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Prescription Drug Coverage and Formulary Use in California:

Different Approaches and Emerging Trends



William M. Mercer, Incorporated
May 2001

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and Emerging Trends

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Prepared by

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The **California HealthCare Foundation (CHCF)** is a private philanthropy based in Oakland, California. The Foundation focuses on critical issues confronting a changing health care marketplace by supporting innovative research, developing model programs, and initiating meaningful policy recommendations.

William M. Mercer, Inc. is a leading global consulting firm dedicated to helping employers use the power of their people to enhance business success. Mercer has more than 13,000 employees in more than 132 cities in 37 countries and territories. This report was developed by Mercer's Health Care & Group Benefits Practice by consultants in Mercer's Los Angeles, San Francisco, and New York offices. These consultants work with private and governmental plan sponsors, insurers, and health care systems to anticipate benefit trends and health system changes and to consistently improve the value of care delivered to consumers.

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This report is third in a series of studies on prescription drugs published by CHCF. To obtain other reports in this series, visit our Web site at www.chcf.org.

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I. Executive Summary

Nationwide, more than 50 percent of people with pharmacy coverage will be in a three-tier plan by the end of 2001, but the three-tier plan will have slower adoption in California.

THE COST OF PROVIDING PRESCRIPTION DRUG benefits for most employer plan sponsors in the United States increased between 10 percent and 20 percent in each of the last few years, and this rate of increase is expected to continue or even grow over the next few years. In response to increasing costs, employer plan sponsors, health plans, and stand-alone pharmacy benefit management companies (PBMs) have implemented a variety of prescription drug benefit and formulary designs. Such changes strongly influence access to and utilization of prescription drugs.

This report reviews prescription drug coverage and the use of formulary in California, and offers a forecast of future prescription drug benefit and formulary design possibilities. It brings together facts and opinions from published sources, national surveys, and stakeholder interviews with California health plans, national stand-alone PBMs with clients in California, California-based employer plan sponsors and employer coalitions, pharmaceutical companies, and industry experts.

A Profile of Prescription Drug Coverage and Formulary Use in California

Employers, private and public, are the largest sponsors of prescription drug benefits both nationally and in California. It is estimated that employers help fund the prescription drug benefits for more than half of California's residents, while state and federal public programs cover approximately 19 percent. That means that almost one-third of California residents do not have coverage for prescription drugs.

Of those California residents with coverage, an estimated 77 percent obtain their pharmacy benefits through their health plan provider, about 12 percent through a stand-alone PBM, and the remaining 11 percent via a Medi-Cal fee-for-service program.

The majority of California residents with pharmacy coverage are in a health plan that uses a closed formulary model. (A closed formulary generally does not cover drugs not listed in the formulary, although some health plans permit physicians to follow an exception process to obtain approval for a patient to receive coverage for an unlisted drug.) The closed formulary model is much less prevalent outside of California. One likely reason is that many Californians have participated in restricted or closed managed care health plans for years and so appear to be comfortable with more restrictive prescription drug coverage as well.

The three-tier plan, a prescription drug benefit design intended to encourage formulary use, has received significant media attention. Under a three-tier plan, patients have broad access to and choice of prescription drugs, but pay a higher co-pay for drugs not listed on the pharmacy benefit provider's formulary or list of preferred drugs. To date, however, the three-tier plan appears to have generated much greater interest outside California. Nationally, an estimated 35 percent of people with pharmacy coverage were in a three-tier plan as of mid-2000, and more recent reports place this figure at more than 40 percent. In contrast, for those California residents with pharmacy coverage, only 16 percent were in a three-tier plan as of mid-2000.

Several stakeholders and industry experts predict that nationwide, more than 50 percent of people with pharmacy coverage will be in a three-tier plan by the end of 2001, but that the three-tier plan will continue to have slower adoption in California. Many experts believe that the use of three-tier plans in California is relatively low because patients and physicians are generally satisfied with the closed formulary model implemented by many California health plans.

California-based employers will likely implement three-tier plans at a slower pace than the rest of the country because of the perceived success of the closed formulary approaches already in place.

If a physician knows which prescription drugs are included on a closed formulary list—and prescribes effective medications accordingly—patients are not likely to resist the benefit coverage. Consequently, it is understandable that employer plan sponsors in California will proceed cautiously in changing the basic structure of a prescription drug benefit design that appears to be working. However, several health plans, including Health Net, Aetna, and CIGNA, are actively promoting three-tier plans to plan sponsors.

Formulary Development and Management

The major California health plans and large national pharmacy benefit management companies appear to have a similar formulary development process. Most say they make decisions on what drugs to include and exclude based on a dual focus—quality of care and cost management—with quality of care rated the top priority. Despite the seemingly similar development process, the resulting formularies of health plans and PBMs vary considerably.

In general, it appears that formularies established by California health plans are more limited than the national formularies of the large stand-alone PBMs. For example, the publicly available commercial formularies of the major California health plans do not list a drug from the COX II inhibitor class (an arthritis treatment), although all of the large national PBMs include both of the COX II inhibitor drugs currently available. Also, the commercial formularies from three health plans do not include even one angiotensin II inhibitor (a cardiovascular medication), while all of the large national PBM formularies include at least one of the available drugs.

California health plans appear to utilize one of two approaches in the development of their respective formularies:

1. Offer a formulary with limited drug products, but include the market leader, or the drug within each specific class that is most frequently prescribed.
2. Offer expanded choice of drug products, but limit the choice to market followers or less popular drugs.

The coverage of so-called “lifestyle” drugs also varies among health plans. Kaiser Permanente offers relatively broad coverage of many of these lifestyle drugs in its base plan. Some of the other health plans exclude these drugs from the formulary, but make coverage available through a separate premium rider. In self-insured plans administered by a national PBM, plan sponsors decide whether to cover these drugs.

Since California health plans primarily use a closed formulary model, encouraging physician compliance with the formulary tends to be focused on prospective education of physicians about preferred drug choices. Some health plans do a retrospective analysis of prescribing decisions, mainly in the form of physician profiling reports and comparisons. A few health plans periodically share these profiling reports with participating physicians, but financial incentives are not connected with these comparisons.

Under the carved-out prescription drug benefits commonly managed by the large national PBMs, open formularies are prevalent. These PBMs rely upon proactive interventions to encourage therapeutic substitutions designed to assure formulary compliance. They use any combination of written communication, telephone calls, and even face-to-face discussions to influence physicians to modify prescribing decisions immediately or in the future.

While some health plans and industry experts believe that putting physicians at risk for pharmacy costs could be an effective means to improve formulary compliance, all stakeholders concur that risk contracts for prescription drugs are being eliminated in the California marketplace.

Key Findings

Based on the California-focused research done for this report, key findings about prescription drug benefit and formulary designs are as follows:

- ◆ Employers are concerned about the inconsistency of different formularies and the confusion that creates for physicians. Several employers “wish” there were some way for pharmacy benefit providers to work together to facilitate a more consistent approach to the management of prescription drug utilization.
 - ◆ Employers believe that their employees will insist upon better disclosure about which prescription drugs are included on formularies and will increasingly select a health plan on that basis.
 - ◆ While most California-based employers acknowledge the greater use of closed formularies within California, several think that some health plans approve too many formulary exceptions for medical necessity. These employers believe that broader access to drug products under a three-tier plan might ease administration and improve physician satisfaction.
 - ◆ Most health plans, stand-alone PBMs, and employer plan sponsors cite direct-to-consumer advertising by the pharmaceutical industry as a significant contributing factor to increased demand and utilization of specific prescription drugs as well as a good reason to manage prescription drug benefits more tightly.
- ◆ Health plans and stand-alone PBMs rank quality of care as the most important factor in the development of formulary programs. Employers, however, are highly skeptical of the value provided by these supposedly quality-based decisions.
 - ◆ With respect to the rising cost of prescription drug benefits, pharmaceutical companies are perceived as an “adversary” by many health plans and employers in the California health care marketplace, mainly because of perceptions about direct-to-consumer advertising and drug pricing.
 - ◆ Many employers believe that utilization management of prescription drugs could improve if it were made more consistent, for instance, by using best-practice prescribing guidelines with physicians and coordinating the development of point-of-care technology across the industry.
 - ◆ Because research has been sparse, little is known about the impact of prescription drug benefit designs (such as the three-tier plan) on outcomes such as medical costs, quality of care, or indirect value (such as worker productivity). Much of the research to date has been confined to measuring member satisfaction and prescription drug cost savings.

Formularies established by California health plans are more limited than the national formularies of the large stand-alone PBMs.

Forecast of Future Plans and Strategies

Nationwide

- ◆ Employer plan sponsors based outside of California will continue to adopt three-tier plans for self-insured groups as well as groups administered by contracted health plans in order to maintain (or even increase) employee cost sharing while allowing greater access to more prescription drug products.
- ◆ Employer plan sponsors cite achieving short-term savings and keeping benefits competitive as reasons for considering a three-tier plan design. If pharmacy benefit providers eventually show that the three-tier plan is unable to control future benefit trend rates, employer plan sponsors will demand other ideas.
- ◆ Employers will increasingly demand that health plans and stand-alone PBMs do a better job demonstrating the value of pharmacy benefit designs and formulary management to show that best pharmacy practices are in fact driving formulary decisions.
- ◆ The pharmaceutical industry will be pushed by health plans, national PBMs, and employer plan sponsors to demonstrate clearly the value of pharmaceutical therapy and more directly address ongoing concerns about pricing and promotion. Nevertheless, employers will be reluctant to work directly with pharmaceutical companies in helping to demonstrate this value and will be more likely to work through their pharmacy benefit providers.
- ◆ Aware of the demand for a better demonstration of value, pharmacy benefit providers along with industry experts predict a future approach to formulary management that will reflect the value of specific drug products on the overall care of the individual patient. Interestingly, pharmaceutical companies all agree that a value-based approach to formulary management is essential to ensure appropriate utilization and proper medical care.

California

Health plans throughout the United States, as well as several within California, are increasingly promoting the use of three-tier plans. Employers with employees outside California will likely see the use of three-tier plans as a necessary step to maintain consistency and competitiveness of their health benefits nationwide. If the use of three-tier plans by national employers expands in California, competitive pressures may lead health plans and employers predominantly based in California to follow suit.

Even if interest in three-tier plans grows, California-based employers will likely implement these types of plans at a slower pace than the rest of the country because of the perceived success of the closed formulary approaches already in place.

Consumer demand could influence a health plan's decision to implement a three-tier plan design. Closed formularies do restrict access to certain prescription drugs and sometimes to an entire class of drugs. If plan participants begin to perceive that greater access to prescription drugs means improved quality of care, then participant demands on employer plan sponsors could have an impact on health plan offerings and plan design decisions.

California-based stakeholders expect use of the Internet and point-of-care (POC) technology to grow because of the opportunity to make administration more efficient and to improve access to pharmaceutical information, but they are uncertain about the timeline for widespread adoption. At the same time, California-based stakeholders do not expect the use of technology to improve the management of prescription drug utilization or influence physician prescribing decisions. Employers call for more consistency in the development of technology, even asking about the possibility of a joint effort by the pharmacy benefit providers.

II. Goals and Methodology

IN REVIEWING PRESCRIPTION DRUG COVERAGE and the use of formulary in California, this report seeks to:

- Compare prescription drug coverage in California to nationwide coverage
- Assess the prevalence of varying formulary use within California and the United States
- Review the formulary development and management approaches described by various health plans and national PBMs that serve California residents
- Highlight views about benefit provisions and management approaches that affect access to and utilization of prescription drugs
- Offer a forecast of future prescription drug benefit and formulary design.

In addressing these specific objectives, we take into account what has become a national prescription drug debate. Prescription drugs are a major issue for many stakeholders: employer plan sponsors, the government, health plans, national PBMs, and the pharmaceutical industry as well as physicians and their patients. These stakeholders often have conflicting views about such issues as how to:

- Manage prescription drug benefit cost and utilization trend
- Ensure appropriate utilization of the right prescription drug for the right patient at the right time
- Improve the quality of care through the use of consistent information and the efficiency of advanced technologies
- Moderate the impact of aggressive pharmaceutical company promotion to patients and physicians while leveraging the valuable information that is arguably provided
- Determine if there is a positive return on investment from increasing prescription drug benefit expenditures, and if so, what the value of that return is.

This report addresses prescription drug benefit designs and formulary management approaches used by the private payer marketplace. Our research focuses on the stakeholders most responsible for developing prescription drug benefit strategy for this marketplace: health plans, employer plan sponsors, national PBMs, and the stakeholder most often blamed by the others for the increasing prescription drug benefit costs, the pharmaceutical industry.

We do not include input from all stakeholder groups. Physicians, patients, and retail pharmacists are key stakeholders, but rarely have direct input into prescription drug benefit design decisions. And certainly other stakeholders such as unions and county hospitals provide prescription drug coverage in California, but these entities do not change prescription drug benefit design as frequently as employers and health plans.

