05 at [http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599\\_49695983\\_69891394,00.html](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695983_69891394,00.html)

## Wholesale Distributors

Wholesale distributors purchase pharmaceutical products from manufacturers and distribute them to a variety of customers, including pharmacies (retail and mail-order), hospitals, and long-term care and other medical facilities (e.g., community clinics,

physician offices and diagnostic labs). Some wholesalers sell to a broad range of potential clients while others specialize in sales of particular products (e.g., biologic products) or sales to particular types of customers (e.g., nursing homes).

### Exhibit 9. Wholesale Distribution Industry

In 2004, the wholesaler distributor industry is valued at approximately \$212 billion in annual U.S. sales. The following three wholesalers represent 88% of the market:

#### 1) McKesson

- Merged with health-care software giant HBO & Co. in 1998
- Rolling 12-month sales as of September 2004: \$72.2 billion; Market Share: 34.1%

#### 2) Cardinal Health

- From 1999 – 2002, Cardinal merged with many other wholesalers including Allegiance Corporation and Bindley Western Industries
- Rolling 12-month sales as of September 2004: \$63.3 billion; Market Share: 29.9%

#### 3) AmerisourceBergen

- Began operations in August 2001 following merger of AmeriSource Health Corporation and Bergen Brunswig Corporation
- Rolling 12-month sales as of September 2004: \$52.4 billion; Market Share: 24.8%

Source: *GICS Sub-Industry Revenue Share (09/04/2004)*.  
Copyright © 2004 Standard & Poor's.

In the past, wholesalers limited their operations to a traditional distribution function. They provided the link between manufacturers and pharmacies (and other entities, e.g., government sites and physicians) by warehousing products and managing inventory. While “traditional” distribution services remain the cornerstone of the business, the industry has developed a more comprehensive list of services in response to the evolving

marketplace. Today, wholesale distributors provide a number of specialized services, including specialty drug distribution, drug repackaging, electronic order services, reimbursement support, and drug buy-back programs.<sup>3</sup>

The wholesale distribution industry has gone through significant change and consolidation in the last 30 years, due in part to the increasing pressures to lower costs. Between 1975 and 2000, the number of wholesale distributors in the U.S. declined from approximately 200 to fewer than 50.<sup>4</sup> The top three wholesale distributors, McKesson, Cardinal Health, and Amerisource-Bergen, account for almost 90 percent of the entire wholesale drug market.<sup>5</sup>

This consolidation has forced the industry to change its revenue model, evolving its core distribution business into a low-margin enterprise that makes money by maximizing economies of scale, creating physical efficiencies in the distribution system (such as “just-in-time” deliveries to customers), and realizing financial efficiencies (such as retaining discounts for prompt payment). The industry has also extended and augmented its business model by moving into specialty pharmacy and disease management services.

### ***Pharmacies***

Pharmacies are the final step on the pharmaceutical supply chain before drugs reach the consumer/patient. Pharmacies purchase drugs from wholesalers, and occasionally directly from manufacturers, and then take physical possession of the drug products. After purchasing pharmaceuticals, pharmacies assume responsibility for their safe storage and dispensing to consumers. Pharmacy operations include maintaining an adequate stock of drug products, providing information to consumers about the safe and effective use of prescription drugs, and facilitating billing and payment for consumers participating in group health benefit plans.

Pharmacies also serve as a vital information link between PBMs, drug manufacturers, and wholesale distributors. Unlike most other sectors of the health care delivery system in the U.S., the pharmaceutical supply chain is highly automated and virtually all claims transactions are handled electronically, rather than on paper. Since they are the final point of sale for pharmaceuticals and the interface between the supply chain and the consumer, pharmacies generate the prescription drug claims information that PBMs, as well as health plans, employers, governments, and other payers, rely upon to measure consumer activity. Other types of information, both quality-focused (e.g., drug-drug interaction warnings) and utilization management-based (e.g., formulary compliance

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<sup>3</sup> Drug buy-back programs are offered by manufacturers and are facilitated by wholesale distributors. Buy-back programs are intended to minimize the financial risk that pharmacies must assume in stocking products by allowing them to sell unused products or products with near-term expiration dates back to the manufacturer.

<sup>4</sup> Goldman Sachs Industry Report: Health Care Technology & Distribution, February 27, 2003.

<sup>5</sup> Standard & Poor's, *GICS Sub-Industry Revenue Share*, September 4, 2004.

messaging) can originate from other parts of the supply chain, in particular from PBMs, to the pharmacy as a prescription is being dispensed. As the final actor in the supply chain, it is up to the pharmacy to take action based on the information provided. For example, the pharmacy is expected to contact the prescribing physician if the drug prescribed is not on the patient's health plan's formulary or if a lower-cost therapeutic alternative is available.

There are several types of pharmacies, including independent pharmacies, chain drug stores, pharmacies in supermarkets and other large retail establishments, and mail-order pharmacies. Most pharmacies purchase their drug supply from a wholesale distributor, although in some cases, large institutional and retail chain pharmacies, specialty pharmacies, and mail-order pharmacies obtain drugs directly from a manufacturer. These organizations can deal directly with manufacturers because they already possess the operational infrastructure necessary to bypass wholesalers – warehousing facilities, distribution vehicles, and inventory control systems. Once a pharmacy takes possession of the drug products, it distributes the products to physicians or directly to consumers. In addition, there are specialty pharmacies, which specialize in the distribution of high-cost and more complex drug therapies (e.g., self-injectable drugs and biologics).

