An Employer's Guide to Pharmaceutical Benefits



ACKNOWLEDGEMENTS

his project was conceived during the September, 2001 meeting of WRGH, as we wrestled with the challenges of the "pharmaceutical conundrum". The complexity and promise of this explosive industry places unprecedented demands on providers and payers of healthcare, as well as on consumers.

However, this guide focuses on the role of employer-purchasers in providing pharmaceutical benefits for employees, as they struggle to balance economic pressures with a need to support their workforce. Rather than a research paper, our intent is to provide practical tools to assist employers in meeting these demands.





The guide is the result of a great deal of teamwork. Helen Lippman, our writer, researched this complex topic and was the principal content architect. She should be especially recognized for her patience and perseverance through numerous modifications of direction and rewrites. John Malley and Ron Bachman of PricewaterhouseCoopers tackled the controversial issue of the "Pharmaceutical Food Chain" and are the authors of Chapter IV. Our graphics artist, Sooki Moon is to be commended for her creativity. We are indebted to Mercer Human Resource Consulting for providing the worksheets in the Appendix.

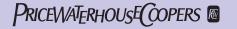


We assembled a cross-section of healthcare stakeholders to review and edit the guide. Several of our committee members spent considerable time on the project and made important contributions including John Malley, Ron Bachman, Phil Hutchison, Jeff Warren, Brian Mefford, Gary Persinger, and Kate Sullivan.



We want to thank those visionary organizations that have financially supported Wye River Group on Healthcare and our many initiatives.

To access the Employers Guide to Pharmaceutical Benefits on the web, please select one of the following links:



http://www.nbch.org http://www.pwc.com http://www.wrgh.org

For more information, to arrange a presentation on our work, or if you are interested in receiving updates about this document, please contact Jon Comola at 512.472.2005 or email jrcomola@wrgh.org.

We believe you will find this document an important asset in understanding pharmaceutical trends and market dynamics and in navigating the options for crafting pharmaceutical benefits.

Jon R. Comola, Chairman, CEO Marcia L. Comstock, MD MPH, COO Wye River Group on Healthcare March, 2003

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EXECUTIVE SUMMARY

Background

n aging workforce, a weakened economy, new therapeutic trends, and double-digit health plan rate increases have all converged, putting enormous pressure on employers struggling to meet their employees' healthcare needs with limited financial resources. These challenges and changes have pushed prescription drugs-or what some industry observers call "the pharmaceutical conundrum"-onto center stage. As one of the fastest growing segments of healthcare benefits, prescription drugs are a main target for employers' efforts to rein in healthcare costs.

Challenges

The challenge is to build a broad-based prescription plan that ensures access to the right medication at the right time and discourages inappropriate drug use, without imposing a financial hardship on either employer or employee. To meet it, benefit managers must keep their employees' interests and an array of cost and quality control strategies in mind. An effective health benefit package is one in which drug coverage decisions are made in the context of their impact on total healthcare costs, productivity costs, employee health outcomes and clinical quality. No two companies have the same employee profile or precisely the same set of concerns, and there's no single formula to follow.

Options

As a relatively new component of

health benefit plans, drug benefits and the techniques for managing them, have evolved rapidly in recent years. As new benefit design techniques are tried and tested, we learn more about their relative effectiveness, their acceptability to employees, and their downsides.

The elements of a prescription drug plan can be simply divided into three categories: design incentives; formulary-based strategies; and clinical interventions. This guide describes the following specific options: generic substitution, tiered co-payments, incentives or requirements (such as use of mail order drugs), therapeutic substitution, formularies, and prior authorization. Disease management, though not directly encompassed in drug benefit design, is a clinical intervention increasingly being incorporated into overall health plan designs to contain total healthcare costs. In addition, the guide describes how health plans or PBMs can negotiate reimbursement rebates to save money on ingredient costs.

In evaluating which design features to include, employers should assess the potential impact of each approach on their overall human resource and health plan goals. Some design features carry a price tag. Some result in savings to the plan and the employer at the expense of access or cost to the beneficiaries. Some are effective at aligning incentives and savings potential to both employers and beneficiaries. Some approaches are invisible to the beneficiaries, and some clearly improve quality of care.

Education of employees about their benefits is essential to optimize the effectiveness of the incentives created and ensure employees know how to obtain the pharmaceutical products that will restore or maintain health and promote productivity. Disclosure about plan options and drug formularies prior to open enrollment, notices about appeal rights, and education regarding use of incentives to the best advantage, are important components of employee education. In addition, employers should be certain that a fair and clinically sound appeals process is available. These consumer protections will help assure that pharmaceutical-related cost

containment efforts do not result in greater total healthcare costs or productivity loss.