By compiling input from the marketplace that has been most active in changing prescription drug benefit and formulary design, the private payers, we hope to provide valuable insight for the use of all stakeholders. This report reflects the results of interviews with the following stakeholders:

- ◆ Executives from six of the largest health plans in California, which represent approximately 80 percent of market share.
- ◆ Executives from six of the largest national PBMs—all of which manage prescription drug benefits in California. (For purposes of this report, PBM refers only to stand-alone organizations providing pharmacy benefit management services and not to any division or subsidiary of an HMO or managed care organization supplying similar services through the health plan.)
- ◆ Executives from 12 California-based employer plan sponsors and two prominent employer coalitions, reflecting a representative cross-section of employers and employees that offer or receive prescription drug benefits in

California. (The report combines this input with information gleaned from Mercer's experience as a consultant to similar employer plan sponsors.)

- ◆ Executives from three major pharmaceutical companies.
- ◆ Seven industry experts familiar with prescription drug management as well as the unique aspects of the California health care marketplace.

The majority of interviews took place in the summer and fall of 2000. Some interviews were face-to-face, while others were conducted over the phone. The duration of interviews ranged on average, from one to two hours in length. A complete list of organizations that participated in the interviews can be found in Appendix A.

The report brings together facts and opinions from these stakeholder interviews, as well as published sources and national surveys in an attempt to compile broad viewpoints in one place. Accordingly, the report reflects a qualitative perspective about prescription drug benefits and the use of formulary in California. An upcoming study being completed by the RAND Corporation for the California HealthCare Foundation will provide a quantitative assessment of the overall cost-effectiveness of prescription drug benefit and formulary designs.

In addition, this report builds upon the recently published study on *Prescription Drug Use and Expenditures in California: Key Trends and Drivers*, which was prepared for the California HealthCare Foundation by AdvancePCS. In that report, AdvancePCS emphasizes that prescription drug benefit and formulary design have a significant impact on the resulting utilization of prescription drugs—a finding consistent with the view shared by all of the stakeholders interviewed for this report.

III. A Formulary Primer

Most industry experts consider the formulary the cornerstone for all of pharmacy management.

THE FORMULARY APPROACH—USING A LIST OF selected drugs to manage the cost of medications—had its beginning in hospital-based organizations as a means to better coordinate the variation in number and types of drugs purchased by the hospital. The goal was to limit purchase of the number of different medications used to treat similar diseases or conditions, thereby allowing the hospital to more effectively negotiate competitive pricing with sellers looking for greater market share. The formulary approach worked well in the closed environment of the hospital system and was subsequently adopted in various forms by health plans and stand-alone PBMs.

Most industry experts consider the formulary to be the basis for all of pharmacy management. One expert calls the formulary the cornerstone for all pharmacy management programs developed by health plans and national PBMs. In California, the acceptance of managed care concepts and closed model health plans (such as Kaiser Permanente's) that embrace managed care concepts led to the current widespread use of the closed formulary approach by California-based health plans.

To permit all readers to understand the formulary approach and to supply a common background for this report, we provide the following basic review.

What Is a Formulary?

A formulary is a list of prescription drugs recommended to patients and prescribers. In its simplest form, a formulary is a list of FDA-approved products covered by the health plan. In its most complex form, according to pharmacy benefit providers, a formulary is a complete system created to provide the best possible care for all patients through clinically and economically appropriate use of drugs.

A formulary is developed and maintained by a formulary committee, usually called a pharmacy & therapeutics (P&T) committee. Most pharmacy benefit providers have a P&T committee and at least one type of formulary in place.

One of the most controversial financial elements associated with a formulary is the use of pharmaceutical manufacturer “rebates.” Most pharmacy benefit providers describe rebates as discounts that pharmaceutical companies pay them to reflect factors such as total volume and/or market share of particular drug products. For example, a typical prescription drug might cost \$50. The manufacturer may agree to retrospectively pay the PBM or MCO a \$5 rebate. In turn the PBM or MCO may share a portion of that rebate with the plan sponsor. Ardent critics of rebates often refer to them as pharmaceutical company “kickbacks.” The value of earned rebates is typically reflected in financial arrangements offered to employer plan sponsors. Under an insured arrangement, rebates may be used to reduce the premium cost or offset administrative fees. Under a self-insured arrangement, usually in a carve-out prescription drug plan through a national PBM, a portion of the rebates is commonly shared to reduce employer plan sponsor costs.

Types of Formularies

To meet the varied demands of plan sponsors and to provide them with a continuum of approaches for managing the cost of prescription drug benefits, health plans and national PBMs have developed several types of formularies. Because customized formularies are required for different purposes, it is not uncommon for a particular health plan or stand-alone PBM to maintain numerous formulary lists within the following basic types of formularies:

An open or voluntary formulary, a broad list of drugs suggested by the PBM or health plan, acts as a prescribing guide for physicians and usually provides information about the relative cost index of alternative prescription drugs within a particular class. In general, there is no penalty to physician or patient if either elects to deviate from the formulary suggestion.

An incentive-based formulary is a multiple-tier co-pay plan, which pharmacy benefit providers commonly promote as incentive-based. The typical approach includes three co-pay levels (a three-tier plan): The lowest co-pay is for generic drugs; the next highest co-pay is for formulary or preferred drugs; the highest co-pay is for “non-preferred”—and typically nonformulary—drugs. Characteristically, the co-pay tiers are fixed dollar amounts (\$5, \$15, and \$30), but occasionally, the tiers are based on percentage co-pay (10 percent, 20 percent, and 50 percent). According to almost all of the PBMs and health plans interviewed, most, if not all, multi-source, brand-name drugs (brand-name drugs that have come off patent and have approved generic substitutes) are subject to the nonpreferred co-pay tier under three-tier plans. Some pharmacy benefit providers have introduced four-tier and five-tier plans with further variations on formulary and nonformulary product selections.

A restricted formulary limits coverage of some specific drugs or classes of drugs to those prescribed by certain physicians or specialists with expertise in a particular medical condition. Examples are long-acting beta blockers that may require continued monitoring by a qualified cardiologist, or medications used to treat infertility that require oversight by an infertility specialist or reproductive endocrinologist. Under this type of formulary, drugs prescribed by physicians not specified by the formulary are not usually covered by the plan.

A step-care formulary requires patients and physicians to follow a particular sequence of drug treatment. In general, a patient must fail to respond to a recommended first-line therapy before a second- or third-line medication is prescribed. What this typically means is that patients will be asked to try medications that have been on the market for a longer period of time and are usually less expensive than the newer medications available to treat a specific condition. For example, use of the newer COX II inhibitor anti-inflammatory drugs for relief of arthritic pain or proton pump inhibitors (PPIs) for treatment of gastrointestinal conditions may be subject to a step-care formulary approach under some health plans and PBM programs.

Ardent critics of rebates often refer to them as pharmaceutical company “kickbacks.”

Some pharmacy benefit providers have introduced four-tier and five-tier plans.

A closed or mandatory formulary limits benefit coverage to formulary medications only. Typically, the patient is required to pay the full cost of any nonformulary drug unless a prior authorization has been received. In many cases, a closed/mandatory formulary will contain several elements of the formulary types described above, and may be considered a “partially closed” formulary. For example, certain therapeutic classes may be closed, some may be restricted, and others may be open. Typically an appeals process is made available to plan members for particular drugs that are not covered. If the appeal is approved, then the member is usually charged the co-pay amount established for formulary drugs.

For purposes of this report, restricted, step-care, and closed/mandatory formularies are categorized as closed formularies because they can all result in a denial of a prescription under pre-defined circumstances.

IV. A Profile of Prescription Drug Coverage in California

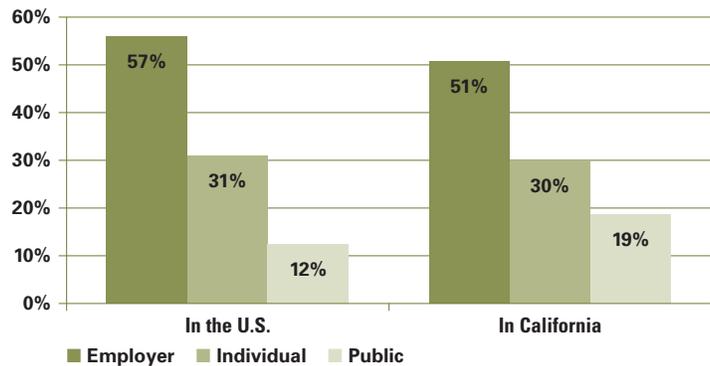
California has a higher percentage of people receiving their prescription drug coverage through some type of public program than does the United States as a whole.

Who Pays for the Cost of Prescription Drugs?

Employers are the largest payers of prescription drug benefits in California. (State and local governments as well as state universities that buy coverage for their employees are considered to be employers in Figure 1.) Programs funded by employers account for approximately half of all prescription drug coverage.

California has a higher percentage of people receiving their prescription drug coverage through some type of public program than does the United States as a whole. Public programs financed by the state and federal governments, which include both Medicare and Medicaid HMOs, as well as the Medi-Cal fee-for-service program, are responsible for providing coverage for about 19 percent of the state's population. The remaining 30 percent of California residents either pay for pharmacy coverage through individually purchased or private non-group insurance or do not have pharmacy coverage and pay for the cost of prescription drugs directly.

Figure 1. Who Pays for Prescription Drug Benefits in the United States and in California?

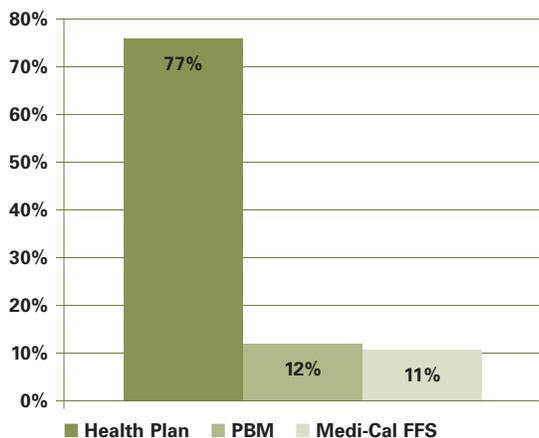


Sources: *Prescription Drug Trends—A Chartbook*, The Henry J. Kaiser Foundation, July 2000. 1996 data. William M. Mercer, Inc., data derived from survey and related research, 2000.

Who Provides Prescription Drug Coverage in California?

Of those California residents with prescription drug coverage, it is estimated that approximately 77 percent receive prescription drug benefits directly through their health plan. Health plans include those serving commercial HMO members, Medicare and Medicaid populations, as well as other health care plans such as point of service (POS) plans and preferred provider organizations (PPOs). For the remaining covered California residents, employer-sponsored prescription drug benefits are provided to 12 percent through a stand-alone PBM and to 11 percent through the Medi-Cal fee-for-service program (see Figure 2).

Figure 2. Sources of California Prescription Benefit Drug Coverage



Source: William M. Mercer, Inc., 2000.
Includes only residents with prescription drug coverage.

Nationally, approximately 16 percent of all Medicare eligibles were enrolled in a Medicare HMO as of January 2000 compared to about 40 percent in California.

Table 1 demonstrates a picture of overlapping complexity in how prescription drugs are currently obtained by different population segments. This complexity is not unique to California.

Add to this complexity the following possibilities:

- ♦ Plan participants can decide at any time to purchase medications outside of their plan simply by not using the plan's identification card and acting like any consumer.
- ♦ Some HMO plans maintain in-house pharmacies while others outsource some or all pharmacy services to a carve-out PBM.
- ♦ Discount cards—from both retail and mail-order pharmacies—are being introduced that allow almost anyone to join a pharmacy discount plan at a nominal fee.

All these multiple and overlapping arrangements make management of appropriate utilization through prescription drug benefit and formulary design a highly challenging proposition.

Table 1. How Prescription Drugs Are Currently Delivered

Segment	Indemnity/ PPO plans	HMO plans	Carved-out PBM plan	Discount card
Employer	Yes	Yes	Yes	No
Medicare	No	Yes	Yes	Yes
Medicaid	Yes	Yes	No	No
Uninsured	No	No	No	Yes

Public Programs

Lack of health care coverage in general, and prescription drug coverage in particular, continues to be a concern throughout California as it is in the rest of the country. Many Californians are unable to buy needed medications and may in fact ultimately generate higher medical expenses if essential drugs are not available to them. According to a 1999 report, approximately 24 percent of the non-elderly California population (7.3 million) did not have health insurance coverage in 1998.¹ Furthermore, an estimated 31 percent of all Medicare beneficiaries in California do not have prescription drug coverage.²

Medicare. Penetration of the Medicare HMO market is much higher in California than it is nationwide. Nationally, approximately 16 percent of all Medicare eligibles were enrolled in a Medicare HMO as of January 2000 compared to about 40 percent in California.^{3,4} California's comparatively higher enrollment figure may be due in part to the greater acceptance of managed care penetration and utilization in California compared to much of the United States.