In 2003, there were 55,000 community retail pharmacies, including 19,000 independent drug stores, 21,000 chain drug stores, and 16,000 pharmacies in supermarkets and other retail merchants.<sup>6</sup> In 2004, there were 3.5 billion prescriptions dispensed in the United States through community pharmacies, including about 1.8 billion filled at chain drug stores, 780 million filled at independent pharmacies, and 470 million filled in supermarkets. Another 214 million prescriptions were filled through the mail.<sup>7</sup>

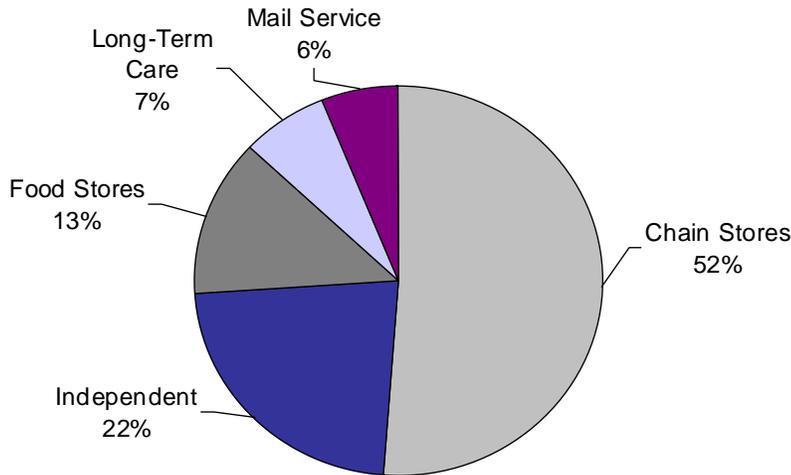
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<sup>6</sup> National Association of Chain Drug Stores, [http://www.nacds.org/user-assets/PDF\\_files/Retail\\_Outlets2003.pdf](http://www.nacds.org/user-assets/PDF_files/Retail_Outlets2003.pdf).

<sup>7</sup> IMS Health, National Prescription Audit™Plus, January 2005, accessed 2/28/05 at [http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599\\_49695974\\_68913551,00.html](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695974_68913551,00.html)

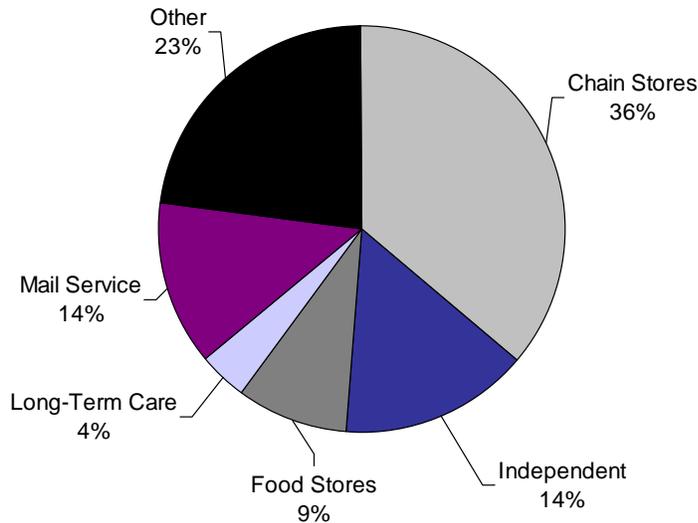
Exhibits 10 and 11 depict the distribution of pharmaceuticals in the U.S. through the various types of “retail” pharmacy channels:

**Exhibit 10. Number of Prescriptions by Pharmacy Distribution Channel, 2004**



Note: Represents total dispensed prescriptions, including insulin dispensed through chain, food store, independent, long term care, and mail service pharmacies.  
Source: IMS Health, National Prescription Audit™ Plus, January 2005, accessed 2/28/05 at [www.imshealth.com/ims/portal/front/articleC/0,2777,6599\\_49695974\\_68913551,00.html](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695974_68913551,00.html)

**Exhibit 11. Drug Sales by Pharmacy Distribution Channel, 2004**



Note: Represents wholesale prices. Sales include prescription products only.  
Source: IMS Health, IMS National Sales Perspectives,™ February 2005, accessed 2/28/05 at [http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599\\_49695983\\_69891354,00.html](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695983_69891354,00.html)

Like all other parts of the pharmaceutical supply chain, the pharmacy industry has gone through significant consolidation as well as diversification of its businesses over the past five to ten years. Several retail pharmacy chains have merged, primarily as a way to gain buying power for use in negotiations with drug manufacturers and wholesale distributors.

As shown in Exhibit 12, Walgreens, CVS, and Rite Aid were the top three retail pharmacy chains based on market capitalization:

**Exhibit 12. Top 5 Retail Pharmacy Chains in the U.S., By Market Capitalization**

Rank	Pharmacy Chain	2004 Market Cap
1	Walgreens Company	\$35.2 bil.
2	CVS Corporation	\$16.1 bil.
3	Rite Aid	\$2.6 bil.
4	Longs Drug Stores	\$0.7 bil.
5	Duane Reade	\$0.4 bil.
	Total for Industry	\$103.0 bil.

Source: Health Strategies Consultancy analysis of Pharmacy/Drug Store Industry based on market cap data obtained from Dow Jones (factiva.com)<sup>8</sup>

In addition to traditional retail pharmacy services, consumers have increasingly been using specialty and mail-order pharmacies over the past several years. Growth in the use of these types of pharmacies is expected to increase rapidly for the foreseeable future, as more payers adopt the view that these specialized retail distribution channels can be important components of their strategies to manage the rate of growth in their pharmacy benefit expenditures. Residents of long-term care facilities (LTC) rely almost exclusively on dedicated LTC pharmacies.

- **Specialty pharmacies** serve patients with chronic diseases by dispensing high-cost biotechnology drugs. Specialty pharmaceuticals typically are administered by injection or infusion (intravenously), and often, are administered by a clinical professional in a doctor’s office. The diseases treated with specialty pharmaceuticals range from relatively common conditions, some of which are treated with multiple drug therapies, such as HIV/AIDS, multiple sclerosis, cancer, and rheumatoid arthritis, to rare diseases that are treated with a single drug therapy, such as hemophilia and growth hormone deficiency. The specialty pharmacy industry today is dynamic, with new companies entering continuously. Types of firms in the market range from publicly-traded stand-alone firms to subsidiaries of PBMs, retail pharmacies, and home health companies.<sup>9,10</sup>

<sup>8</sup> Market capitalization is the value of a company's outstanding shares of stock, which is measured by multiplying the number of shares outstanding by the current share price. Speaking very generally, the larger the market capitalization, the more financially stable the company.

