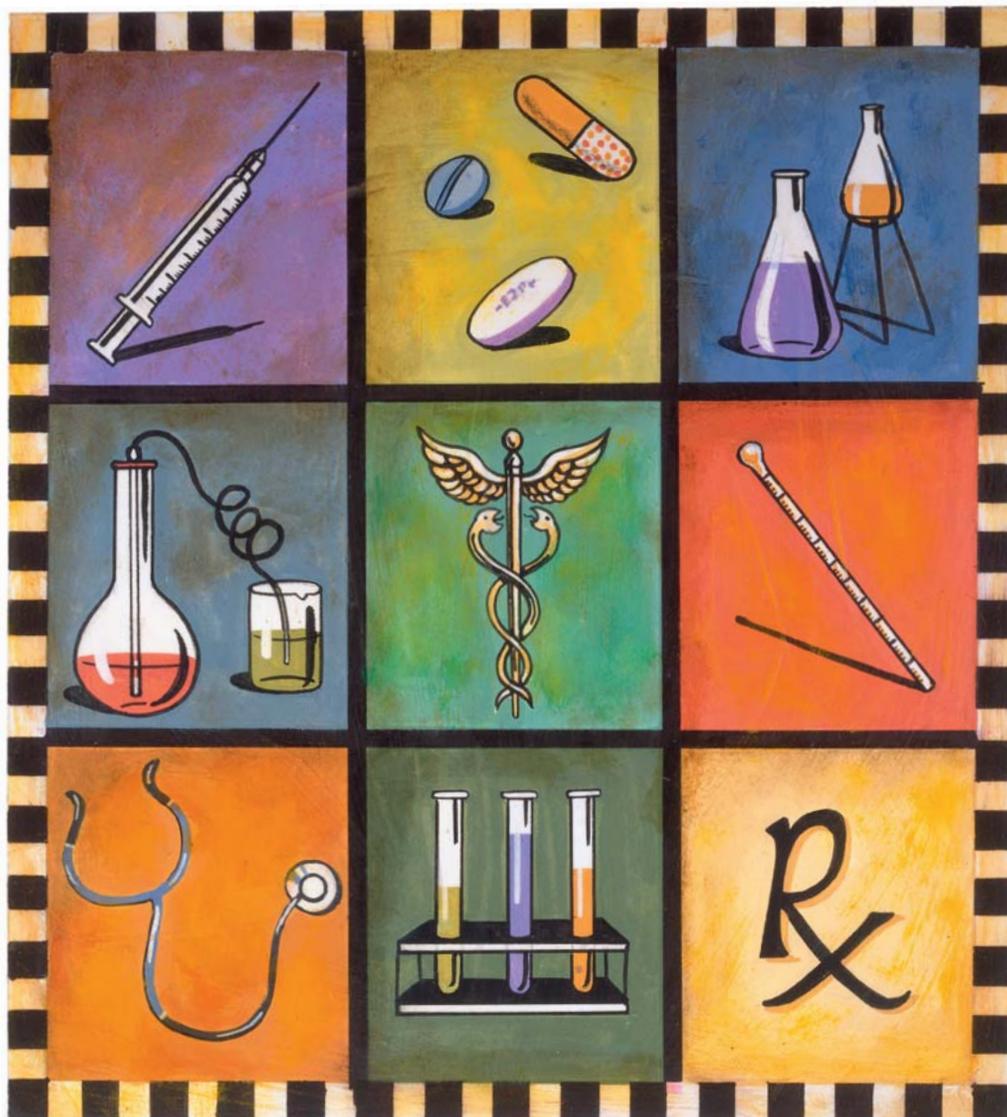




CALIFORNIA
HEALTHCARE
FOUNDATION



Navigating the Pharmacy Benefits Marketplace

January 2003

Navigating the Pharmacy Benefits Marketplace

Prepared for
CALIFORNIA HEALTHCARE FOUNDATION

by
Mercer Human Resource Consulting



January 2003

Acknowledgments

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Executive Summary

WITH PHARMACEUTICAL PRICES CONTINUING TO climb, cost containment will likely remain a priority for sponsors of medical plans containing pharmacy benefits. This report is intended to help plan sponsors navigate the complex and often confusing financial arrangements that determine the ultimate cost of pharmacy benefits to employers and consumers. The report explores the multitude of forces that influence pricing—from legislation and market dynamics to the flow of money and interactions among pharmaceutical manufacturers, pharmacies, pharmacy benefit administrators, employers, and consumers.

Who Pays for Prescription Drugs?

There are considerable variations in pricing among the major purchasers of pharmaceuticals, not only between public and private purchasers, but also among private purchasers.

Public purchasers for prescription drugs provide a variety of programs for low-income and elderly patients; veterans; members of armed forces; and federal, state, and local government employees. While public outpatient prescription drug expenditures constitute only about 2 percent of total U.S. health expenditures,¹ the federal government exerts far more influence on pricing than do either the private sector large purchasers or individuals. In general, public programs experience the greatest level of savings off the original list price for prescription drugs because they possess tremendous concentrated purchasing power, and because legislation mandates that pharmaceutical manufacturers offer their lowest prices to public programs. For example, if a pharmaceutical manufacturer discounts a price to a particular managed care organization, then the manufacturer is legally obligated to offer that “best price” or a lower one to the entire Medicaid system nationwide.

Private purchasers include health plans and pharmacy benefit managers purchasing on behalf of employers. While private spending accounts for the largest proportion of total U.S. pharmaceutical expenditures, large private purchasers enjoy less of the concentrated purchasing power and none of the favorable legislation of public programs. Consequently they have less clout than public purchasers.

Consumers purchase drugs from pharmacies at retail drugstores or by mail. Consumers who have insurance coverage and those who are eligible for government programs (such as Medicaid) typically pay less than consumers who do not have such coverage.

The act of filling a prescription represents the end point of a complex, multistage transaction chain that determines the ultimate cost of pharmacy benefit programs to employer plan sponsors and consumers. This report tracks the financial arrangements and relationships among the key players involved in purchasing prescription drugs.

Manufacturers and Wholesalers

Manufacturers establish a wholesale acquisition cost (WAC) as a baseline for sales to wholesalers. The price wholesalers pay to manufacturers for any given product can fluctuate with the quantity purchased. For instance, the manufacturer may quote a wholesaler a price close to WAC, but this price does not take into account volume discounts that occur in actual sales to wholesalers.

Wholesale prices are also related to public program prices. Using records supplied by manufacturers of their sales to wholesalers, the Centers for Medicare and Medicaid Services (CMS, formerly HCFA) calculate the average manufacturer's price (AMP) on a quarterly basis for all drugs. AMP is the benchmark used in determining the Medicaid "best price," but it is not made available to private payers, making it difficult for private payers to assess the differences between AMP and WAC.

Pharmacies

Of the money spent for prescription drugs, 64 percent is channeled through retail pharmacies (chains, independent pharmacies, and pharmacies within food stores); 24 percent through medical facilities (hospitals, nursing homes, clinics, home health care, and federal facilities); and 12 percent through mail-order sales.²

Retail Pharmacies

The four largest drugstore chains account for more than 60 percent of the retail pharmacy market share today, compared to less than 25 percent in 1996.³ Some large national or regional retail chains (including pharmacy, supermarket, and mass merchandiser chains) purchase drugs in large enough volumes so that they can bypass the wholesaler and buy directly from the manufacturer. Manufacturers offer these pharmacies both up-front discounts for purchasing their products and "back-end" discounts (formulary rebates) for selling specific volumes of certain drugs or achieving a certain share of a specified market.

Smaller retail entities, such as independent retail pharmacies and regional retail chains, purchase directly from wholesalers or join group purchasing organizations (GPOs) in order to leverage their combined purchasing power and negotiate discount pricing from wholesalers or even manufacturers. Some of these groups further reduce their costs through direct rebate deals offered by manufacturers.

To obtain reimbursement from private payers, and to have access to a greater number of customers, retail pharmacies contract with pharmacy benefit administrators, including pharmacy benefit managers (PBMs) and health plans, to join a pharmacy network—a group of independent pharmacies and pharmacy chains where members of a benefit plan have to go to get their prescriptions filled, usually for a lower cost per prescription. To be included in such a payer's network, retail pharmacies are required to offer a guaranteed

reimbursement formula for prescription drugs purchased through the benefit plan. This formula specifies how the pharmacy will calculate the cost of the drug and the dispensing fee.

Mail-Order Pharmacies

Mail-order pharmacies, most of which are owned and operated by PBMs, are popular with employer plan sponsors, 87 percent of whom offered mail service in 2001.⁴ Mail-order pharmacies can be more cost-effective than retail pharmacies, yielding greater discounts and lower dispensing fees. By consolidating purchasing from consumers across the country, mail-order facilities can buy pharmaceuticals in bulk and can economically dispense large quantities through automated processes. Also, mail-order pharmacists usually have a greater opportunity than retail pharmacists to focus on utilization management efforts and interchange therapeutically equivalent products, which can significantly reduce the cost of prescriptions.

Mail-order dispensing also has the advantage of having a higher rate of correctly filled prescriptions than retail dispensing, because mail-order pharmacies have largely automated the prescription filling process, which has led to greater accuracy.

Pharmacy Benefit Administrators

To administer their prescription drug benefits program, employer plan sponsors usually contract the services of an outside organization such as a PBM, health plan, or third-party administrator (TPA).

Pharmacy Benefit Managers

PBMs are independent specialty administrators; they focus on administering pharmacy benefits, and managing the purchasing, dispensing, and reimbursing of prescription drugs. About 45 percent of the U.S. population has pharmacy coverage provided directly by a PBM.⁵ Depending

on its size and other factors, a PBM may perform some or all of the following functions:

- Purchase and dispense medications. Major PBMs purchase pharmaceuticals for their mail-order pharmacies and dispense medications directly to consumers. They negotiate both purchasing agreements and rebate contracts with manufacturers for the products they dispense.
- Pay claims.
- Act as a financial intermediary between pharmacies and the plan sponsor, negotiating with retail pharmacies to contract reimbursement levels for prescriptions filled by plan members. They often create and maintain pharmacy networks.
- Manage prescribing choices. PBMs can influence which drugs are ultimately dispensed at retail and mail order. They do this by developing formulary management, health and disease management, therapeutic interchange, and other education programs that inform physicians and consumers about preferred drugs.
- Create and maintain pharmacy networks.