According to the most recent national statistics available, 70 percent of all Medicare beneficiaries have some type of prescription drug coverage. The sources of this coverage are employer-sponsored health plans (31 percent), Medicare+Choice plans (16 percent), Medigap (10 percent), and Medicaid (11 percent). However, many Medicare eligibles who have prescription drug benefits through a Medicare+Choice plan are faced with reductions in prescription drug benefits or possible termination of drug coverage by some health plans.^{5,6}

Most of the Medicare+Choice plans offered in California provide some level of prescription drug benefits. It is unclear how many of the individuals in these plans will be dropped from coverage as health plans continue to cut back or withdraw from the Medicare managed care market. A recent estimate from the California Medicare Project placed the number at 3.7 percent of all California Medicare managed care enrollees, or about one out of every ten enrollees.⁷ As shown in Table 2, two health plans (Kaiser and PacifiCare) currently hold an estimated 1.15 million (almost 70 percent) of California's Medicare+Choice contracts.⁸

According to another California HealthCare Foundation report, an estimated 31 percent of Medicare managed care enrollees within California will experience increased prescription drug co-pays in 2001, while the maximum prescription drug benefit amount will be reduced for about 30 percent of all Medicare enrollees.⁹

Table 2. Medicare+Choice Health Care Coverage in California

Name of Plan (multiple products may be included)	HMO Members Covered by Prescription Drug Benefits (as of 1/1/2000)
Kaiser Foundation Health Plan, Inc.	600,000
PacifiCare	550,000
Health Net	150,000
Blue Shield	82,000
Aetna U.S. Healthcare	67,000
Blue Cross	35,000
Maxicare	11,000
Total	1,500,000

Sources: *The InterStudy Competitive Edge 10.2*; William M. Mercer, Inc. MVP Database; self-reported data from health plan interviews; all figures rounded.

A relatively smaller percentage of California residents (only 12 percent) receive prescription drug coverage directly from a stand-alone PBM compared to elsewhere in the country (about 35 percent to 40 percent).

Medicaid. In 1999, approximately 15 percent of California's population (about 5 million people) were covered under Medi-Cal, California's Medicaid program. The program serves families and other individuals receiving cash grants through programs such as Temporary Assistance to Needy Families or Supplemental Security Income. California's Medicaid population is the largest of any state in the United States. Nationwide, slightly more than 11 percent of the population (roughly 32 million individuals) are enrolled in Medicaid programs.^{10,11}

At present, Medi-Cal eligible enrollment in California is fairly evenly divided between fee-for-service programs and managed care plans. Historical coverage numbers show a downward trend in fee-for-service enrollment, with a corresponding increase in the Medi-Cal managed care plan.¹²

Employer-Sponsored Drug Coverage

Nationwide, many employees have prescription drug coverage directly through a national PBM. This occurs when an employer decides to move prescription drug coverage from the health plan to a stand-alone PBM, commonly described as a carve-out. Carve-out prescription drug benefits are usually limited to the self-insured plans offered by an employer.

A relatively smaller percentage of California residents (only 12 percent) receive prescription drug coverage directly from a stand-alone PBM compared to elsewhere in the country (about 35 percent to 40 percent).¹³ However, these stand-alone PBMs indirectly provide coverage to many more individuals in California by acting as outsourcing services to health plans.

More than half of the HMOs in California outsource major components of their pharmacy benefit services to a carve-out PBM. As shown in Table 3, certain national PBMs provide services to several health plans covering a significant number of people in California. Prescription drug claims processing and mail-order pharmacy services are most often outsourced. Some health plans also outsource the management of formulary and clinical programs to a national PBM.

Health plans explain that outsourcing of pharmacy benefit management is done for a variety of reasons, including capitalizing on efficiency and leveraging the larger book of business owned by a national PBM. However, some industry experts contend that outsourcing may be an impediment to integrated health care management if the prescription drug data is not effectively used in the management of overall care.

Table 3. Services Provided by a National PBM*

National PBM*	Services provided by a National PBM*					
	Health Plan	Claims Processing	Retail Network	Mail Order	Formulary	Clinical Programs
AdvancePCS	Lifeguard		■	■	■	■
	Health Net (some plans)	■	■	■	■	■
Argus	BS of CA	■				
	CIGNA	■				
EDS	Medi-Cal	■				
Express Scripts	BS of CA			■		
	National Health plans	■	■	■	■	■
	Aetna U.S. Healthcare			■		
MedImpact	Kaiser	■†	■			
	Maxicare	■				
	Universal Care	■		■	■	
Merck-Medco	United HealthCare	■	■	■		■
Walgreens	Health Net			■		

Sources: Survey of California-based health plans, William M. Mercer, Inc. MVP database.

† (for all IPA)

*PBM provides service for one or more of the plans offered by the health plan. Argus and EDS provide mainly pharmacy data processing services compared to the comprehensive services provided by the other organization listed.

V. Formulary Use in California

Employers want pharmacy benefit providers to figure out a way to offer more consistency among their formularies and their efforts to encourage formulary compliance by physicians.

THROUGHOUT THE UNITED STATES, EMPLOYERS rely heavily upon their pharmacy benefit providers to determine the type of formulary that will be used. As might be expected, the managed care environment in California, which has embraced the closed formulary model, has produced a very different profile of formulary use compared to outside California. Furthermore, the perceived success achieved by the closed model formulary in California appears to result in less employer interest for health plans to generate alternative formulary approaches.

Employers' Understanding of Formulary

Most employers appear to understand and accept that formulary lists vary by pharmacy benefit provider. Several employers express a desire for pharmacy benefit providers to figure out a way to offer more consistency in their formularies and their efforts to encourage formulary compliance by physicians.

Probably because employers rely upon the pharmacy benefit provider to make formulary decisions, they have limited familiarity with the various types of formulary approaches. In fact, some employers acknowledge that they have adopted a hands-off approach with respect to HMO prescription drug benefits so that when employees complain, they can hold the HMO responsible. Most employers categorize formularies as either open or closed, and they usually connect open formulary with their self-insured arrangements and closed formulary with their insured arrangements.

Almost half of the employers interviewed initially insisted that there was “no formulary” within their non-HMO, or self-insured, prescription drug plans. However, when questioned, most acknowledge that rebates are included in the financial arrangement from their pharmacy benefit providers. California-based employers, accustomed to closed formulary models within HMO plans, apparently do not view an open approach as a “real” formulary since members have access to almost any medication. In contrast, the conventional belief among many employers outside California appears to be that an open formulary combined with communication efforts to encourage formulary compliance constitutes fairly aggressive formulary management.

A national benefit survey has shown year after year that a greater percentage of large employers report using formulary within their pharmacy program than do smaller employers.¹⁴ This finding is inconsistent with the fact that pharmacy benefit providers employ formulary across their entire book of business—regardless of employer size. It may be that a greater number of large employers self-insure their health benefits compared to smaller employers, and therefore are at risk for prescription drug expenditures. It is also possible that pharmacy benefit providers may not educate smaller employers as effectively as they do larger employers.

Table 4. Percent of Individuals Enrolled in Three Major Formulary Benefit Designs Within Major California-Based Health Plans in 2000

	Open	Three-Tier	Closed
Aetna	20%	75%	5%
BC of CA	0%	4%	96%
BS of CA	1%	43%	56%
Health Net	18%	40%	42%
Kaiser	0%	0%	100%
PacifiCare	5%	16%	79%
Health Plan Average	4%	16%	80%

Source: Estimates derived from data reported by the health plans and interviews for this report. Health plans represent approximately 80 percent of California market.

What Types of Formularies Are Used in California?

California-based employers have some type of formulary in place for almost all covered populations, either through their health plan or with a stand-alone PBM. Employers confirm that they rely on their health plan to choose the appropriate formulary, and most do not review formulary decisions made by the health plan. The prevalence of the three major types of formularies used by California health plans is shown in Table 4.

The California health plans and large national PBMs interviewed generally agree that interest in a three-tier plan is increasing. Employers using an HMO are more likely to keep pharmacy benefits with the HMO, while larger employers providing a PPO, POS, and/or indemnity plan(s) frequently, although do not always, carve out prescription drug coverage to a stand-alone PBM. However, even reflecting carve-out prescription drug coverage with the national PBMs, the percentage of total California residents enrolled in three-tier plans is relatively low.

As shown in Table 5, a greater percentage of the employer clients of national PBMs have opted to move to a three-tier plan (41 percent) than the employer clients of HMOs (16 percent).

Table 5. California Enrollment by Type of Formulary and Pharmacy Benefit Provider

Pharmacy Benefits Provider	(% of Individuals Enrolled)		
	Open	Three-Tier	Restricted/Closed
Health Plan	4%	16%	80%
National PBM	56%	41%	3%
Medi-Cal FFS	0%	0%	100%
Total	10%	17%	72%

Source: Estimates derived from self-reported data by PBMs and health plans interviewed for this report. Distribution includes covered individuals only. Health Plan includes HMOs.

Employers rely on their health plan to choose the appropriate formulary, and most do not review formulary decisions made by the health plan.

Despite the current slow pace, one industry expert predicts that prescription drug benefit design in California will increasingly adopt a multitier approach, in particular the three-tier plan, over the next two years. This expert also expects that when California employers eventually make this change, they will ultimately lead the way in innovative ideas about how to use multitier plans effectively to manage prescription drug utilization.

National PBMs concur that certain California employers may be leading the way. The largest California-based employers serviced by PBMs appear more willing to implement a three-tier copay plan design than do smaller employers in the state (Table 6). The PBMs speculate that this could be because large employers are more likely to have employees in different states, where three-tier plans are more prevalent. Thus, it is conceivable that the shift to three-tier plans for employer groups outside California will eventually influence more widespread adoption within California.

Table 6. Enrollment by Type of Formulary Under Self-Insured Employer Plans (as reported by PBMs)

	Open/ Voluntary	Three- tier	Closed
Book of Business (Nationwide)	61%	37%	2%
Large Employers (in California*)	74%	26%	0%

Source: Mercer PBM database, October 2000.

*Based on the five largest employer clients in California as reported by each PBM.

Use of Three-Tier Plans Is Growing

Nationwide, HMOs utilize closed and/or restricted formularies more often than other pharmacy benefit providers.¹⁵ Most California health plans believe that a closed formulary encourages formulary compliance better than a three-tier plan. In contrast, the national PBMs administering open formularies generally view the three-tier plan as a means for increasing formulary compliance.

According to a report tracking the use of three-tier plans, 80 percent of pharmacy benefit providers nationwide now have a three-tier plan option available and 35 percent of covered individuals are enrolled in a three-tier plan. Moreover, the percentage of individuals covered under a three-tier plan nationwide has been doubling in each of the past two years (see Table 7).

Table 7. National Enrollment in Three-Tier Plan Designs

	% of Pharmacy Benefit Providers Offering Three-Tier Plans	% of Individuals Enrolled
Spring 1998	36%	9%
Spring 1999	60%	16%
Spring 2000	80%	35%

Source: BW HealthWire, August 2000, from Scott-Levin, Managed Care Formulary Drug Audit.

New data recently released by the Health Industries Research Companies (HIRC) indicates this trend should continue. In February 2001, the HIRC reported 40 percent of HMOs and 50 percent of large employers use three-tier plans, and predicted that 60 percent of prescription drug benefit recipients nationwide will be covered by a three-tier plan by the end of 2002.¹⁶

Another related study reports that more than 40 percent of three-tier plans now in place have a \$15 differential between the “preferred” and “nonpreferred” co-pay amounts.¹⁷ The HIRC report supports this finding, predicting that the average co-pays will be \$25 for preferred drugs and \$40 for nonpreferred drugs within the next two years.¹⁸

California employers are adopting three-tier plans at a slower pace than employers nationwide. Industry experts maintain that this slower adoption is the result of California employers having offered health plans with closed formulary for a longer time period and with relatively high employee satisfaction compared to employers based outside California. Health plans agree with the industry experts, pointing out that a lack of evidence demonstrating the cost effectiveness of three-tier plans is likely causing California employers to be more hesitant about moving from the more managed approach provided by closed formularies. In fact, under the progression of formulary management commonly promoted by national PBMs, changing from closed formulary to a three-tier plan could be perceived as a step backward in effective formulary management within California. Pharmaceutical companies, on the other hand, view three-tier plans more favorably than closed formularies since plan members have greater access to any medication their physician prescribes.

California employers, according to PBMs, are showing a growing interest in three-tier plans, as evidenced by an increasing number of requests for cost projections related to this type of formulary. These national PBMs believe that employers are interested in the choice and access offered by the three-tier plan.

Who Offers What Types of Formularies?

Health plan formularies. Health plans operating in California all report using a single, base formulary for the different products offered, with some minor variation by geographic location within the state. For example, Kaiser reports that there are some “minor” differences between its closed formularies in Northern and Southern California, but that those differences account for only a small percentage of the formulary listed drugs. Kaiser expects these differences to disappear in the future since the regional plans intend to adopt a more uniform formulary in Northern and Southern California. Similarly, PacifiCare indicates that while its formulary does not differ by employer plan sponsor, employers can purchase riders for drug categories that are excluded from the health plan’s formulary, such as smoking cessation drugs.