<sup>9</sup> Credit Suisse First Boston, “Pharmacy Benefit Managers and Specialty Pharmacies: Initiating Coverage,” July 14, 2003, p. 22.

<sup>10</sup> Raymond James & Associates, Inc., “Specialty Drug Distribution,” July 16, 2002, p. 3.

- **Mail-order pharmacies** receive prescriptions by mail, fax, phone, or Internet at a central location; process the prescription in large, mostly automated centers; and mail the prescribed drugs back to the consumer. An aging population, convenience, and the recent upswing in pharmaceutical treatments for common chronic ailments, such as diabetes and depression, are some of the driving forces behind the rapid growth in the use of mail-order pharmacies.<sup>11</sup> While representing a small overall percentage of total prescriptions filled (approximately 6.1 percent in 2004<sup>12</sup>), mail-order pharmacy sales remained the fastest-growing sector of the U.S. prescription drug retail market in 2004, increasing by 18 percent over the previous year.<sup>13</sup> The majority of mail-order facilities are owned and operated by PBMs, and a number of the large retail pharmacy chains also own mail-order pharmacies.<sup>14</sup>
- **Long-term care pharmacies**, sometimes called institutional pharmacies, are a third type of specialized retail pharmacy. Long-term care pharmacies address the special needs of nursing homes, providing packaging for controlled administration (called unit-dose supply or bubble packs), and special services that are more extensive than those provided by retail pharmacies. These special services include: quality assurance checks, emergency drug kits and medication carts, regular and emergency (24-hour-a-day) delivery services, and in-service training programs for nurse aides, nurses, and other professional nursing facility staff. Four national chains provide the bulk of institutional pharmacy services to nursing homes: Omnicare, PharMerica, NeighborCare, and Kindred Healthcare. In 2003, these four chains served over two-thirds of all nursing home beds and had collective revenues of more than \$6 billion.<sup>15</sup> The two largest national long-term care pharmacies, Omnicare and PharMerica (which is a subsidiary of AmerisourceBergen, a wholesale distributor), provide drugs to over half of the nursing home beds in the United States. Omnicare is the largest provider with over \$3 billion in 2003 revenues.<sup>16</sup>

### ***Pharmacy Benefit Managers (PBMs)***

According to one leading report on the PBM industry, PBMs currently manage prescription drug benefits for as much as 57 percent of the U.S. population,<sup>17</sup> and the

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<sup>11</sup> National Health Policy Forum, *The ABCs of PBMs*, October 1999.

<sup>12</sup> IMS Health, National Prescription Audit™Plus, January 2005, accessed 2/28/05 at [http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599\\_49695974\\_68913551,00.html](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695974_68913551,00.html)

<sup>13</sup> IMS Health, IMS National Sales Perspectives,™ February 2005, accessed 2/28/05, at [http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599\\_49695983\\_69891354,00.html](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695983_69891354,00.html)

<sup>14</sup> California Health Care Foundation, *Navigating the Pharmacy Benefits Marketplace*, January 2003.

<sup>15</sup> Long-Term Care Pharmacy Association, 2003.

<sup>16</sup> Omnicare Annual Report, 2003.

<sup>17</sup> Atlantic Information Services (AIS), Inc., *A Guide to Drug Cost Management Strategies (2<sup>nd</sup> Edition)*, 2004, p. 329. AIS states that its data are based on a quarterly survey that the firm has been using to track all publicly-traded and privately-held PBMs since 2000.

National Association of Chain Drug Stores estimates that approximately two-thirds of all prescriptions written in the U.S. are processed by a PBM.<sup>18</sup> While not a direct link in the physical supply chain for pharmaceutical products (PBMs in most instances do not take possession or control of prescription drugs), PBMs have become an integral part of most consumer drug purchases. PBMs work with third party payers (private insurers, self-funded employers and public health programs) to manage consumer drug purchases by defining which drugs will be paid for and the amounts that the pharmacy will receive and the consumer must pay out-of-pocket when the prescription is filled.

PBMs have evolved over the last three decades from basic claims administrators to more complex organizations offering a wide range of prescription drug management tools. In addition to offering their basic services – claims processing, record keeping, and reporting programs – PBMs offer their customers a wide range of services including drug utilization review, disease management, and consultative services. PBMs also assist clients with establishing their benefit structure. Options for plan design include: developing and maintaining a prescription drug formulary; developing a network of pharmacy providers; and providing mail order fulfillment services. A PBM's core services and tools include:

- **Formularies:** PBMs use formularies to negotiate deeper price discounts with manufacturers, set cost-sharing levels to influence beneficiary utilization rates, and encourage beneficiaries to use a mix of preferred or lower-cost covered products.
- **Rebates:** PBMs negotiate with pharmaceutical manufacturers for rebates on products selected for the formulary. Rebate amounts are based on the contracts negotiated between the PBM and plan sponsors and the PBM and manufacturers. Typically, contracts are structured so that PBMs retain a portion of the rebate in exchange for developing the formulary and negotiating with manufacturers.
- **Pharmacy Networks:** Pharmacy networks consist of pharmacies that have agreed to dispense prescription drugs and provide pharmacy services to a health plan's enrollees under specified terms and conditions. Pharmacy networks can be broad or narrow. These networks allow PBMs to lower prescription drug prices by negotiating the reimbursement rate and dispensing fee with pharmacies.
- **Mail-Order Pharmacy Service:** Almost all PBMs offer mail-order pharmacy service, especially targeted toward individuals with chronic medical conditions who take maintenance medications. The medications are dispensed typically in 90-day amounts per prescription, as opposed to the usual 30-day supply per prescription dispensed by a retail pharmacy. PBMs are able to lower the cost of pharmaceuticals to consumers and payers by using mail-order services to more successfully drive market share for particular products, based on the terms of

