PHARMACEUTICAL

Benefit Design:

HELPING EMPLOYERS
Understand, Assess, Select and Manage Pharmacy Benefits
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I. INTRODUCTION


While a great deal of attention has focused on the high cost of drugs, numerous studies show that drug therapy is among the least expensive medical intervention. Thus, if we are better able to promote appropriate prescription drug use to prevent and manage illness, we will be in a better position to help people avoid diseases and expensive treatments such as surgery.

It is important that we use all the tools at our disposal as we commit to doing what we can to become a nation that values prevention and health maintenance as much as it does cutting-edge medical interventions. Understanding, assessing, selecting and managing prescription drug benefits has never been more important, with U.S. prescription drug spending projected to increase 148 percent over 11 years (from $200.7 billion in 2005 to $497.5 billion in 2016).

The Pharmaceutical Council has developed this guide to deepen understanding and simplify decision making for benefits professionals who must be able to keep up with the rapidly evolving pharmaceutical industry while constructing fair and affordable benefits. It is no longer enough to delegate pharmacy management to your pharmacy benefit manager (PBM): collaboration is key to success. If you work closely with a trusted PBM, you can increase the likelihood that you will meet your objectives for lowering costs and improving your employees’ health outcomes.

This guide took shape after many months of research that allowed us to define a vision and identify best practices. We describe the current state of employer-funded pharmacy care and pharmaceutical benefit design in order to illustrate the role employers play as major payers. And we reflect on the immeasurable contribution of pharmaceuticals to a healthier, more productive workforce.

A sound pharmacy benefit strategy can result in an employee population that experiences less illness, fewer hospital stays, a lower incidence of surgery, greater productivity and a higher quality of life. We hope this guide contributes to the success of your strategy. We welcome suggestions about how the Business Group and the Pharmaceutical Council can provide additional tools, information and resources to assist pharmacy benefit strategy and management. Let us know what we can do to help your company.
II. BACKGROUND

The Pharmaceutical Council was established in 2001 to provide tools and information about pharmaceutical companies and pharmacy benefits for members of the National Business Group on Health. The Pharmaceutical Council’s primary objective is to support the sustainability of employer-sponsored prescription drug benefits. Council members represent the following major players in the pharmaceutical system:

• Employer benefit managers
• Pharmacy benefit managers (PBMs)
• Pharmaceutical manufacturers
• Retailers
• Consultants
• Managed care organizations (MCOs)

These diverse players participate in the Pharmaceutical Council because they share the following vision:

• Employer-sponsored prescription drug benefits should be maintained and supported.
• Pharmaceutical care should be affordable and appropriate to medical need.
• Accuracy, quality and cost drive value.
• Value in pharmaceutical spending must be defined and acknowledged.

The Pharmaceutical Council’s activities support the vision by educating employers about the following:

• Best practices for optimizing pharmaceutical benefit value;
• The role of pharmaceutical companies in total health care spending;
• Links between medication adherence and health and productivity;
• Practical solutions for future pharmacy benefit design and health care management;
• The business case for pharmaceutical coverage; and
• Return-on-investment methodologies that evaluate effectiveness relative to:
  – Overall health care costs, and
  – Employee health and productivity.
Getting the Basics Right

Is there such a thing as an “ideal” pharmacy benefit? In attempting to answer this question, an employer might talk about the challenges a benefit poses in terms of both cost and complexity. From that way of looking at it, the “ideal” benefit would be one that is well-contained in expense and scope. This is a limiting perspective. The ideal benefit should be thought of as a systematic approach to pharmacy planning that aligns the pharmacy benefit with the corporate health care strategy to maximize value and support the health and productivity of the workforce and their dependants.
Value, moreover, should be thought of as more than just total dollars spent. It should acknowledge the extent to which the benefit does the following:

• Supports the maintenance and improvement of employee productivity;
• Drives waste from the system;
• Encourages use of medications that are clinically effective; and
• Saves employer spending on other health-related initiatives (e.g., medical and disability costs) while also saving employee spend.

Proper valuation requires understanding that there is a vast difference between cost and price. In addition to seeking to optimize the unit price of each prescription drug, employers need strategies to optimize their overall pharmacy utilization. This would include optimizing the therapeutic mix and taking advantage of the opportunities provided by generic pharmaceuticals. While unit prices are important, employers should focus primarily on managing net cost for the overall pharmacy benefit without compromising health outcomes or inappropriately shifting costs to employees.

All employer-sponsored health care spending is strongly interrelated. The structure and design of one benefit impacts the use, and thus the cost, of the others. For this reason, total pharmaceutical value needs to consider not only overall employee health but also how much time an employee spends in a hospital, in a doctor’s office, on disability leave and at work but not feeling well. These represent costs due to lost productivity stemming from absenteeism and presenteeism (i.e., not showing up for work or not performing well while at work).

― Milliman (ss)
Benefits Perspective
Current Issues in Employee Benefits

“In you look for a cost-containment solution by focusing only on benefit design, you’re getting ahead of yourself. You’ve overlooked the more fundamental problem, which is to understand the prescription drug benefit’s building blocks and how they fit together … benefit changes alone are not sufficient to solve the problem of cost. This requires a more holistic approach tackling delivery and dispensing, provider contracting, drug product availability, and ultimately benefit design as well.”

― Milliman (ss)
Benefits Perspective
Current Issues in Employee Benefits
Employees lose about 10.4 productive workdays a year as a direct result of family illness or poor personal health. These lost workdays cost employers nearly $2,000 per employee per year. While these costs are “soft,” difficult to measure and require multiple assumptions for modeling, several studies assessing the cost-effectiveness of pharmaceutical treatment for chronic and recurrent health conditions show that providing pharmaceutical benefits can in fact save employers money by avoiding medical treatment, preventing sick days or both.

An Optimal Pharmacy Benefit Strategy

Employers and their PBMs need to work together to develop a pharmacy benefit plan that can do the following:

- Cover medications that are effective in treating patients by improving significant clinical outcomes and reducing overall medical costs;
- Encourage prescribers to select medications that are in accordance with an evidence-based practice of medicine;
- Preserve appropriate access to pharmacies while enhancing an employer’s ability to leverage volume, safety, and price;
- Monitor and encourage patient adherence with drug therapies;
- Maintain and use patient-medication records to prevent unnecessary and potentially harmful drug interactions and other problems;
- Monitor employee drug usage for over- and under-utilization; and
- Promote prudent utilization of pharmaceuticals by plan members with benefit designs that provide a mixture of incentives and disincentives to facilitate access and support cost- and quality-effective choices.

Ultimately, the pharmacy benefit should be designed to meet the medical, educational, economic and physical needs of most beneficiaries. Employers should manage unusual situations as exceptions to broad policy, rather than build the benefit around these potential exceptions.
Other Opportunities for Cost Savings

Use the pharmacy benefit design to promote more prudent prescription drug usage by doing the following:

- Supporting appropriate use of generic drugs;
- Promoting the use of over-the-counter medications where appropriate;
- Encouraging reduced use of drugs that are not proven to be optimally effective; and
- Shifting toward mail-order pharmacy services where appropriate and share savings between both the employer and the beneficiary (e.g., for maintenance medications).

**Promote adherence:** Adherence is essential to the cost-effective use of medications. For example, a recent study revealed that a 20 percent increase in adherence to a diabetic medication resulted in an average return on investment (ROI) of 7.1 to 1.3 A similar increase in adherence to cholesterol-lowering medication produced an average ROI of 5.1 to 1.3 A 20 percent rise in patient adherence to a cardiovascular medication resulted in an average ROI of 5.1 to 1.3 In summary, for patients with diabetes, hypertension or hypercholesterolemia, this study showed that high levels of adherence with condition-specific drugs were associated with lower medical costs, despite the increased drug costs.

**Get employees immunized:** A cost-benefit analysis indicates that every dollar invested in vaccines dose saves $2 to $27 in health care expenses in the United States.
III. U.S. HEALTH CARE SPENDING

Any discussion of the U.S. health care system must begin with an acknowledgment of cost. Americans spend more on health care than do citizens in any other industrialized country. Nonetheless, health outcomes for Americans are relatively poor compared with those of residents of other first-world nations in terms of measures such as life expectancy and birth outcomes. In 2006, the nation spent $2.1 trillion — 16 percent of the gross domestic product (GDP) — on health care. In 2006, this translated into an average of $7,026 per person. This spending growth is expected to continue. The Centers for Medicare & Medicaid Services (CMS) estimates U.S. health care spending will double by 2016 to $4.1 trillion — 19.6 percent of GDP.

How are Americans spending their health care dollars? In 2006, the top U.S. health care costs were hospital care (30.8 percent), physician and clinical services (21.3 percent) and prescription drugs (10.3 percent).

Pharmaceutical spending has grown significantly over time and is expected to continue to do so. Spending in 2006 totaled $216.7 billion, as compared to $51.0 billion in 1993. The estimated increase in drug spending in 2007 was 6.75%. U.S. prescription drug spending is projected to increase to $497.5 billion by 2016, a 130 percent increase over 10 years.

Compared with surgery, which is invasive, and lifestyle changes, which are difficult to sustain, pharmaceuticals are sometimes the most practical course of treatment. This is evidenced by the growing reliance on pharmaceutical intervention: 63 percent of the U.S. population took at least one prescription medication in 2004.

### Table 1: Retail Outlet Prescription Drug Spending (PDS) and PDS as a Percentage of National Health Expenditures (NHE). Selected Calendar Years 1970–2006

<table>
<thead>
<tr>
<th>Year</th>
<th>PDS, billions</th>
<th>PDS, as percentage of NHE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1970</td>
<td>$5.5</td>
<td>7.3%</td>
</tr>
<tr>
<td>1980</td>
<td>$12.0</td>
<td>4.7%</td>
</tr>
<tr>
<td>1993</td>
<td>$51.0</td>
<td>5.6%</td>
</tr>
<tr>
<td>1997</td>
<td>$77.7</td>
<td>6.9%</td>
</tr>
<tr>
<td>1999</td>
<td>$120.6</td>
<td>8.9%</td>
</tr>
<tr>
<td>2000</td>
<td>$174.2</td>
<td>10.1%</td>
</tr>
<tr>
<td>2003</td>
<td>$188.8</td>
<td>10.2%</td>
</tr>
<tr>
<td>2004</td>
<td>$199.7</td>
<td>10.1%</td>
</tr>
<tr>
<td>2005</td>
<td>$216.7</td>
<td>10.3%</td>
</tr>
</tbody>
</table>

Drug Utilization

Prescription drug utilization is at an all-time high. Two factors determine drug utilization rates: prevalence and intensity. “Prevalence” refers to the number of people who are being treated with a prescription medication; “intensity” refers to the number of prescriptions people take each year.

What drives prevalence of prescription drug use? The following three factors are key:

- **Demographic patterns** — The U.S. population is aging. In 2000, people 65 years of age and older represented 12.4 percent of the population; by 2030, they will make up 20 percent of the population.\(^{11}\) Compared to younger patients, older patients:
  - Experience a higher prevalence of disease;
  - Are more likely to have multiple chronic conditions;
  - Experience more-severe diseases or disabilities;\(^ {12}\) and
  - Are more likely to be obese.

- **Greater prevalence of identified and treated disease** — Rates of diagnosed disease are increasing for a variety of reasons. Some diseases (e.g., asthma) appear to be increasing in prevalence; others (e.g., hyperlipidemia) have recently seen their treatment guidelines broadened. Still other conditions (e.g., restless leg syndrome) have experienced an increase in public awareness, often the result of direct-to-consumer advertising. As a result of these factors, many more people now have diagnoses that are treatable with prescription drugs.\(^ {12}\)

- **Expanding treatment opportunities** — The number of medications on the market is continuing to increase because of the introduction of new therapeutic classes, the retooling of established drug formulations and increased availability of generic alternatives.

What drives intensity?