PBMs use their relatively large customer base and ability to influence physician prescribing patterns and consumer preferences as a negotiating tool with manufacturers to secure formulary rebates. The U.S. Department of Health and Human Services estimates that PBMs receive direct rebates from manufacturers ranging from 2 to 35 percent of brand-name drug sales prices and pass on about 70 to 90 percent of these direct rebates to insurers or self-insured employers.⁶

Health Plans

Health plans employ varying strategies to manage pharmacy benefits. They include:

- Outsourcing claims payments.
- Outsourcing elements of pharmacy benefit management.

- Outsourcing pharmacy benefit management completely to an outside PBM.
- Owning and operating a PBM. Certain large health care plans with national or regional scope employ this strategy. Health plan PBMs typically provide service to the health plan exclusively.
- Operating pharmacies within their outpatient clinics. Some organizations with a high degree of care management, such as group-model managed care organizations (MCOs) like Kaiser Permanente, offer this service.

Most health plans have some clinical/formulary management programs that can influence product preference in the treatment of a particular medical condition. HMOs exert considerable control through both provider education and plan design, including the use of formularies. In 1999, about 97 percent of HMOs relied on some type of formulary.⁷

In MCOs (including HMOs) formulary compliance is generally high — approximately 90 percent of members' prescriptions are filled with formulary drugs⁸ because (1) participating physicians agree to enforce the MCO's utilization management programs; (2) the plan generally does not cover brand medications when generic equivalents are available; and (3) the plan generally does not cover off-formulary brand medications. These high formulary compliance rates spur manufacturers to offer rebate incentives in order to successfully negotiate a place for their products on the MCO's formulary.

Third-Party Administrators

Third-party administrators engage in primarily administrative functions; they process pharmacy claims, but have no influence over what the retail pharmacy charges, or what is dispensed. Plan sponsors rarely use TPAs to process pharmaceutical claims without PBM support. It implies this could be a more expensive way to offer pharmacy benefits to employees.

How Plan Sponsors Can Manage Costs

While employers have little control over some of the factors that determine how much the pharmacy benefit ultimately costs, some factors can be influenced. Employers can use their influence to their best advantage by carefully evaluating the following key decisions.

Will the benefit be administered by a health plan or will it be managed separately by a PBM? A health plan offers the potential for an integrated health care approach, although the level of integrated care varies significantly among health plans. While health plans can and do offer a range of PBM-related services, PBMs are more likely to offer discounts and guarantees on rebate payments, provide a wider range of formulary options, and allow the plan sponsor greater ability to customize the program.

Will the employer purchase an insured pharmacy benefit, or assume financial risk and self-insure? While an insured benefit transfers the risk for the pharmacy benefit from the employer to the PBM, self-insuring provides more opportunity to offer input on how the benefit is structured and more often allows for the possibility of rebates from manufacturers. For small plan sponsors, self-insuring may pose too great a financial risk.

What portion of the cost of prescription drugs will the employer absorb? This will vary by employer, but can be controlled by the design of the benefit plan — including how the employee's share of the drug cost is structured (such as flat dollar co-pay, tiered pricing, coinsurance); the formulary (which drugs are covered); and the actual plan design in place (for example, two-tier versus three-tier). Employers can choose to absorb anywhere from the full cost of prescription drugs to none of the cost.

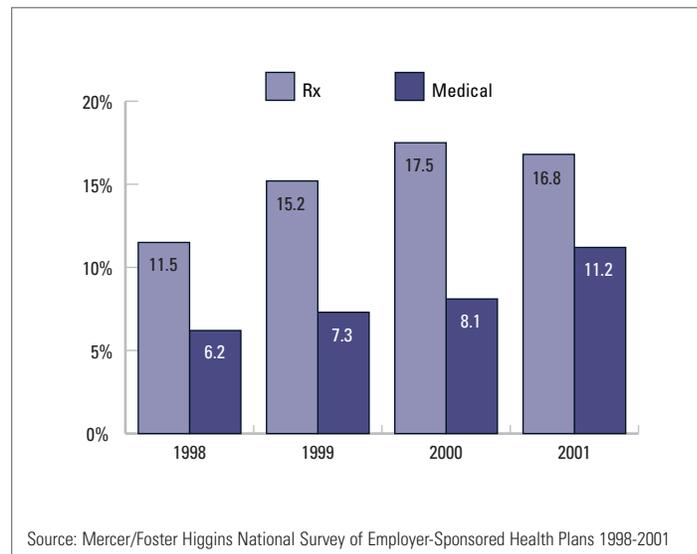
How much influence will the employer plan sponsors have over which drugs are covered in the benefit? Manufacturers' discounts and rebates are available to plan sponsors willing to allow their PBM or other pharmacy benefit administrator to educate physicians and consumers about preferred drugs. This is accomplished through plan design and formulary management.

Will the employer engage in collective purchasing? An employer can realize the benefits of collective purchasing by (1) consolidating its benefit plans with a single provider so that the sum total represents a larger group, and (2) joining together with other employers in group purchasing coalitions to collectively negotiate for even better financial as well as service arrangements.

I. Scope of This Report

THE COST OF PROVIDING PHARMACY BENEFITS has risen significantly during the last decade, surpassing the cost increases experienced by employers for any other category of medical services.

Figure 1. Pharmacy Benefit Cost Increases Continue to Outpace Overall Medical Trend Rates



Newer drugs are often more expensive than the ones they replace, and the utilization of drugs is growing dramatically. Multiple drugs are more often used to treat single conditions, and there is a burgeoning emphasis on using pharmaceuticals in preventive care and chronic disease management. As the growing elderly population and the emergence of new drugs to treat previously untreatable conditions continue to drive up the cost of pharmacy benefits, cost containment will likely remain a priority for prescription drug plan sponsors.

In providing pharmacy benefits, an employer's primary challenge is to secure the best pricing for the most appropriate mix of drugs and services for its employee population. Given the varied interests of the stakeholders and the sometimes complex turns and twists that characterize the flow of money and interactions through the pharmaceutical marketplace, this is no easy task.

This report attempts to demystify the pricing process by describing the following variables:

- How pricing strategies vary in different sectors of the pharmaceutical marketplace;
- What principles are at work in determining pricing for various purchasers;
- What direct and indirect forces influence the ultimate cost of the pharmacy benefit to the employer and consumer; and
- What roles and complex relationships exist among the major players in the pharmaceutical distribution chain.

Employers can use this information to negotiate the most appropriate and cost-effective pharmaceutical services and products.

Research Materials and Methods

Information for this report was gathered from both primary and secondary sources.

Primary information came largely from an extensive database of financial arrangements negotiated by Mercer on behalf of employer plan sponsor clients with PBMs and health plans. Additional data were derived from Mercer's work with pharmaceutical manufacturers to define the value proposition of pharmaceutical therapy versus the cost of the prescription drug.

Secondary sources include published articles and studies about the flow of money in the pharmaceutical market from a variety of viewpoints. Some of these analyze or observe trends in the prescription drug industry (for example, Standard & Poor's, PhRMA publications, and Kaiser Family Foundation's "Prescription Drug Trends"). Others reflect a strong constituent position (for example, *Human Resource Executive*).

To ensure that the report reflected broad-based viewpoints from all pharmaceutical market segments, we asked a spectrum of stakeholders to review it and made revisions based on their comments. Reviewers included representatives from brand-name and generic pharmaceutical companies, retail and mail-order pharmacies, PBMs, and California-based health plans, as well as industry experts.

II. Who Pays for Prescription Drugs?

Public programs' legislatively mandated prices influence the prices that manufacturers charge private purchasers.

WITHIN THE PHARMACEUTICAL MARKETPLACE, A number of purchasers are involved in the complex flow of money and interactions that ultimately determine prescription drug prices. Each of these purchasers represents or serves a particular population or group of consumers. At the most basic level, prescription drug expenditures are funded by either private or public sources. Of the total U.S. expenditures of \$99.6 billion on outpatient prescription drugs in 2000, approximately 78 percent was privately funded and 22 percent was publicly funded.⁹

Variations in Pharmaceutical Pricing

There are considerable variations in pharmaceutical pricing, not only between private and public purchasers, but also among the various private purchasers. These pricing differentials result from the interacting influences of government regulation, marketplace dynamics, and purchasing decisions.

Public Purchasers

Public funding for prescription drugs covers consumers participating in federal, state, and local public programs. The federal government funds multiple programs including the Department of Veterans Affairs, Department of Defense (DOD), the Coast Guard, and Medicaid (Medi-Cal in California). State and local governments sponsor programs that supplement or expand the federal programs for low-income or elderly persons.

Federal and some state legislation mandates that pharmaceutical manufacturers offer their lowest prices to public programs. The net cost for public programs is determined by a combination of legislatively mandated discounts and rebates. These legislatively mandated prices can impact the prices charged to private purchasers.

Private Purchasers

A large proportion of prescription drug spending is made by what might be termed “private purchasers,” or pharmacy benefit plan sponsors. These benefit plan sponsors, who pay for part or all of the cost of prescription drugs for their covered beneficiaries, include employers and health plans. Most of

these plan sponsors purchase prescription drugs through pharmacy benefit administrators (either health plans or pharmacy benefit management companies (PBMs)) who negotiate discounts with retail pharmacies and rebates from drug manufacturers. The vast majority of such purchases tend to be outpatient drugs.

While spending by private plan sponsors accounts for a larger proportion of total U.S. pharmaceutical expenditures than public spending, these plan sponsors, lacking the favorable legislation of public programs, tend to have less clout than public purchasers.