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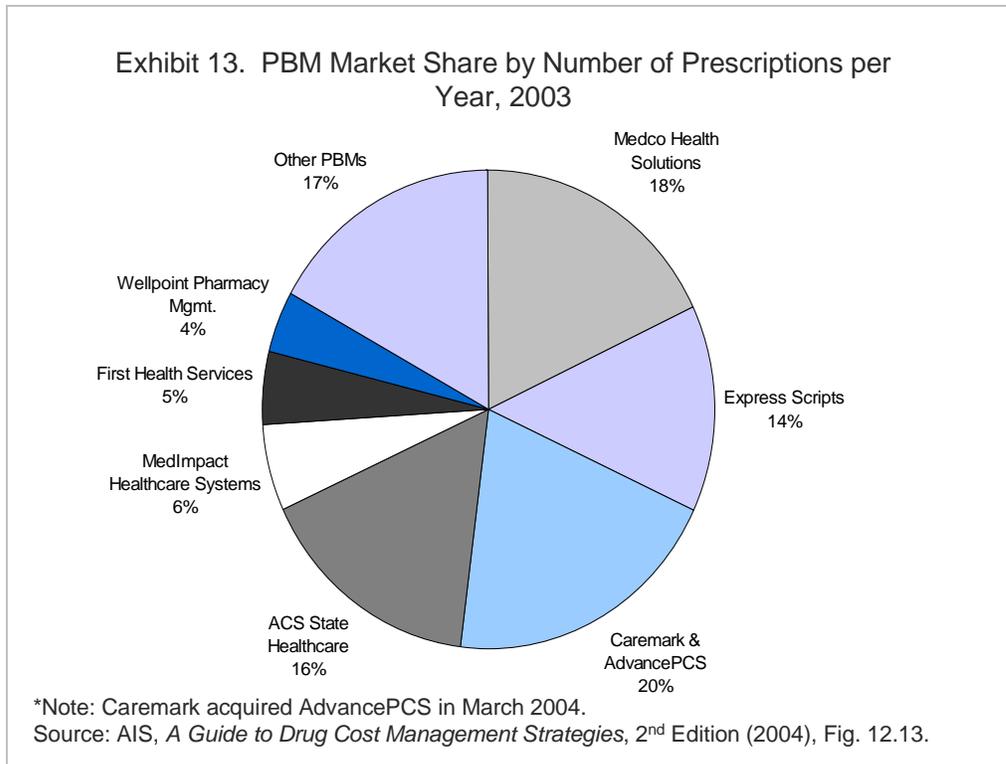
<sup>18</sup> Ibid., p. 331.

contracts negotiated with pharmaceutical manufacturers (e.g., encouraging generic and branded therapeutic substitution and other forms of managing formulary compliance), and (relative to the typical retail pharmacy operation) by automating dispensing processes.

- ***Claims Adjudication:*** All PBMs use a real-time, point-of-sale system linked to retail and mail-order pharmacies and distribution centers. This process provides verification of coverage, formulary restrictions, drug interactions, and individual co-pay information. This process also provides prescription drug information back at the PBM data warehouse, where it can be used for customized reporting and quality-focused clinical and intervention programs.
- ***Generic and Therapeutic Substitution:*** Generic substitution promotes the shift from brand to chemically equivalent generic drugs as a cost savings device. Therapeutic interchange programs promote the use of preferred drugs (i.e., drugs on a plan's formulary) that are determined to be clinically similar.
- ***Quality-Focused Programs:*** PBMs develop programs that provide disease management, compliance strategies, and other clinical expertise promoting the safe, educated use of prescription drugs.

PBMs generally do not take physical possession of prescription drugs when performing their core pharmaceutical management functions. However, in their mail-order and specialty-pharmacy businesses, PBMs buy drugs from wholesalers or manufacturers and dispense them directly to patients in a manner similar to other pharmacies.

During the 1990s, there was a great deal of jockeying within the PBM market, a highly penetrated market compared to just a decade ago. In order to remain competitive, PBMs have merged and acquired new businesses. Most recently, in March 2004, Caremark acquired AdvancePCS; in 2001, Express Scripts acquired National Prescription Administrators; in 2000, Medco Health Solutions acquired Provantage; and in 1998, Express Scripts acquired Value Rx. As shown in Exhibit 13, the PBMs that controlled the most market share measured by prescriptions per year in 2003 were Medco Health Solutions, ACS State Healthcare, AdvancePCS/Caremark, and Express Scripts.<sup>19</sup>



<sup>19</sup> Atlantic Information Services, Inc., *A Guide to Drug Cost Management Strategies*, 2<sup>nd</sup> Edition, 2004.

### **III. The Flow of Money and Key Financial Relationships in the U.S. Pharmaceutical Supply Chain**

The flow of money between manufacturers and end-users is more complex than the physical distribution of drugs. The manufacturer typically interacts with three primary entities when dealing with price: wholesale distributors, retail pharmacies, and pharmacy benefit managers. Pharmaceutical manufacturers negotiate separate contracts with these entities and offer various discounts and rebates based largely on the entities' varying ability to influence the quantity of drugs that are sold. This section looks at these financial relationships and charts the flow of funds among the key players, starting with manufacturers, who play by far the most important role in establishing prices.

#### ***Pharmaceutical Manufacturers***

Manufacturers have the most influence over pharmaceutical prices. They develop algorithms to account for expected demand for the product, future competition for the product, and projected marketing costs, and use those algorithms to establish the “wholesale acquisition cost” (WAC), which is the baseline price at which wholesale distributors purchase products. After the WAC is established, the average wholesale price (AWP), or the retail list price, is established either by the manufacturer or by one of the companies that publishes price compendia. The AWP, and sometimes the WAC, is listed in drug compendia published by a small number of private firms, such as the Red Book, published by Thomson Medical Economics, and First DataBank. The AWP has two purposes: (1) it is often used by public and private third-party payers as the basis for reimbursement, and (2) it often serves as the base price for negotiations between manufacturers and private sector purchasers of drugs (e.g., health plans, pharmacy benefit managers, self-insured employers, etc.).

The negotiation process and the price points on which negotiations are based are different for brand and generic manufacturers. Brand manufacturers typically offer discounts based on a percentage of AWP or WAC, depending upon the purchaser. End purchasers can typically acquire brand drug products for a price in a range of AWP minus 5 to 40 percent, depending upon their purchasing power or that of their designated agent, such as a PBM. Generic pharmaceutical manufacturers operate in a more aggressive and dynamic negotiation environment than brand manufacturers and thus the prices for generic drugs change much more frequently, sometimes daily, in response to market forces. The most common kinds of discounts and rebates include: retroactive rebates based on market share (i.e., rebates paid by the manufacturer to the pharmacy or PBM based on its ability to direct consumers to certain products); volume discounts (discounts that are triggered when predetermined sales volume targets are met); and “prompt pay” discounts (discounts that are triggered when the purchaser reimburses the manufacturer in an expedited fashion).