- **Increasing quantities (dosing) of medication per patient** — Intensity changes when a provider increases or decreases medication dosages (e.g., more medication is required over the same time period, treatment is required for a longer periods of time).

- **Duration of treatment** — How long do people stay on medication regimens. Many with chronic diseases are expected to take medication for the rest of their lives.

Direct-to-consumer advertising impacts both the prevalence of prescription drug use and the intensity of treatment. It increases public awareness of a greater number of conditions as well as the possibility of treatment through pharmacotherapy.
Drug Prices and Cost

What affects the price of medications? Ultimately, there are three drivers of pharmaceutical price over time: inflation, altered usage patterns of available pharmaceuticals (mix), and entrance of new products (new therapeutic agents and generics) to the market.

What drive price?

- **Inflation** — Increased charges for existing therapies.

- **Altered usage patterns of available pharmaceuticals** — Given a variety of pharmaceutical treatment options, the percentage of patients on any given medication may shift over time. This can happen for a variety of reasons (e.g., new medical evidence suggesting one drug should be used over another, changing provider practice patterns, marketing, and pressure from consumers of health plan sponsors). This shifting mix can cause price to increase or decrease, depending on whether the shift is toward more or less expensive products.

- **Entrance of new products to market** — Introduction of a new drug can increase price if it is relatively more expensive than products currently available. The reverse is also possible; new drugs can reduce spending if they are cheaper and bring price competition to a given therapeutic category, such as with the introduction of a new generic drug.

How much of the increase in pharmaceutical spending is due to increased price versus the various factors affecting utilization? Consider the nation’s experience during 2006:

- The number of prescription drugs purchased increased more rapidly in 2006 than in 2005. Growth in medication usage accounted for roughly half of the nation’s increased drug spending in 2006 as compared to only 20 percent of the growth in 2005.

- Introduction of new medications had a minimal effect on spending in 2006.

- The generic drug dispensing rate reached 63 percent in 2006, a 7 percent increase over the previous year.

- Shifts in the therapeutic mix (changes in the relative shares of drugs within a class or among classes, or in strengths of existing drugs) contributed to the growth in retail prescription drug spending in 2006. Given a variety of treatment options, the percentage of patients on any given medication shifts over time. This can happen for a variety of reasons (e.g., new medical evidence suggesting one drug should be used over another, changing provider practice patterns, marketing and pressure from consumers or health plan sponsors).
• Full implementation of Medicare Part D (Medicare drug benefit) affected overall prescription drug spending by changing the payer mix and affecting access. In 2006, retail drug spending grew by 8.5 percent, as compared to an almost 30-year low of 5.8 percent in 2005.¹³

• Double-digit increases in the utilization of specialty medications (see Section VII: The Challenge of Specialty Pharmacy).

For more-detailed information about how various components contribute to spending growth, see Chart 1.

**Chart 1: Factors Contributing to Growth in Pharmaceutical Spending**

<table>
<thead>
<tr>
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<th></th>
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</thead>
<tbody>
<tr>
<td>Price</td>
<td>7.5%</td>
<td>6.6%</td>
<td>6.0%</td>
<td>5.3%</td>
<td>4.3%</td>
</tr>
<tr>
<td>Units per Rx</td>
<td>-0.1%</td>
<td>0.3%</td>
<td>0.2%</td>
<td>0.1%</td>
<td>0.4%</td>
</tr>
<tr>
<td>Brand/Generic Mix</td>
<td>-2.3%</td>
<td>-2.6%</td>
<td>-2.6%</td>
<td>-2.7%</td>
<td>-2.9%</td>
</tr>
<tr>
<td>Therapeutic Mix</td>
<td>5.3%</td>
<td>2.6%</td>
<td>3.7%</td>
<td>0.8%</td>
<td>1.7%</td>
</tr>
<tr>
<td>= Cost per Rx</td>
<td>10.5%</td>
<td>6.8%</td>
<td>7.2%</td>
<td>3.3%</td>
<td>3.5%</td>
</tr>
<tr>
<td>Times Utilization</td>
<td>6.3%</td>
<td>6.8%</td>
<td>2.9%</td>
<td>4.0%</td>
<td>2.2%</td>
</tr>
<tr>
<td>= Common Drugs</td>
<td>17.5%</td>
<td>14.0%</td>
<td>10.4%</td>
<td>7.5%</td>
<td>5.8%</td>
</tr>
<tr>
<td>Plus New Drugs</td>
<td>1.0%</td>
<td>0.5%</td>
<td>0.3%</td>
<td>0.4%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Overall Rx Trend</td>
<td>18.5%</td>
<td>14.5%</td>
<td>10.6%</td>
<td>7.9%</td>
<td>5.9%</td>
</tr>
</tbody>
</table>

Source: Express Scripts data.
IV. AN EMPLOYER PERSPECTIVE

Employer-sponsored insurance covers about 158 million non-elderly Americans. Nearly all (98 percent) covered workers in employer-sponsored health plans had a prescription drug benefit in 2006. For this reason, employers must be considered primary players in the pharmaceutical system.

The pharmaceutical system is complicated and often poorly understood. It involves numerous players, a complex drug path and complicated financing arrangements. To be an effective purchaser (payer), an employer must understand:

• How medications flow from manufacturer to user (i.e., the drug supply chain); and
• How money flows from end user, via the payer, through the distributor, and back to the manufacturer (i.e., financial logistics).

About the Supply Chain

The path of pharmaceuticals from manufacturer to consumer is multi-step (see Figure 2).

• **Drug manufacturers** send their products to wholesalers or distributors that manage dispensing to pharmacies, hospitals and physicians’ offices.

• **Health plans and PBMs** enter the pharmaceutical system where financing and distribution meet. They provide multiple services, all aimed at helping purchasers manage a complicated pharmaceutical system. More specifically, they:
  
  – Negotiate pricing with manufacturers, leveraging volume, market share and formulary placement in return for discounts and rebates for plan sponsors and individuals enrolled in their plans;
  
  – Contract with retail pharmacies, establish payment levels for provider pharmacies and adjudicate pharmacy claims;
  
  – Enhance safety by checking for drug interactions for individual patients receiving care from multiple prescribers and dispensing pharmacies;
  
  – Offer manage mail-order pharmacies to facilitate the purchase and dispensing of maintenance medications for patients with chronic conditions; and
  
  – Adjudicate pharmacy claims in accordance with the plan sponsor’s benefit design, serving as an intermediary between the payer and the pharmacy.
- **Pharmacies** dispense drugs. They receive payment from the health plan or PBM for drugs dispensed to plan beneficiaries on the basis of negotiated formulas. In 2003, the number of brick-and-mortar pharmacies (independent, chain, mass merchant, and supermarket) in the United States was estimated at nearly 57,000. These retailers filled 3.2 billion prescriptions.

- **Individuals** with employer-sponsored insurance coverage purchase medication at a pharmacy or another point-of-sale. They pay a copayment or coinsurance. The specifics of cost sharing are determined by the plan sponsor’s benefit design. Individuals who lack coverage pay the pharmacy’s retail price (also known as the usual and customary, or U&C, price) for their medications.

- **Physicians and other providers** may act as medication-distribution points. Health plans and PBMs may negotiate the payments these providers receive for drugs administered directly to beneficiaries (e.g., immunizations, allergy shots and biologics).

According to the Kaiser Family Foundation, the average retail price for a prescription medication in 2006 was $68.26. Of this amount, the manufacturer received 78 percent, the retailer received 19 percent and the wholesaler received 3 percent. Figure 2 describes how products, services and payments flow through drug distribution channels.

**Figure 2: Drug Distribution Model: Flow of Goods and Financial Transactions Among Players in the U.S. Commercial Pharmaceutical Supply Chain**


*Note: For an explanation of the above acronyms, see Appendix A.*
How Dollars Flow

In recent years, much political and public attention has been paid to the costs of pharmaceuticals; specifically, how prices are determined at every stage by each and every player. Drug-payment arrangements are complicated because distribution, related services and resulting payments vary widely by payer type. Figure 3 depicts how this type of negotiation affects the flow of drugs, dollars and services in the U.S. health care system within the context of the pharmacy benefit.

Figure 3: Pharmacy Benefit (Other than the Medicare Prescription Drug Benefit) and Dollar Flow

Source: Academy of Managed Care Pharmacy Guide to Pharmaceutical Payment Methods. Academy of Managed Care Pharmacy Task Force on Drug Payment Methodology. October 2007
Historically, pharmaceutical reimbursement methodology has set benchmarks for pricing. The benchmarks serve as a starting point from which prices can be negotiated based on such things as volume and preferred formulary placement. The benchmarks are a virtual alphabet soup: AAC, AWP, ASP, AMP, BP, and MAC. (For a description of what these acronyms stand for, see Appendix A.) The most common benchmark used to set payment to providers for delivery of pharmaceuticals has been the AWP, or average wholesale price. Litigation in 2006 revealed that the AWP did not actually constitute an average of prices. That litigation also revealed that the primary sources of AWP figures had unilaterally elected to adopt a 20 to 25 percent markup in AWP values. Government and private payers are now debating fundamental changes in how they pay for pharmaceuticals.

Figure 4: Pharmaceutical Spending: Who’s Paying What?

Federal/State Government

- Medicaid – payments to retailers directly for prescriptions filled. Net prices are determined by manufacturer rebates. Reimbursement price is typically AWP minus 15 percent. Manufacturers also pay a ‘best price’ rebate.
- Veterans Affairs (VA) – Stock for military personnel is purchased directly from manufacturers for distribution by VA pharmacies or providers. Reimbursement price is typically half off AWP.
- Public Health Service – Drugs are purchased for entities that serve vulnerable populations. The Department of Public Health typically pays 49 percent of AWP.
- Medicare – Beneficiaries have access to drug coverage for which they are responsible for a monthly premium, an annual deductible and variable cost-sharing as determined by their level of drug usage. Prices are negotiated by individual plans.

Out-of-Pocket

Year 2005: Total=$223.5 billion

29%

24%

47%

Private Health Insurance

Insurance plans and employers contract with PBMs to manage their prescription drug benefits. PBMs control spending by leveraging volume sales to negotiate:

- Lower retail prices with pharmacies.
- Drug rebates with manufacturers.
- Lower prices given increased use of mail order.
- Manage drug mix, utilization, etc.

Year 2006: Total=$249.3 billion

20%

41%

39%

Out-of-Pocket

Federal/State Government

Private Health Insurance
Nearly all covered employees (98 percent) in employer-sponsored plans have prescription drug coverage. There are two ways by which an employer can administer the pharmaceutical benefit: the employer can include it in the medical benefit (carve in) or administer it separately (carve out) from the medical benefit. Carving in the benefit delegates the responsibility for all company-related health care spending, including pharmaceuticals, to the employer’s health plan. Employers that choose to carve out their pharmacy benefit separate pharmaceutical plan design and spending from other components of health plan design and spending. Pharmacy spending is managed separately by in-house company personnel, a PBM or both. There are two types of carve-outs: of design (i.e., different cost sharing than found in the medical plan); and of administration (i.e., the pharmacy benefit is administered by a different vendor than the medical plan). Managing the pharmaceutical benefit involves determining what pharmaceuticals are covered, at what price, and by whom, and adopting tools to accomplish the goals of the benefit.

There is an association between the size of a company and whether or not it chooses to carve in or out its pharmacy benefit. The larger a company is, the more likely it is to carve out its pharmacy benefit. About 60 percent of companies with 5,000 or more employees and 78 percent of companies with more than 19,000 employees carve out their pharmaceutical benefit.

An employer’s decision on whether to carve in or carve out a pharmaceutical benefit is usually determined by two factors:

1. Which arrangement the company believes will offer the greater leverage in terms of negotiating pharmaceutical prices; and
2. What the company is able to manage given its size, budget and employee resources.

Companies that carve in their pharmaceutical benefits lump their benefit costs into a large risk pool in which medical and pharmacy benefits are combined. Companies that carve out their pharmaceutical benefits believe that they will achieve greater value by managing the pharmaceutical benefit separately.
Managing the Benefit

For an employer, the best way to control pharmaceutical costs is to make appropriate decisions about the design of the pharmacy benefit plan. Through the plan’s design, the employer can influence pharmaceutical utilization and associated costs.