Consumers Who Make Out-of-Pocket Payments

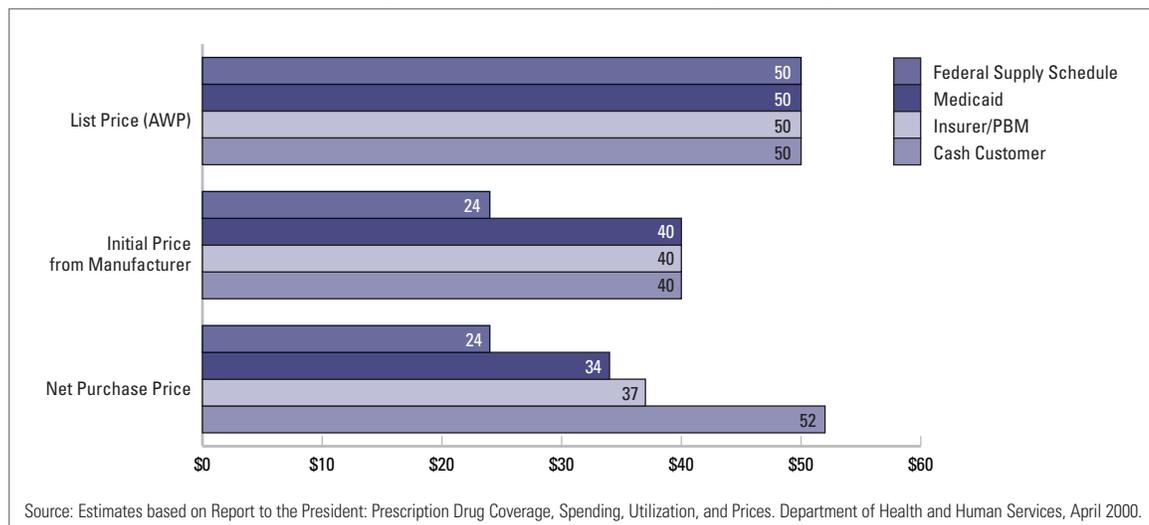
There are primarily two types of consumer: those who have some type of pharmacy benefit coverage and pay a portion of the cost of a drug (copayment, coinsurance, deductible), and those who have no coverage and pay the entire cost of the prescription drug at the retail pharmacy. Sometimes referred to as “cash-paying consumers,” many of these individuals without insurance coverage are seniors who are eligible for Medicare. Data collected on this type of consumer typically

include both those with no prescription drug coverage and those who are covered by traditional indemnity plans and must pay the full amount at the pharmacy and later be reimbursed. Although there are limited data on prescription drug expenditures by cash-paying consumers, recent estimates suggest these consumers account for approximately 21 percent of private prescription drug expenditures at retail pharmacies (excluding mail order).¹⁰

Cash-paying consumers have limited, if any, ability to negotiate for better pricing. They may comparison shop among a number of retail pharmacies and Internet pharmacy sites or join discount card programs, but still tend to pay the highest net prices of any purchasers for their prescriptions.

Figure 2 illustrates the magnitude of cost differentials among the different classes of prescription drug purchasers. In general, public programs experience the greatest level of savings off the original list price, although the cost to Medicaid is somewhat higher than for other public programs. MCOs, hospitals, PBMs, and other insurers pay a higher manufacturer price for prescription drugs than do the public programs.

Figure 2. Cost Differentials among Different Classes of Prescription Drug Purchasers



A closer look at how drug prices are determined for each of these purchasing groups will enable employer plan sponsors to understand some of the dynamics of pharmaceutical pricing and the extent to which employer plan sponsors and private insurers indirectly influence pricing for private purchasers.

Pricing for Public Programs

As previously noted, public (government) outpatient prescription drug expenditures constitute a relatively small proportion of total U.S. health care expenditures. There are two primary reasons that the government exerts far more influence on pricing than do other prescription drug purchasers:

1. Legislation regulates the amount paid for prescriptions under public programs.
2. Public purchasers can realize greater economies of scale because of the size of the populations they include.

Unlike many other countries around the world, the United States does not impose price controls on pharmaceutical products. Manufacturers are free to price their products as they see fit, seemingly constrained only by the demand for each particular product. However, legislation mandates discount levels for prescription drugs in order for them to be covered under the public programs.

The following is a brief overview of the public programs that fund prescription drugs. For a more detailed analysis, see von Oehsen's "Pharmaceutical Discounts Under Federal Law: State Program Opportunities."¹¹

Medicaid

Of all the public programs, Medicaid may have the most significant impact on prescription drug pricing. This program, jointly financed through federal and state funds, is designed to aid certain low-income people, and covers more than 36 million individuals.

In the years after the Medicaid best-price regulation took effect, discounts beyond the specified 15.1 percent to any entity, public or private, became less generous and less common.

Pharmaceutical pricing for the Medicaid drug rebate program is primarily regulated through the Omnibus Budget Reconciliation Act (OBRA) of 1990. OBRA 1990 is administered by the Centers for Medicare and Medicaid Services (CMS, formerly HCFA) an agency within the federal Department of Health and Human Services (HHS). OBRA 1990 specifies that pharmaceutical manufacturers whose products are listed on the Medicaid formulary must give state Medicaid programs the lesser of:

- The "best price" offered to any purchasing entity, including wholesalers, retailers, nonprofit entities, or governmental entities within the states (but excluding specific federal agencies), OR
- The average manufacturer price (AMP) charged to wholesalers with a 15.1 percent discount for brand drugs or an 11 percent discount for generic drugs.

Regulations Governing Pharmaceutical Pricing for Non-Medicaid Public Programs

Section 340B

Enacted in 1992, Section 340B of the Public Health Service Act requires pharmaceutical manufacturers to provide reduced price outpatient drugs to eligible federally funded grantees, including federally qualified health centers, safety net hospitals, and clinics. The statute sets the maximum price that cannot be exceeded for certain outpatient and over-the-counter drugs, called the ceiling price. The ceiling price must be at least as low as the price that state Medicaid programs pay (lower prices may be negotiated). According to recent information available from the Office of Pharmacy Affairs, there are more than 8,600 eligible covered facilities participating in the 340B program.*

Section 603 and the Federal Supply Schedule

The federal supply schedule (FSS) is a list of prices that assists federal departments, agencies, and institutions in purchasing specific products and services. Individual agencies can take advantage of public programs' combined purchasing power to extract greater discounts from various suppliers, including pharmaceutical manufacturers. The VA is in charge of collective pharmaceutical purchasing; it negotiates, awards, administers, and maintains contracts under two VA federal supply schedule programs for pharmaceuticals.[†] The VA negotiates with each manufacturer for its "most favored customer" price, which is a discount equal to or greater than what that manufacturer currently offers a comparable customer.

Section 603 of the Veterans Health Care Act of 1992 makes participation in FSS a requirement for manufacturers who wish to participate in the Medicaid program. Other rules require any manufacturer wishing to contract with the VA to disclose discounts and pricing information for other customers. This allows the VA to analyze and compare pricing and to target particular drugs for negotiation.

FSS prices are typically more deeply discounted than even Medicaid best prices because manufacturers and wholesalers can offer prices for the FSS list without considering the Medicaid best price. This creates a critical advantage for the VA in its negotiations with pharmaceutical manufacturers.

Section 603 and the "Big Four"

Section 603 also mandates minimum drug discounts for the "big four" federal agencies that procure pharmaceuticals: VA, DOD, portions of HHS, and the Coast Guard. Even though these agencies benefit from FFS pricing, Section 603 sets a minimum discount to protect these purchasers from large fluctuations that can occur in prices on the FSS schedule. This price cap is set at 24 percent less than AMP to nonfederal purchasers (also known as non-FAMP, the nonfederal average manufacturer's price is the weighted average of the prices paid by all wholesalers and the lower prices paid by manufacturers' largest purchasers). These prices reflect manufacturers' discounts and rebates, but exclude the discounted prices paid by the VA and other federal agencies, and rebates paid to state Medicaid programs. The manufacturer faces a penalty if the non-FAMP rises faster than inflation (as measured by the consumer price index). As with the federal supply schedule, pharmaceutical manufacturers must agree to these price caps for the "big four" in order to be a supplier to Medicaid programs.[‡]

* Health Resources and Services Administration, Office of Pharmacy Affairs (<http://www.hrsa.gov/odpp>)

[†] "How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmacy Industry," Congressional Budget Office Papers, January 1996.

[‡] The Federal Supply Service (<http://www.fss.gsa.gov/aboutUs.cfm>)

OBRA 1990 legally obligates participating pharmaceutical manufacturers to give the Medicaid program the best price available in the private marketplace. In other words, if a pharmaceutical company discounts a price to a particular MCO or other insurer, it is mandated to offer that price or lower to all Medicaid programs nationwide.

If a pharmaceutical company discounts a price to a particular insurer, it has to offer that price or a lower one to the entire Medicaid system nationwide.

The price paid by a state Medicaid program is not determined at the time the prescription is filled. The final cost of the prescription drug is determined retroactively on a quarterly basis. Manufacturers are legally required to supply CMS with records of the prices charged to wholesalers, and using these records, CMS computes the average manufacturer price (AMP) for all drugs. The state Medicaid programs pay the pharmaceutical manufacturer for the cost of the medication, taking into account both the upfront discounts offered by the manufacturers and rebates “owed” on the basis of the volume of medications sold to Medicaid participants. These rebates help bring the costs down to the level specified by OBRA 1990.

The final price that Medicaid pays the manufacturer remains confidential. Information about AMP is not publicly available, so a private plan sponsor cannot determine how its pricing compares to best price.

Forty-nine states and the District of Columbia cover drugs under the Medicaid program and approximately 520 pharmaceutical companies participate in this program.¹² The Medicaid

program’s immense purchasing power creates a compelling incentive for participating manufacturers to conform to the best price regulations; otherwise they will be barred from all Medicaid programs — that is, their products will not be listed on, or covered by, the Medicaid formularies nationwide.

While specific information on AMP is not available, reports from the Congressional Budget Office have shown that in the years after the Medicaid best price regulation took effect, discounts beyond the specified 15.1 percent to any entity, public or private, became less generous and less common.¹³ Discounts to private purchasers that were on average the equivalent of 36 percent off AMP in 1991 diminished to 19 percent in 1994.¹⁴ The reduction is understandable from the manufacturers’ point of view: If discounts in excess of 15.1 percent are given to any commercial purchasers, a commensurate discount must be given to Medicaid purchasers.

After OBRA 1990, when non-Medicaid discounts became less generous, pharmaceutical costs went up for other government purchasers as well as private purchasers. A cascade of legislation ensued. The resulting regulations specified that in order for a pharmaceutical manufacturer to participate in Medicaid programs, the manufacturer must agree to the legislatively mandated price specified for the other governmental programs, which are generally at least as low as the Medicaid best price.

Pricing for Private Plan Sponsors: Employers and Health Plans

The purchasing experience is more complex for private plan sponsors than for government entities. The price paid by public programs is legislatively mandated and directly negotiated with the manufacturer, whereas the price paid by the private plan sponsor is a combination of discounts, fees, and rebates negotiated with intermediaries (such as PBMs and health plans). Moreover, private plan sponsors typically do not have the same access to pricing information as government purchasers. Later sections of this report explain the intertwined relationships and transactions that ultimately determine the employer's net cost for pharmaceuticals.

Private plan sponsors typically do not have the same access to pricing information as government purchasers.