Pricing for prescription drugs purchased and dispensed by certain federal programs, including Medicaid and the Veterans Administration, are subject to special rules which

generally result in those programs getting lower prices than other purchasers. These rules are outlined in the Appendix.

#### **PRICING TERMS DEFINED**

- **Average Manufacturer Price (AMP):** The average price paid to a manufacturer by wholesalers for drugs distributed to retail pharmacies. AMP was a benchmark created by Congress in 1990 in calculating Medicaid rebates and is not publicly available. (See Appendix for additional discussion of pharmaceutical pricing in Medicaid).
- **Average Sales Price (ASP):** The weighted average of all non-Federal sales to wholesalers net of chargebacks, discounts, rebates, and other benefits tied to the purchase of the drug product, whether it is paid to the wholesaler or the retailer. The basis for reimbursement for products covered under Medicare Part B changed under the Medicare Modernization Act of 2003 from AWP to ASP.
- **Average Wholesale Price (AWP):** Although not defined in statute, AWP is recognized as retail list price (sometimes referred to as a “sticker” price) and is currently used by some public and private third-party payers as the basis for reimbursement (e.g., AWP minus 5 or 25 percent). AWP has been widely criticized as a price that is (1) not reflective of the true market price, and (2) easily manipulated. The basis for reimbursement for products covered under Medicare Part B changed under the Medicare Modernization Act of 2003 from AWP to average sales price (ASP).
- **Estimated Acquisition Cost (EAC):** EAC is a state Medicaid Agency’s best estimate of the price generally paid by pharmacies for a particular drug.
- **Maximum Allowable Cost (MAC):** MAC lists are designed to cap reimbursement for certain generic and multi-source brand products. States and private payers with MAC programs typically publish lists of selected generic and multi-source brand drugs along with the maximum price at which the program will reimburse for those drugs. In general, pharmacies will receive payment no higher than the MAC price when billing for drugs on a MAC list.
- **Wholesale Acquisition Cost (WAC):** The price paid by a wholesaler for drugs purchased from the wholesaler’s supplier, typically the manufacturer of the drug. Publicly disclosed or listed WAC amounts may not reflect all available discounts.

#### ***Wholesale Distributors***

Wholesale distributors purchase drugs from manufacturers. For branded products, the purchase price is fairly uniform, with little negotiation on the part of the wholesale distributor. The distributor typically purchases branded products for a discounted rate off of WAC. Examples of discounts for branded products include volume discounts, prompt pay discounts, and discounts related to the sale of short-dated products (because the wholesaler is assuming a risk that the product will expire before it can be resold). The wholesale distributor then sells the product to its end consumer, typically a pharmacy, at WAC plus some negotiated percentage.

For generic products, the purchase price is highly variable, largely depending upon competition in the class and the ability of the wholesale distributor to drive market share or increase the volume sold. In this case, wholesale distributors play a larger role in the negotiation of the price of the product. The price to the end consumer also is highly elastic depending upon the negotiated contracts with the retail pharmacies.

In some cases, the wholesale distributor may facilitate discounts negotiated between manufacturers and other customers. For example, wholesaler A may distribute drugs to pharmacy B based on negotiations between pharmacy B and manufacturer C. Although wholesaler A directly distributes the drugs to pharmacy B, it plays a minimal part in pricing negotiations for these drugs. In this case, wholesalers use an important pricing mechanism, *chargeback*, which allows them to carry products destined for customers paying very different prices to manufacturers. The wholesaler keeps track of sales to various customers under prices negotiated between the manufacturer and the customer. The wholesaler then “charges back” the manufacturer for any difference between the negotiated prices paid by the customer and the wholesaler’s cost of goods (WAC).

### ***Pharmacies***

Payment for prescription drugs flow from the pharmacy to the manufacturer according to a negotiated contract involving manufacturers, PBMs, and pharmacies. Retail pharmacies negotiate with manufacturers for discounts and rebates based on the pharmacy’s ability to sell specific volumes of certain drugs or achieve a certain share of a specified market. As discussed in the wholesale distributor section, pharmacies may be able to negotiate discounts with manufacturers that are more substantial than the wholesale distributor’s cost. In these instances, the wholesale distributor facilitates the discount and “charges back” the manufacturer for any difference between the negotiated prices paid by the customer and the wholesaler’s cost of goods (WAC). Pharmacies also negotiate with PBMs for inclusion in a PBM’s pharmacy network and for reimbursement for the cost of the drug plus dispensing fees.

Manufacturers may offer volume discounts on selected drugs to pharmacies when they achieve predetermined market share targets. These discounts provide an incentive for pharmacists to work with patients and physicians to switch products from a prescribed non-preferred drug to a preferred drug.

Pharmacies contract with PBMs to join their pharmacy network. This structure provides pharmacies with guaranteed, stable reimbursement from private payers and access to a greater number of customers. The network consists of a group of retail and independent pharmacies and serves to offer plan members with lower prescription drug costs. As part of the pharmacy network contract, retail pharmacies must agree to a guaranteed reimbursement formula for prescription drugs. For brand-name medications, the reimbursement formula is usually determined by subtracting a negotiated percentage from the drug’s AWP and adding the dispensing fee. For generic drugs, reimbursement may be determined in the same way as for a brand drug (for less competitive generic drug classes), but more often is based on an amount specified referred to as the maximum allowable cost (MAC).

Smaller retail stores, such as independent pharmacies and smaller retail chains, either purchase directly from wholesalers – at a price significantly higher than retail pharmacies – or join group-purchasing organizations (GPOs). As members of a GPO, small

pharmacies receive the benefits of volume purchasing by leveraging their combined purchasing power to negotiate discount pricing from wholesalers or even in some cases from manufacturers. Some of these groups further reduce their costs through direct rebate deals offered by manufacturers.