Employers can use benefit design to enhance cost- and quality-management efforts. Pharmaceutical benefit design has evolved over time to incorporate various cost-sharing mechanisms (e.g., copayments, coinsurance and deductibles), along with utilization management programs, as a means to affect drug usage.

The degree of cost sharing can influence medication usage. Closed or highly restrictive formularies cover only certain drugs or drug classes, thereby discouraging use of other drugs. If an enrollee uses a non-formulary drug, its entire cost, or a significant portion thereof, would fall to that individual. Following widespread expressions of beneficiary dissatisfaction, and as part of the movement away from managed care to PPOs, closed or highly restrictive formularies have become less common than they were a few years ago.

Today, the average four-person family covered by a standard employer-sponsored preferred provider organization (PPO) generates $2,081 in pharmaceutical costs a year, including approximately $510 in cost sharing (i.e., personal, out-of-pocket costs). In other words, enrollee out-of-pocket costs represent about 25 percent of total drug expenditures.27

The most common benefit design integrates copayments or coinsurance (i.e., cost sharing) with designated minimums and maximums. This design may incorporate “tiering” to provide further incentives for prudent drug usage. In 2007, 91 percent of covered workers had some sort of tiered cost-sharing formula for prescription drugs.20 Under such arrangements, enrollees are responsible for a copayment or coinsurance, the magnitude of which depends on the tier to which a particular drug is assigned. Cost-sharing provisions are intended to encourage participants to choose more cost-effective therapies.

A tiered benefit design may have two, three, four or more levels of cost sharing; the three-tiered design is most common. In 2007, 75 percent of all covered workers were enrolled in a three- or four-tiered pharmaceutical benefit plan in which:20

• Generic drugs required the lowest level of cost sharing. These are drugs whose patent life has run out and are manufactured and distributed by multiple drug companies.

• Formulary or preferred drugs, typically brand-name drugs whose prices have been lowered as the result of manufacturers’ rebates or PBM negotiation, required mid-level cost sharing.
• Non-formulary, brand-name medications required the second-highest level of cost sharing.
• The highest level of cost sharing was associated with fourth-tier drugs, which include lifestyle drugs and biologics. As noted, not all employers offer a fourth tier, although virtually all large employers do cover biologics.

According to the Kaiser Family Foundation, in 2007 the average required copayments in a three-tiered plan were $11 for generic drugs, $25 for preferred drugs, and $43 for non-preferred drugs (30-day supplies).20 The average cost-sharing amount for drugs in a fourth tier was $71. For covered workers with coinsurance rather than copayments, coinsurance levels averaged 21 percent for generic drugs, 26 percent for preferred drugs and 40 percent for non-preferred drugs.20 Results from a 2006 National Business Group on Health member survey indicate that large employers are predominately looking to coinsurance, three-tier benefit design and pre-authorization and step therapy program requirements to contain their pharmacy costs (see Figure 5).

Figure 5: Pharmacy Management Techniques

<table>
<thead>
<tr>
<th>Technique</th>
<th>Yes (%)</th>
<th>No (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increasing Copays</td>
<td>79</td>
<td>21</td>
</tr>
<tr>
<td>Using Coinsurance</td>
<td>37</td>
<td>63</td>
</tr>
<tr>
<td>Using Separate Deductible</td>
<td>70</td>
<td>30</td>
</tr>
<tr>
<td>Using 3—Tier Design</td>
<td>13</td>
<td>87</td>
</tr>
<tr>
<td>Making Formulary/Generics Mandatory</td>
<td>58</td>
<td>42</td>
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<tr>
<td>Requiring Mail Order for Maintenance Drugs</td>
<td>77</td>
<td>23</td>
</tr>
<tr>
<td>Using Preauthorization for Selected Drugs</td>
<td>38</td>
<td>62</td>
</tr>
</tbody>
</table>

Employer Pharmacy Benefit Design

Employers pay significantly more for their prescription drug plans today than they did 10 years ago. Not surprisingly, they approach designing their pharmacy benefit with increasing awareness about the types of drugs on the market, Food and Drug Administration-approved uses, possible generic substitutions or equivalents, manufacturers and potential rebates. To maximize the value of pharmacy benefits programs, employees must purchase their medications at the lowest possible price without compromising clinical outcomes. This is the balancing act that benefit design must manage.

There are significant gaps in what is known about the comparative effectiveness of various drug classes and other treatment types, making it difficult to use effectiveness as the sole criterion to guide pharmaceutical benefit decision making.

Despite having taken well-reasoned approaches to pharmaceutical coverage, employers are finding that strong benefit design is not sufficient to prevent cost increases. They must utilize the full spectrum of pharmacy benefit management strategies to manage spending (see Chart 3).
### Chart 3: Additional Tools of the Trade

<table>
<thead>
<tr>
<th>TOOL</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost Sharing with Employees</td>
<td>Drug-benefit design plan that includes limits, exclusions, coinsurance and copayments, as well as a tiered approach or utilization-management provisions.</td>
</tr>
<tr>
<td>Formulary Management</td>
<td>The identification of preferred drugs intended to be both cost and clinically effective. Formulary utilization is closely tied to the benefit plan’s cost-sharing provisions.</td>
</tr>
<tr>
<td>Pharmacy Network Discounts</td>
<td>Negotiations with pharmacies for brand-name and generic drugs based on discounts off benchmark costs or on a Maximum Allowable Cost list (applies only to multi-source products, as well as dispensing fees).</td>
</tr>
<tr>
<td>Rebate Negotiations</td>
<td>Pharmaceutical manufacturers may offer rebates to PBMs or employers for including certain drugs on formularies, performing certain administrative services, providing data for research, rewarding increases in market share, etc. In negotiations, employers take into account how rebates are handled either as an offset with administrative fees, built into what the employer pays, or passed entirely to the employee.</td>
</tr>
<tr>
<td>Mail-order Pharmacies</td>
<td>Automation allows mail-order pharmacies deliver maintenance medications at a lower cost and higher degree of accuracy. Many plan sponsors balance savings with employees by proportionally reducing copayments (to the cost difference between mail pharmacy purchases and retail pharmacy negotiated prices) for prescriptions filled by mail (e.g., a 90-day supply for less patient cost-share than that of three 30-day supply copayments).</td>
</tr>
<tr>
<td>Therapeutic Equivalency Programs</td>
<td>Therapeutically equivalent drug substitutions suggested at a retail or mail-order pharmacy that must be acceptable to the patient’s physician before being made.</td>
</tr>
<tr>
<td>Point-of-Service Drug Utilization Review</td>
<td>An online system that evaluates prescription drug claims for potential adverse drug interactions, eligibility, benefit coverage and more.</td>
</tr>
<tr>
<td>Disease Management Programs</td>
<td>Programs that identify and stratify consumers with chronic medical conditions and assign a treatment protocol to support them and improve their medication compliance and condition.</td>
</tr>
<tr>
<td>Retrospective Review/Retrospective Clinical Review</td>
<td>A review conducted after prescription services have been provided to the patient to gauge outcomes. These programs alert doctors and patients to care-improvement opportunities, including eliminating potentially unsafe drug use and essential care omissions.</td>
</tr>
</tbody>
</table>
VI. THE ROLE OF THE EMPLOYER AS PHARMACEUTICAL BENEFIT PURCHASER

Creating effective pharmaceutical benefits requires establishing the pharmaceutical benefit in the context of the employer’s overall corporate health care strategy. To do so, employers need to define intentions and constraints, scrutinize how the benefit is ultimately used and be willing to change the benefit as necessary to meet identified objectives. An employer who wants to design a strong pharmacy benefit program should take the following three steps:

**Step One:**
Identify corporate pharmaceutical objectives.

- What do we hope to accomplish with our pharmaceutical benefit?
- How will we measure success?
  - By trends in pharmaceutical costs?
  - By the overall costs of medical claims?
  - By employee productivity?
  - By employee satisfaction?
- What are our employees’ health care needs?
- What are we trying to accomplish in terms of employee health in the long and short terms?
- What are our constraints in terms of budget? Employee demographics? Senior management support?
- Have we set **measurable** and **reasonable** goals for the following:
  - Outcomes;
  - Process;
  - Quality;
  - Accessibility;
  - Efficiency;
  - Member satisfaction; and
  - Convenience?
- Do we understand how altering our benefit design will alter usage patterns?

Ask the following:
Has the company placed enough emphasis on lifestyle changes so that pharmaceuticals do not become necessary? Does the company have a comprehensive health improvement strategy that would reduce the need for prescription drugs or other medical interventions?
Step Two: Make sure your employees can are using the benefit appropriately and effectively.

Paying attention to the following issues can help achieve this goal:

- Minimize risk and unsafe medication usage. Look to your PBM for strategies.
- Determine what medications are over-utilized, under-utilized or inappropriately utilized:
  - Determine whether the incentives inherent in your benefit structure are having their intended consequence, namely, encouraging the necessary use of pharmaceuticals, discouraging their wasteful use, and analyzing the impact of the medical plan;
  - Consider providing incentives for adherence through benefit design; and
  - Consider integrating laboratory data with pharmacy data to measure results.
- Manage employee expectations. What can the employee reasonably expect from the pharmaceutical benefit?
- Align the pharmaceutical benefit to your disease management, case management programs, and medical benefit.
- Match your benefit to accepted practice guidelines.

Step Three: Remain informed. Continually re-evaluate.

- Sort through the available information. Look to your resources (e.g., your PBM, drug manufacturers and the Business Group) for information. Leverage all resources to their maximum.
- Use your data to make informed decisions. For example:
  - Integrate all your data (e.g., direct medical, prescription drugs, short-term disability, long-term disability); and
  - Look for indicators of systemic errors in utilization.
Role of the Pharmacy Benefit Manager (PBM)

Most employers do not administer their own pharmacy benefit. Because these programs are complex, they hire a health plan or PBM to provide this service. Today, over 95 percent of consumers with pharmaceutical drug benefits receive them through various types of PBMs, including health plan PBMs.28 Most large employers contract with PBMs to do the following:

1. Help the payer design an optimal benefit structure;
2. Adjudicate employee and dependent pharmacy claims in accordance with the cost-sharing provisions of the benefit plan;
3. Assist employees in making prudent drug selections by encouraging the use of generic or less-expensive brand-name products that are therapeutically equivalent;
4. Negotiate discounts or rebates for brand-name and generic drugs with manufacturers, wholesalers and dispensing pharmacies;
5. Provide mail-order dispensing alternatives for maintenance medications;
6. Negotiate dispensing fee discounts with pharmacies;
7. Promote patient safety by encouraging the use of comprehensive medication profiles across physicians and dispensing pharmacies, influencing potentially inappropriate drug use; and
8. Assist in overall strategic planning.