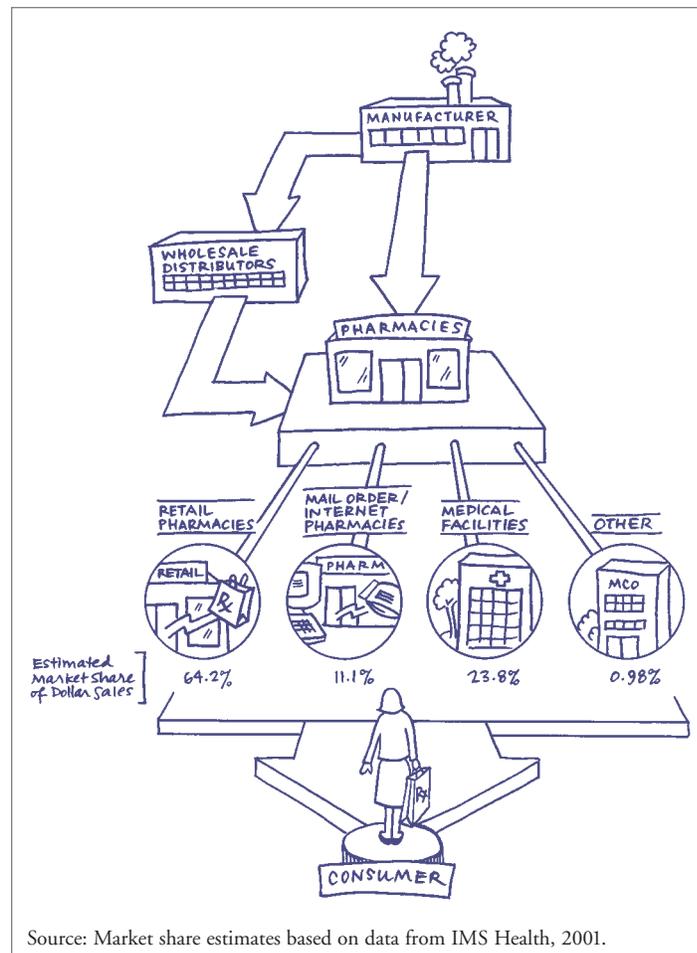
III. Pricing for Private Insurers: The Flow of Money

Securing the best pricing for the right goods and services can be a daunting task for the employer in a pharmaceutical marketplace where the price determination process is less transparent than that for other employee benefits.

A PRESCRIPTION DRUG GETS FROM THE pharmaceutical manufacturer to the privately insured individual via a multifaceted distribution and pricing system and a range of stakeholders. The complex relationships among key players in this multistage transaction chain directly and indirectly determine the ultimate cost of the prescription drug to employers and consumers.

The distribution of products through the pharmaceutical chain to the consumer is generally carried out by manufacturers, wholesale distributors, and pharmacies. The key players in the pharmaceutical marketplace can be seen in Figure 3.

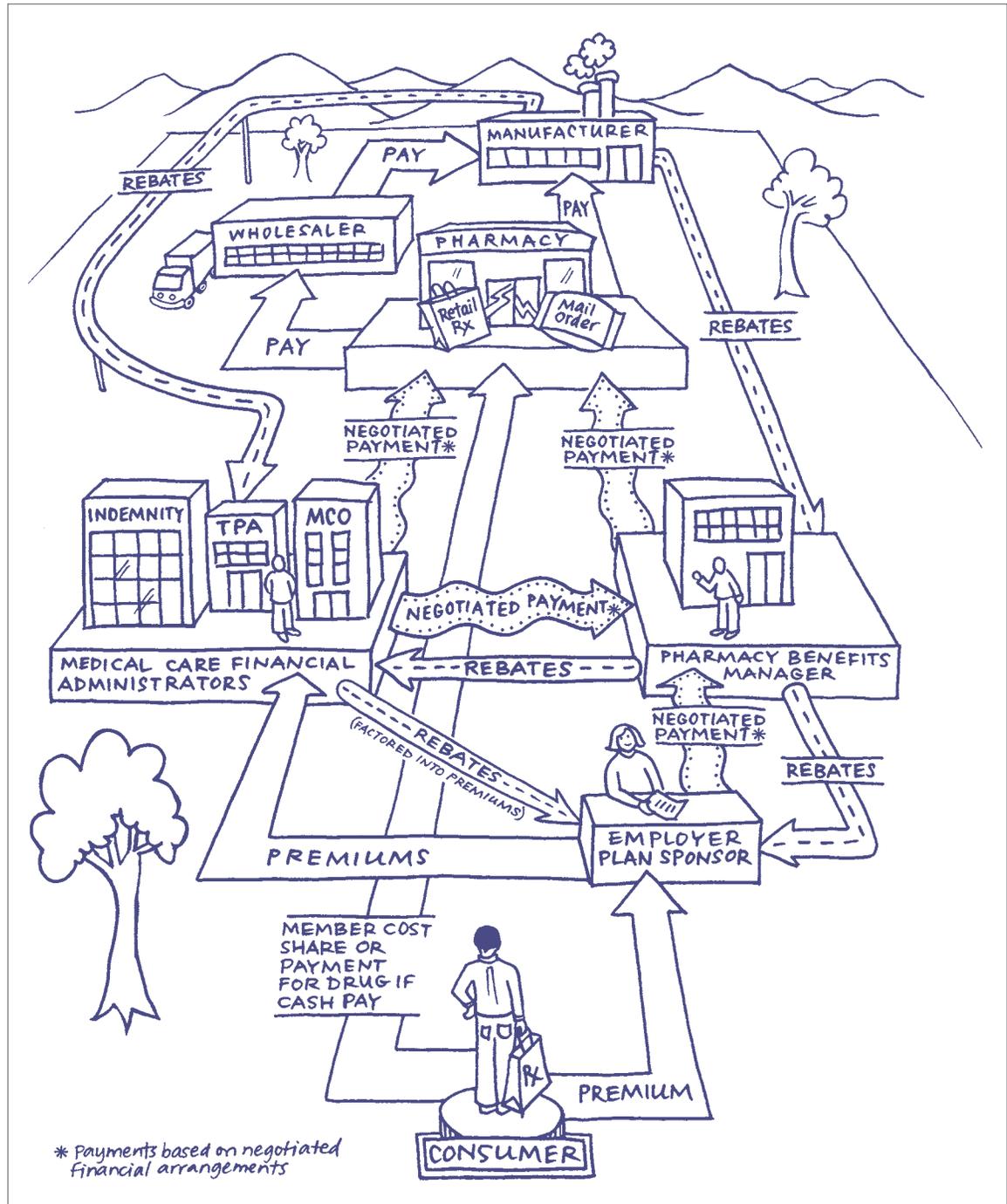
Figure 3. Pharmaceutical Product Flow



While the flow of products through the pharmaceutical chain is relatively straightforward, the flow of money involves a wider range of players and complex financial relationships (see Figure 4).

Because of the number of players involved in the flow of money, the price paid to the pharmaceutical manufacturer for a given drug is rarely the same as the price paid by the consumer. In 2001, the average estimated retail prescription cost of

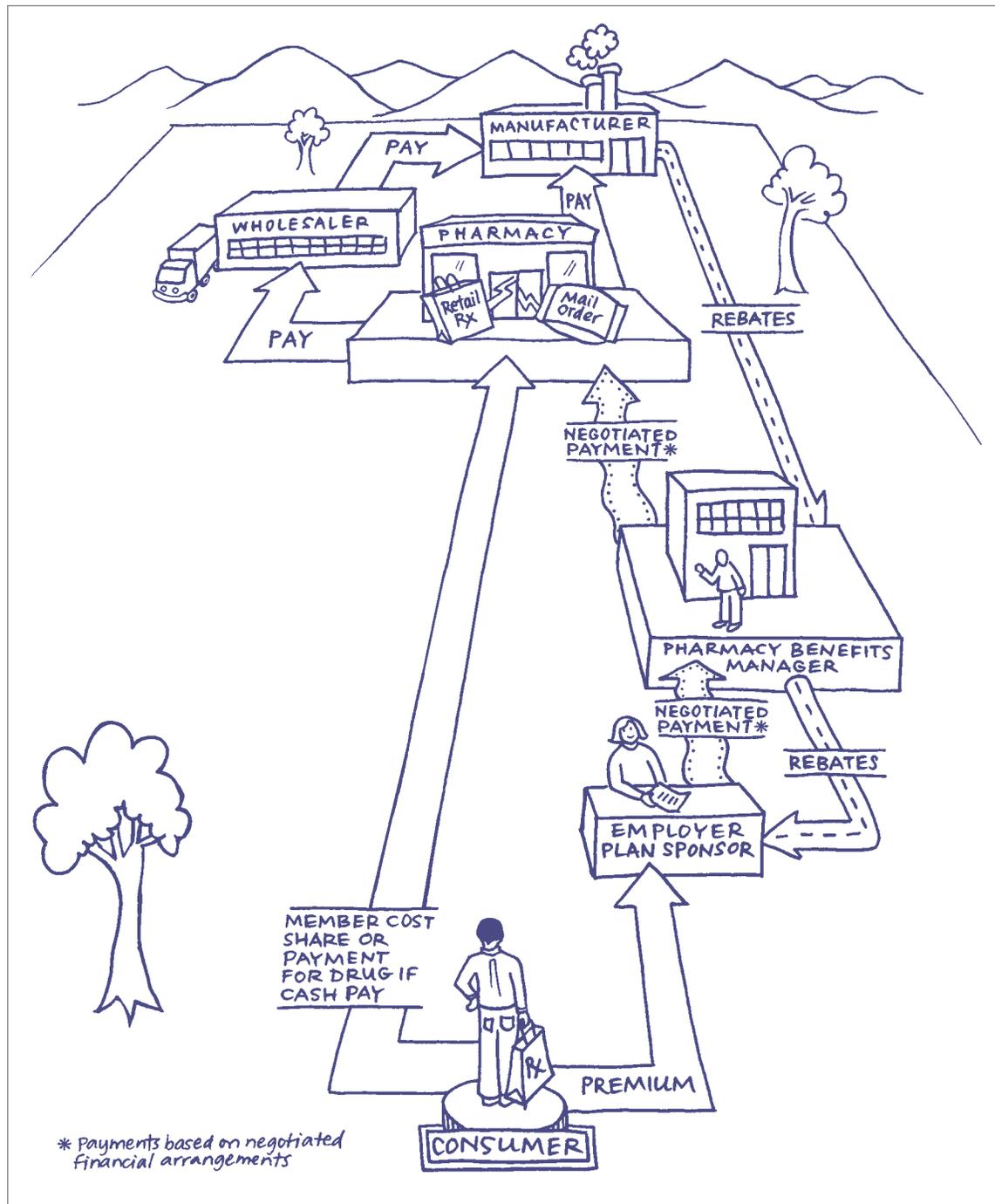
Figure 4. Pharmaceutical Money Flow: Carve In



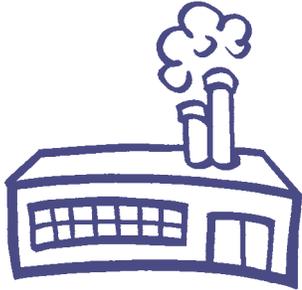
a drug to the consumer was \$50.17. Of this amount, the manufacturer received \$37.93; the wholesaler received \$1.67; and the retail pharmacy received \$10.57. In other words, for every

prescription dollar sale at a retail pharmacy, 76 percent went to the manufacturer, 3 percent went to the wholesaler, and 21 percent went to the pharmacy.¹⁵

Figure 5. Pharmaceutical Money Flow: PBM Carve Out



IV. Pharmaceutical Manufacturers



In 2000, U.S. prescription drug sales totaled \$145 billion, an increase of 15 percent from the previous year.