Mail-order and specialty pharmacy services are increasingly becoming a more attractive and demanded option for health plan sponsors and other payers seeking to rein in pharmaceutical expenditures for their members. Mail-order and specialty pharmacies are able to generate increased savings by driving market share, streamlining the distribution chain, and automating drug dispensing processes.

- **Specialty Pharmacy:** Most specialty pharmacy providers manage the cost of specialty pharmaceuticals by negotiating directly with manufacturers and by running quality-focused programs intended to improve patient care and lower costs. Large PBMs or retail pharmacy chains own a number of the specialty pharmacies, and in some cases these entities are able to negotiate greater discounts with manufacturers.<sup>20</sup> Nearly all specialty pharmacies also administer programs designed to enforce patient compliance. Industry representatives claim that these programs save the patient and health plan money by averting acute incidences.
- **Mail-Order Pharmacy:** In 2000, the U.S. Department of Health and Human Services estimated that mail-order pharmacies were able to generate savings between two and 35 percent compared to retail pharmacies.<sup>21</sup> Representatives from the mail-order industry attribute these savings to their ability to “manage” prescriptions because the majority of mail-order prescriptions are filled in 90-day units (the equivalent of three prescriptions).<sup>22</sup> The considerable lead time associated with filling a 90-day prescription gives the pharmacists and other clinical staff at a mail-order pharmacy the time to analyze whether the prescribed drug is on the client’s (i.e., insurer’s or health plan’s) approved formulary, if there is a generic equivalent available, and if there are any potential interactions of the prescribed drug with other medications the member’s physician or physicians may have also prescribed.
- **Long-Term Care Pharmacy:** LTC pharmacies have long-term, almost exclusive contracts with nursing homes to provide medications and services for residents. LTC pharmacies capture a large volume of customers in this way. LTC pharmacy chains have developed formularies and use them in many states that do not have Medicaid preferred drug lists (PDLs) applicable in the nursing home setting. The large LTC pharmacy chains negotiate rebates with manufacturers in exchange for

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<sup>20</sup> Berg, Kevin I. “Health Care Industry Report: The Down Low,” *First Albany Corporation* 6 (2003): 1-153.

<sup>21</sup> Department of Health and Human Services, *Report to the President: Prescription Drug Coverage: Spending Utilization and Prices*, April 2000.

<sup>22</sup> California HealthCare Foundation, *Navigating the Pharmacy Benefits Marketplace*, January 2003.

moving market share on their formularies. In addition to receiving rebates, many pharmacies are reimbursed at higher rates than acquisition costs, because they purchase drugs through wholesalers and group purchasing organizations.

### *Pharmacy Benefit Managers (PBMs)*

Although PBMs are a relatively unknown entity to the end consumer, they play a fundamental role in negotiating the price that is ultimately paid for the product through their relationships with other entities in the supply chain.

PBMs contract with health plans to manage their prescription drug costs. Each contract is different between health plans and PBMs; however, there are generally three basic components of the payment negotiated between PBMs and their sponsors. First, PBMs receive payment for the services they provide. These services may include claims adjudication processing and disease management services. Second, PBMs typically assume some type of performance risk in the contracts they negotiate. Performance metrics can include: customer service (e.g., adequacy of pharmacy networks, timeliness of reporting), clinical quality measures (e.g., the number of people averted from taking inappropriate medications), and cost management techniques (e.g., the number of generic substitutions made in a given time period). Third, PBMs also retain a portion of rebates they secure from manufacturers.

PBMs do not typically assume full insurance risk for drugs. This type of risk is assumed when an insurer takes full or partial financial responsibility for claims incurred under a specified benefit. Insurance risk can further be segmented into three sub-categories: price, utilization, and selection risk. PBMs do not typically guarantee either the unit prices of drugs, the volume of drugs (utilization) or the kinds of patients that sign up for the drug plan (selection). Insurance risk for drugs is often assumed by self-insured entities in the context of a full medical benefit. For an entity to assume insurance risk, the entity must demonstrate that it has adequate financial reserves, be licensed and overseen by state insurance regulators, and be prepared for underwriting cycles.

While performance risk arrangements are very common for PBMs, insurance risk arrangements are not. During the mid-1990s, some PBMs experimented with risk contracts. ValueHealth, PCS, and Medco had contracts in which the PBM assumed full insurance risk. The contracts typically contained actuarial carve-outs for new biotechnology products and unexpected changes in demographics, but put the PBM at risk for other drug utilization and cost. Many of these contracts were with large manufacturing clients who were self-insured, concerned about drug spending, and bid out the pharmacy benefit competitively to multiple vendors. The experience was uniformly negative from the PBM perspective. The PBMs consistently lost money because they under-estimated the development and diffusion of new technology. Many were able to negotiate out of these contracts, but some contracts persisted until the late 1990s. Most, if not all, are now gone.

PBM relationships with manufacturers are governed under guidance from the Department of Health and Human Services (HHS) Office of the Inspector General, and subject to oversight by the Department of Justice for compliance with federal anti-kickback statutes. PBMs are further regulated in many states under consumer protection statutes. In recent years, some industry practices, for example switching of medications and associated pricing issues, have come under scrutiny by state Attorneys General and the Department of Justice. Allegations have also included accepting undisclosed incentives from pharmaceutical manufacturers, not passing manufacturer rebates through to plan sponsors, and driving beneficiaries unnecessarily to mail-order services for the benefit of the PBM. False Claim Act lawsuits also have been filed by the federal government and several states. Medco Health Solutions settled in April 2004 with twenty State Attorneys General on a case involving therapeutic interchange and price disclosure. While this legal scrutiny has focused on a few industry practices, the typical business practices of PBMs have also been heavily scrutinized by plan sponsors, such as health plans and self-insured employers. Further guidance from the HHS Office of the Inspector General on PBM operations and safe harbors under the anti-kickback statute is expected.<sup>23</sup>