The Guide

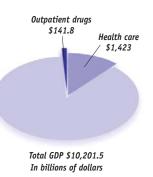
This guide is designed to highlight key areas to address, present prominent studies to consider, and explore primary sources of the data benefit managers need to make well-reasoned decisions about Rx coverage. Perhaps more importantly, throughout *An* Employer's Guide to Pharmaceutical *Benefits* we emphasize the facts and figures needed to make optimal choices, often by highlighting key questions to ask.

Not all of the sections of the Guide will be of interest to all employers. To some extent it depends on how involved a company is in working directly with its health plan and pharmacy benefit manager (PBM) to shape benefit design. Some of the information is provided as a reference.

Chapter I, Choosing and Using the *Right Tools*, is the foundation of the Guide. It provides an overview and examples of design incentives, formulary-based strategies, and clinical interventions that support the management of pharmaceutical benefits. Chapter II, Engaging *Employees*, emphasizes the fact that the best benefit design and programs will fall short if employees are not aware and engaged. Chapter III, Choosing and Managing a PBM, provides pointers on working effectively with health plans, PBMs, and other vendors. Chapter IV, Understanding the Pharmaceutical "Food Chain" covers in detail the

The American Healthcare Pie

The final tally on overall health spending for 2001 is projected at over \$1.4 trillion, or 14% of the Gross Domestic Product. That represents a slight increase for the 2nd year in healthcare's share of the GDP, after remaining relatively flat for most of the '90s. But the slowed economy, coupled with inflation in health plan premiums and wages for healthcare workers, suggests that healthcare's share will continue to grow, the government reports. A graphic look at expenditures helps put pharmaceutical spending in its proper perspective.



(Ref http://cms.hhs.gov/statistics/nhe/projections-2001/t2.asp.)

EXPENDITURE	% OF TOTAL
Hospital care	32
Physician and clinical services	22
Prescription drugs	9
Nursing home care	7
Program administration/net cost	6
Other spending *	24

^{*}Includes dental and other professional services, home health, durable medical products, OTC products, public health, research, and construction.

Source: Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group, www.cms.hhs.gov/statistics/nhe/historical/

critical, confusing, and controversial subject of prescription drug pricing. Chapter V, Evaluating Outcomes, looks briefly at measures that can be used to determine the value of benefit programs. Proactive employers who wish to delve deeper will want to carefully review Chapter VI, Rx and *the Workforce*, which provides information for benefit managers seeking to evaluate direct and indirect healthcare costs in the context of workforce productivity. Chapter VII, *Drug Costs in Context*, explores the cost of pharmaceuticals relative to total healthcare spending and looks at the drivers of drug expenditures. Chapter VIII, Toward Patient-Directed Healthcare, provides an overview of newer financing models for health benefits. Finally, Chapter IX, Looking to the Future, provides a glimpse of what is on the horizon. The Guide also contains appendices with worksheets for employers, information on additional tools, disease management resources

and a glossary of common terms and definitions.

Employers are at the center of one of our greatest healthcare challenges managing their employees' demands for each new advance in medical technology—including innovative drugs—with the reality of its cost. This is not a comfortable position for any employer. This guide is designed to help pharmaceutical benefits manager build a foundation for decisionmaking. Make no mistake, this is one of the most difficult issues for employee benefit managers to "get their arms around". The guide is organized so each employer can target those sections that are most relevant. The document was developed to enlighten those new to the game, support those wishing to take a more active role in design and administration and challenge the seasoned professional to explore new possibilities.

I. CHOOSING AND USING THE RIGHT TOOLS

emographic drivers of the continued surge in healthcare and drug costs are unavoidable. Our nation's rapidly aging population makes the proliferation of chronic and complex conditions and the need for more drugs and more effective treatments inevitable. In this context, the increasing use of Rx therapy in place of more traditional medical services is a key factor. The genomics revolution and the development of medicines, tests, and drug response markers that could not even be envisioned just a decade ago will only make the challenge that much greater.

Given the inevitability of demographics, science, and technology, it is vitally important that employers take appropriate steps to manage the current situation. The same reports that highlight high Rx costs reveal areas where benefit managers can effect change and exert at least some management of the pharmacy budget. Section B of the Appendices provides specific worksheets prepared by Mercer Human Resource Consulting that are designed to help employers make better informed decisions about their plan designs.