Each PBM has its own relationship with distributors, manufacturers and retailers. This relationship influences which drugs are covered, at what price and by which dispensing channel. Employers must select a PBM that can best meet their objectives for cost management, access and quality of care. PBMs are the primary tool that third-party payers can use to contain costs.29

To support continuous quality improvement in the pharmaceutical system, nationwide standards are emerging for pharmacy benefit quality management. URAC, a not-for-profit organization that promotes continuous improvement in the quality and efficiency of health care management through processes of accreditation, education and measurement, offers an accreditation program for monitoring the safety, effectiveness and service quality of PBMs. Industry standards provide operational and quality standards for pharmacy benefit management programs, helping purchasers make more-informed decisions about their programs. For specific information on URAC standards, see Chart 4. URAC’s PBM accreditation launched in 2007. Most large PBMs are already URAC accredited.
Chart 4: URAC Standards

<table>
<thead>
<tr>
<th>SUBJECT</th>
<th>SOME IMPORTANT QUESTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organizational Integrity</td>
<td>Does the PBM have an organizational structure in place, and does it adhere to its company policies? Does the PBM have adequate measures in place to ensure that member information will be secure? Is there a disaster-recovery plan? A continuous quality improvement plan? A compliance process?</td>
</tr>
<tr>
<td>Customer Service</td>
<td></td>
</tr>
<tr>
<td>Communication/Disclosure</td>
<td>Does the PBM have the capacity to educate its members on how to maximize their benefit as well as to contain costs? Is member literature about the benefit at the right reading level? Is it culturally sensitive? Does the PBM provide members who need information access to a Web site, a call center or both?</td>
</tr>
<tr>
<td>Pharmacy Distribution Channels</td>
<td>Does the PBM meet the industry access standard for retail pharmacies? Are pharmacies credentialed? How well does the mail service perform? Does the claims operation meet industry standards?</td>
</tr>
<tr>
<td>Drug Use Management</td>
<td>What utilization guidelines are followed? Does the PBM adhere to them? What is the therapeutic interchange policy? How is over–or under-utilization monitored and managed?</td>
</tr>
<tr>
<td>Formulary/P&amp;T Committee</td>
<td>Does the formulary have a sound clinical basis? Are the members of the Pharmacy and Therapeutics (P&amp;T) Committee qualified and free of conflicts of interest? Does the PBM have a formulary-management process for transitional situations experienced by plan members?</td>
</tr>
<tr>
<td>Medication Therapy Management</td>
<td>Does the PBM offer a medication therapy management program that strives to optimize therapeutic outcomes for people with chronic illnesses (e.g., improving medication use, reducing adverse drug interactions)?</td>
</tr>
</tbody>
</table>

Working with Your PBM

Competitive health benefits are critical tools to attract and retain employees. The pharmaceutical plan is an essential piece of the benefit package. Almost all large employers are self-insured, serving as the purchaser while delegating administrative and day-to-day management responsibility to a PBM. The employer’s role is to define the objectives of the pharmaceutical benefit and to maintain fiduciary responsibility. The employer must work closely with the PBM to maximize the value of the pharmaceutical benefit.

As an employer, you should:

- **Define the objective of your pharmaceutical benefit.** Are your company’s decisions concerning the pharmaceutical benefit made on the basis of total pharmacy spending, pharmacy cost-containment or total health care cost containment? Does your company recognize the contribution of the pharmacy benefit to employee health, well-being and productivity?
• **Maximize the PBM relationship.** Do not underestimate the importance of managing your PBM relationship. To leverage the best discounts, the most seamless integration with other health benefits and the most appropriate mail-order pharmacy participation, you will want to work closely with your PBM. PBMs have inside knowledge and can help you achieve your objectives. Strive to create a relationship that will make it possible for you to work with the PBM to meet corporate health goals and to manage total net cost. At the same time, remember that your PBM has its own profit objectives.

• **Set expectations for the PBM.** Decide what you expect from your PBM. Possibilities include the following:
  
  – Finely balanced benefits, appropriately balancing effectiveness, employee satisfaction and cost.
  
  – As inexpensive a plan as possible;
  
  – Patient-management services;
  
  – Price/cost transparency;
  
  – The lowest contracted prices;
  
  – Integrated laboratory, medical and pharmacy data that demonstrate and measure outcomes; and utilization management programs to drive cost-effective use of clinically proven therapies.

If you do not set expectations and develop an implementation and management plan, your PBM may not meet your needs.

**TIP:** Look at the net cost to the plan from every delivery channel (retail, mail order, specialty, hospital, physician’s office, and home). Just because the pharmacy discount looks favorable does not mean the plan cost has been minimized.
Questions to Ask a PBM

1. How are generic and multi-source drugs priced? What are the differences in pricing for retail and mail-order products? How effective is the PBM at driving to the lowest-cost drugs and delivery channel?

2. What is included in the basic prior-authorization process? How much more will it cost if an intervention is required?
   - What does the prior-authorization process look like from the perspectives of the patient and the physician?
   - Does the PBM offer “grandfather” clauses that may determine a beneficiary’s access to medications? Does the PBM have any recommendations for managing these clauses?

3. What is the size of the PBM’s retail network? Will employers have access to pharmacies within two miles? Five miles? Ten miles or more? Conduct a disruption analysis.

4. How are your pharmaceutical claims adjudicated at all points of sale? To fully understand the adjudication process, ask the following:
   - How is the cost to the patient determined at point of sale?
   - How are claim costs charged back to the employer for retail and mail products?
   - What happens when the cost of a claim is less than that of the copayment? Is there a minimum copayment, or is the minimum charge the cost of the claim? Does this vary for mail-order versus retail products?

   • Based on which of the following does the PBM adjudicate claims:
     - At the lower of some guarantee discount off of brand or generic;
     - Usual and Customary (average retail price); or
     - Maximum Allowable Cost (MAC) list (“MAC” refers to the highest unit price that will be paid for a drug. For a more detailed definition of MAC, see Appendix A.)

   • At the lower price point of two, of the above three, or lowest of all three.

   • What MAC list(s) does the PBM use, and under what circumstances? Is the same MAC list used for all price guarantees? Is the same MAC list used for both retail and mail-order pharmacies as well as for charging the plan sponsor?

TIP: There may or may not be value to shrinking the retail network. Consider the impact of reducing the retail network on access as well as on cost.
• Does the MAC list(s) include:
  – Multi-source brands or just generics?
  – All generics or just some?
• How broad is the MAC list? What percentage of your generic and multi-source brand drug expense is covered by the MAC list(s)?
• What happens if a particular drug is not on the PBM’s MAC list? Is that claim adjudicated at the brand-name price or at a generic discount?

5. Does the PBM guarantee:
• That it will offer discounts for mail, retail, specialty, brand-name and generic products?
• That using the formulary/coverage review/prior authorization process saves money?
• That payments from manufacturers and other third parties are shared with plan sponsors? Are any payments excluded from sharing?

How are savings calculated? How are guarantees calculated?

6. How does the PBM promote the use of generic drug alternatives (beyond chemically identical substitutions)? What incentives exist to promote this shift? To what extent are substitutions taking place (brand-to-generic and brand-to-brand)? If it is brand to brand, is the result cost-effective to the patient and/or the employer? Does the PBM switch patients only to less-expensive drugs, or do they also switch patients to higher-cost drugs? If so, when? Is the measure of “cost” calculated before or after the application of any rebates?

• Ask about the PBM’s generic substitution rate, (i.e., the percentage of times that a generic is substituted for the identical brand when the patent on the brand has expired and there is a generic equivalent on the market). The national average is currently above 95 percent.

• Ask about the PBM’s generic fill rate, (i.e., the percentage of all prescriptions that are filled with a generic drug). The national average is currently in the low 60 percent range.

• Will your PBM guarantee a generic fill rate for your company?
7. Does the PBM’s P&T committee address issues related to racial and ethnic disparities in response to drugs?

8. How flexible are formularies and coverage-review processes? Can exceptions be made for people who do not respond to prescribed therapy?

9. What member-satisfaction measures (e.g., number of minutes on time on hold) are included in the PBM contract?

10. Is the PBM URAC-accredited or attempting to become so?

**Hints for Optimizing Cost-Containment and Cost-Effectiveness Goals**

1. Run last year’s claims under the terms of the new PBM contract to see how it would affect company drug spending.

2. Ask your PBM to report all third-party payments associated with plan utilization.

3. Consider engaging a pharmacy benefit consultant to audit your contracts if you have concerns about PBM reporting.

4. Make sure the PBM’s MAC lists are broad and deep. The MAC is the upper-limit price that will be reimbursed for a generic or multi-source drug product. A MAC list outlines generic sequence numbers (GSN) that identify products specific to chemical formula, dosage form, strength and route of administration. GSNs group chemically identical pharmaceutical products. The MAC list should cover most GSNs, because this would mean that most drugs are covered at a discounted price.

5. Ask your PBM what type of compliance reports they will run to measure medication prescription and adherence rates. If possible, check for the integration of laborator value, diagnosis and medical history to measure patient outcomes and safety.

As reported in various studies by the Pharmaceutical Care Management Association, the Government Accountability Office, the Congressional Budget Office and the Federal Trade Commission, as well as private-sector experts such as PricewaterhouseCoopers, the tools and techniques pioneered by the PBMs typically reduce costs about 25 percent they also help expand access, promote quality and improve outcomes.
VII. THE CHALLENGE OF SPECIALTY PHARMACY

Specialty drugs are the fastest-growing segment of the pharmaceutical market (see Figure 6). These sophisticated medications are used to treat complex chronic conditions such as rheumatoid arthritis, hemophilia, cancer, hepatitis C, anemia, cystic fibrosis, human growth deficiency and other diseases that do not respond well to conventional therapeutic interventions.

There is no industry standard for what constitutes a specialty drug. Therefore, each PBM can establish its own list of specialty medications. Such products generally include injectable, infused, oral or inhaled agents of biological origin. They require close medical oversight and more patient support and education than do traditional small-molecule drugs. They can be self- or provider-administered in an outpatient or home setting.24

From a financial perspective, the distinctive feature of a specialty drug is cost. Specialty drugs are expensive. The Medicare Modernization Act of 2007’s Final Guidance on Formularies reserves the specialty drug tier for “Part D drugs with plan-negotiated prices that exceed $500 per month.”21 Specialty drugs generally range in cost from $6,000 to $350,000 per year, per patient.24

Approximately $62 billion was spent on specialty drugs in the United States in 2006.30 This was a 16.5 spending percent increase over the previous year.22, 30 The year-to-year growth in specialty drug spending and utilization outstrips non-specialty pharmaceutical spending growth. Information from the country’s three largest PBMs indicates that specialty drugs are a significant part of prescription drug spend. Specialty pharmacy accounts for 23 percent of the overall drug sales in the US.30 Given current trends, both the cost of specialty drugs and their share of total drug spend are likely to increase.

Figure 6: Growth in Specialty Drug Use

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<thead>
<tr>
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<tbody>
<tr>
<td>Caremark¹</td>
<td>8%</td>
<td>11.4%</td>
<td>20.4%</td>
</tr>
<tr>
<td>ExpressScripts²</td>
<td>9.2%</td>
<td>9.7%</td>
<td>20.9%</td>
</tr>
<tr>
<td>Medco³</td>
<td>9.7%</td>
<td>10.3%</td>
<td>16.9%</td>
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* Numbers are not directly comparable; each PBM has its own proprietary specialty drug list and has different access to limited distribution drugs. Growth numbers presented above reflect the effects of shifting specialty from the medical benefit to the pharmacy benefit.

Two factors drive the continuing increases in specialty drug spending: increased utilization and rising unit costs. Why is specialty drug utilization increasing? There are many reasons. Existing drugs are being approved for new disease indications, treatment patterns have changed (e.g., increased dosing and increased use of medication for non-FDA approved purposes), new and reformulated products are becoming available, and specialty drugs are being used as first-line therapies. Specialty pharmacy spending is growing at least twice as fast as traditional pharmaceutical spending. This may be the result of AWP price increases; newer, more expensive drugs introduced to the market; and changing market forces involving drug exclusivity.29, 30

Specialty drugs challenge how the United States provides and pays for pharmaceuticals.