According to a January 2003 study conducted by the federal Government Accountability Office (GAO), PBMs achieved significant discounts for drugs purchased at retail pharmacies (in comparison to cash-paying customers) and offered even greater discounts for their mail-order services.<sup>24</sup> However, cost savings are largely driven by how restrictive or open the cost-containment programs are. This is a point usually negotiated between the health plans and PBMs. For example, open formularies (where consumers are free to access all prescription drugs) typically yield lower cost savings than closed formularies (where consumers are limited to certain drugs). Cost sharing differences by the type of formulary also increase members' sensitivity to prescription drug costs and provides an incentive to use lower-cost or preferred products on the formulary. Common private-sector, cost sharing tools include flat copayments, percent copayments with a minimum/maximum dollar amount, and front-end deductibles with a benefit maximum and/or stop loss.<sup>25</sup>

- **Manufacturer-PBM Relationship:** As discussed above, the relationship between manufacturers and PBMs is centered around inclusion of a drug on a plan's formulary and the PBM's ability to increase a manufacturer's market share for certain drugs through inclusion or exclusion on a formulary. Manufacturers pay rebates to PBMs retroactively based on the PBM's ability to meet both of these goals. These rebates are passed in whole or in part back to the employer. According to the California HealthCare Foundation, PBMs are often able to secure rebates of 5-25 percent for branded drugs.<sup>26</sup>

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<sup>23</sup> For more information about the Medco settlement, see *The Pink Sheet*, May 3, 2004, pages 22-30.

<sup>24</sup> U.S. Government Accountability Office, "Federal Employees' Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies," GAO-03-196, January 2003.

<sup>25</sup> Joanne Sica, "Managing prescription drug costs," *Employee Benefits Journal*, March 2001, pp. 35-40.

<sup>26</sup> California HealthCare Foundation, *Navigating the Pharmacy Benefits Marketplace*, January 2003.

- ***PBM-Pharmacy Relationship:*** As discussed above, PBMs negotiate with pharmacies for drug reimbursement and dispensing. The pharmacies negotiate for inclusion in a PBM's pharmacy network. There is often significant tension between the two entities because (1) in general, pharmacies are reimbursed by PBMs at levels below uninsured cash-paying customers and other government payers, like Medicaid, and (2) pharmacies are often required to perform more administrative tasks when filling a prescription for a PBM customer.

## **IV. Conclusion**

Pharmaceuticals are a vital part of patient care, and their importance will only grow as the population ages and pharmaceutical innovation continues. Understanding current pharmaceutical issues (including the sources of prescription drugs, pricing and discounts, cost containment methods, and brand/generic questions) requires knowledge about the various actors in the supply chain. State and federal policymakers increasingly are looking to private sector financing strategies to shape the ways in which individuals with public coverage receive medications. Passage of the Medicare Modernization Act of 2003 (MMA) makes knowledge about the pharmaceutical chain even more important as the large public Medicare program and its beneficiaries begin to access the chain, and pharmaceutical chain entities make changes in response to the new coverage.

The pricing of prescription drugs and the flow of money among the various links in the pharmaceutical supply chain is more complex than the physical distribution of drugs through the chain. This complexity can result in substantial variations in what different purchasers pay for the same drugs. As we have shown, the price of prescription drugs paid by the consumer is determined by a constellation of negotiated contracts between manufacturers, PBMs, wholesale distributors, pharmacies, and plan sponsors. The price charged by each entity in the chain is largely driven by the ability of contracting entities to sell specific volumes of certain drugs or achieve a certain share of a specified market. It is also affected by the value each entity brings to the subsequent actors in the supply chain.

Rapid increases in spending on pharmaceuticals in recent years have led policymakers to more closely scrutinize drug pricing and the relationships among key actors in the marketplace, and the greatly enhanced federal role in the market brought about through the MMA will only intensify public interest in these areas. Experiences with the Medicare price comparison website for the drug discount card has increased consumer and government interest in internet-based price comparisons. The price differences highlighted by these and other analyses lead to questions about the basis for these pricing differentials. Medicare's activities to detect and remedy fraud and abuse will also require continued oversight and need for transparency and fiscal accountability. Public policy discussions regarding transparency and price disclosure are thus likely to continue to be active over the coming years.

## **V. Appendix**

This Appendix briefly describes: (A) special pricing rules applicable to Medicaid and some other federal programs, and (B) the roles physicians, large employers, and health plans have in the pharmaceutical supply chain.

### **A. Special Pricing Rules Applicable to Federal Programs**

Several federal programs that are significant purchasers of prescription drugs have special rules for pricing.

#### **Medicaid**

Federal rules require that states pay for brand name prescription drugs based on the lower of (1) the estimated acquisition cost (EAC) of a drug (the method most states use); or (2) the usual or customary charge to the public. Most Medicaid programs use a drug's AWP to calculate the EAC, generally AWP minus some percentage. An additional limit, known as the Federal Upper Limit (FUL), applies to the purchase of generic drugs. Manufacturers who want to have their drugs covered by Medicaid also must provide rebates to state Medicaid programs. For brand name drugs, the basic rebate is the larger of (1) 15.1% of the AMP (the average price paid to manufacturers by wholesalers for drugs distributed to retail pharmacies; the AMP is usually lower than the AWP); or (2) the difference between the AMP and the lowest price the manufacturer offers to most other purchasers. An additional rebate is required if the price of brand name drugs rises faster than the change in Consumer Price Index. Rebates for generic drugs are calculated by multiplying the AMP by 11%.

#### **Department of Veterans Affairs, Department of Defense, Public Health Service, Coast Guard**

The Department of Veterans Affairs (VA) administers a program known as the Federal Supply Schedule (FSS), through which the VA and certain other government agencies can purchase prescription drugs at prices that are equal to or lower than the prices that drug manufacturers charge their "most-favored" private customers. In addition, manufacturers must sell brand-name drugs to these agencies at a minimum of 24% off the AMP (known as the federal ceiling price).

#### **Section 340B Drug Pricing Program**

Section 340B of the Public Health Service Act requires drug manufacturers, as a condition of having their drugs covered by Medicaid, to provide prescription drugs to certain nonfederal entities (public and disproportionate share hospitals, community health centers, certain grantees of Federal agencies, and health centers that serve migrant, homeless, public housing, and Native American populations)

at prices that are equal to or below the AMP reduced by the applicable Medicaid rebate percentage.