Just as the overall design of medical benefits in the past has shielded consumers from the true cost of healthcare, so too there is a growing recognition that prescription drug plans with minimal (and fixed) copayments provide little or no incentive to consumers to discuss treatment options with their physicians. While consumers do not directly determine what drugs their physicians prescribe, many patients

specifically request brand-name products despite the availability of lower-cost generic medications. Incremental changes in the design of cost-sharing strategies can encourage greater accountability, particularly when they go hand in hand with employee education.

Such education can help employees have better discussions with their doctors about which drug is most appropriate for a particular condition. Benefit incentives—a tiered plan in which the choice of a generic equivalent over a branded drug results in a significantly lower copay, for example—and a number of other cost-sharing formulas and design strategies offer employers greater room to maneuver. In considering which ones meet a company's needs, however, it is vital to keep the role pharmaceuticals play in maintaining a healthy workforce in mind.

Selecting the Strategies

While all employers can benefit from understanding the array of options that are available to influence the cost and quality of a pharmaceutical benefit program, some of the tools described here are likely to be most feasible for mid-size or large, sophisticated "value" purchasers, and small companies in coalitions.

In designing or revising a pharmacy benefit plan, there are two key questions to keep in mind:

 How can the company maximize its health benefit investment by maintaining or improving the health status of its employees and attracting and retaining workers?



 Which strategies will contribute to better management of spending on prescription drugs?

The elements of an Rx plan can be simply divided into three categories:

- Design incentives
- Formulary-based strategies
- Clinical interventions

These three elements should be designed to balance cost effectiveness and clinical efficacy. The various pharmacy benefit design tools should be evaluated based on their ability to promote health, boost productivity, maintain employee satisfaction, and yield the best return on investment.

Maximize design incentives

Choosing and using the right incentives is one of the most difficult aspects of pharmacy benefit design. Money, of course, is a powerful human motivator. The challenge lies in finding a formula that will encourage employees to make cost-effective choices without imposing so heavy a burden that they end up foregoing needed treatment.

Recognizing that approximately 30 % to 40% of patients that are taking medication are partially non-compliant, any benefit design that might worsen compliance should be monitored for unintended consequences that impact quality and cost-effectiveness. Here are the main design incentives and factors to consider for each. Pairing incentives with employee education will yield optimal results.

(See the cost-sharing worksheet in Section B of the Appendices.)

Cost sharing

What cost-sharing formula is right for a given company? The answers to this and other questions about pharmacy benefit design depend on corporate goals, the level of understanding of the factors driving up drug spending, and recognition of the implications and tradeoffs.

In deciding on a cost-sharing formula, there are two major features to focus on. One is structure:

- Two tiers, three, or more?
- Fixed copay or coinsurance?

The other is price:

- How large or small should out-ofpocket fees be?
- How big a differential between tiers?

The vast majority of employers have abandoned the single copay strategy in favor of a two-tier plan or, increasingly, a three-tier design, currently used by about 40% of large employers. Research suggests that employee satisfaction with both designs is roughly equivalent—if the differential between the second tier (reserved for brand drugs on formulary) and the third tier (for non-formulary branded products) is no more than \$10.2

But is \$10 enough of a difference to influence employee choice? Many employers would say it isn't. Benefit managers generally acknowledge that replacing copayments with coinsurance, a percentage-based contribution strategy, would foster greater consumer responsibility because it exposes people to the true cost of pharmaceuticals.

To date, however, few companies have made the switch, in part because

coinsurance is believed to be unpopular with employees. Many consumers dislike the uncertainty of not knowing in advance how much they will have to pay for a prescription. A more pressing problem is the possibility that the contribution for a high-priced but necessary drug would discourage an employee from filling the script at all.

Higher copays and differentials have a disproportionate effect on sicker and/or low-wage workers, but there are creative ways to address this, as a strategy recently adopted by a large health plan illustrates: Introduce disease management or educational programs targeting your most costly conditions, then waive copays or coinsurance charges for those who participate.³

Low-wage workers as well as older employees with chronic health problems may respond well to such an incentive. The design could be expanded to encompass a variety of self-care measures: Regular attendance at classes or support groups related to a particular condition, ongoing participation in an exercise program, or evidence of strict compliance with a treatment regimen could all be accepted as reasons to waive or reduce out-of-pocket fees.