To meet the varying needs of their customer base, most health plans in California offer different benefit options. For example, Health Net actively promotes a three-tier plan, citing the broader access to medications as a major selling point, although its Medicaid HMO product uses a restricted/closed formulary. By comparison, PacifiCare has most of its HMO, PPO, POS, and indemnity plan participants in a closed/restricted formulary and feels strongly that this approach—if managed well—can be just as patient friendly as a three-tier plan.

Kaiser considers its approach to be closed formulary, and reports that formulary compliance is exceptionally high, consistent with the typical closed formulary experience. Nevertheless, Kaiser physicians can prescribe nonformulary medications by simply following established medical exception prescribing procedures, which means its “closed” formulary essentially operates like the open formulary.

Stand-alone PBM formularies. Most national PBMs that manage carved-out prescription drug benefits offer formulary options. The objective of each formulary is to provide a varying level of drug product choices in all therapeutic categories. While there may be a number of reasons why an employer plan sponsor selects one type of formulary over another, the PBMs believe that cost is usually the most significant factor in an employer’s decision about which formulary option to use.

To respond to different plan sponsor needs, most stand-alone PBMs provide more than one option and/or more than one way to administer the formulary. All the PBMs interviewed offer open/voluntary, incentive-based, and closed/restricted formularies, viewing these alternatives as a progression in the intensity of formulary management. The underlying formulary for each of these plan designs can be the same or different depending on the PBM.

Examples from two major national PBMs illustrate the range of formulary approaches offered. One offers a standardized approach with only a single formulary, encourages plan sponsors to utilize that formulary, and generally discourages customization. Another employs a distinctive approach nationally publicized as the “*BID GRID*” but now known as the “*Preferred Savings*” grid. Under this approach, plan sponsors can select from a matrix of formulary list options and types of formulary management approaches (open, incentive-based, or closed). Though other PBMs report achieving comparable financial savings through different mechanisms, this

particular PBM’s approach appears to allow customers greater decision making ability in formulary selections. The foremost national PBMs have all published studies that consistently estimate prescription drug benefit costs can be reduced from 5 percent to 15 percent through formulary management alternatives.¹⁹

PBMs report no significant variations in formulary design by employer plan sponsor or geographic location within California, with the exception of rural areas where there is less enforcement of restrictive formulary designs. National PBMs also note that collectively bargained groups and Taft-Hartley trusts tend to have pharmacy benefit plans with low co-pays and minimal formulary management. This observation is consistent with general experience about the plan design differences within a given employer’s benefit program, but conflicts with the information provided by the employers interviewed. One PBM does mention that Taft-Hartley trusts in southern California are becoming somewhat aggressive in implementing formulary management programs, more so than their counterparts in northern California.

Employer formulary selections. As previously noted, employers are more likely to carve out self-insured plans to a stand-alone PBM, and less likely to include more restrictive design elements. Formulary approach appears to vary by type of employer and size of the covered population. Larger employers as well as employers in benefits-sensitive situations (such as tight labor markets or high-growth business areas) tend to offer richer benefits in general, including prescription drug benefits, within their self-insured plans. These employers prefer more passive formulary management in their self-insured plans, and indicate practically no interest in a closed formulary, yet they also offer HMO options with closed formularies. They consider this apparent inconsistency acceptable as the “best approach” that can be employed given that different pharmacy benefit providers are used.

VI. The Formulary Decision Process

Since employers rely on pharmacy benefit providers to determine their formulary approach, many employers do not have a thorough understanding of how these decisions get made.

FORMULARY DECISIONS DIRECTLY IMPACT THE access and choice of prescription drugs available to plan participants. Since employers rely on pharmacy benefit providers to determine their formulary approach, many employers do not have a thorough understanding of how these decisions get made. Almost all employers are unaware of which therapeutic classes are most often affected by formulary decisions. Also, while employers express concern that physicians are confused by the differences among pharmacy benefit provider formularies, they have limited comprehension of what these differences actually are. This description of the decision process used for including or excluding drugs in the formulary should help clarify the picture.

How It Works

The formulary development process described by the California health plans and large national PBMs interviewed for this report is similar. Each health plan and national PBM maintains a P&T committee with members representing various medical specialties. The majority of P&T committee members are not employees of the health plan or PBM. The function of the P&T committee is to make formulary decisions that result in appropriate and sound drug choices for the health plan members.

Kaiser's formulary approach differs somewhat from the other health plans in that its P&T committee consists of medical group employees—Kaiser physicians representing both northern and southern California—rather than a committee of external individuals. Kaiser does not really have to encourage physicians to comply with the formulary since the medical group already has buy-in. Kaiser's formulary documentation includes detailed clinical criteria that support the formulary list.

The number of P&T committee members ranges from 15 to 30. The committees of all of the health plans and PBMs interviewed include physicians and clinical pharmacists and most include members who are employees. To balance the input, some national PBMs include qualified clinicians from prominent managed care clients. Even though most P&T committees include both internal (employee) and external members, not all members are allowed to vote. For example, one health plan's P&T committee, with almost 30 members, includes

both clinical and medical professionals, as well as a guidelines committee that conducts necessary research. While everyone votes on inclusions to the formulary list, only physicians and clinical pharmacists vote on matters of medical interpretation.

Support staff usually assist the P&T committees to prepare clinical reviews and cost information about the drugs as well as to organize meeting agendas. They review drugs in development and prepare detailed clinical and cost reviews based on published data, information from the manufacturer, and in some cases interviews with specialists such as principal investigators.

The majority of P&T committees convene at least quarterly. Some health plans' P&T committees meet more frequently when deemed necessary. The P&T committee for one health plan meets six times per year, although voting occurs at only four meetings.

All the health plans and PBMs explain that their P&T committees use an evidence-based approach, meaning that the committee relies on published scientific information and evidence about the efficacy of the products to make decisions regarding the addition or deletion of specific drugs to the formulary. While the approach is clinical in terms of evaluating the efficacy of each particular drug, committee

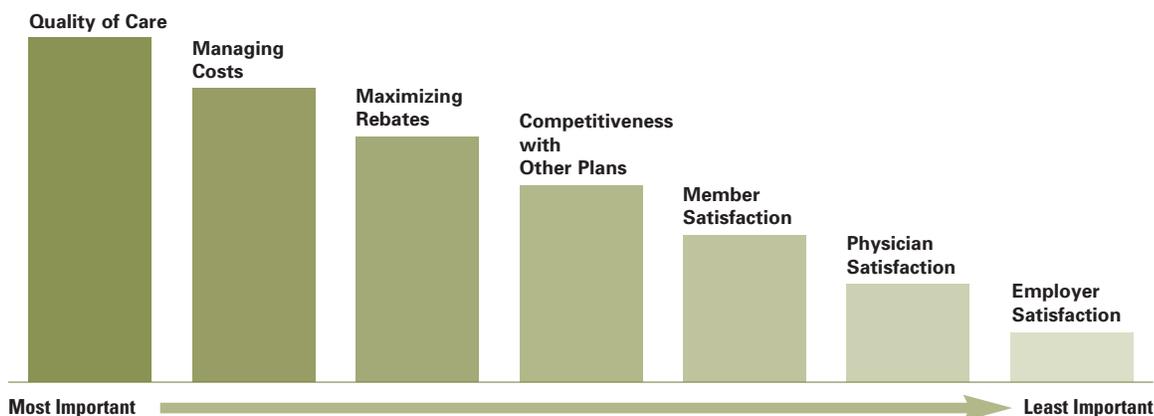
members also take other factors into account, such as safety and relative value compared to other products in the same therapeutic class.

To prevent P&T committee members from being unduly influenced by outside sources, many health plans and PBMs do not allow pharmaceutical companies to have direct access to formulary decision makers. Pharmaceutical company representatives are prohibited from attending P&T committee meetings, and some health plans and PBMs do not publicize the identities of their committee members.

In general, pharmacy benefit providers consider a new drug for formulary inclusion only after it is approved by the FDA, becomes available on the market, and is supported by peer-reviewed literature. Some health plans make exceptions for "life-saving" drugs, and will review these immediately upon approval by the FDA.

Most PBMs have established a process to hold an ad hoc P&T committee meeting via conference call or ballot to make timely decisions on new therapeutic breakthrough drugs. Some health plans and PBMs employ a three- to six-month waiting period to consider a new drug for formulary, unless economic incentives make it beneficial to review it sooner. Until a formulary review is completed, new drugs are automatically considered nonformulary and therefore may be subject to the third-tier co-pay under a three-tier plan, prior authorization under a closed formulary, or even non-covered status.

Figure 3. Health Plans: Importance of Factors in Formulary Design Development

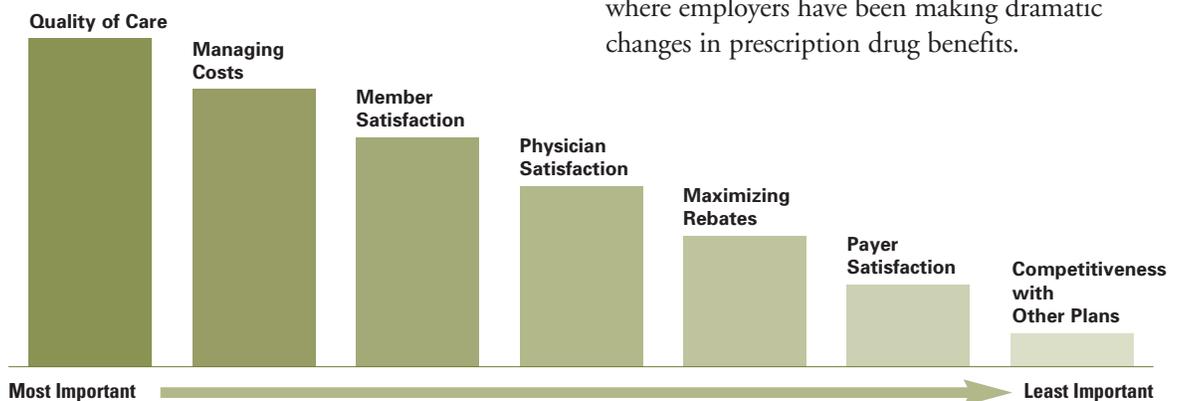


Criteria for formulary inclusion. In their selection process, most health plans and PBMs say they focus on both quality of care and cost management, but view quality of care as the first priority. While all the pharmacy benefit providers interviewed state that cost plays a secondary role in formulary development, two health plans acknowledge that they take drug price and/or formulary rebates (net unit cost) into consideration in the decision process.

Many employers and industry experts are skeptical that health plans and stand-alone PBMs use formulary primarily to improve health maintenance or manage patient care; instead they believe that formulary is mainly used to help offset prescription drug benefit cost increases. Their viewpoint is buttressed by the fact that prescription drug benefit cost can be measured but, as all stakeholders agree, the other areas of potential value are difficult to measure.

Several California health plans hint that as drug costs continue to rise, cost will come into play more often in the selection process, shifting the focus to the products with the lowest average wholesale price (AWP). One health plan acknowledges that most of its currently negotiated manufacturer contracts are market share driven—that is, driven by many pharmaceutical companies’ willingness to offer rebates or better financial arrangements if more of a particular drug product is used.

Figure 4. National PBMs: Importance of Factors in Formulary Design Development



One national PBM challenges the notion that market share–driven rebate arrangements are limited, claiming that in fact all health plans and national PBMs have negotiated such arrangements with pharmaceutical companies. The pharmaceutical companies agree but point out that some companies are moving back to financial arrangements based on drug product position within the formulary rather than payment for increased market share.

The results of health plans’ and national PBMs’ ranking of seven criteria in selecting formulary drugs (from most important [1] to least important [7]) are shown in Figures 3 and 4. *Note:* All the participating health plans and PBMs state that all the criteria asked about are important.

While quality of care and cost management are most important for both health plans and national PBMs, the health plans express a stronger need to remain competitive with other health plans than do the PBMs with their counterparts. This is understandable since health plans compete more directly with each other on a local basis than do the national PBMs. Also, PBMs rank concern for member satisfaction with the formulary design higher than do the health plans. The California health plans explain that member and physician satisfaction is somewhat stabilized since many of the health plans have used a consistent formulary approach for years. As a result, members and physicians have become accustomed to a closed formulary model and do not tend to voice objections as frequently as in the stand-alone PBM environment, where employers have been making dramatic changes in prescription drug benefits.

Comparing Health Plan and PBM Formularies

Despite seemingly similar approaches and criteria used in formulary development, formulary lists vary considerably among health plans and national PBMs. A side-by-side comparison of the most widely utilized formularies of the California

health plans and the national PBMs is shown in Tables 8 and 9. The comparison focuses on the single source brand-name drugs for commonly used therapeutic classes. (Note that health plans frequently provide access to therapeutic classes not included in the formulary either through an exception process or with a coverage rider.)