PHARMACEUTICAL MANUFACTURERS HAVE BEEN under increasing scrutiny as the cost of prescription drugs continues to rise and consume a greater share of the U.S. health care dollar. In 2000, according to IMS, U.S. prescription drug sales (based on wholesale prices) totaled \$145 billion, an increase of 15 percent from the previous year.¹⁶ The pharmaceutical industry points to demographic changes in the population and the rapid introduction of life-extending medications and procedures as the primary reasons for this increase. Increased utilization accounts for approximately 9 percent; price increases for 4 percent; and new medicines for 2 percent of the rise in prescription drug costs.¹⁷

Pharmaceutical manufacturers fulfill various roles, including (1) research and development of new drug therapies, (2) manufacturing products, and (3) marketing to inform the medical community and consumers. Not all pharmaceutical manufacturers assume all these roles. A number of lesser-known companies do not develop new therapies, but instead manufacture generic compounds—drugs that are no longer protected by patents. After a drug's patent has expired, generic versions of the same compound can be introduced into the market to compete with the original branded version.

The pharmaceutical industry maintains that development costs are the key drivers of escalating prices for patented prescription drugs. The Tufts Center for the Study of Drug Development estimates that the average cost of developing a new drug is \$802 million.¹⁸ Another Tufts study reports that the time from initial drug creation to market approval has increased from around eight years in the 1960s to approximately 14.2 years in the 1990s.¹⁹ Added to the high cost and increasing amount of time required to bring a drug to market is the fact that only a relatively small number of drugs ever attain commercial success.

Manufacturers' primary customers are wholesalers, retail pharmacy chains, mail-order pharmacies, hospital chains, and some health plans. Occasionally an employer with an on-site pharmacy will purchase drugs directly from the manufacturer, but the typical employer plan sponsor does not. Wholesalers are manufacturers' largest group of purchasers, and wholesale prices depend partially on volume purchased.

Manufacturers offer up-front discounts to pharmacies for purchasing their products, and rebates (back-end discounts) to wholesalers and PBMs that sell specific volumes of certain drugs or achieve a target market. Purchasers who are able to more closely manage the pharmacy benefit or influence the market share of a specific drug are likely to receive greater formulary rebates than those who do not.

How Manufacturers and Wholesalers Determine Prices

Manufacturers and wholesalers use several pricing standards to arrive at their pricing arrangements. To develop introductory drug prices within the United States, manufacturers use “employed financial modeling,” which takes into account research and development costs, launch and marketing costs, competitor prices, and estimates of consumer and physician demand. Once an introductory price has been set, the manufacturer establishes a wholesale acquisition cost (WAC), which it uses as a baseline for sales to wholesalers.

retail price; that is, the price that manufacturers recommend that wholesalers use to resell a drug to retail pharmacies.²⁰

To complicate matters, wholesale prices are indirectly related to public program prices; that is, WAC is loosely related to the average manufacturer’s price, the benchmark used to determine the Medicaid “best price.” AMP is the average price paid by wholesalers for a drug, as calculated quarterly by CMS with records supplied by manufacturers of their transactions with wholesalers. While this information is the benchmark used in determining the price to governmental purchasers, it is not made available to private payers. This makes it difficult for private payers to assess the differences between AMP, AWP, and WAC.

Purchasers who are able to manage the pharmacy benefit more closely or influence the market share of a specific drug are likely to receive greater formulary rebates than those who do not.

In addition, the manufacturer establishes the benchmark price known as the average wholesale price (AWP), which is published in recognized sources such as FirstData Bank and its supplements or other nationally recognized pricing sources. Until recently, there has been no standardized definition of AWP. A commonly accepted one is the manufacturer’s suggested

V. Wholesalers

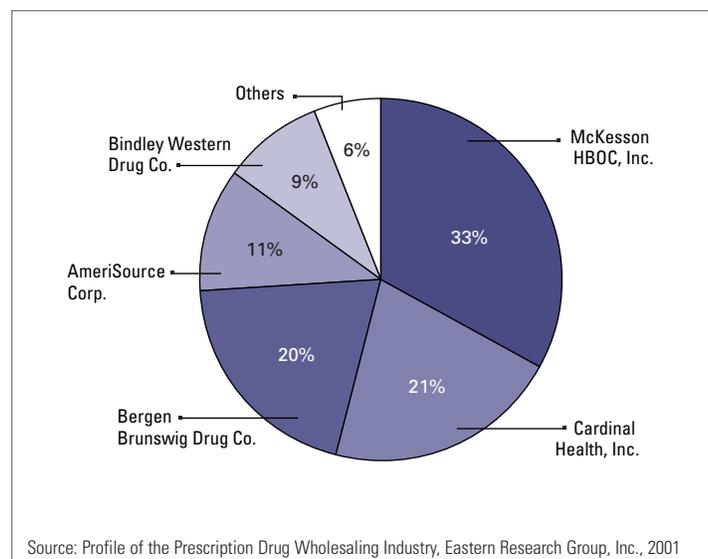


The top five wholesalers now account for approximately 90 percent of the entire wholesale drug market.

LIKE MOST OTHER TYPES OF WHOLESALERS, pharmaceutical wholesalers purchase goods from manufacturers and then resell them to other businesses. Wholesalers, whose main customers are retail and mail-order pharmacies, buy pharmaceuticals in bulk, sort them by customer needs, and disperse them in usable quantities, selling them at a profit. They offer their customers either a full line of pharmaceutical products or a narrow, more specialized line, such as oncology drugs or biotech products. Some wholesalers sell to a wide variety of customers; others distribute pharmaceutical products to a narrower customer base, such as physician offices or diagnostic labs.

Pharmaceutical wholesalers have undergone significant consolidation during the past 25 years, with the number of firms declining from approximately 200 in 1975 to fewer than 50 by 2000.²¹ The top five wholesalers now account for more than 90 percent of the entire wholesale drug market.²² While wholesalers have experienced lower operation margins over the past several years, larger wholesalers are in a better position to negotiate prices with manufacturers.

Figure 6. Wholesalers' Market Share, 2000



Although some of the largest drugstore chains find it more advantageous to assume the role of wholesaler for their own retail operations than to outsource that role, wholesalers continue to play an important role in the pharmaceutical distribution chain. Their ability to buy drugs in large quantities creates efficiency in the marketplace that is reflected in the discounted pricing they receive. Wholesalers alleviate the need for manufacturers to negotiate and distribute products to numerous pharmacies, and they pass along the savings of economy of scale to pharmacies by supplying smaller purchasers with products at a lower price than they would pay manufacturers.

While wholesalers do not generally interact directly with employer plan sponsors, one major wholesaler, AmeriSourceBergen (formerly Bergen-Brunswig), has recently offered PBM-type services to employers. Whether or not this direct wholesaler-to-employer connection will provide additional savings to employer plan sponsors remains to be seen.

VI. Pharmacies

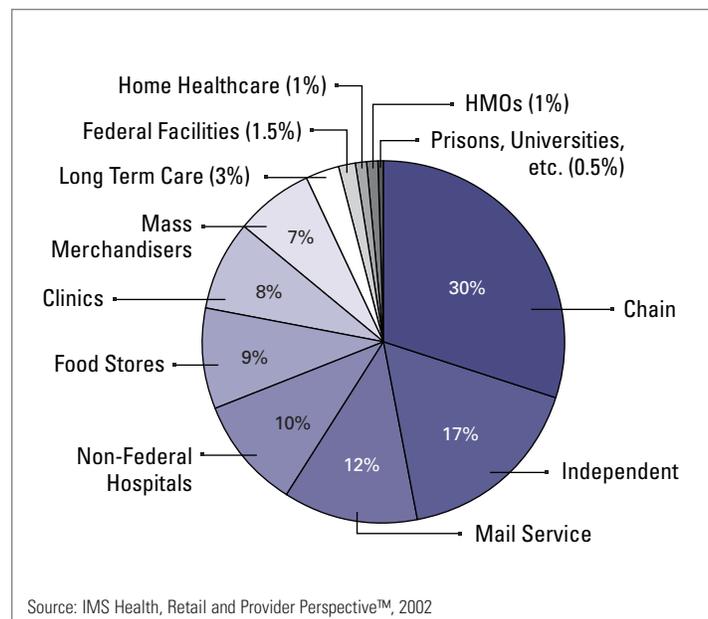


ALL PHARMACIES — INCLUDING RETAIL CHAINS, food stores, mass merchandisers such as Target and Wal-Mart, independently owned pharmacies, and mail-order facilities — play a pivotal role in the distribution chain. They fill prescriptions for consumers and serve as a link between prescription drug benefit administrators and manufacturers/wholesalers. Among their key functions, pharmacies:

- Maintain adequate stock to provide products on an as-needed basis to consumers in a convenient way,
- Provide meaningful information to consumers to ensure safe and effective use of prescription drugs, and
- Facilitate billing and payment for consumers participating in group benefit plans.