Any incentive programs must be based on actions or efforts, however, rather than on physiological changes. Bestowing rewards for actual weight loss, decline in blood pressure, or other measures that are not entirely within people's control leaves a

company open to discrimination claims.

Generic substitution

Fostering the use of generic drugs, whenever appropriate, is key to a cost-effective benefit design. Pairing a voluntary generic substitution policy based on a financial incentive with an educational campaign may encourage employees to request that their physicians prescribe generics—or to agree to a pharmacist's suggestion of a generic substitute. The size of the differential is a factor here, too, of course. The \$81 or so that separates the generic copay from the copay for branded products in a typical two-tier plan may not be enough to convince an employee to forsake a trusted name-brand drug. But the \$22 between the average generic copay (\$9)1 and the copay (\$31)1 for the brand version of the same product in a three-tier plan may be substantial enough to make the difference.

A mandatory generic substitution policy is another option as well. Requiring a plan participant who opts for the brand-name version of a drug available in generic form to pay the full differential can lower average drug expenditures by \$35 to \$50 per member per year, researchers who studied claims data from some 700,000 beneficiaries estimate. 4 To avoid a negative effect on employee health and morale, however, a campaign to educate employees about generics and explain that the generic equivalent has the same active ingredients as the brand drug should precede a switch to a mandatory substitution policy.

Therapeutic substitution

Generic substitution is not to be confused with therapeutic substitution,

which with physicians concurrence authorizes the pharmacist to dispense an alternate chemical entity from the same therapeutic class instead of the drug the doctor originally prescribed. The practice is highly controversial and opposed by medical societies. It is important for an employer to understand the process the PBM uses for making changes to the original prescription when dispensing drugs.

Not only could a switch to a drug in the same therapeutic class be harmful to a patient being maintained on a particular medication for a chronic condition, it may be that the replacement is a higher priced drug with a larger rebate for the PBM. To avoid such problems, an employer should consider requiring the PBM to demonstrate a clearcut clinical rationale for any such change—or prohibiting Rx switches unless evidence that the previously used drug is unsafe emerges. Any provision for a switch to a preferred drug that is not the generic equivalent of the previously used medication should call for the approval of the prescribing physician.

Mail order pharmacy

Education is crucial to the success of mail order programs, which double as a design incentive and patient satisfaction tool. These programs also tend to boost patient compliance and bolster an employer's ability to manage the care of the chronically ill—if they're used, that is. Because they rely on bulk purchasing discounts, mail order programs can be an effective cost-control strategy and a way for the chronically ill to mitigate the effects of higher retail co-pays. More than half the nation's large employers offer them. Smaller

companies may find opportunities to offer their employees mail order pharmacy and other programs through membership in local or regional healthcare purchasing cooperatives.

Mail order programs are not designed to be used by all enrollees, however, or to supply any and all drugs; typically, they only provide medication that is needed on a long-term basis. Thus, it is important that enrollees understand the difference between a maintenance medication (taken for a chronic condition) and a drug taken sporadically (for an acute flare-up) or seasonally, such as an antihistamine needed only when the pollen count is high. Employee education should highlight the potential for cost savings as well. The average mail order copayment for 2001, \$221 for a brand drug on formulary, for instance, saves a participant close to \$10 a month. At a retail pharmacy, the same 90-day supply—which would be dispensed in three separate 30-day quantities and thus require three separate copays would cost the participant \$51, based on the \$17 average copayment for a preferred drug in a three-tier plan. Thus, what may seem like a large copay initially actually represents a significant savings.

In addition, enrollees with chronic conditions that require long-term drug therapy often welcome the opportunity to get a 90-day Rx supply and, in some cases, to receive automatic refills without having to make frequent trips to the local pharmacy. Compliance with treatment is enhanced by eliminating or diminishing lapses in treatment, and a readily available supply of medication helps prevent acute flare-ups and costly medical emergencies.

Building the Right Formulary

(See formulary "must haves" and "maybes" on page 9.)

The formulary, or preferred list, has been called the cornerstone of the Rx plan and the key to employee access. It is also the basis for a range of strategies that aim to balance cost effectiveness and clinical efficacy. The key consideration here:

• How open or restrictive a model should it be?

To answer the question, it is necessary to consider the ramifications: An open formulary, in which the vast majority of FDA-approved prescription drugs are covered, generates the highest level of employee satisfaction but the least control on Rx spending. Conversely, a closed, or mandatory formulary, does the best job of limiting Rx costs, but it restricts enrollees' access and has been found to be associated with a drop in worker satisfaction and on-the-job performance.