Table 8. Comparison of Single Source Brand-Name Drugs in Common Therapeutic Classes: Health Plans

	Kaiser—Northern CA	Kaiser—Southern CA	PacifiCare	Health Net	Blue Shield of CA	Blue Cross of CA
Proton Pump Inhibitors	Prilosec	Prilosec	Aciphex Helidac Protonix	Aciphex Prilosec Protonix	Aciphex Protonix	Prevacid Prevpac
SSRI Antidepressants	Paxil Prozac	Paxil Prozac	Celexa Paxil	Celexa Paxil Prozac Zoloft	Celexa Paxil Prozac	Celexa Luvox Paxil Prozac Zoloft
Angiotensin II Inhibitors	None*	None*	None*	Diovan	Diovan	Avapro Diovan
Cholesterol Reducing Drugs	Mevacor Zocor	Mevacor Zocor	Baycol Pravachol	Lescol Lipitor Pravachol	Baycol Lescol Lipitor	Lescol Lipitor Pravachol
Ace Inhibitors	Prinivil Zestril	Prinivil	Lotensin Univasc Zestril	Accupril Lotensin Monopril Zestril	Lotensin Monopril Prinivil	Accupril Lotensin Monopril Zestril
COX-II NSAIDs	None*	None*	None*	None*	None*	None*
Calcium Channel Blockers	None*	Plendil	Cardene SR DynaCirc Plendil Sular Tiazac	Nimotop Norvasc Plendil Sular	Plendil Sular Tiazac	DynaCirc Norvasc Plendil Sular Vascor
Migrane Drugs	Imitrex	Amerge Imitrex Maxalt	None*	Amerge Imitrex Maxalt	Amerge Imitrex Maxalt	Amerge Imitrex Zomig
Non-sedating Antihistamines	Allegra	Allegra Claritin	Allegra Claritin	Allegra Claritin	Allegra Claritin	Allegra Claritin

Sources: Commercial HMO formularies as of October 2000.

*There are no single source brand-name drugs listed. This does not indicate whether generic drugs are listed.

Table 9. Comparison of Single Source Brand-Name Drugs in Common* Therapeutic Classes: National PBMs

	Caremark	Express Scripts (National Formulary)	Merck-Medco (Preferred Prescriptions Formulary)	AdvancePCS
Proton Pump Inhibitors	Prevacid	Prevacid Prilosec	Prilosec Protonix	Aciphex Prevacid Prilosec Protonix
SSRI Antidepressants	Prozac Zoloft	Paxil Prozac Zoloft	Paxil Prozac Zoloft	Celexa Luvox Paxil Prozac Zoloft
Angiotensin IIs	Avapro Diovan	Atacand Avapro Cozaar Diovan Micardis	Atacand Cozaar Diovan Hyzaar Micardis	Avapro Cozaar Diovan
Cholesterol Reducing Drugs	Lipitor Pravachol	Baycol Lipitor Pravachol	Baycol Lipitor Zocor	Baycol Lescol Lipitor Pravachol Zocor
Ace Inhibitors	Accupril Monopril Zestril	Accupril Lotensin Mavik Zestril	Accupril Altace Lotensin Prinivil	Accupril Altace Lotensin Mavik Monopril Univasc Zestril
COX-II NSAIDs	Celebrex Vioxx	Celebrex Vioxx	Celebrex Vioxx	Celebrex Vioxx
Calcium Channel Blockers	Covera-HS Norvasc Tiazac	Norvasc Plendil Tiazac	Covera-HS Verelan	Cardene SR Dynacirc CR Norvasc Plendil Sular Tiazac
Migraine Drugs	Amerge Imitrex Zomig	Amerge Imitrex Maxalt	Amerge Imitrex Maxalt	Amerge Imitrex Maxalt Zomig
Non-sedating Antihistamines	Claritin	Allegra Claritin	Allegra Claritin	Allegra Claritin

Source: Published PBM formularies, 2000.

*Some PBMs have introduced subclasses, but the most prevalent categorization has been used for this comparison.

In general, formularies established by the California health plans appear more limited than the national formularies of the large stand-alone PBMs. For example, none of the health plans include either drug (Celebrex or Vioxx) included in the latest class of drugs (COX II inhibitors) used to treat acute and chronic pain and inflammatory conditions such as arthritis on their commercial formularies. All of the large national PBMs include both drugs. Also, half of the health plan formularies do not include any of the angiotensin II inhibitor drugs used to treat hypertension, while all of the national PBM formularies include at least one.

Among the California health plans, one of two alternative approaches in the development of their respective formularies is apparent:

1. Offer a formulary with limited drug products, but include the market leader, or the drug within each specific class that is most frequently prescribed.
2. Offer an expanded choice of drug products, but limited to market followers or less commonly used (or popular) drugs.

It was not possible to assess the cost rationale behind formulary decisions. While the list prices of drugs are published, the amount of formulary rebate earnings by drug is not typically disclosed; thus relative net cost can not be compared. The relationship between pharmacy benefit providers and pharmaceutical manufacturers can be complex, given the level and number of different pricing structures in use. Pharmacy benefit providers contend that manufacturer arrangements are proprietary in nature, therefore little information about how rebates are designed and passed from manufacturer to pharmacy benefit provider is known. Interestingly, some pharmaceutical manufacturers indicate that the arrangements might not be as proprietary as pharmacy benefit providers say they are.

“Lifestyle” drugs. Health plans and stand-alone PBMs differ in their approach to coverage and/or management of “lifestyle” prescription drugs. Some California health plans exclude from their formulary many of these lifestyle drugs, though most make such drugs available through a separate rider. An exception is Kaiser, which has fairly broad coverage of lifestyle drugs under its base plan.

For the national PBMs serving self-insured employers, lifestyle drug coverage is an employer benefit decision. Under self-insured plans administered by a stand-alone PBM, the PBM decides to include a particular drug on its formulary, but the employer decides whether to exclude the drug or the entire class from its pharmacy benefits.

In general, formularies established by California health plans appear more limited than the national formularies of the large stand-alone PBMs.

Table 10. Comparison of Select Formulary Inclusions/Exclusions: Health Plans and National PBMs

	Health Plans					
	Kaiser— Northern CA	Kaiser— Southern CA	PacifiCare	Health Net	Blue Shield of CA	Blue Cross of CA
Erectile Dysfunction	Viagra	Viagra	None	None	Viagra (PA) Muse (PA)	Caverject Edex Muse
Smoking Cessation	Habitrol Patch Good Sense	Habitrol Patch Good Sense	None	None	None	None
Infertility	Pergonal Repronex	Humegon Pergonal	None	None	None	None
Oral Contraceptives	Broadly Included					
Weight Loss	Excluded					
Antifungal Agents (nail/foot)	None	Lamisil Sporanox	Lamisil (PA) Sporanox (PA)	Lamisil (PA) Sporanox (PA)	Lamisil (PA)	Lamisil Sporanox

	National PBMs			
	Caremark	Express Scripts (National Formulary)	Merck-Medco (Preferred Prescriptions Formulary)	AdvancePCS
Erectile Dysfunction	Edex Muse Viagra	Viagra	Caverject Muse (PA) Viagra	Caverject Edex Muse Viagra
Smoking Cessation	None	None	Habitrol Nicotrol Zyban	Zyban
Infertility	Broadly Included			
Oral Contraceptives	Broadly Included			
Weight Loss	Xenical	None	Didrex Ionamin Merida Prelu-2	Ionamin Meridia Xenical
Antifungal Agents (nail/foot)	Sporanox	Lamisil Sporanox	Lamisil Sporanox	Lamisil Sporanox

Source: Commercial HMO formularies as of 10/2000. Formularies provided by health plans or accessed on-line.

PA = Prior authorization required.

VII. Efforts to Encourage Formulary Compliance

Employers are reluctant to permit too much management of physician prescribing decisions, especially from national PBMs.

CALIFORNIA HEALTH PLANS CONSISTENTLY POINT out that formulary compliance programs are not really necessary with a closed formulary. The open formulary approach employed by carved-out prescription drug plans managed by a national PBM, on the other hand, does require efforts to improve formulary compliance. Most employers are not that familiar with national PBM formulary compliance efforts, such as therapeutic interchange interventions, yet efforts to encourage formulary compliance may impact the prescribing decisions of physicians as well as the access and choice provided to plan participants.

Formulary Compliance in California

In general, pharmacy benefit providers measure formulary compliance by calculating the number of formulary drugs utilized as a percent of the total prescription drugs utilized by plan participants. Assuming that the formulary covers all necessary therapeutic classes and the drug selections satisfy sound clinical rationale, a higher formulary compliance percentage should reflect greater financial savings without compromising quality of care. If the formulary selections result in a lower net cost, then there should be greater financial savings as formulary compliance increases.

All market segments appear to have an interest in increasing formulary compliance in order to maximize the economic advantages. Pharmaceutical companies feel formulary compliance is an appropriate goal if the formulary decisions reflect appropriate access to the medications patients need.

Among health plans, Kaiser reports a 98 percent formulary compliance rate—a figure that gains credibility from its wide acceptance among employers and industry experts as well as other health plans and pharmaceutical companies. Another health plan reports “almost 98 percent” compliance with its closed formulary and optimistically implies that “physician awareness” is a likely factor in its relatively high (91 percent) formulary compliance rate under a three-tier plan offering. This health plan has not analyzed the adverse possibility that the higher co-pay for nonpreferred drugs in its three-tier plan is a factor contributing to the lower formulary compliance for the three-tier compared to the closed formulary compliance.

Health plans and PBMs have turned their formulary compliance efforts to physician and patient education as well as to patient cost-sharing incentives. Employers express a general reluctance to permit too much management of physician prescribing decisions, especially from national PBMs. In fact, several employers do not believe that national PBMs can effectively change physician behavior.

However, two California employers do express a strong desire to actively manage prescription drug utilization and are aware and supportive of the therapeutic interchange efforts provided by their stand-alone PBMs, believing that such efforts effectively manage utilization. Both employers indicate that plan members have not displayed any significant level of dissatisfaction. The few mem-

ber complaints received are related to concern over the PBM’s “intrusion” upon their physicians’ decisions. Another employer believes therapeutic interchange efforts will prove to be more effective than three-tier plans in maximizing formulary compliance and so feels no need to burden employees with a three-tier cost share structure.

Physician and Member Education

The health plans interviewed are opting for more aggressive physician education, using analysis of prescribing decisions rather than financial incentives to encourage formulary compliance. Most health plans and national PBMs managing prescription drug benefits in California use some variation of the basic approaches summarized in Table 11.

Table 11. Methods of Physician and Member Education to Encourage Formulary Compliance

Prospective Education	Point of Sale Education	Retrospective Education
<ul style="list-style-type: none"> ◆ Distribute the formulary in paper form and/or make it available on an Internet site. ◆ Develop interactive formulary Web services that enable physicians and members to research formulary alternatives. ◆ Distribute advance notices on changes to the formulary to members and physicians with an explanation that proactively addresses concerns and discusses clinical rationale. ◆ Identify members affected by an upcoming change in formulary and send targeted mailings to these members to notify them in advance of the change and to outline alternatives. 	<ul style="list-style-type: none"> ◆ Mail order: Use a pharmacist to contact the prescribing physician for approval to change a prescription to a formulary or preferred drug. If approved, the member receives the new drug with a letter explaining the change. In most cases, there is no transaction fee for this service; it is funded out of the formulary management fee withheld from formulary rebates earned. ◆ Retail: Send pharmacists a systematic prompt to call the physician to request permission to switch to a formulary or preferred drug. In some cases, PBMs pay retail pharmacists a transaction fee for their time to complete this activity. 	<ul style="list-style-type: none"> ◆ When the retail pharmacist cannot reach the physician, contact the physician retrospectively to switch the prescription to a formulary drug for subsequent refills. In this situation, the member usually receives a new prescription in the mail. ◆ Do periodic mailings to members who are not compliant with the formulary to educate members about formulary alternatives and possible cost savings to members and the plan sponsor. ◆ Do periodic mailings to physicians listing their patients on non-formulary drugs, supplying information on formulary alternatives and dosage, and providing cost charts to assist in the transition. ◆ Do academic detailing through face-to-face meetings with physicians to review prescribing patterns and to identify opportunities for improved formulary compliance.

Physician Financial Incentives

According to all the stakeholders interviewed, financial incentives intended to influence physician prescribing were more prevalent two years ago than they are today. Most health plans and national PBMs agree that the use of capitated arrangements for prescription drug costs has given way to physician profiling and proactive intervention efforts. Health plans are doing data analysis and peer group “report cards” of physician prescribing decisions. National PBMs are taking things a step further by using similar information in telephone calls or face-to-face meetings with physicians.

Decreased use of financial incentives has essentially shifted the risk of prescription drug cost back to the health plans. Some industry experts believe that the health plans may reverse this risk arrangement as injectables increasingly become covered under the pharmacy program and a greater number of higher cost drug therapies are introduced into the marketplace.

Member Cost-Sharing Incentives

All national PBMs interviewed report that the three-tier plan has been an effective tool for plan sponsors in managing the cost of prescription drug benefits. There are generally three sources of cost savings:

- ◆ Increased member copayments
- ◆ Movement to lower-cost drugs
- ◆ Higher formulary rebates.