1. Specialty drugs do not fit well into traditional benefit design structures. Because specialty drugs are administered in a variety of settings, administration of the benefit does not sit comfortably in either the medical or pharmaceutical plan. These medications are covered under both medical and pharmacy benefit plans, presenting challenges to cost and utilization management for plan sponsors. Historically, injectable medications were administered by a doctor in a hospital or clinic and covered by the medical benefit. Under this arrangement, a patient was responsible for copayments. Today, some specialty drugs need not be administered in a hospital or clinic. The patient can access the drug from a physician, a community pharmacy or mail-order company and can often self-administer it at home.31 This increased flexibility in the delivery mechanism means that specialty pharmacy coverage can be moved into the pharmacy benefit.24 Managing specialty drugs within the pharmaceutical benefit allows plan sponsors to cost share with the patient, although given the desperate health needs of the treatment population, some believe that cost sharing will not impact utilization except in the negative (e.g., seriously ill people will not have enough money to pay required cost sharing).24 Cost sharing can be designed to drive beneficiaries toward preferred products and preferred pharmacies. Given the extremely high cost of these drugs, the very small proportion of the population that needs them and the lack of alternative therapies, employers need to consider what level of cost sharing is appropriate and how it will fit into existing out-of-pocket limits.
2. **Specialty drugs are typically tailored to meet the needs of small, defined segments of the population.** By offering a variety of health care benefits, employers contribute to improving health of the greatest possible number of employees. Specialty drugs are usually required by only a small percentage of beneficiaries (about 1 to 5 percent of all plan users). These specialty drug users consume a significant proportion of total health care resources. Employers can expect specialty drugs to comprise an even greater share of drug expense in the future. Approximately 43 percent (104 products total) of all pharmaceuticals now in late-stage development are specialty drugs. At a time when employers are trying to better define their benefit contributions, they will need to manage the very expensive specialty pharmacy needs of a few against the general health care needs of many. In this instance, what should be considered fair? There is no easy answer to this question.

3. **The Food and Drug Administration (FDA) has not established drug review processes for generic biologic drugs.** While new drugs for conditions that affect larger populations (e.g., diabetes, osteoporosis and rheumatoid arthritis) will be introduced in coming years, patents on existing products are expiring. At present, no process exists for authorizing generic alternatives (follow-on biologics) to patented specialty drugs. This presents a great opportunity to manage long-term financial trends in the health care industry. Introduction of biogenerics could result in a price reduction close to 25 percent. According to Express Scripts’ calculations, the savings opportunity over a 10-year period if generic biologic medications were available in four therapeutic categories of medications (interferons for multiple sclerosis, erythropoietin for anemia, growth hormone for growth failure and insulin for diabetes) would be approximately $71 billion.

**POLICY ISSUE:** The Business Group supports legislation giving the Food and Drug Administration (FDA) the authority to approve safe, effective, more affordable follow-on biologics. Congress needs to empower the FDA to issue guidance about how it will authorize follow-on biologics. The two most contentious issues for legislation are protections for innovator manufacturers (the duration of patent exclusivity) and legislative constraints around the FDA’s authority to determine an analytic approach to bioequivalence.
How can specialty pharmacy products and services be better managed? The following suggestions merit consideration:

• Decide how to manage specialty pharmacy for your organization in a way that engages the health plan, the PBM and/or a specialty pharmacy network.

• Implement all traditional pharmacy management strategies: benefit design, biologic care managers, specialized clinical support, prior authorization, formulary management, utilization review and claims review.

• In discussions with your vendors, consider how system incentives for employees and providers might be changed to encourage more-appropriate use of specialty pharmacy products. Will identifying preferred providers direct patients to physicians of high quality who are under contract? Can specialty drugs be obtained more cheaply and more safely by using mail-order pharmacies? Ultimately, employers need to identify the most cost-effective and clinically appropriate distribution and administration channels for specialty drugs.

• Specialty drugs necessitate a sophisticated approach in order to avoid drug toxicities, adverse reactions, treatment failures and drug waste. Because specialty drugs are complex to administer, outcomes should be measured with a focus on individuals, health outcomes, and evidence.

• Support a delivery system that eliminates waste. For example, make every effort to prevent prescriptions from getting lost in the mail. In the case of specialty medicines, where per unit costs are extremely high, secured delivery is essential. Establish processes that assure that only those who need the medication are provided with it can likewise be very effective in managing drug spending.

As they pursue the most clinically effective pharmaceutical benefit, employers should be well-informed about a variety of factors that impact how their employees may interact with the pharmaceutical benefit.
VIII. ADDITIONAL ISSUES IN PHARMACY BENEFIT DESIGN

Appropriate Medication Usage

Research indicates that while a wide variety of medications are available to treat a wide variety of chronic ailments, they are often underused. In other words, many people:

• Have undiagnosed conditions that could be effectively treated with medication;
• Have not been prescribed needed medication; and/or
• Do not take prescribed medications as directed.

The following sections address a variety of issues related to appropriate medication usage.

Adherence

Adherence to a medication regimen may be defined as “the extent to which patients take medications as prescribed by their health care providers,” which are presumably the correct medications. The term “adherence” is preferable to “compliance” because the latter term suggests that the patient passively follows doctor’s orders rather than a treatment plan that has been jointly established by the patient and the physician.

There is no generally accepted standard for what constitutes good medication adherence. Researchers have, however, identified six patterns of medication-taking behaviors among patients treated for chronic diseases. Among these patients:

• One-sixth achieve near-perfect adherence to a regimen;
• One-sixth take nearly all doses, but with some timing irregularity;
• One-sixth miss an occasional single day’s doses and have some timing inconsistency;
• One-sixth take drug holidays three to four times a year, with occasional omissions of doses;
• One-sixth have a drug holiday at least monthly and omit doses frequently; and
• One-sixth take few or no doses while giving the impression of good adherence.

Adherence to medication regiments does matter. Poor adherence leads to substantial health declines, increased health care costs and even death. Of all medication-related hospital admissions, 33 to 69 percent are due to poor medication adherence. This translates into health care costs of approximately $100 billion a year. A recent study found that among patients under age 65 with one of four common chronic conditions, high medication adherence levels resulted in cost offsets for three conditions (diabetes, hypercholesterolemia and hypertension) and lower utilization of medical services for all four conditions (diabetes, hypercholesterolemia, hypertension. congestive heart failure) (see Figure 7).
Why do patients not adhere to their prescribed medication regimens? The reasons are many. As shown in Figures 8 and 9, they include poor provider–patient communication, lack of access to medications, side effects and drug costs. The primary reason people are non-compliant with a drug regimen, however, is that they simply forget.

Methods to improve adherence can be grouped into the following four broad categories:

- Patient education;34
- Improved dosing schedules;34
- Increased availability of providers and pharmacies;34 and
- Improved communication between physicians and patients.34

Another way to improve patient adherence is to reduce or eliminate copayments, especially for low wage employees.
Research suggests that reducing selected prescription drug copayments for people with chronic diseases can increase adherence levels when the reductions are part of a comprehensive medication-adherence program.\textsuperscript{45, 46}

\textbf{Figure 8: Selected Reasons for Non-Adherence}

Figure 9: Major Predictors of Poor Adherence to Medication

- Presence of psychological problems, particularly depression
- Presence of cognitive impairment
- Treatment of asymptomatic disease
- Inadequate follow-up discharge planning
- Side effects of medication
- Patient’s lack of belief in benefit of treatment
- Patient’s lack of insight into the illness
- Poor provider-patient relationship
- Presence of barriers to care or medications
- Missed appointments
- Complexity of treatment
- Cost of medication, copayment, or both


Racial-Ethnic Disparities

Racial and ethnic disparities in prescription drug usage are a pressing problem. One study revealed that among privately insured individuals with at least one chronic condition who did not purchase a prescription drug because of cost, 21.5 percent were African-American, 17.8 percent were Latino and 10.8 percent were White.47 Similar disparities exist for African-American and Latinos without a diagnosis of chronic illnesses.

Off-Label Medication Usage

A nationally representative survey of office-based physicians performed in 2001 found that about 21 percent of medications are prescribed for off-label uses, and that 15 percent of medications are prescribed for uses with existing scientific proof.47,48 Off-label prescriptions were most common for cardiac (46 percent) and anti-asthmatic (42 percent) agents.48 Among off-label prescriptions, 73 percent lacked evidence of clinical efficacy, meaning only 27 percent were supported by strong scientific evidence.48
The greatest disparity between supported and unsupported off-label prescription occurred among psychiatric therapies (4 percent strong support vs. 96 percent limited or no support) and allergy therapies (11 percent strong support vs. 89 percent limited or no support).\textsuperscript{48}

According to an estimate by the National Comprehensive Cancer Network, 50 to 75 percent of all uses of drugs in cancer care are off-label.\textsuperscript{48}

Depending on the source, off-label usage may or may not be a significant problem. Physicians may legally prescribe an FDA-approved medication for any diagnosis, even one that is not cited on the drug's label or in the manufacturer's application for FDA approval.

On the one hand, off-label prescribing can be innovative — it can turn scientific knowledge into innovative clinical practice. It can be considered evidence-based or can reflect basic standards of care. Off-label prescribing is often considered appropriate and medically necessary.\textsuperscript{49}

On the other hand, under-evaluated, off-label practices can jeopardize patient safety or waste resources.\textsuperscript{49}

**Misuse, Abuse, Dependence and Addiction**

According to the 2005 National Survey on Drug Use and Health, the number of Americans reporting abuse of prescription medications was higher than the combined total of those reporting abuse of cocaine, hallucinogens, inhalants and heroin.\textsuperscript{50} Approximately 48.7 million Americans age 12 or older, or 20 percent of that population, reported non-medical use of a psychotherapeutic agent at some point during their lifetime.\textsuperscript{50} Of those, approximately 6.4 million Americans age 12 or older (2.6 percent of the population) reported current (past month) use of psychotherapeutic drugs for non-medical purposes.\textsuperscript{50}

According to National Institute on Drug Abuse (NIDA) research, three classes of prescription drugs are most commonly abused: opioids, central nervous system (CNS) depressants and stimulants.\textsuperscript{51} According to the 2005 National Survey on Drug Use and Health, 4.7 million Americans used pain relievers, 1.8 million used tranquilizers and 1.1 million used stimulants (including 512,000 using methamphetamine).\textsuperscript{50}

\textbf{TIP: Leverage your vendor relationships to minimize medication misuse and to support treatment opportunities for addicted employees. PBM\textregistered s have extensive systems in place to identify medication misuse. An employer can use this information to maximize the effectiveness of their employee assistance program and health plan-sponsored addiction treatment services.}
The Drug Abuse Warning Network (DAWN) receives reports of emergency department (ED) episodes involving the non-medical use of legal drugs. During 2005, 598,542 ED visits involved non-medical use of prescription or over-the-counter pharmaceuticals or dietary supplements. CNS agents were involved in 305,973 ED visits and psychotherapeutic agents were involved in 275,430 visits.

### Aging Workforce, Retiree Coverage and Medicare Part D

Employers are facing the medical and pharmaceutical costs of an aging workforce. Their skilled labor force is aging without a replacement generation to follow. For this reason, employers will be increasingly dependent on the current workforce. This necessitates keeping aging workers healthy and productive. To maximize the health status of employees and retain older workers, employers may increasingly rely on health care benefits.

Employers also struggle with the financial burden of retiree benefits. Medicare Part D, implemented in January 2006, alters an employer’s responsibility to provide pharmaceutical benefits for retirees and employees over age 65. Relevant provisions of the legislation are as follows:

- Employers receive a tax-free subsidy if they offer a pharmaceutical benefit plan that is actuarially equivalent to that provided under Medicare Part D. Companies that do so receive a 28 percent subsidy from the federal government for each Medicare-eligible retiree enrolled in that plan.

- Employers can purchase wrap-around pharmaceutical coverage to enhance Medicare Part D. Employers whose plans are not actuarially equivalent to Medicare Part D can maintain their current plan and offer wrap-around coverage, as they traditionally have done for Medicare Parts A and B beneficiaries.

- An existing pharmaceutical plan sponsor can contract with the CMS to become an approved Medicare Part D plan sponsor. In this instance, employers can continue to operate their own ERISA plans. In turn, CMS pays a capitated rate covering both the basic and the catastrophic components of Medicare Part D.

- Employers can move Medicare-eligible beneficiaries into managed care plans that offer more enhanced benefits than the standard Medicare Part D benefit does.

**TIP:** Educate employees about the ramifications of their retirement drug benefit choices. How does your benefit compare with those available through other available drug plans?
High-Deductible Health Plans

The purpose of high-deductible health plans is to:

• Better control employer costs;
• Obligate greater consumer responsibility in health care decision making, and
• Focus on the value of preventive care.