As Figure 7 shows, the majority of dollars spent for prescription drugs flow through retail pharmacies. In 2000, 64 percent of sales were channeled through retail pharmacies (chains, independent pharmacies, and food stores with pharmacies), 12 percent through mail-order sales, and 24 percent through medical facilities (hospitals, nursing homes, clinics, home health care, and a number of federal facilities).²³

Figure 7. U.S. Prescription Market Share by Distribution Channel

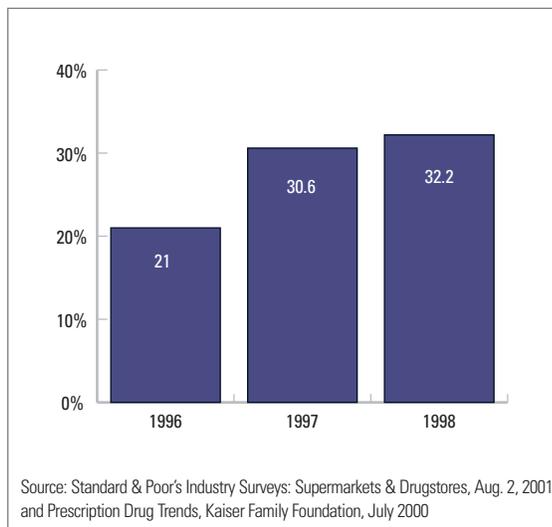


Retail Pharmacies

For many Americans, the local retail drugstore remains the primary distribution channel for prescription drugs, although other channels such as mail order are growing in popularity.²⁴ According to the National Association of Chain Drug Stores, there are approximately 50,000 retail pharmacies in the United States (20,000 are independent and 30,000 are operated by chains, supermarkets, and the like).²⁵

Retail pharmacy chains have merged to gain buying power from manufacturers and wholesalers and to broaden and strengthen the regional presence of their stores. In 2001, the top four drugstore chains accounted for 51 percent of market share compared to less than 25 percent in 1996.²⁶

Figure 8. Market Concentration of Top Four Retail Chain Pharmacies



Ironically, one by-product of retail pharmacy consolidation may be higher costs for employer plan sponsors. As retail chains grow in size and regional and national presence, many are able to command higher dispensing fees (fees paid to the pharmacist for filling the prescription) as a condition for continued participation in a PBM's or MCO's network. As PBMs and MCOs pass the

cost on to plan sponsors, these higher dispensing fees translate into potentially higher prescription drug benefit costs for employers.



One by-product of retail pharmacy consolidation may be less competition among the retail pharmacies and potentially higher costs for employer plan sponsors.

Retail pharmacies obtain prescription drugs from manufacturers or wholesalers. Some large national or regional chains (including pharmacies, food stores, and mass merchandiser chains) purchase in large enough volumes that they can bypass the wholesaler and buy directly from the manufacturer, negotiating discounts equivalent to those that a wholesaler would obtain from a manufacturer. These organizations already have the operational infrastructure necessary to bypass wholesalers—such as warehousing facilities, distribution vehicles, and inventory control systems.

Smaller retail stores, such as independent retail pharmacies and smaller retail chains, purchase directly from wholesalers or join group purchasing organizations. As members of a GPO, smaller entities receive the benefits of volume purchasing by leveraging their combined purchasing power to negotiate discount pricing from wholesalers or even manufacturers.

Additionally, some retail pharmacies reduce their costs through rebate deals for selling selected drugs or achieving market share targets for selected manufacturers' drugs. These rebates provide an incentive for pharmacists to switch interchangeable medications in favor of the one that has a rebate.

Although rebate payments to pharmacists are generally confined to prescriptions for cash-paying customers, pharmacists sometimes use this substitution approach to fill prescriptions from PBM and health plan members whose plans cover all medications.

While mail order may offer the same level of service, the opportunity to establish a personal relationship with a pharmacist is a priority to some consumers.

Retail pharmacies offer consumers convenience and the opportunity to establish a personal relationship with a pharmacist.

Retail pharmacies generally do not have the economies of scale that large mail-order pharmacies have; therefore their costs are higher than those of mail-order pharmacies. Retail pharmacies can compete by offering a high level of service and convenience to consumers. They may, for example,

- Stock a large and varied inventory of pharmaceuticals at convenient locations;
- Offer an opportunity for face-to-face consultations with pharmacists; and
- Obtain payments from PBMs and other payers.

To be included in a pharmacy benefit administrator's network, retail pharmacies are required to offer a guaranteed reimbursement formula for prescription drugs purchased through the benefit plans.

This reimbursement formula specifies how the pharmacy will calculate the cost of the drug—including the discount—and the dispensing fee.

For a brand-name medication, the drug cost is usually determined by subtracting a negotiated percentage from the drug's AWP. For a generic drug, reimbursement may be determined in the same way as for a brand drug, but is more often based on an amount specified as the maximum allowable cost (MAC) per unit (such as tablet or capsule) dispensed.

MAC Pricing

To stabilize the cost variance of different generic products of the same compound, pharmacy benefit administrators calculate a maximum allowable cost based upon the listed average wholesale prices of competing generic drug manufacturers. The resulting proprietary price list varies from PBM to PBM. CMS also issues a MAC list, but only for generic products that have three or more manufacturers or distributors on the market. Because of this limitation, not all generics have a corresponding CMS MAC. PBMs often utilize this government issued MAC as the basis of their MAC list and supplement it with other generic products.

Mail-Order Pharmacies

Mail-order pharmacies are typically available to consumers whose plan sponsor includes them in the benefit. Consumers send their prescriptions by mail, fax, phone, or Internet to a central location where the prescriptions are filled and mailed back to the consumer. Mail-order pharmacies are popular with employer plan sponsors, 87 percent of whom offered mail service in 2001.²⁷ While the majority of mail-order facilities are owned and operated by PBMs, a number of retail pharmacy chains also own mail-order facilities.

Mail order is best suited for maintenance medications when treatment is predictable and medication can be ordered in advance of need. Mail order is not appropriate for consumers with acute conditions, such as an infection that requires antibiotics, in which the treatment must be started as soon as possible.



Mail-order pharmacies are popular with plan sponsors, 87 percent of whom offered mail service in 2001.

Cost Savings

One of the advantages promoted by mail-order facilities is their dispensing accuracy. Because mail-order pharmacies have largely automated the prescription filling process, they typically operate with less than a .01 percent error rate.

Mail-order pharmacies generally offer cost savings over retail pharmacies. By consolidating purchasing from consumers across the country, mail-order facilities can buy pharmaceuticals in bulk and dispense them economically through automated processes. As high-volume purchasers, these pharmacies can choose the most cost-effective source for products by negotiating directly with manufacturers, or negotiating volume discounts with wholesalers.

PBMs that use mail-order pharmacies also have a greater opportunity than retail pharmacists to earn rebates by interchanging therapeutically equivalent products. When they are passed along to employer plan sponsors, rebates can significantly reduce the cost of prescriptions. HHS estimates that PBMs receive rebates from manufacturers ranging from 2 to 35 percent of certain

brand-name drug sales prices. PBMs pass on about 70 to 90 percent of these rebates to insurers or self-insured employers.²⁸

Mail-order pharmacists can substitute generic or less expensive brand medications for high-cost brand medications more frequently than retail pharmacies because the pharmacist has more time between when the prescription is received and when it is filled to contact the prescribing physician and request a change. The cost difference between the generic drug and the brand-name drug can lead to significant savings.

These factors combine to make mail-order pharmacies potentially more cost-effective than retail pharmacies. Industry sources with a stake in the mail-order business estimate that plan sponsors using a relatively high percentage of mail order can achieve approximately 10 percent in additional savings over retail.²⁹ However, the cost-effectiveness of mail order relative to retail depends largely on the plan design—for example, the amount of copayments or coinsurance—to ensure that the members' cost sharing properly reflects the larger prescriptions (for example, 90-days supply) at mail order.

According to some mail-order providers, plan sponsors using a relatively high percentage of mail order can potentially achieve up to 10 percent in additional savings over retail.

Other Pharmacies

Though not as widespread and accessible as retail and mail-order pharmacies, other pharmacies open unique opportunities for plan sponsors whose needs fit within these pharmacies' special niche.



An Internet pharmacy constitutes a different contact interface for mail-order distribution.

Internet Pharmacies

Stand-alone Internet-based “drugstores” were first developed in the late 1990s to offer consumers the convenience of ordering prescription drugs online. For the most part, these businesses have failed to attract the number of customers initially anticipated. Part of the reason may be that PBMs and other providers built their own Internet pharmacies, making it unnecessary for plan members to use the stand-alone Internet pharmacies.

Also, in response to the Internet pharmacies, retail pharmacies developed their own Internet capabilities. Some retail chains allow consumers to order refill prescriptions via the Internet and then either pick them up at a nearby chain store or have them delivered to the home. This increases the number of options available to consumers. They may choose to transmit the original signed prescription from their physician to the pharmacy via traditional means (fax, mail, or bring it to the store), or they may send the information through the Internet. The availability of these options varies by state.

In general, an Internet pharmacy constitutes a different contact interface for mail-order distribution. From a cost perspective, the efficiencies of mail-order purchasing apply equally to Internet pharmacies, with the added advantage of decreased administrative costs resulting from the efficiency of the Internet interface. However, Internet pharmacies generally do not provide the level of service offered at retail pharmacies or through a PBM-operated mail-order pharmacy.



According to one manager of worksite corporate health programs, employers who offer worksite pharmacies can save up to 20 percent on their prescription drug coverage costs.

Employer-Sponsored Worksite Pharmacies

When employees are concentrated almost exclusively in one or more work locations, as in the case of workers at a large manufacturing plant, employers sometimes find it cost-effective to operate a worksite pharmacy exclusively for their employees. This allows employers to offer all of the advantages of retail purchasing with the added convenience of not having to leave the work site, while reducing costs. The employer, who is financially at risk for the operation of the pharmacy, usually hires a managing agency that specializes in worksite health facilities (such as clinics or nurse stations) to oversee the operation.

Aside from the convenience to employees, a worksite pharmacy offers the financial advantage of eliminating the middlemen. According to CHD Meridian Healthcare, a developer and manager of worksite corporate health programs, employers who offer worksite pharmacies can save up to 20 percent on their prescription drug coverage costs.³⁰ The managing agent (e.g., CHD Meridian HealthCare) is able to take advantage of volume purchasing from manufacturers and wholesalers by pooling orders from all the facilities it operates. Likewise, it is able to obtain rebates to the extent that its pharmacists are able to influence which medications are dispensed. However, these rebates are frequently not shared with the employer.

Given the specific circumstances needed to make the employer-sponsored worksite pharmacy option viable, this arrangement is not often utilized. There are at most 40 worksite pharmacies currently in operation in the United States.³¹



Some MCOs with on-site pharmacies can negotiate lower prices because they have greater ability to influence the prescribing behavior of in-house physicians.

Managed Care Organization On-Site Pharmacies

Primarily located in MCO-owned outpatient facilities, which house physicians' offices as well as some diagnostic facilities, MCO on-site pharmacies are for the exclusive use of the MCO's plan members, and are typically staffed by MCO employees. For plan members, this type of pharmacy offers all of the services of a retail pharmacy plus the unique convenience of being able to fill a prescription at the same facility as their physician's office. While the number of customers for this type of pharmacy is limited to the participants in the MCO, this arrangement presents some distinct advantages.