The possible savings for any particular plan sponsor largely depend on the co-pay levels under the old and new plan designs. For a plan sponsor moving from a traditional two-tier plan without any formulary compliance efforts to a three-tier plan with a formulary compliance focus, cost savings in the range of 5 percent to 15 percent of net pharmacy benefit costs are typical.²⁰ However, the impact on net pharmacy benefit costs may not be the same for plans that

change from a closed formulary to a three-tier plan, since the three-tier plan essentially offers open access to all prescription drugs, regardless of cost.

Based strictly on a measurement of prescription drug benefit costs, the greatest source of savings appears to come from higher member co-pays rather than movement to more cost-effective drugs (Table 12). Formulary rebates—the retrospective “discounts” paid by pharmaceutical companies to pharmacy benefit providers—could actually be less if a change is made from a closed formulary to a three-tier plan. Therefore, it will be critical for any plan sponsor to work with the pharmacy benefit provider to accurately assess the financial impact of implementing a three-tier plan.

Many national PBMs feel that employers implementing a three-tier plan for cost savings should understand that the bulk of savings comes from shifting cost to consumers, not really from increased rebates. In fact, the California health plans point out that rebate earnings are more likely to be optimized under closed formulary approaches where one drug is clearly preferred over another (coverage vs. no coverage) than under the co-pay differential in three-tier plans. Consequently, the health plans believe that rebate earnings may decline if a plan with a closed formulary changes to a three-tier plan. A reduction in rebates obviously offsets any potential savings.

Table 12. Potential Sources of Savings in Moving from a Two-Tier to a Three-Tier Plan

	Distribution of Typical Savings
Increased member copays	50% – 80%
Lower cost drugs	10% – 40%
Higher formulary rebates	10% – 15%

Source: Composite of national PBM reported data.

Table 13. Advantages and Disadvantages of Moving to a Three-Tier Plan, According to Employers

Advantages	Disadvantages
<ul style="list-style-type: none">■ Provides unrestricted access to prescribed medications■ Increases member awareness of prescription drug cost■ Encourages a different type of discussion between patients and physicians■ Forces members to seek out lower-cost alternatives■ Improves benefits and access to medications for members coming from a closed formulary	<ul style="list-style-type: none">■ Offers no real cost savings, but merely shifts costs to plan members■ Creates added inconsistency in the formulary lists of preferred/nonpreferred drugs among different pharmacy benefit providers■ Increases inconsistency among the co-pay amounts used by different pharmacy benefit providers■ May not ensure price sensitivity among members who use its most expensive drugs■ Could confuse California members and physicians, who already accept closed formularies■ May not be an effective utilization management approach with physicians■ May not encourage appropriate utilization by patients

Employers voice strong opinions for and against the use of three-tier plans. About one-fourth of the employers interviewed will have a three-tier plan effective 2001, about half are “seriously” considering a three-tier plan design, and the remaining one-fourth are strongly opposed to the use of three-tier plans.

Whatever its pros and cons, a three-tier plan, say employers, is fraught with a number of potentially problematic issues that need to be carefully considered before it is implemented:

- ◆ There is no convincing data to support the overall impact on cost or quality of care.
- ◆ The income level of the workforce will influence the ultimate acceptance of the plan.

- ◆ The influence of potential legislative and regulatory action is unknown and may skew the benefits and costs associated with a three-tier plan.
- ◆ Pharmaceutical manufacturer pricing will affect the co-pay savings differential.
- ◆ As more expensive breakthrough drugs become available, accessibility will depend on what co-pay level is applied to these new drugs.

Even though the majority of California employers interviewed for this report believe there is fairly high compliance to current prescription drug formularies, almost three-quarters of them indicate that they will consider patient cost-sharing incentives, namely the three-tier plan, to improve formulary compliance.

VIII. Utilization Management Strategies

Some health plans show interest in additional co-pay tiers, but more out of curiosity about what other plans are doing rather than from a desire to implement this approach.

ALTHOUGH THE USE OF THREE-TIER PLANS HAS received much attention, employer plan sponsors and health plans are considering a variety of other prescription drug benefit utilization management strategies. While the main objective of these strategies is to increase member sensitivity to prescription drug costs and to make them better informed consumers of prescription drugs, all of these provisions can influence the utilization of prescription drugs.

Cost Control Strategies

In a 1999 national survey, employers were asked to disclose their prescription drug cost control strategies. Not surprisingly, about 40 percent of employers reported that a tiered co-pay plan design would be considered and 39 percent indicated that increasing employee cost sharing was likely (Table 14).²¹

Table 14. How Employers Are Controlling Prescription Drug Costs

Tiered co-pay plan design	40%
Increased employee cost sharing	39%
PBM Carve-Out	35%
Mandatory generic substitution	30%
Other	28%
Closed formulary with non-formulary drugs available for higher co-pay	15%
Mandatory mail order for maintenance drugs	11%
Closed formulary	10%
Participation in purchasing group or coalition	6%
None	12%
PBM's (smaller network)	4%

Source: Deloitte & Touche 1999 Employer Survey on Managed Care.

The opinions of the California employers we interviewed are generally consistent with the results of this national survey. California employers also identified current or emerging prescription drug utilization management strategies that were not addressed by the survey.

Strategies Currently in Place or Being Considered

Additional co-pay tiers. Some PBMs and employer plan sponsors are considering adding additional co-pay tiers for drugs that are not medically necessary, so-called “lifestyle” drugs, or for drugs typically excluded from coverage. This plan provision requires members to pay 100 percent of the discounted price for drugs that are excluded from the pharmacy benefit (such as drugs for cosmetic uses). This is actually a benefit enhancement in many plans because these drugs are traditionally excluded from all coverage, which means that members have to pay the undiscounted or “counter price.”

Some health plans express interest in these additional co-pay tiers, but seemingly more out of curiosity about what other health plans are doing rather than from a desire to implement this approach. Most PBMs report that they are currently able to administer such plans, which are already in place for a “handful” of plan sponsors, and describe them as the “next generation” of prescription drug benefit design. Pharmaceutical companies agree that multiple-tier plans are consistent with a consumer-based approach to health benefits, but caution that if the higher co-pay tiers are too high and patients cannot afford the payment, then the plan may not really offer greater access. All market segments believe that further analysis must be done to assess the true cost-effectiveness and quality of care impact from multiple-tier plans.

Higher member cost share. Almost all employers indicate that they will consider increasing member co-pay amounts if prescription drug benefit costs continue to rise at the current trend levels. Several employers implemented increased co-pay amounts effective January 2001. A recent employer benefits survey reports the following average co-pays based upon the number of tiers used by the employer plan sponsor (see Table 15).²²

Table 15. Average Co-pay Amounts by Number of Co-pay Tiers in Plan Design

Number of Co-pay Tiers Type of drug	Retail Pharmacy*	Mail-Order Pharmacy*
2-tier plans		
Generic drug	\$7	\$9
Brand drug	\$15	\$18
3-tier plans		
Generic drug	\$8	\$11
Preferred brand drug	\$16	\$22
Non-preferred brand drug	\$29	\$39

*Days supply limits are typically greater at mail order than at retail, with the most prevalent days supply limits being 30 days at retail pharmacies and up to 90 days at mail order pharmacies.

Percent co-pay or coinsurance. With percent co-pays or coinsurance, members pay a fixed percentage of the drug costs, sometimes with a cap on out-of-pocket payment per prescription. This plan design has the advantages of continually reminding members about the relative cost of prescription drugs and serving as a hedge against cost inflation. However, it can be unpopular with members who are accustomed to fixed dollar co-pays. According to two recent employer benefit surveys, between 10 percent and 17 percent of employers nationally currently utilize percent co-pays.^{23,24} However, analysts predict that percent co-pays will receive renewed interest over the next two years as employers seek to protect against rapidly increasing prescription drug benefit costs.^{25,26}

Full prescription drug carve-out. Nationwide, many employers have elected to carve out prescription drug benefits from PPO, POS, and indemnity plans, preferring to self-insure the benefit under a uniform design with a stand-alone PBM. Far fewer employers have carved out prescription drug coverage from HMOs. A carve-out from HMOs does not appear to be receiving strong consideration in the near future, mostly because these are insured arrangements and stand-alone PBMs generally do not provide insured products. Moreover, most employers

seem to be satisfied with Kaiser, and a large number of California residents participate in the Kaiser plan. Several employers say they are “rethinking” existing prescription drug coverage carve-outs from PPO/POS health plans because stand-alone PBMs have not “lived up to expectations.” Nevertheless, according to an industry expert, two employers, CalPERS and Pacific Business Group on Health, have looked at the possibility of a full carve-out.

Generic substitution incentives or mandatory generic substitution. The simplest form of a generic substitution incentive is merely having a lower co-pay amount for generic drugs. The formulary list can also reflect coverage of generic drugs, but not their multi-source brand-name counterparts. Another generic substitution incentive makes it mandatory that members pay the cost difference between the brand or generic drug whenever a generic equivalent is available, regardless of whether they or their physician request the brand-name drug. According to national surveys, about 29 percent of employer plan sponsors have this type of mandatory generic pricing.²⁷ By contrast, in California, almost half of the employees with HMO coverage are subject to a mandatory generic program, compared to 36 percent of employees covered by POS plans, 32 percent of those covered by insured PPOs, and 24 percent of employees covered by self-funded PPO plans.²⁸ While generic dispensing is about 50 percent nationwide, some health plans in California report generic dispensing rates well over 50 percent and Kaiser has reported a generic dispensing rate of more than 60 percent.²⁹

Restricted pharmacy networks. Although employers understand there are potential cost savings associated with a restricted pharmacy network, most indicate that they are not likely to reduce member choice and access to pharmacies. One employer is considering development of a custom network based on the actual pharmacy utilization by its employees. Restricted pharmacy networks typically exclude many independent

pharmacies and select pharmacy chains. Development of a restricted pharmacy network in California is possible since the state has no regulations in place mandating admittance of any pharmacy into a network. However, the impact of a restricted pharmacy network may be limited in California since health plans believe they have optimized retail pharmacy discounts. While national PBMs may promote the potential savings, some industry experts contend that the discounts available may only match the levels already in place under the pharmacy networks offered by the health plans.

Mail order. All the health plans and PBMs we interviewed offer a mail-order pharmacy and all the employers interviewed include a mail-order option in their pharmacy program. Most employers report that mail-order co-pays are one or two times the retail monthly co-pays for up to a three-month prescription. For example, a patient who fills his/her prescription at a retail pharmacy may pay a \$10 copay each month or \$30 over three months. The same patient can get a three-month supply at mail-order for a single \$10 or \$20 copay. These employers explain that a lower co-pay multiple is used to encourage members to fill maintenance prescriptions at a mail-order pharmacy. The plan sponsor generally benefits from the greater discounts and lower administrative costs at mail-order. Yet because of the lower copay, some employers have learned that the mail-order benefit can actually increase an employer’s prescription drug benefit costs. A couple of employers have implemented mandatory mail-order plan designs that require or strongly encourage members to use mail order for maintenance drugs after a set number of fills at retail. While all HMOs offer a mail-order option, none appear to proactively encourage mail order to the same extent as national PBMs and employers.

Emerging Strategies

Therapeutic maximum allowable cost (MAC) program. The therapeutic MAC is a reimbursement limitation approach similar to MAC programs utilized by most health plans and national PBMs for generic drugs. In a therapeutic MAC program, the PBM reviews prices for the range of available drugs in a particular therapeutic class and sets a maximum allowable cost (or MAC) that is supposed to reflect a fair and reasonable price per prescription. Members who fill prescriptions that exceed this MAC amount are responsible for paying the cost difference in addition to the co-pay required by the plan.

Therapeutic MAC could be an appealing approach since it forces members to become more cost sensitive and potentially lessens the need for a formulary. However, early experience shows it can be difficult to administer and communicate to members and physicians. Several national PBMs and health plans indicate an interest in this approach and at least two PBMs have such a program available. Likewise, several employers express interest and have discussed the approach with a health plan or stand-alone PBM.

Benefit limits or caps. Benefit caps are common in Medicare managed care products but much less common in other plans. Some employers say that they might consider limitations on total prescription drug benefits, or possibly on specific drug classes, if prescription drug costs continue to increase at the current levels.

Defined contribution. None of the employers we interviewed foresee implementing a defined contribution approach for active employees within the next three years. Many employers across the United States indicate that a defined contribution approach for retiree prescription drug benefits is possible as an effort to curb rising prescription drugs cost in retiree medical plans. Pharmaceutical companies consider the defined contribution approach appealing because it allows complete patient choice.

Reduction or elimination of retiree coverage.

Several employers express an interest in reducing—or even eliminating—coverage if prescription drug benefits are added to Medicare. These employers would make Medicare primary and their plan secondary. The arguments that appropriate use of prescription drugs can lower medical cost and improve workplace productivity is seen by employers as offering little value for retiree groups since Medicare covers most non-prescription drug medical expenses, and retirees are no longer working.