Employers are increasingly offering consumer-driven health plans (CDHPs) that incorporate high-deductible health plans (HDHPs), flexible savings accounts (FSAs), health savings accounts (HSAs) or health reimbursement accounts (HRAs). According to a National Business Group on Health member survey, 48 percent of member companies offered HDHPs in 2006. As employers move to HDHPs, they struggle with incorporating high-deductible plan financing mechanisms into their current pharmaceutical system without jeopardizing PBM negotiating power, employer cost savings and individual health. Such employers are often in a quandary as to what constitutes appropriate spending on preventive care. A related concern is whether the greater financial impact on patients will result in reduced utilization of important medical services, such as drugs to treat chronic diseases. The impact of such policies on drug adherence is an area of ongoing research and debate.

Marketing: Direct-to-Consumer and Direct-to-Physician

The role of direct-to-consumer and direct-to-physician advertising in the growing cost of prescription drugs in the United States is a matter of intense debate. Evidence suggests that direct-to-consumer advertising of prescription drugs increases pharmaceutical sales. Studies show a direct correlation between the increase in pharmaceutical marketing and an increase in the number of prescriptions written. Total spending on pharmaceutical promotion grew from $11.4 billion in 1996 to $29.9 billion in 2005. Paradoxically, direct-to-consumer advertising helps avert underuse of medications (as undiagnosed conditions are discovered and treated) yet can also lead to overuse (when patients seek medications they do not need).
Table 2: U.S. Sales Revenues and Promotion Spending for Leading Therapeutic Classes of Drugs, According to Dollar Sales in 2005

<table>
<thead>
<tr>
<th>Variable</th>
<th>U.S. Sales Revenues</th>
<th>Total Promotional Spending</th>
<th>Percentage of Sales</th>
<th>Type of Promotion</th>
<th>No. of Drugs in Class with Direct-to-Consumer Advertising</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Millions of Dollars</td>
<td>Percent</td>
<td></td>
<td>Direct-to-Consumer Advertising</td>
<td>Detailing</td>
</tr>
<tr>
<td>HMG-CoA reductase inhibitors</td>
<td>16,000</td>
<td>858</td>
<td>5</td>
<td>34</td>
<td>52</td>
</tr>
<tr>
<td>Proton-pump inhibitors</td>
<td>12,900</td>
<td>884</td>
<td>7</td>
<td>34</td>
<td>57</td>
</tr>
<tr>
<td>SSRIs or SNRIs</td>
<td>12,500</td>
<td>1018</td>
<td>8</td>
<td>12</td>
<td>68</td>
</tr>
<tr>
<td>Antipsychotic agents</td>
<td>10,500</td>
<td>513</td>
<td>5</td>
<td>10</td>
<td>64</td>
</tr>
<tr>
<td>Erythropoietin</td>
<td>8,700</td>
<td>100</td>
<td>1</td>
<td>31</td>
<td>45</td>
</tr>
<tr>
<td>Seizure-disorder agent</td>
<td>8,000</td>
<td>348</td>
<td>4</td>
<td>12</td>
<td>65</td>
</tr>
<tr>
<td>Angiotensin II antagonists</td>
<td>5,000</td>
<td>598</td>
<td>12</td>
<td>0</td>
<td>78</td>
</tr>
<tr>
<td>Calcium-channel blockers</td>
<td>4,600</td>
<td>94</td>
<td>2</td>
<td>1</td>
<td>79</td>
</tr>
<tr>
<td>ACE inhibitors</td>
<td>3,800</td>
<td>251</td>
<td>7</td>
<td>2</td>
<td>71</td>
</tr>
<tr>
<td>COX-2 inhibitors</td>
<td>1,800</td>
<td>299</td>
<td>17</td>
<td>4</td>
<td>78</td>
</tr>
</tbody>
</table>

* Data on direct-to-consumer advertising are from TNS Media; data on detailing, professional meetings and events, journal advertising, and online promotions to physicians are from Verispan; and data on sales revenues are from IMS Health. Leading therapeutic classes of drugs were identified on the basis of publicly available IMS Health ranking of therapeutic classes according to spending for 2004. Values for selective serotonin-reuptake inhibitors (SSRIs) and selective norepinephrine-reuptake inhibitors (SNRIs) match the classification scheme used by Verispan, which was the source of our data on promotions. Value in the far right-hand column refer to product-specific advertising only. HMG-CoA denotes 3-hydroxy-3-methylglutaryl coenzyme A, ACE angiotensin-converting enzyme, and COX-2 cyclooxygenase-2.

IX. THE VALUE OF PHARMACEUTICAL COVERAGE

In an ideal world, an employer could provide the right drug, to the right person, at the right dosage, at the right time with no risks. There is, however, no such thing as the perfect pharmaceutical benefit. Benefits cannot provide everything to everyone. At the same time, all health interventions, including prescription drugs, offer benefits as well as harms and risks. In the real world, it is the employer’s responsibility to design a benefit that meets the needs of most people in a safe, efficient, effective and economical way that also provides a method for managing exceptions. The purpose of this document is to advise employers on how to fulfill this important responsibility.

Theoretically, pharmaceutical benefits exist along a spectrum: from the complete absence of a benefit to unrestricted access to all medications. Both extremes are impractical and inappropriate. Open-access pharmaceutical benefits are rare, yet virtually every large employer offers extensive pharmaceutical coverage. The pharmacy benefit should be designed to support overall organizational health care goals and objectives, as well as balance benefits, risks, and need for an affordable health care package.

What influences corporate health care goals? Every company must think about the following five factors when determining the structure and breadth of its health benefit plan:

**Employee health care access:** Are a wide variety of medical services available with reasonable employee contributions?

**Financial cost:** How much can a company reasonably expend on employee health care? What cost sharing levels balance the need for consumer engagement with affordability for patients?

**Employee satisfaction:** What type of health care benefits will attract and retain talented employees?

**Workplace productivity:** Considering that health care benefits are an investment in the long-term health of employees, how important is it to maintain the health of the current workforce to improve productivity?

**Corporate culture:** How responsible does a company feel for the health and well-being of its employees?
The pharmaceutical benefit is one component of a larger health care benefit and should be managed as such. Administering the pharmaceutical benefit independently or in an ad hoc manner will:

• Limit the potential effectiveness of the overall health care benefit; and

• Minimize the perceived effectiveness of the pharmaceutical benefit.

For these reasons, the employer should manage the pharmaceutical benefit as a part of the whole. Doing so requires understanding how pharmaceutical spending affects other direct and indirect health care costs (e.g., the health plan, worker disability and productivity). Gaps in pharmaceutical coverage can result in other costs, such as emergency room use, hospitalizations, and provider visits. Those gaps are expensive to an employer in terms of lost productivity.

Integration

Many companies manage pharmaceuticals as an independent health benefit. In other words, pharmaceuticals are a line item in their budget. They are not integrated into total health care spending. As the costs of pharmaceuticals rise, senior management takes note and requires that payouts be better controlled or cut back. In this type of environment, managing the benefit becomes a continued effort at cost containment. The constant question is how can the pharmaceutical benefit be redesigned to control medical spend? This approach is equivalent to fixing a leaky water pipe by plugging the holes. If too many people are using more-expensive medications, the solution is to change that behavior by creating disincentives to using that medication (i.e., increase the cost sharing or eliminate the coverage entirely).

Cost Containment

Managing to contain costs only may undermine the value of the pharmaceutical benefit. This strategy assumes that value is determined wholly by how much the pharmaceutical benefit costs: spending less, it reasons, is always better than spending more. The problem with this approach is that minimized usage may receive greater priority than appropriate usage. If management’s goal is to limit financial liability, continuously integrating cost-containment strategies can work. The problem is that the desired effects may be of short duration. Plugging a hole is at best a temporary fix. If a permanent solution is not found, the hole will grow and others will eventually appear. Similarly, there are only so many ways to contain costs in a pharmaceutical benefit. The long-term trend in pharmaceutical usage indicates that utilization will continue to increase. As a result, pharmaceutical benefit costs will also continue to rise. A comprehensive strategic approach is needed.
Comprehensive Approach to Pharmaceutical Benefits

Pharmaceutical coverage should be evaluated not only in terms of cost and but also in terms of its benefit to employees and employers. The benefit to the employee should be clear: improved health. For the employer, improved employee health translates into increased productivity and improved overall organizational health. Pharmaceutical benefits can save employers money by averting medical treatment (e.g., surgery) and preventing absenteeism and presenteeism (see Figure 10). In other words, to fully understand the value of the pharmaceutical benefit, employers must look at their full health care picture. This entails:

- Integrating all direct and indirect spending;
- Understanding employee health status and need; and
- Working with their health care partners (e.g., PBMs) to leverage their health care purchases to the greatest extent possible.

Figure 10: Top 10 Health Conditions Contributing to Loss of Productivity and Absenteeism

<table>
<thead>
<tr>
<th>Condition</th>
<th>Average Days Absent per Year</th>
<th>Average Annual Dollar Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression/Mental Illness</td>
<td>25.6</td>
<td>$4,741</td>
</tr>
<tr>
<td>Cancer</td>
<td>16.9</td>
<td>$3,133</td>
</tr>
<tr>
<td>Respiratory Disorders</td>
<td>14.7</td>
<td>$2,727</td>
</tr>
<tr>
<td>Asthma</td>
<td>12.0</td>
<td>$2,221</td>
</tr>
<tr>
<td>Migraine/Headache</td>
<td>10.7</td>
<td>$1,988</td>
</tr>
<tr>
<td>Allergy</td>
<td>8.2</td>
<td>$1,521</td>
</tr>
<tr>
<td>Heart Disease</td>
<td>6.8</td>
<td>$1,257</td>
</tr>
<tr>
<td>Arthritis</td>
<td>5.9</td>
<td>$1,089</td>
</tr>
<tr>
<td>Diabetes</td>
<td>2.0</td>
<td>$365</td>
</tr>
<tr>
<td>Hypertension</td>
<td>0.9</td>
<td>$170</td>
</tr>
<tr>
<td>Average Loss</td>
<td>10.4</td>
<td>$1,921</td>
</tr>
</tbody>
</table>

Several large companies, institutions and localities have implemented innovative solutions to their own pharmaceutical challenges. Employers can learn strategies for managing their own pharmacy benefit plans by looking at what their peers have done in this area as they can in all health care activities. Few companies are willing to adopt change without knowing how other organizations fared following adoption of a similar strategy. The Business Group’s Pharmaceutical Council presents the following case studies in the hope that they will provide information that other employers may find useful. Please look for updates to this information, as well as new case studies, as information and new practices become available.

**X. PHARMACEUTICAL BENEFIT CASE STUDIES**

IT IS IMPORTANT TO BE CRITICAL ABOUT RESEARCH. IS THERE ANYTHING ELSE, BESIDES THE INTERVENTION, THAT EXPLAINS THE FINDINGS?

- **Consider the Hawthorne effect.** The Hawthorne effect describes a temporary change in behavior or performance in response to a change in environmental conditions. In the case of medical intervention, many argue improvements in clinical and financial outcomes may be driven by new or increased attention on the topic rather than by the intervention being studied.

- **Validated scientific research should include a control group to correct for “regression to the mean” and other potential flaws in statistical methodology.** Employers may create programs to manage their most expensive health and/or benefit challenges. When there appears to be improvement following the intervention, employers should be reticent about attributing that success to the intervention. Without a control group, it is difficult to measure true change. Randomized or matched control groups provide a reference point that enable the researcher to see what would have happened without the intervention. Additionally, outliers tend to return to normal.

- **While many early studies of the impact of pharmaceutical design change on human behavior are intriguing and encouraging, they do not provide definitive evidence of success from any one individual factor, such as copayment adjustment or education regimens.** These interventions introduced many changes at once, making it difficult to determine the impact of any one particular change.
Pitney Bowes

In 2001, having implemented full managed care in the early 1990s, Pitney Bowes conducted a full review of its health care strategy. The company, specializing in global, integrated mail and documents, also re-evaluated its approach to benefit design. Company executives recognized that health care was the only corporate expense that was assumed to grow each year. They also were aware that the benefit seemed to offer less value year after year. In other words, additional investment in health care did not necessarily translate into improved employee or organizational health.