MCOs with on-site pharmacies can negotiate lower prices because, compared to almost any other pharmacy, they have the ability to influence the prescribing behavior of physicians through the use of their formularies. Moreover, to the extent that managed care organizations directly purchase and distribute prescription drugs, some data indicate that MCOs are able to achieve lower acquisition costs than other privately funded pharmacies.³²

VII. Pharmacy Benefit Administrators



The number of PBMs operating in the United States has shrunk from more than 100 companies in 1998, to 80 in 1999, to fewer than 60 in 2000.

IN PROVIDING PRESCRIPTION DRUG BENEFITS, employers usually contract for the services of a PBM, health plan, or third-party administrator to administer the program. Some of these TPAs pay claims and exert some level of control over dispensing; others only pay claims. Some are willing to bear risk; others are not.

Pharmacy Benefit Managers

PBMs are independent administrators that focus exclusively on pharmacy benefit administration. They manage drug purchasing, dispensing, and reimbursement for prescription drug benefit plans. It is estimated that about 45 percent of the U.S. population has pharmacy coverage directly through a PBM.³³

The PBM industry has undergone significant consolidation over the past several years, with clear industry leaders now emerging. The number of PBMs operating in the United States has shrunk from more than 100 companies in 1998, to 80 in 1999, to fewer than 60 in 2000.³⁴ According to a first-quarter 2001 market survey, there are approximately 55 distinct PBM companies currently in existence.³⁵ This industry consolidation could affect employer plan sponsors by supplying them with fewer PBMs to choose from but potentially more competitive financial deals as PBMs compete to capture market share from each other.

A PBM may do the following:

- Purchase and dispense medications. PBMs purchase pharmaceuticals for their pharmacies — mail-order facilities — and dispense medications directly to consumers. They negotiate purchasing agreements and rebate contracts with manufacturers for the products they dispense.
- Pay claims.
- Act as a financial intermediary between pharmacies and the plan sponsor, negotiating with retail pharmacies to contract reimbursement levels for prescriptions filled by plan members. They often create and maintain pharmacy networks.
- Manage prescribing choices. PBMs have the opportunity to influence which drugs are ultimately dispensed at retail and mail order, thereby leveraging their negotiating power.

They do this through formulary management, health and disease management, therapeutic interchange, and educational programs that can

steer physicians and patients toward preferred drugs.

Tools to Manage Prescribing Choices

The Formulary

PBMs develop a formulary (a list of prescription drugs that members are encouraged to request and participating pharmacies are encouraged to dispense) as the foundation of their pharmacy management approach. This list is issued to inform physicians which medications are the most cost-effective and clinically efficacious, and therefore preferred, in a particular therapeutic class. When deciding whether to add or delete particular drugs from its formulary, a PBM looks at both the clinical and financial impact.

From a clinical perspective, the PBM's pharmacy and therapeutics committee evaluates the efficacy of the drug and determines whether or not it should be included in the PBM's list of formulary drugs.

On the financial side, a PBM negotiates with individual pharmaceutical manufacturers for rebates or incentive payments for including their drugs in the formulary. The inclusion or exclusion of a drug can significantly impact the manufacturer's sales volume. Rebates may be based on the sales or market share targets for the manufacturer's drugs sold through the PBM.

Manufacturers pay substantial rebates to PBMs for increasing their market share. Some sources estimate PBM rebate revenues to be between 5 and 25 percent of brand-name drug spending; other sources estimate the figure as high as 35 percent.

Examples of PBM Gross Revenue per Transaction

ADMINISTRATIVE FEES:	\$0.20–1.00
DRUG SALE TO RETAIL PHARMACY NETWORK (SPREAD):	\$0.10–0.35
MAIL ORDER PRESCRIPTION SALES:	\$50–150
DISEASE MANAGEMENT:	\$5 PMPM
REBATES (% OF BRAND-NAME DRUG SPENDING):	5–25%

Source: FAC/Equities, Research Report-Caremark Rx, October 2001

Health and Disease Management Programs

Some PBMs offer clinical programs that maintain wellness; provide case management services for particular conditions, such as asthma and diabetes; and disseminate educational information to patients and physicians. Manufacturers often subsidize development and management of these programs by the PBM, believing that they will help achieve greater product recognition and influence physicians and consumers toward a preferred therapy.

Pharmacy Claims Data

Pharmaceutical manufacturers often pay PBMs and health plans to supply them with sanitized claims data detailing the volume and types of drugs sold. These data provide valuable information for manufacturers about drug utilization.

Therapeutic Interchange Programs

These programs are employed by PBMs to substitute generic or less expensive brand medications for higher-cost brand drugs when available and appropriate. The ability to make such changes is often dependent on the physician's willingness to modify prescriptions (has not indicated "dispense as written"), as well as the patient's willingness to change medications.

For plan sponsors, the PBM's volume discounts, rebate savings opportunities, and therapeutic interchanges can yield significant cost savings.

For plan sponsors, the PBM's volume discounts, rebate savings opportunities, and therapeutic interchanges can yield significant cost savings.

Health Plans

Health plans adopt a range of strategies in administering outpatient pharmacy benefits. A few health plans reimburse patients for prescriptions on a fee-for-service basis, but health plans rarely use this method to process pharmaceutical claims because it allows no opportunities to reduce costs or control utilization. More commonly, health plans employ one of the following strategies:

- ***Outsource claims payment to a Third-Party Administrator.*** There may be more efficiencies and greater savings to be gained through outsourcing if the claims processing is centralized and performed by an expert in that area.
- ***Outsource pharmacy benefit management to an external PBM.*** With their primary focus on inpatient and outpatient medical care, some health plans prefer to use a specialist for outpatient pharmaceuticals.
- ***Operate their own PBMs.*** Certain large health plans with national or regional scope own PBMs. These PBMs typically provide dedicated service to the health plan. Examples include CIGNA, operating Rx Prime; PacifiCare, operating Prescriptions Solutions; and Wellpoint, operating Wellpoint Pharmacy Management. In some cases, these internal

PBMs eventually become a service of the health plan that can be purchased on a stand-alone basis. MCOs extend the integration of pharmacy and medical administration to include purchase and distribution of pharmaceuticals, and even operate pharmacies within their outpatient clinics. For some organizations with a high degree of care management, such as group model MCOs like Kaiser Permanente, it makes sense to maintain control over pharmacy procurement and utilization. Kaiser procures its own pharmaceuticals from manufacturers and dispenses to members at on-site pharmacies.

Given the range of administrative strategies that health plans use, the cost of pharmaceutical coverage can vary considerably from plan to plan. For plan sponsors with fewer than 5,000 members, a pharmacy benefit program provided through a health plan is likely to provide a better financial arrangement than direct negotiation with a PBM because the health plan essentially offers the smaller plan sponsor a vehicle for aggregate pharmaceutical purchasing.

National and regional health plans obtain perhaps the most advantageous pricing of any nongovernmental entity.

Health plans such as nationally and regionally based MCOs tend to negotiate fairly competitive arrangements with pharmacy networks because they are able to ensure that a relatively large group of members will be using a relatively concentrated number of pharmacies. Most health plans further reduce drug costs through formulary management programs that influence medication preference in the treatment of a particular medical

condition. In 1999, about 97 percent of MCOs relied on some type of formulary.³⁶

MCO Advantage

Among health plans, national and regional managed care organizations obtain perhaps the most advantageous pricing of any nongovernmental entity not only because of their volume of purchases but, more importantly, because these organizations are uniquely positioned to control the prescribing behavior of their staff physicians and members through the use of their formularies.

Among MCOs with formularies, approximately 90 percent of members' prescriptions are filled with formulary drugs.

For many MCOs, formulary compliance is generally high because (1) the plan will not readily pay for more expensive medications when less expensive equivalents are available, and (2) participating physicians agree to enforce the plan's utilization management programs, allowing the plan to influence the physician's behavior before the prescription is written rather than after the fact. For the most part, physicians are cognizant of the formulary and prescribe accordingly. As a result, among MCOs with formularies, approximately 90 percent of members' prescriptions are filled with formulary drugs.³⁷

A Congressional Budget Office study showed that for MCOs that directly purchase and distribute prescription drugs, acquisition costs are, on average, 18 percent below retail pharmacy acquisition costs, whereas hospitals' acquisition costs are only 9 percent below. By comparison,

federal facilities such as VA hospitals achieve acquisition costs of 40 percent below retail.³⁸ Among privately funded pharmacies, MCOs are able to achieve some of the lowest acquisition costs.

Third-Party Administrators (TPA)

TPAs may process pharmacy claims but are not involved with dispensing drugs or controlling utilization. Their approach can vary, with some TPAs subcontracting the pharmacy benefit administration to a PBM. In other cases, plan sponsors require the employee to pay the full cost of the prescription at the pharmacy and submit a claim form to the TPA for reimbursement. Whatever the approach, the TPA has no influence over what the retail pharmacy charges or what is dispensed.

VIII. How Employer Plan Sponsors Can Contain Costs



EMPLOYER PLAN SPONSORS FACE A NUMBER OF challenges, not the least of which is balancing cost containment against the pressure to provide adequate pharmacy benefit coverage for employees and their dependents. How much the pharmacy benefit ultimately costs each employer is the result of many factors involving numerous parties and a chain of financial transactions, many of which are played out behind the scenes. While employers have no control over some of these factors (such as government regulations), others are open to their influence (for example, the choice between a health plan and a PBM). Employers can use this influence to their best advantage by carefully evaluating how the following key decisions will affect the goals of their benefit program.

To Carve in or Carve Out

Will the benefit be administered by a health plan or will it be carved out and managed by a PBM? A health plan offers the potential for an integrated health care approach, combining information from both medical and prescription drug data to identify at-risk members and implement disease and health management programs. In practice, however, there is significant variation in the level of integrated care offered by health plans.



For smaller plan sponsors, health plans often offer more aggressive pricing terms leveraged by their ability to purchase large quantities. On the other hand, they tend to limit the employer's flexibility to modify the benefit, and tend to offer a limited range of formulary options.

PBMs focus solely on the prescription drug benefit; therefore, they can work with employer plan sponsors to develop an effective combination of appropriate employee access and pharmacy management. Many PBMs have also developed programs to identify and manage the care of at-risk members. While these programs utilize pharmacy data only, lacking the potential to integrate clinical and pharmaceutical care, some use sophisticated methods to effectively use pharmacy data to identify members with chronic conditions.