Other utilization management controls. In addition to changing plan design, health plans and stand-alone PBMs typically offer other tools to improve the management of the pharmacy benefit and achieve cost savings. Many PBMs and health plans can provide enhanced utilization management programs. These programs include concurrent and retrospective drug utilization reviews to:

- ◆ Target inappropriate drug utilization
- ◆ Increase compliance with drug therapy
- ◆ Improve quality of pharmacy care
- ◆ Reduce adverse medical events often associated with inappropriate drug utilization.

Prior authorization programs target high-cost drugs with the potential for abuse or misuse. Prescriptions are reviewed against a set of clinical criteria, sometimes requiring input from the physician, and approved only if they meet these criteria. Some PBMs have expanded this concept to include more frequently used drugs. In these programs, the PBM sets specific dispensing parameters such as quantity and dosage limits per co-pay and step-care protocols.

Many employer plan sponsors, particularly those with high HMO enrollment, have not been educated about these types of programs and are therefore not familiar with them or are uncomfortable with them because of the potential for negative reactions from plan members.

IX. How Effective Are Current Benefit Designs?

Employers are frustrated with PBMs' lack of disclosure about formulary rebates and not knowing whether rebate earnings are accurate.

EMPLOYERS GIVE MIXED REVIEWS TO THE PERFORMANCE of their pharmacy benefit providers and the effectiveness of formulary use. A couple of perceptions about the marketplace contribute to their general frustration:

- A number of California employers believe that HMOs are stymied by their inability to effectively manage prescription drug costs. In fact, many health plans blame recent premium rate hikes on increasing prescription drug costs. Some employers report that one HMO went to the extreme of actually encouraging employers to carve out prescription drug coverage.
- Many of the California employers express skepticism that stand-alone PBMs are really focused on quality of care as the most important priority in making formulary decisions.

Cost Trend Rates: A Basic Measurement

Plan sponsors, both health plans and employers, typically equate benefit cost trend rates with effectiveness of benefit design and plan performance. While such a number may not reflect the ultimate measure of performance for a prescription drug plan, it is a number that many employers use to measure their satisfaction with the pharmacy program.

Several California employers could not provide their actual trend rate for prescription drug benefits since they had not been provided with the necessary data from their pharmacy benefit providers. California employers with access to the necessary data report pharmacy benefit cost trend rates from 8 percent to 18 percent. Employers with the lower rates explain that having increased member co-pays and/or making other program changes could have affected per capita costs. Employers with the higher rates found themselves in line with national prescription drug benefit trends. In 2000, the estimated pharmacy cost trend rates were 17.5 percent compared to a medical trend of 8 percent.³⁰

Industry experts have mixed reactions about the ability to control prescription drug trend. One expert is adamant that the prescription drug benefit trend can be controlled if physicians follow established treatment guidelines and patients comply, eliminating inappropriate prescribing and utilization. Another industry expert feels it is extremely difficult to change physician-prescribing behavior and modify utilization. This expert believes that while a health plan or national PBM could potentially negotiate better prices with manufacturers, given the increase in the number of drugs for prevention, new treatments for existing conditions, and the saturation of direct-to-consumer advertising, changing utilization will present a “relentless, constantly changing, uphill battle.”

Satisfaction with PBMs

A national survey of more than 400 employers was conducted to assess satisfaction with a variety of available PBM services. While the survey does not claim to include a statistically valid sample, the results are interesting and show a relative level of satisfaction with most PBM services (Table 16).³¹ The findings are somewhat consistent with broader survey results from a December 2000 study that found 91 percent of employers contracting directly with a national PBM were either satisfied or very satisfied with the PBM’s ongoing services.³²

Table 16. How Employers Rate PBM Services

	Average Satisfaction Rating*
Pharmacy network	8.8
Claims processing	7.7
ID cards	7.6
Overall performance	7.5
Eligibility management	7.4
Value for administration cost	7.4
Customer services	7.3
Mail service pharmacy	7.2
Cost of drugs	7.1
Promised savings	7.0
Promised services	7.0
Drug utilization management	7.0
Management reports	7.0
Formulary management	6.9
Plan implementation	6.8
Amount of rebates	6.7
Proactive management	6.6
Consulting services	6.4
Disease management	6.3

Source: PBMI 2000 Pharmacy Benefit Manager Customer Satisfaction Survey Report.

*based on 1=worst, 10=best

California employers express satisfaction levels consistent with the national survey results. For example, they are very satisfied with pharmacy network access, the highest rated service in the survey. At the low end, while California employers express interest in disease management programs, most do not believe that they are receiving effective disease management services from their stand-alone PBMs, which is again consistent with the national survey result.

Like their national counterparts, California employers have a relatively low level of satisfaction with formulary management and rebates. Many point to the problems created by the inconsistency among different formularies and in the communication about the formularies to physicians. These employers also cite the lack of disclosure about formulary rebates and express a general frustration at not knowing whether rebate earnings are accurate.

Consumer Satisfaction

The majority of California health plans have not sufficiently measured the impact of different formularies on overall health care or patient satisfaction. Many health plans report few complaints regarding the availability of drugs, but most admit they do not measure patient satisfaction on any regular basis. While some health plans do conduct regular patient satisfaction surveys, they focus on member experience with pharmacies and not on formulary.

However, California may well lead the nation in legislation focused on patient-friendly and consumer rights issues. Currently, health plans in California are required to request regulatory approval on most formulary changes.

Pharmaceutical companies believe that closed/restricted formulary models frequently create barriers to pharmacy care that may frustrate the “sickest patients” by limiting access to needed drugs when these patients most need them. One pharmaceutical company refers to internal data showing that less than 15 percent of the population constitutes the “sickest patients,” but these patients are the ones that most need appropriate access to the right medications.

Overall Medical Costs, Quality of Care, and Other Outcomes

California health plans exhibit varied levels of sophistication in terms of analyzing the impact of formulary changes on subsequent prescription drug benefit and overall medical costs. Some plans measure changes in pharmacy spending as a result of formulary changes and then simply apply that change as a percentage of overall medical costs. Others have done more focused analyses of the impact of formulary on cost for specific medical conditions or have examined the overall impact of prescription drug utilization on medical spending. For example, one health plan conducted independent studies on the use of cholesterol-lowering drugs and AIDS drugs; each study produced results indicating per capita savings on overall medical costs for the respective patient subpopulation.

However, because these types of studies have not been done across a broad range of drug therapies, health plans have not been able to establish a direct correlation between higher overall pharmacy costs and lower overall medical costs. Health plans and employers continue to demand published studies about appropriate prescription drug utilization and the value of pharmaceutical therapy.

In contrast to California health plans, the major national PBMs have developed programs to measure the impact of formulary changes on compliance, patient satisfaction, and overall drug trend and spending. Most national PBMs offer several programs designed specifically to address prescription drug utilization patterns and to increase formulary compliance. Stand-alone PBMs have faced greater difficulty trying to measure the impact on overall medical costs since they usually have access only to the prescription drug data.

X. Forecasting the Future

Younger physicians more willingly embrace and use the new technology to aid in their prescribing.

IN THE NEXT FEW YEARS, STAKEHOLDERS EXPECT several factors to influence prescription drug coverage and the use of formulary: (1) formulary benefit/program design, (2) Internet technology solutions, and (3) direct arrangements with pharmaceutical manufacturers.

What Type of Formulary Design Will Become Most Prominent in California Within the Next Few Years?

Opinions vary among California health plans. While Health Net believes strongly in the future of the three-tier plan and is actively promoting this across most lines of business, Kaiser prefers a single co-pay structure for generics and brand-name drugs, believing that effective management can occur without an incentive-based design. However, even Kaiser is responding to marketplace demand by expanding its offerings and implementing a standard brand/generic two-tier co-pay in 2001. Other health plans, sensing a market need for different formulary designs, are beginning to explore incentive-based formularies, though with less conviction than national PBMs about their ultimate success as long-term solutions.

Experts in the pharmacy industry offer conflicting predictions. One thinks that California-based employers, because of their “progressive” nature, will readily adopt the three-tier plan design; others feel that employers might not be so ready to change. One expert cites studies implicating the institution of formulary into a drug plan as a potential cause of higher total costs and decreased member satisfaction. What most experts seem to agree on is that there is definitely a heightened interest on the part of California employers in finding out more about multitiered co-pay designs.

It is reasonable to assume that as the use of three-tier plans continues to increase across the United States, California-based employers with out-of-state employees may join the trend as they seek to achieve consistency by offering similar benefits everywhere. As the number of employers with a three-tier plan increases in California, staying competitive with other employer plans will take on new meaning. Simultaneously, as more health plans seek to differentiate their products, the availability of three-tier plan options will likely increase in response to the competition for health care business.

One key variable could be the regulatory environment in California. If regulators determine that access to all medications, albeit certain non-preferred medications at a higher member co-pay, is worse than no access to those same non-preferred medications under the existing closed formulary programs, then adoption of three-tier plans by employers may be slowed. For example, the state's Department of Managed Care has focused on the maximum amount for the third tier and has refused to allow one health plan to implement a certain co-pay level, even though another plan already had implemented an even higher co-pay.

The pharmaceutical companies believe that health plans and employers must adopt a broader perspective about pharmacy benefits. All point to studies showing that prescription drug therapy can reduce other medical costs, improve the quality of life, and contribute to increased workplace productivity.³³ Pharmaceutical companies believe that many health plans use prescription drug costs as a scapegoat for high-cost trend increases. Many feel health plans and PBMs should better educate their employer plan sponsors about the return on investment associated with higher prescription drug costs for certain medical conditions.

Interestingly, the pharmaceutical companies all agree that a value-based approach to formulary management is essential to ensure appropriate utilization and proper medical care. They see development of formulary alternatives that focus on overall quality of health care and productivity impact as the future approach to formulary decisions.

Will the Internet Revolutionize Pharmacy Benefits?

A variety of technological advances in development or testing have the potential to improve the delivery of pharmacy care in general and formulary management in particular. Most industry experts believe that the Internet provides an opportunity to “revolutionize pharmacy benefits.” While some experts are concerned about physicians’ receptivity to gadgets or systems that promote specific products, they generally agree that instant connectivity to information such as formulary and compliance programs will be of interest to many physicians. National PBMs and pharmaceutical companies agree that younger physicians are more willingly embracing and using the new technology to aid in their prescribing.

Point-of-care technology (POC) has received increasing media attention over the past few years, and a number of medical groups, and to some extent health plans, in California have begun to add this technology to their systems by partnering with one or more of the numerous e-technology vendors in the market. A few health plans have begun piloting one or more of the available POC programs. Large national PBMs have also embraced POC technology, working with various vendors and piloting efforts in different markets, although none of the PBMs report any extensive pilots within California.

Electronic medical records. Computer systems used by physicians and medical groups at Kaiser in California will soon be outfitted with the capability to access patient medical records, eliminating the need for paper charts. The goal is to integrate formulary information with each chart, so that a patient's medical care and drug history can be managed appropriately. Medical, pharmacy, and lab data will all be accessible in a single platform along with clinical practice guidelines specific to particular disease states and patient demographics. Other health plans acknowledge the benefits of electronic medical records, but do not appear to be as far along with their efforts.

Electronic prescribing (e-prescribing).

Physicians will be outfitted with a wireless handheld device that electronically transmits prescriptions over the Internet to a retail, mail-order, or online pharmacy. The software will contain each health plan and stand-alone PBM formulary, so physicians can check to see whether a drug is covered prior to writing the prescription. Depending on which vendor the health plan is partnering with, the program software can be loaded on a regular PC or a pocket PC. In some cases the formulary can also be downloaded to a handheld device. Future enhancements include the ability to incorporate drug utilization review edits and prior authorization of certain medications. At the end of 2000, legislation in the form of Assembly Bill 2240 was passed to allow electronic prescribing (digital prescribing) in California. The legislation eliminates the requirement that electronically transmitted prescriptions be reduced to a written or hard copy under specified conditions, and authorizes prescribers to electronically enter prescriptions and hospital drug orders into a pharmacy's or hospital's computer from any location, with the permission of the pharmacy or hospital.

Pros and cons of POC technology. Health plans agree that POC technology will continue to gain interest and will likely increase in popularity with physicians, particularly as younger physicians, who have been raised in an electronic era, grow in number. How can POC technology be used? Health plans describe the following quality and process improvements:

- ◆ Promote formulary compliance
- ◆ Increase generic utilization
- ◆ Streamline the prescription writing process by providing physicians with easy access to multiple plan formularies through a single device
- ◆ Simplify the medical exception/prior authorization process
- ◆ Reduce administrative expenses and improve administrative efficiency in the physician's office
- ◆ Decrease retail pharmacy wait time for patients
- ◆ Reduce call backs from the pharmacy as a result of illegible prescriptions
- ◆ Improve patient safety by eliminating dispensing errors due to illegible handwriting.

Not all health plans have high expectations for POC technology. One plan believes that managed benefit design more effectively promotes formulary compliance than POC technology and that the primary benefit of the technology is administrative efficiency and added convenience for providers and patients.