As a first step, Pitney Bowes scrutinized its workforce and health care spending. Analysis of its integrated database of pharmacy, medical, clinical, disability and workers’ compensation data showed that 50 percent of employees had a chronic illness. These chronic illnesses (e.g., asthma, diabetes, cardiovascular disease, cancer and depression) were primary cost drivers. At the same time, the company’s pharmacy program was extremely fragmented (multiple PBMs, carve-ins and carve-outs). This complexity resulted in adverse selection within its own population.

After completing this review, Pitney Bowes undertook a staged revision of its pharmaceutical benefit plan. In the initial stage, they took the following steps:

• Selected a new PBM vendor to manage both retail and mail-order pharmacy operations. The PBM was also expected to supply data to the company’s integrated database so as to inform the development and delivery of other employer-sponsored health care services (e.g., disease management).

• Moved to a triple-tier pharmacy plan with a “buy-up” provision. Employees who relied on pharmaceutical products extensively could choose to pay higher premiums and pay less at the point of sale. The formulary was a three-tier retail coinsurance plan with no deductible. Drugs on tier one required 10 percent coinsurance, those on tier two required 30 percent coinsurance and those on tier three required 50 percent coinsurance. No per-prescription maximums were applied.

• Eliminated required mail-order, mandatory generics and step therapy.

• Limited prior authorization.

In light of the large proportion of workers with chronic medical conditions, the company:

• Changed the pharmacy plan design, moving all medications commonly used to treat asthma, diabetes and cardiovascular disease to tier one, regardless of whether the drugs were generic, brand, preferred or non-preferred.

• Linked disease management, case management and on-site clinics to the pharmacy program.
• Automatically added new drug treatments for the above-described chronic diseases to the first-tier category without:
  – A waiting period, or
  – Review by its Pharmacy and Therapeutics (P&T) Committee.

In 2007, benefit design was expanded to include pharmaceuticals for treatment of osteopenia/osteoporosis, seizure disorders and anticoagulants on tier one. Statins were made available free of charge to all persons with either diabetes or a history of a cardiac event (myocardial infarction, bypass surgery, stent implantation).

The average cost of a 30-day prescription fill dropped by 50 percent to 80 percent compared with previous costs.54 The annual costs of care for diabetes decreased 6 percent between 2001 and 2003.54 Although Pitney Bowes’ total annual pharmacy costs per covered person showed a mild increase, pharmacy costs for those with diabetes actually decreased by 7 percent.54 The number of employees with suboptimal adherence to insulin decreased by two-thirds.54 The proportion of employees using fixed-combination oral hypoglycemics increased from 9 percent to 22 percent. Increases in adherence rates were particularly high for individuals taking combination therapy. The rate of emergency department visits for diabetes dropped by 26 percent.54 Pitney Bowes also saved in short-term disability. The annual hospitalization rate for those with diabetes decreased from 0.06 days per 100 employees in 2002 to 0.03 days in 2004, whereas the average length of stay decreased 29.3 percent from 58 days in 2002 to 41 days in 2004. This translated into short-term disability cost savings of 75 percent.55

Pitney Bowes’ efforts proved successful. The company’s many actions effectively communicated the organization’s commitment to better preventive care and personal health. Following implementation of the new plan, Pitney Bowes’ health care spending did not grow as fast as the national average. Between 2001 and 2002, Pitney Bowes experienced an 8.3 percent growth in health care spending as compared to 15 percent for its benchmarked competitors.56 Per member per month pharmacy cost increases from 2001 to 2002 were 1 percent at a time when the external average was 12 percent.56

Recent data show that its 2007 plan design changes increased the number of diabetics on a statin by more than 10 percent. Ultimately, the variance from the benchmark for what 2007 health care costs should have been was $40 million. Of this, $12 million was attributed to improved health plan efficiency. The remaining savings were due to better health care management.

While it is difficult to identify the impact of each individual strategy the Pitney Bowes used (consolidating vendors, optimized benefit design, disease management, on-site clinics, etc.) this experience demonstrates the enormous value of an integrated approach to benefits.
The Asheville Project

**Project Beginnings**

Asheville, North Carolina, is a recognized leader in disease management. Over the past decade, Asheville, like many other employers, watched its health care expenses rise and struggled with how to contain costs. In March 1997, Asheville introduced a one-year pilot project with objectives to:

- Improve the health of employees with Type 1 and Type 2 diabetes, and
- Lower total health care costs.

The goal of the Asheville Project, formally known as the Asheville Pharmaceutical Care Services (PCS) program, was to lower the amount spent on diabetes, a common and costly disease among city employees. Many employees with diabetes did not adhere to treatment because of the high costs of prescription medications and supplies. The program’s underlying philosophy was that poor medication adherence leads to expensive health care utilization, such as emergency room visits and longer, more frequent hospital stays. In effect, the City of Asheville believed that it could save money by improving medication adherence.

The Asheville Project tapped into an existing, although underutilized, resource: local pharmacists. The PCS program recruited pharmacists from 12 local pharmacies. Pharmacists were reimbursed for their participation. Each went through a rigorous training process developed by two North Carolina pharmacy schools and the Mission St. Joseph’s (MSJ) Diabetes Education Center. The training included knowledge and skill training in how to attend to the needs of patients with diabetes (i.e., disease monitoring, treatment review and specific techniques for educating and supporting patients with diabetes).

Employees insured by the City of Asheville and the MSJ Health System were invited to participate in the program. To encourage people to participate, copayments on diabetic medications and supplies were waived. Following enrollment and selection of a PCS-identified provider from the list of the 12 participating local pharmacies, patients were provided with the following opportunities:

- Monthly meetings with pharmacists at no personal cost;
- A free home blood glucose meter to measure daily glucose levels;
- Pharmacist-provided training in monitoring blood glucose levels through the meter;
- Pharmacist monitoring of patient treatment goals;
- Pharmacist-provided diabetes management education;
- Pharmacist-provided physical assessments; and
- Pharmacist-provided information about medication adherence.
Program participants used the services offered to achieve better diabetes management. Patients with diabetes visited the pharmacist up to eight times as often as other patients. The pharmacist became an active part of the health care team.\textsuperscript{58} As a result of the new relationship between pharmacists and patients, patients visited their physicians more regularly than they had previously. Program staff concluded that patients with diabetes adopted better health behaviors because they had received repeated messages about health maintenance.\textsuperscript{58}

Although the total cost of medications rose (because of better adherence and more aggressive treatment), employers saw a decrease in mean projected medical costs.

- One employer estimated that every dollar invested in the PCS program resulted in four dollars saved.\textsuperscript{42}

- In the long term, the average direct medical care cost per patient per year decreased between $1,622 and $3,356.\textsuperscript{57}

- The number of sick days taken by employees with diabetes decreased, resulting in increased productivity valued at $18,000 per year.\textsuperscript{57}

- The City of Asheville is paying half of the national average health care cost for employees with diabetes.\textsuperscript{42}

The Asheville Project has been successful in improving the health of patients with diabetes. Over the past decade, the project has brought about reductions in the number of sick days used as well as in overall health care costs.

The City of Asheville has expanded the program to include patients with asthma, high blood pressure, high cholesterol and depression. The program has been emulated by more than 30 employers nationwide.\textsuperscript{44} The Asheville Project demonstrates that if employees take care of their health in the present, employer health care costs can be minimized in the long run.
Mohawk Industries, Inc.

The American Pharmacists Association (APhA) Foundation offers a service to help employers organize and implement diabetes management programs under its Patient Self-Management Program for Diabetes, based on the Asheville Project Model. The program began in 2003 as a pilot program. Representative companies and organizations from five sites were chosen to implement this project. Among them was Mohawk Industries, Inc., a carpet factory located in Dublin, Georgia. Mohawk has 750 employees.

Alan Christianson, Mohawk’s benefits administrator, said that the company realized that it could eventually face health costs so high that employees could not afford insurance. “We felt that we had to do something about it,” he said.

Mohawk employees received a flyer describing the program’s benefits. Incentives for employees to enroll, including waived copayments on diabetes-related medicines, were created. There was no out-of-pocket charge for diabetes education, and patients received a new blood glucose meter at no charge. Patients were able to select their top three pharmacists of choice during the enrollment process. Each pharmacist managed five patients. Twelve pharmacy providers participated and 60 patients were enrolled. The patients were assessed during three monthly visits. The first visit focused on nutrition, diet, exercise and diabetes education. The second visit addressed controlling blood sugar, foot care, proper insulin use and reading food labels. The third visit focused on managing diabetes over the long term.

Visits were documented and faxed to the patient’s physician at the end of each visit. Pharmacists also recorded hemoglobin A1C, blood pressure, cholesterol, current influenza vaccination, current foot examination, current eye examination, and medication adherence.

In addition to the pharmacist visits, 20 to 25 patients participated in a monthly support group at Mohawk’s on-site education room. During these sessions, they discussed topics related to managing their diabetes. At the end of the first year, 92 percent of the patients had blood sugar (A1C) levels less than the Health Plan Employer Data Information Set goal of 9.0, and 59 percent had A1Cs less than the American Diabetes Association goal of 7.0. By the end of the second year, the proportion of patients with A1Cs below 7.0 rose to 61 percent.

By the end of year two, medical costs for these diabetics decreased by 53 percent as compared with costs at the end of year one. The average annual medical claims costs per patient dropped from $8,202 at baseline to $6,870 at the end of year one, and to $3,677 at the end of year two. Total per-patient drug expenditures rose from $2,194 at baseline to $3,870 at the end of year one to $4,025 at the end of year two. The increase in drug spending is the result of patients becoming more adherent to their medication regimens and is expected to level off over time.
Wake Forest University Baptist Medical Center

Wake Forest University Baptist Medical Center in Winston-Salem, N.C., manages its own health plan. Prior to intervention, the 22,000 plan members had a three-tiered pharmacy plan. A 30-day medication supply cost $10 for generic products, $25 for preferred name-brand products and $50 for non-preferred name-brand products. Because the institution had on-site pharmacies, it did not offer a mail-order option. The plan did not cover over-the-counter medications.

In an effort to reduce its prescription drug spend, Wake Forest University Baptist Medical Center implemented the following changes:

- Shifted all brand-name drugs from preferred to non-preferred status for classes of medications with similarly effective or potentially safer generic substitutions. This eliminated the preferred brand-name tier.
- Removed from the formulary prescription drug classes for which similarly effective over-the-counter medications were available.
- Introduced quantity limits for medications not indicated for daily use.
- Established a program of mandatory pill splitting (based on a similar effort undertaken by Department of Veteran Affairs Mid-Atlantic Health Network) and applied it to six brand-name antidepressants and three brand-name statins.

A local advisory committee of clinical leaders, pharmacists and administrators examined published literature to determine which interventions members would support. Ultimately, following committee support, the above interventions were launched in three phases over the course of two years (fourth quarter 2003–third quarter 2005).

At baseline, 36 percent of plan members used the prescription drug benefit, averaging about 2.8 drug claims per member, per quarter. Sixty percent of claims were for brand-name-only drugs. This translated into $10.1 million prescription drug dollars spent in 2003 ($35.37 per member per month).

Following implementation, total prescription drug spending remained constant over the next three years. National pharmaceutical spending increased 8 percent each year during that same period. This resulted in cost avoidance of $6.6 million. A detailed breakdown of the financial impact of each proposed intervention is shown in Table 5. Research shows that:

- Using cost-effective alternatives to brand-name drugs through formulary changes may yield cost savings; and.
- Pill splitting can yield cost savings, but it can also be risky.
Health plans need to continually re-evaluate their pharmacy offerings to maximize their savings. Carefully selected interventions can minimize pharmaceutical costs without increasing member costs. However, missing from this evaluation is an assessment of whether reducing costs also reduces value. Employers should be cautious about implementing cost-containment measures without considering the overall impact.