## **B. The Role of Physicians, Employers and Health Plans in Supply Chain**

### **Physicians**

Physicians play an important role in the pharmaceutical supply chain. They are the first to interact with the consumer (i.e., patient), the end-user in the supply chain. Doctors typically diagnose a patient's illnesses and prescribe a medication. The physician is also responsible for ensuring the appropriate quantity and dosage of the prescribed medication. If the prescribed drug is not covered under the patient's health plan, the physician may have to submit additional information substantiating the necessity of the specific medication for the treatment of the injury or illness. This is called "prior authorization." Once a drug is prescribed, patients typically fill prescriptions at their local retail pharmacies. In some cases, the physician may administer the drug in their office (e.g., chemotherapy).

Historically, patient compliance with whatever treatment the doctor ordered was assumed as part of the physician-patient relationship; increasingly, however, patients are becoming more proactive in their interaction with physicians, particularly in the area of prescription drug treatment decisions. Greater access to health information (fueled, in part, by widespread use of the Internet), the loosening of "direct-to-consumer" (DTC) advertising restrictions on drug manufacturers, and a general increase in the public's awareness of health care issues have helped transform many once-passive patients into inquiring and demanding consumers.<sup>27</sup> This trend has affected physician choices of specific medications prescribed and the modes of delivery used, and it has increased the complexity of the information transmitted to physicians and consumers. Now more than ever, physicians and patients/consumers play a large role in driving the market demand for pharmaceuticals.

### **Large Employers**

Large employers that self insure their employees for health benefits generally negotiate contracts with PBMs (and sometimes with specialty pharmacy companies as well) to provide pharmaceutical coverage to employees. Employers exercise control over the supply chain through the contracts they set with PBMs. The contracts govern the prices of pharmaceuticals paid by the employer, the cost sharing to the insured population, the type of formularies that will be applied, the network standard for pharmacies, and what types of drug utilization review will be applied. Employers pay PBMs either on an administrative services basis, or by

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<sup>27</sup> *Health Affairs*, March/April 2000.

allowing the PBMs to retain a portion of manufacturer rebates. Employers retain audit rights to exercise oversight of PBM operations.

### **Health Plans**

Health plans employ the use of a range of strategies to manage prescription drug benefits, most of which involve the use of a PBM or PBM-like strategies. There are a few remaining plans that compensate pharmacies on a fee-for-service basis, but plans are using this method less frequently, as it does not allow for use of cost-containment strategies to lower prescription drug costs. More commonly, plans do one of the following: (1) outsource management to an external PBM, (2) operate their own PBM, or (3) outsource claims administration only. Notable exceptions include certain group models, such as that of Kaiser Permanente, which has maintained control of pharmaceutical procurement. Kaiser streamlines the distribution process by purchasing pharmaceuticals from manufacturers and dispensing the medications to consumers at on-site pharmacies.

Regardless of the strategy used, health plans often influence the cost-containment strategies utilized by PBMs. For example, managed care organizations may negotiate a more restrictive formulary or more competitive pharmacy networks. Managed care companies have a greater ability to enforce formulary compliance and to drive consumers to a smaller number of pharmacies.

## VI. Key Acronyms and Glossary of Key Terms

**AMP** – Average Manufacturer Price

**ASP** – Average Sales Price

**AWP** – Average Wholesale Price

**EAC** – Estimated Acquisition Cost

**MAC** – Maximum Allowable Cost

**PBM** – Pharmacy Benefit Manager

**WAC** – Wholesaler Acquisition Cost

**Average Manufacturer Price (AMP)** – The average price paid to a manufacturer by wholesalers for drugs distributed to retail pharmacies. AMP was a benchmark created by Congress in 1990 in calculating Medicaid rebates and is not publicly available.

**Average Sales Price (ASP)** – The weighted average of all non-Federal sales to wholesalers net of chargebacks, discounts, rebates, and other benefits tied to the purchase of the drug product, whether it is paid to the wholesaler or the retailer. The basis for reimbursement for products covered under Medicare Part B changed under the Medicare Modernization Act of 2003 from AWP to ASP.

**Average Wholesale Price (AWP)** – A national average of list prices charged by wholesalers to pharmacies. AWP is sometimes referred to as a "sticker price" because it is not the actual price that larger purchasers normally pay.

**Estimated Acquisition Cost (EAC)** – EAC is a state Medicaid Agency's best estimate of the price generally paid by pharmacies for a particular drug

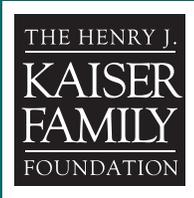
**Maximum Allowable Cost (MAC)** – MAC is a cap set by payers on reimbursement for certain generic and multi-source brand products. States and private payers with MAC programs typically publish lists of selected generic and multi-source brand drugs along with the maximum price at which the program will reimburse for those drugs. In general, pharmacies will receive payment no higher than the MAC price when billing for drugs on a MAC list.

**Medicaid Best Price** – The lowest price paid to a manufacturer for a brand name drug, taking into account rebates, chargebacks, discounts, or other pricing adjustments, excluding nominal prices. Best price is a variable used in the Medicaid rebate statute to calculate manufacturer rebates owed to State Medicaid agencies. Prices charged to certain governmental purchasers are statutorily excluded from best price including prices charged to the Veterans Administration, Department of Defense, Indian tribes, the Federal Supply Schedule, State Pharmaceutical Assistance Programs, Medicaid, Public Health Service "340B" entities, and Medicare Part D prescription drug plans (starting in 2006). Best price data are reported by manufacturers to CMS, but are not publicly available.

**Reference Pricing** – System of fixed reimbursement for pharmaceuticals, in which the government or other third party payers establish a level at which they are willing to reimburse “interchangeable” products. Manufacturers may charge above the reference price, but patients must pay the excess cost.

**Wholesale Acquisition Cost (WAC)** – The price paid by a wholesaler for drugs purchased from the wholesaler's supplier, typically the manufacturer of the drug. Publicly disclosed or listed WAC amounts may not reflect all available discounts.





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