Despite the potential advantages, widespread implementation of POC technology faces the following challenges:

- ♦ How willing are physicians to change patterns of behavior and adopt new technologies?
- ♦ Will physicians be able to integrate new POC technologies with existing internal practice management systems?
- ♦ What about firewalls around confidential information?
- ♦ How will patient confidentiality concerns be managed?
- ♦ Will the POC technologies be able to meet the Health Insurance Portability and Accountability Act of 1996 (HIPAA) requirements for confidentiality and format requirements?
- ♦ How can the potential for unwanted direct-to-consumer advertising/banners on software be handled?
- ♦ How much will lack of standardization of the technology hamper its effective use? (There is no standardization to date.)
- ♦ Will the fact that there are too many “players” in the POC market, resulting in little integration, negatively affect the efficient use of POC devices?

Other Internet developments. Most consumers have already discovered the potential benefit of the Internet as a source of instant information, as evidenced by the high number of “hits” to health-related sites as well as the increasing number of individuals downloading health data and bringing it to their physician.

Partially in response to this booming use of the Internet, many health plans are, or have begun, making use of the Internet to some extent, mostly to provide information to members and other interested consumers. In particular, many health plans are using the Internet to post their respective covered drug lists, because California state regulations require that formulary information be readily accessible.

Several California health plans have added, or plan to add, the following functionality within the next few years:

- ♦ Benefit design summaries
- ♦ Consumer purchasing of over-the-counter medications
- ♦ Electronic customer service representatives to respond to member questions
- ♦ Member scheduling of doctor visits
- ♦ Member education on such items as pharmacy benefits, specific disease states, and medication information (“talk with a pharmacist”)
- ♦ Provider education via access to journals, health plan bulletins, and prescribing guidelines
- ♦ Pharmacy utilization reporting tools for physicians
- ♦ Hyperlink to other qualified wellness and health information sites
- ♦ Management of pharmacy supply chain procurement and distribution.

Employers’ perspective. What impact will the Internet have on prescription drug benefit and formulary design as well as overall health care? Almost all employers respond initially by focusing on the advantages of administrative efficiency and reduced administration cost. Most also report that essentially all “paperwork” related to plan administration is already available on a company benefits Web site and that links are installed for some, if not all, health care providers. Several employers used their benefits Web site for 2001 member enrollment.

Employers are less certain how access to health care information via the Internet will be coordinated among benefits programs. Nevertheless, all express high expectations about the potential improvements to physician prescribing that might be gained from the use of handheld technology. Employers generally agree that information will have to be objective and the technology easy to use in order for physicians to accept these technological advancements.

Employers anticipate many benefits through the use of the Internet, among them:

- ◆ Easy and quick access to important data for all health care providers
- ◆ Improved communication among health care providers
- ◆ Significant reduction in prescription translation errors
- ◆ Added avenues for consumers to conveniently request prescription drug refills, change primary care physicians, and schedule physician appointments
- ◆ Up-to-date access to useful information allowing members to compare providers in terms of medical groups, hospitals, HMOs, formulary drug lists, and the like
- ◆ Ability to offer educational campaigns directed at the consumer and targeted to specific drugs or drug classes where direct-to-consumer advertising may be affecting utilization
- ◆ Easily accessible wellness efforts online that can target specific communities and worksite locations
- ◆ Acceleration of provider ability to demonstrate indirect value.

All employers agree that pharmaceutical manufacturers need to do more to demonstrate the direct and indirect value of prescription drugs.

Despite these benefits, employers' enthusiasm for full-speed-ahead implementation of Internet solutions is dampened by their awareness of certain clear challenges. They are wary because:

- ◆ Web applications vary greatly by provider.
- ◆ Access to the Internet varies greatly by member.
- ◆ Not all information available on the Internet is accurate or useful.
- ◆ There is a risk of unauthorized access to confidential information.
- ◆ Miscommunication errors on the Internet (because of the speed and scale of communication) can take on a significantly greater magnitude than errors made on paper.

In light of the Internet's challenges and opportunities, employers offer the following suggestions for ensuring successful use of the Internet in delivering health care to employees:

- ◆ Use collective efforts between employers and providers to advance technology, resolve confidentiality issues, and qualify health care information.
- ◆ Permit worksite access to benefits Web site.
- ◆ Provide employer subsidies to support Internet access for all employees.

Will Employers Engage in Direct Contracts with Pharmaceutical Manufacturers?

Employers may contract directly with manufacturers for formulary rebates, research studies and clinical/health management programs. While these types of direct contracts are not common now, there have been recent discussions in this area. Almost all employers we spoke with are reluctant to enter into direct contracts with pharmaceutical manufacturers because they believe that an objective third party is necessary to evaluate and manage these arrangements. With respect to disease/health management programs that involved direct arrangements, employers believe that key issues will be physician acceptance, patient confidentiality, and concerns about being “tied” to a specific manufacturer or having to deal with too many manufacturers.

Los Angeles-based employers express practically no interest in pursuing direct arrangements with pharmaceutical manufacturers. They say this would complicate the pharmacy benefit situation. On the other hand, San Francisco/San Jose-based employers express some interest, but with some skepticism about the feasibility of doing so.

All employers agree that pharmaceutical manufacturers need to do more to demonstrate the direct and indirect value of prescription drugs by providing more data, demonstrating a more substantive value proposition, and accepting a greater level of risk for the broader value propositions they put forth. Employer plan sponsors appear to be reluctant to work directly with pharmaceutical companies in helping to demonstrate this value. They are more likely to work through their pharmacy benefit providers.

Some large employers have been contacted to serve on a pharmaceutical company-sponsored “advisory board,” but none have participated. A couple of employers voluntarily provide examples of the indirect value of prescription drugs (such as the increase in productivity related to use of non-sedating antihistamines, or coverage of oral contraceptives, which cost less than maternity health care), showing an understanding of the value propositions that pharmaceutical companies are promoting.

The pharmaceutical companies we interviewed acknowledge that the industry must improve in demonstrating the value provided by prescription drugs. They explain that historically the pharmaceutical industry focused on demonstrating safety and efficacy of the drug product as required by the FDA, rather than the direct and indirect value of the drug therapy to the employer plan sponsor. Pharmaceutical companies appear to understand the future needs and expected demands of employer plan sponsors. Some pharmaceutical manufacturers have expressed interest in partnering with employers. However, to date, pharmaceutical companies appear to be mainly interested in establishing the value of their products to employers and encouraging employers to lobby health plans and PBMs for broad coverage policies. There have been limited direct contracts between employers and manufacturers.

XI. Endnotes

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Appendix A. Interview List

Pharmacy Benefit Providers Health Plans

Aetna U.S. Healthcare
Blue Cross of California/Wellpoint
Blue Shield of California
Health Net
Kaiser Foundation Health Plan—Northern CA
Kaiser Foundation Health Plan—Southern CA
PacifiCare

PBM

AdvancePCS
Caremark
Express Scripts
MedImpact
Merck-Medco
Prescription Solutions

California-based Employers & Coalitions

APL
Avery Dennison
California Portland Cement
CalPERS
Chevron
Cisco Systems
City of Los Angeles
Computer Sciences Corporation
Fujitsu
Los Angeles Department of Water & Power
Loyola Marymount University
Pacific Business Group on Health (PBGH)
Stater Brothers Markets
University of California

Appendix B. Glossary of Terms

Pharmaceutical Companies

Eli Lilly & Company
Pharmacia Corporation
Schering-Plough Corporation

Industry Experts and Researchers

Harvard University
Arnold Epstein, M.D.
Institute for Clinical Outcomes Research (ICOR)
Susan D. Horn, Ph.D.
RAND
Dana Goldman, Ph.D.*
Geoffrey Joyce, Ph.D.*
RxPerts
Debi Reissman, Pharm.D.*
StrategiCare
Diane Giaquinta, Pharm.D.
University of California, San Francisco
Helene Lipton, Ph.D.
William M. Mercer, Incorporated and PBGH
Arnold Milstein, M.D. *

*Member of review committee for this report.

AWP—Average Wholesale Price. The published suggested wholesale price of a drug. Often used as a cost basis for pricing prescriptions.

Brand-name drug—A pharmaceutical product that is trademarked by its originator or a licensee.

Capitation—A financial arrangement with a fixed fee per member.

Closed/restricted formulary—A formulary in which benefit coverage is limited to formulary medications only. Typically, the patient is required to pay the full cost of any nonformulary drug unless the physician has followed an exception process.

Counterdetailing—A program by a health plan or stand-alone PBM to educate physicians on the appropriate use of pharmaceuticals.

Defined contribution—A benefits approach in which the employer plan sponsor sets a dollar amount for benefits and the employees use these funds to finance benefits of their choice.

Department of Managed Health Care—In 1999 the California legislature created this department to focus primarily on managed care plans and health care issues. It took over some responsibilities from other organizations and added other responsibilities related to managed care. Part of its purpose is to help employer plan sponsors and plan participants make more informed decisions about managed care–related issues.

Employer plan sponsor—An employer funding a benefit program.

FDA—Food and Drug Administration. The federal government agency responsible for reviewing and approving prescription drugs.

Formulary—A list of prescription drugs that are recommended to patients and prescribing physicians.

Formulary compliance programs—Programs to encourage members and their physicians to select formulary drugs.

Formulary rebates—See “Rebates.”

Generic drug—Prescription products that are introduced after the brand-name product loses marketing exclusivity.

Generic substitution—A program to switch a brand-name drug to a generic equivalent alternative.

HCEA—Health Care Financing Administration. The federal agency that administers Medicare, Medicaid, and the State Children’s Health Insurance Program (SCHIP).

Health plan—For purposes of this study, any organization that provides, administers, and/or manages health care services to various organizations and its members covered under a health benefit program.

HIPAA—Health Insurance Portability and Accountability Act of 1996. HIPAA protects health insurance coverage for workers and their families when they change or lose their jobs.

MAC—Maximum Allowable Cost. A maximum reimbursement price for generic drugs and in some cases multi-source brand-name drugs.

Mail order—A program that offers maintenance prescriptions mailed directly to participants from a mail-order pharmacy.

Medi-Cal—California’s Medicaid program. Medi-Cal provides health services through a federal and state medical assistance program for eligible low-income persons.

Medicare+Choice—A Medicare managed care plan offered by a private insurance company or health plan.

Multi-source brand-name drug—A brand-name drug available from more than one manufacturer because of approved generic substitutes.

Nonpreferred drug—A prescription drug determined by criteria typically established by a pharmacy benefit provider to be disfavored over other products within the drug class by being subject to a higher copayment or nonpreferred brand copayment.

Open/voluntary formulary—A list of drugs suggested by the PBM or health plan. It represents a prescribing guide for physicians, and usually provides information about the relative cost index of alternative prescription drugs within a particular class. In general, there is no penalty to physician or patient if either elects to deviate from the formulary suggestion.

PBM—Pharmacy Benefit Manager/Management. An organization that provides administrative, analytical, and management services related to prescription drug benefit programs.

Pharmacy benefit provider—Health plan or PBM that is responsible for administration and/or management of prescription drug benefits.

P&T committee—Pharmacy & therapeutics committee. A group of health care professionals

that regularly reviews medical and other clinical literature to evaluate drug safety, efficacy, and value; to select drugs for inclusion on a formulary; and to establish and approve utilization management rules.

Point of care (POC) technology—Technology used in the physician’s office, at the hospital bedside, or at any place where direct care is given, to improve the practice of medicine.

POS—Point of service plan. A benefit plan that offers members either in-network, HMO-type coverage with low co-insurance and deductible rates but limited choice, or out-of-network care with greater choice but higher deductible and coinsurance rates.

PPO—Preferred provider organization. A network of providers who have agreed to accept a plan’s payment rates and service utilization controls. PPOs pay for covered services from non-network providers, but the cost sharing requirements they impose are lower when network providers treat the enrollee.

Preferred drug—A prescription drug, determined by criteria typically established by a pharmacy benefit provider, to be favored over other products within the drug class by being subject to a lower copayment or preferred brand copayment.

Prescription drug carve-out—Prescription drug benefit administered by a stand-alone PBM rather than a health plan.

Prior authorization—A process that requires participants to receive approval as to the appropriateness of a medication before it can be dispensed. Usually reserved for high-cost drugs with the potential for abuse or misuse.

Rebates—Payments made by pharmaceutical manufacturers based on utilization or market share of their products.

Taft-Hartley plan—A benefit plan based on the Congressional act passed in 1947 that estab-

lished control of labor disputes by enlarging the National Labor Relations Board and giving employees the right to refrain from participating in union activities. The act also includes a series of prohibited unfair labor practices by unions.

Therapeutic interchange or substitution—A program to switch a nonformulary or a non-preferred drug to a therapeutically equivalent formulary or preferred alternative.

Therapeutic MAC—A reimbursement method with a maximum reimbursement rate for a therapeutic class of drugs.

Three-tier plan—A pharmacy benefit plan design with three different copayments, typically for generic drugs, formulary or preferred brand-name drugs, and nonformulary or nonpreferred brand-name drugs.

TPA—Third party administrator.

Two-tier plan—A pharmacy benefit plan design with two different copayments, typically for generic drugs and brand-name drugs.

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