PBMs regularly provide a range of formulary options. They are also likely to offer guarantees on financial and service performance, and are typically more flexible with plan design and program management customization. On the other hand, a PBM's financial arrangements may be complex and difficult to understand, and some PBMs tend to be unwilling to disclose key information about their pharmaceutical agreements.

Risk Sharing

Will the employer purchase an insured pharmacy benefit, or assume financial risk and self-insure? Many employers purchase an insured benefit so as to avoid the greater risk and potentially higher costs of providing prescription drug coverage. However, some employers prefer to self-insure, seeing this as a way to provide greater input on how the benefit is structured and provide greater likelihood of rebates from pharmacy providers.



For some plan sponsors, especially smaller employers, limiting financial exposure by purchasing an insured benefit may be more advantageous than choosing unlimited exposure along with the guarantee of rebates. However, the insured arrangement often subjects the employer to mandated benefits, premium increases, and specific plan design, which may make the employer more reliant on the health plan to control costs.

Self-insuring allows the employer greater flexibility in plan design, formulary, and pharmacy management, and can be of particular advantage to national employers because it avoids coverage mandates that differ by state. However, self-insuring imposes a greater burden on the sponsor to implement programs to control costs.

Cost Sharing

What portion of the cost of prescription drugs will the employer pay? The proportion the employer pays will depend on how the benefit plan is structured—that is, the amount of the employee's share of cost (in copayment, coinsurance, and deductibles); how many and which drugs are covered and which are not; and whether and how the formulary is tiered. Most PBMs and some health plans offer more than one formulary for plan sponsors to choose from, with some formularies being more restrictive than others. A restrictive formulary is believed to result in greater cost savings. It may, however, lead to member dissatisfaction over coverage limitations or higher co-pays for a larger percentage of drugs.

Some plan sponsors also introduce various utilization management strategies that can vary the level of coverage based on clinically related rules or prescribing guidelines. Plan sponsors also use more narrow retail networks to contain their portion of costs.

Benefit Design

How much influence will the employer have over which drugs consumers use? Manufacturer discounts and rebates potentially are available to plan sponsors willing to allow their pharmacy administrator to steer consumers and physicians toward one drug rather than a competing drug. This is accomplished through plan design and formulary management decisions.

Plan Design

An employer can use plan design to influence which drugs its employees use. By implementing different cost-sharing structures, employers can help move employees from higher- to lower-cost drugs. Examples of plan design include:

- Two-tier co-pays, which favor purchase of generic over brand medications;
- Multi-tiered or percent co-pays; and
- Programs such as prior authorization, mandatory generics, or mail-order and Internet reordering incentives.

Employers moving from open formularies to a two- or three-tier plan design can negotiate higher rebate payments because manufacturers typically provide PBMs and health plans with improved rebates for formulary designs that include incentives for members to utilize drugs on preferred lists.

Plan sponsors receive a greater share of formulary rebate earnings if they allow their PBM or health plan to intervene more intensively with physicians and consumers.

Formulary Management Decisions

Formulary lists can be more or less inclusive, and efforts to achieve compliance can be more or less intrusive. Plan sponsors receive a greater share of formulary rebate earnings if they allow more intensive intervention efforts, including therapeutic interchange programs and targeted communications to patients and physicians. While more restrictive formulary management can result in increased rebate earnings from the administrator,

this management strategy can pose difficulties in certain employer situations, as when benefits are determined by union negotiation.

Collective Purchasing

Will the employer engage in collective purchasing? Almost every player in the pharmaceutical distribution chain seeks the benefits of economies of scale and enhanced bargaining power offered by aggregate or group purchasing. Wholesalers purchase in large volume from manufacturers on behalf of numerous smaller entities. Institutional purchasers such as hospitals and independent pharmacies form group purchasing organizations, or GPOs, to obtain advantageous pricing from manufacturers and wholesalers. National chains (including pharmacies, supermarkets, and mass merchandisers) centralize purchasing on behalf of all stores in the chain. Mail-order facilities amass the purchasing volume of plan members throughout the country, enabling them to receive discounted pricing. Some national and regional MCOs purchase in large volume for their affiliated pharmacies, clinics, and hospitals. PBMs leverage their nationwide presence to negotiate with pharmacies and manufacturers. Finally, public programs secure highly favorable pricing by using both legislative mandates and their own enormous advantages in aggregate purchasing and ability to steer participants toward preferred drugs.

Employer plan sponsors indirectly share in the financial advantages of aggregate pharmacy purchasing when discounted prices or rebates are passed on to them. They can also directly participate in group purchasing through benefit plan consolidation and employer coalitions.

Benefit plan consolidation. When feasible, employers can decrease the number of distinct benefit plans offered to their employees so that each plan represents a larger group. This consolidation often increases bargaining potential.

Employer coalitions. Although both national and regional employer health coalitions have existed for many years, collective purchasing appears to be more widespread for prescription drug benefit administration services than for other health care benefits. The reason is that PBMs offer aggressive financial terms to coalitions or GPOs, such as deeper discounts (particularly at mail order) and more competitive administrative fees and rebates. It is possible for an employer plan sponsor to reduce prescription drug benefit costs simply by joining a coalition, without necessarily changing plan design.

It is possible for an employer plan sponsor to reduce prescription drug benefit costs simply by joining a coalition, without necessarily changing plan design.

Collective purchasing does have its potential drawbacks. Collective purchasing can limit a participating plan sponsor's ability to customize its plan design, and may require compromise to achieve group consensus. Although a single plan sponsor may be offered less aggressive financial terms than could be gained through collective purchasing, the plan sponsor is able to negotiate directly with a PBM to meet individual needs and it retains independent decision making.

For an in-depth look at the number of choices open to plan sponsors and the type of questions they may want to ask their pharmacy benefit vendors to ensure they are taking advantage of all factors available to them in the purchase of prescription drug benefits, see *Prescription Drug Benefit Plans: A Buyer's Guide*.

IX. An Evolving Marketplace



PRICING ARRANGEMENTS WITHIN THE PHARMACEUTICAL marketplace are constantly evolving and the regulatory environment is continually changing. While the future is uncertain, some forces are likely to continue to drive prescription drug prices higher:

- Advances in science and technology will continue to generate new agents (including biotech) that replace older drugs; fill voids where no drug treatment previously existed; and generate more preventive drugs.
- Consumer demand for prescription drugs can be expected to grow as the baby boomers age and need more medical care.
- Direct-to-consumer advertising and manufacturers' sales representative activity with physicians will likely continue to create greater demand for certain drugs while increasing manufacturers' advertising and promotion costs.

New opportunities are surfacing as plan sponsors and other purchasers attempt to cope with these persistent cost increases. For instance, we can expect to see the following:

- Rapid growth of cost-effective means of dispensing pharmaceuticals, such as mail-order and Internet pharmacies;
- Tactics that influence physician and consumer drug choices, such as tiered formularies, more restrictive formularies, generic incentives, and therapeutic interchange programs;
- More extensive use of alternatives like employer-sponsored worksite pharmacies, supplemental discount card programs, and defined contribution initiatives;
- Pressures for more legislation to contain drug costs for some consumer groups—especially in response to the burgeoning Medicare beneficiary population; and
- More MCOs and physician groups taking steps to limit drug representatives' access to physicians.

In the coming decade, employers with successful pharmacy benefit plans will have a clear understanding of the relationships among the key players, keep a vigilant eye on the ever-shifting transactions that determine pharmaceutical pricing, and seize innovative solutions.

Glossary

Average wholesale price (AWP) — A list of benchmark prices set by averaging across the spectrum of prices charged to pharmacies by wholesalers for both brand-name and generic drugs. The current list price is published in recognized sources, including Medi-Span, FirstData Bank and its supplements, and Medical Economics' Red Book.

Collective purchasing group — Also known as group purchasing organizations or GPOs, these are groups of retail entities that join together to leverage their combined purchasing power to negotiate discount pricing from wholesalers or manufacturers.

Formulary rebates — Remuneration received from certain drug manufacturers as a result of inclusion of those manufacturers' products in the formulary.

Formulary — A list of preferred prescription drugs chosen by a pharmacy benefit manager on the basis of quality and cost.

Generic dispensing rate — The percentage of generic drugs within the total of prescription drugs dispensed under a program in a contract year.

Generic drug — A medication that is the chemical equivalent of a brand-name drug with an expired patent. When a brand-name drug's patent expires, other pharmaceutical companies can produce the same active chemical compound and sell the drug under its generic name, typically at a lower price.

Generic substitution rate — The total number of prescriptions dispensed under a program in a contract year that consists of generic drugs, divided by the total number of prescriptions dispensed under the program in the same contract year for which a generic is available on the market.

Health and disease management programs — Some PBMs offer clinical programs that maintain wellness, provide case management services for particular conditions, such as asthma and diabetes, and disseminate educational information to patients and physicians. Manufacturers often subsidize development and management of these programs by the PBM, believing that they will help achieve greater product recognition and influence physicians and consumers toward a preferred therapy.

Maximum allowable cost (MAC) pricing — MAC prices are a schedule of pricing for generically equivalent drugs based upon the listed average wholesale prices (AWPs) of competing generic drug manufacturers. The federal government originally introduced the concept of MAC

pricing for generic medications in the Medicaid program as a mechanism to lower costs. The CMS issues a MAC price list for generic products that have three or more manufacturers or distributors on the market. Because of this limitation, not all generics have a corresponding CMS MAC price. PBMs often utilize this government issued MAC as the basis of their MAC list and supplement the list with other generic products.

Pharmacy benefit managers (PBMs) — Organizations that help manage the purchasing, reimbursement, and dispensing of prescription drugs for employer plan sponsors or health plans. PBMs create and maintain pharmacy networks. They also create formularies that influence physician prescribing patterns and dispensing. Through formulary guidelines and their large customer base, PBMs can secure substantial manufacturer rebates.

Retrospective Drug Utilization Review (DUR) — Retrospective DUR is a program designed to measure and assess utilization, quality, medical appropriateness, and appropriate selection and cost of prescribed drugs. It involves evaluating pharmaceutical therapies after the medications have been dispensed.

Therapeutic interchange programs — These programs are employed by PBMs to substitute generic or less expensive brand medications for higher-cost brand drugs when available and appropriate. The ability to make such changes is often dependent on the physician's willingness to modify prescriptions (has not indicated "dispense as written"), as well as the patient's willingness to change medications.

Third party administrators (TPAs) — Organizations that process pharmacy claims, but have no influence over what the retail pharmacy charges, nor what is dispensed. Plan sponsors rarely use TPAs to process pharmacy claims without PBM support as it greatly increases expense.

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