Table 3: Intervention Savings at Wake Forest University Baptist Medical Center

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Change in Plan Spending ($)</th>
<th>Change in Member Spending ($)</th>
<th>Total Difference ($)</th>
<th>Total Annualized Savings ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Move brand-name drugs to non-preferred status</td>
<td>-261,470</td>
<td>26,207</td>
<td>-235,262</td>
<td>941,050</td>
</tr>
<tr>
<td>Remove items from formulary</td>
<td>-83,074</td>
<td>-58,162</td>
<td>-141,236</td>
<td>564,942</td>
</tr>
<tr>
<td>Limit drug quantities</td>
<td>-28,581</td>
<td>-5,149</td>
<td>-33,731</td>
<td>134,922</td>
</tr>
<tr>
<td>Mandate pill splitting</td>
<td>-74,028</td>
<td>-11,532</td>
<td>-85,560</td>
<td>342,239</td>
</tr>
</tbody>
</table>

University of Michigan

In 2004, University of Michigan (UM) leadership called for the identification, implementation and evaluation of potentially cost-effective investments in the health of the UM workforce. Using pharmacy claims, utilization rates of high-value therapies were assessed. In view of its prevalence, extent of underutilization of essential therapies and health service utilization costs, diabetes was identified for a value-based insurance design intervention.

In July 2006, UM implemented a two-year pilot program “M-Healthy: Focus on Diabetes” for its 2,200 employees and dependents with a diagnosis of diabetes mellitus. The program provides copayment reductions to diabetes patients for interventions with a strong evidence base. These include several drugs that affect blood sugar, blood pressure, cholesterol and depression, and that help prevent or reduce the long-term complications of diabetes. Many of these medications are used for a wide range of other diseases, but only individuals with diabetes were eligible for copayment reductions. The UM pharmacy benefit plan classifies drugs into three tiers for payment. For medications in tier one, copayments decreased by 100 percent (from $7 to $0). Tier two copayments decreased by 50 percent (from $14 to $7); tier three copayments, by 25 percent (from $24 to $18). Copayments for annual eye exams were also reduced.62

All employees and clinicians were notified by letter and e-mail of the pilot program. All UM employees and their dependents were enrolled in the program automatically if they had previously filled a prescription through the UM Prescription Drug Plan for a blood sugar–controlling medication or insulin.

According to Allison Rosen, M.D., Sc.D., an assistant professor of internal medicine and health management and policy at UM, “We implemented this program to improve both the quality and value of care for our workforce with diabetes. In turn, it is our hope that a rigorous evaluation of the impact of these targeted value-based copayment reductions may help inform the efforts of other employers and insurers trying to improve the value of their health care spending.”63
XI. CONCLUSION

Employers are spending a large percentage of their health care dollars on pharmaceuticals. Nearly a quarter of all respondents to a Business Group survey (June 2006) reported spending at least 20 percent of corporate health care dollars on pharmaceuticals (see Figure 11). If history is any indication, this amount will continue to grow.

**Figure 11: Percentage of Corporate Health Care Dollars Spent on Pharmaceuticals**

Employers want value, in both financial and clinical terms, from their pharmaceutical benefits. To develop and maintain clinically effective and fiscally responsible pharmaceutical benefits, employers should do the following:

1. Identify corporate pharmaceutical objectives and structure a benefit accordingly;
2. Understand whether employees are using the benefit appropriately and effectively; and
3. Continually re-evaluate the pharmaceutical benefit within the context of the overall health care benefit.
To accomplish this, employers need to leverage their data and partnerships. A pharmaceutical benefit ill-tailored to the needs of a given workforce cannot be utilized to its full potential. Similarly, it is important that all players involved in pharmaceutical benefit management (employer, PBM, health plan, etc.) work together toward shared goals and objectives.

The value of the pharmaceutical benefit value should be determined in both financial and clinical terms. This can be difficult to do. Employers need to re-examine how they manage the pharmaceutical benefit, with an eye both to cost and to benefit, weighing carefully plan designs that balance net health outcomes, risks and harms. Appropriately prescribed, pharmaceuticals are not only a cost: employers benefit from the pharmaceutical coverage they provide. Prescription medications can help people avoid, minimize or mitigate disease, disability and even death. Effective prevention and treatment can also improve worker productivity. Ultimately, pharmaceutical value – like all investments in health care – should include measurements of both direct and indirect health care costs, other risks and harms and benefits, including health outcomes.
XII. REFERENCES


57. Cranor CW, Bunting BA, Christensen DB. The Asheville Project: long-term clinical and economic


### Terms and Definitions

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
<th>Source</th>
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<tr>
<td>Actual Acquisition Cost (AAC)</td>
<td>Cost of a pharmaceutical to the pharmacy or other health care provider after all discounts, rebates and other prices concessions have been taken into account.</td>
<td>Source: Academy of Managed Care Pharmacy Task Force on Pharmaceutical Payment Methods. AMCP guide to pharmaceutical payment methods, executive edition. <em>JMCP</em>. 2007;13(8).</td>
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<tr>
<td>Average Sale Price (ASP)</td>
<td>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 paid to the wholesaler or the retailer.</td>
<td>Source: Academy of Managed Care Pharmacy Task Force on Pharmaceutical Payment Methods. AMCP guide to pharmaceutical payment methods, executive edition. <em>JMCP</em>. 2007;13(8).</td>
</tr>
<tr>
<td>Best Price (BP)</td>
<td>The lowest price available to any wholesaler, retailer, provider, health maintenance organization (HMO), nonprofit entity or the government. BP includes cash discounts, free goods that are contingent upon purchase, volume discounts and rebates.</td>
<td>Source: Academy of Managed Care Pharmacy Task Force on Pharmaceutical Payment Methods. AMCP guide to pharmaceutical payment methods, executive edition. <em>JMCP</em>. 2007;13(8).</td>
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<tr>
<td>Brand-Name Drug</td>
<td>A drug sold under a proprietary name that is protected by a patent when it enters the market.</td>
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| **Bundled Sales** | The packaging of drugs of different types, where the price for the package is less than the price of the drugs if they were purchased separately.  
| **Closed or Restricted Formulary** | A formulary where only the drug products listed on it will be reimbursed by the health plan. |
| **Concurrent Drug Utilization Review** | The process by which a pharmacist is notified if a newly prescribed medication can be hazardous to the patient. Searches for information from the patient’s medical profile (from a variety of prescribers and retailers) can reveal potential problems with drug-drug interactions, duplicative therapies, inappropriate dosages or quantities or counter-indications based on patient age, sex, pregnancy status and other medical conditions. This information can be inferred from a pharmacy claims database. |
| **Direct Price (DP)** | The price at which the manufacturer has reported it sells a drug to non-wholesalers. DP does not reflect discounts, rebates or other price reductions that may be extended to non-wholesalers.  
| **Dispensing Fee** | A fee paid to the pharmacist for the service of dispensing drugs. |
| **Drug Utilization Review (DUR)** | The review of an insured population’s drug utilization with the goal of determining how to improve prescribing safety, manage cost or both. |
| **Estimated Acquisition Cost (EAC)** | A state Medicaid agency’s estimate of the price generally paid by pharmacies for a pharmaceutical product.  
| **Formulary** | A list of drugs considered by physicians and pharmacy staff of a health care organization as preferred for use in treating patients served by the organization.  
<table>
<thead>
<tr>
<th><strong>Generic Drug</strong></th>
<th>The chemical equivalent of a drug whose patent has expired.</th>
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<tbody>
<tr>
<td><strong>Maximum Allowable Cost (MAC)</strong></td>
<td>The highest unit price that will be paid for a drug. The purpose of MAC is to increase generic dispensing, ensure that the pharmacy dispenses economically and control cost increases. Source: Academy of Managed Care Pharmacy Task Force on Pharmaceutical Payment Methods. AMCP guide to pharmaceutical payment methods, executive edition. <em>JMCP</em>. 2007;13(8).</td>
</tr>
<tr>
<td><strong>National Drug Code (NDC)</strong></td>
<td>A number assigned to a drug that identifies the manufacturer, dosage, strength and package size of the product.</td>
</tr>
<tr>
<td><strong>Open or Voluntary Formulary</strong></td>
<td>A list of preferred drugs that is not necessarily tied to member cost share. An open formulary may have a single copayment or coinsurance amount for all drugs. More typically, however, it is associated with a two-tiered copayment in which there is one copayment (e.g., $5) for generic drugs and a higher copayment (e.g., $20) for brand-name drugs, whether listed on the formulary or not. Physicians prescribing from an open formulary are not restricted in the products they may prescribe. Source: Academy of Managed Care Pharmacy Task Force on Pharmaceutical Payment Methods. AMCP guide to pharmaceutical payment methods, executive edition. <em>JMCP</em>. 2007;13(8).</td>
</tr>
<tr>
<td><strong>Pharmacy Benefits Manager (PBM)</strong></td>
<td>Organizations that manage pharmaceutical benefits for managed care organizations, other medical providers or employers. Source: Academy of Managed Care Pharmacy Task Force on Pharmaceutical Payment Methods. <em>AMCP guide to pharmaceutical payment methods, executive edition. JMCP</em>. 2007;13(8).</td>
</tr>
<tr>
<td><strong>Pharmacy Network</strong></td>
<td>A group 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 large or small. They allow PBMs to lower prescription drug prices by negotiating the reimbursement rate and dispensing fee with pharmacies. Source: Henry J. Kaiser Family Foundation. <em>Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain</em>. March 2005.</td>
</tr>
<tr>
<td><strong>Rebate</strong></td>
<td>Money returned to a payer from a prescription drug manufacturer based on use by a covered person or purchases by a provider. Source: Academy of Managed Care Pharmacy Task Force on Pharmaceutical Payment Methods. <em>AMCP guide to pharmaceutical payment methods, executive edition. JMCP</em>. 2007;13(8).</td>
</tr>
<tr>
<td><strong>Suggested Wholesale Price (SWP)</strong></td>
<td>The manufacturer's suggested price for drugs to be sold by wholesalers to their customers. Wholesalers determine the actual sales price to their customers. Source: Understand the acronyms. <em>PBM News</em>. 2005;(10)3.</td>
</tr>
<tr>
<td><strong>Therapeutic Substitution</strong></td>
<td>Substitution of a prescribed drug that is not on a plan's formulary by a formulary drug that is clinically similar to, but chemically different from, the product prescribed.</td>
</tr>
<tr>
<td><strong>Two-tier copayment</strong></td>
<td>System where a beneficiary pays one price for a generic drug and a higher price for a brand-name drug.</td>
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<tr>
<td><strong>Three-tier copayment</strong></td>
<td>System under which a beneficiary pays one price for a generic drug, a higher price for a preferred brand-name drug and an even higher price for non-preferred brand-name drug.</td>
</tr>
</tbody>
</table>
| **Usual and Customary Price** | The amount that a customer without insurance pays for a drug. Also known as “retail price.”  
Source: Minnesota Rx Connect. Available at: http://www.state.mn.us/portal/mn/jsp/content.do?hpage=true&contentid=536910573&contenttype=EDITORIAL&subchannel=null&sc3=null&sc2=null&id=-536891618&agency=Rx |
| **Wholesale Acquisition Cost (WAC)** | Price paid by a wholesaler for a drug purchased from a supplier, typically the manufacturer of the drug. Publicly disclosed WACs may not reflect all available discounts, such as prompt-pay (cash) discounts.  
Source: Academy of Managed Care Pharmacy Task Force on Pharmaceutical Payment Methods. AMCP guide to pharmaceutical payment methods, executive edition. JMCP 2007;13(8). |
| **Wholesale Distributor** | A company that purchases pharmaceutical products from manufacturers and distributes 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, physicians’ offices and diagnostic laboratories).  
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