A selective, or restrictive, model, like a closed formulary, provides automatic reimbursement only for drugs on the preferred list, but covers others under specified circumstances. It, too, can have a dampening effect on productivity and employee morale without the cost savings to offset it.

But choices are rarely clearcut, and the success of the formulary design depends not only on the model but also on the modifications. Most employers use some sort of hybrid, providing coverage for almost all drugs but using cost differentials to encourage use of preferred products

and, often, design techniques to discourage use of high cost nonformulary medications.

Innovative cost sharing strategies

In addition to the standard two- and three-tier cost-sharing strategies, some pharmacy benefit plans and plan sponsors have begun experimenting with a range of other financial incentives. For example, many PBMs have developed a four-tier model that combines copays—used for the first three tiers—and coinsurance for the fourth. Set at a rate as high as 50%, the top tier would be reserved for so-called lifestyle or life-enhancing drugs and previously excluded medications.⁵

New models based on clinical efficacy are being studied as well. One tiered design would reserve the lowest level for "core therapies" for acute conditions and serious illness, require somewhat higher out-of-pocket costs for prescription drugs that have viable over-the-counter options, and impose the highest fees for lifestyle drugs. Benefit consultants have also raised the possibility of a benefit-based copay in which the beneficial quality of the drug rather than its value to the individual patient would be the determinant. Under such a system, an antihistamine might have a lower copay during allergy season, for example, than at other times of the year. 5-7

Forms of prior authorization

Physician confirmation of medical appropriateness of a particular drug, plan approval of a medical exception—authorizing the use of a non-formulary product for a patient who might otherwise be at risk for an

adverse interaction with a medication he's taking for another condition, for example—and step therapy are all forms of prior authorization. All are intended to balance cost effectiveness and clinical efficacy. Because they limit employee access to certain drugs and annoy both physicians and pharmacists, however, these strategies require careful consideration.

The answer to the question of whether employees generally support or oppose provisions requiring approval of a medical exception or a physician's confirmation of medical appropriateness is unclear. But both can contribute to productivity loss because the inconvenience involved in complying with such requirements may intrude on the workday.

Step therapy is a provision that calls for evidence of an unsuccessful trial with one, typically older and lowerpriced, medication or therapeutic class of drugs before authorizing coverage of a newer, generally higher-priced treatment. It can be effective in controlling widespread use, for example, of a more expensive drug that affords protection against a potentially serious but relatively rare side effect. But here, too, drug cost should not be the sole concern. Productivity loss is a possible side effect of step care if it results in repeat doctor visits or phone calls to the health plan to seek approval of a particular drug.

Is prior authorization worth it? Used judiciously, it can be. The key is to limit the number of products that require it, base decisions on evidence-based clinical guidelines, and keep an eye on the cost/benefit ratio. 8-10

The formulary Rx

What is the basis for decisions about which drugs are placed on the formulary?

Choices are generally based on safety, efficacy, and cost per dosage. Because of the difficulty in quantifying overall value, the broader picture—a drug's ability to improve health and wellbeing and reduce other medical costs related to a particular condition—tends to be left out. What's more, the number of drugs in a particular therapeutic category is often limited. This common practice operates on the assumption that similar products, such as all selective serotonin reuptake inhibitors (SSRIs) for depression, are essentially equal and interchangeable.

FORMULARY "MUST HAVES" AND MAYBES

Although companies do not determine what drugs are placed on the formulary, it is important for employers to ensure that plans and PBMs have a solid process in place to select preferred drugs and to keep members informed about which medications are on the preferred list.

Must haves:

- Drugs recommended in clinical guidelines issued by government agencies and medical societies for prevention and treatment;
- Evidence-based decisions on drug placement;
- A sufficient selection of drugs in each therapeutic class;
- Productivity concerns considered in decisions on drug placement;
- A process for appeals and patient/clinician notification of denial;
- Clinicians making formulary decisions.

Maybes:

- A policy based on CDC recommendations for the appropriate use of antibiotics;
- Out-of-pocket payments covering the full cost differential for branded drugs with generic equivalents;
- A step therapy approach for products whose main benefit is relief from relatively rare side effects;
- A tiered copay or reference pricing system that places new products with minimal differences from older drugs on the top tier.

It is not necessary to include every drug on the formulary, but it is important to recognize that even drugs in the same class have different mechanisms of action and side effect profiles. There are differences in individual response, sometimes related to racial or genetic differences, that today are rarely predictable. It's not unusual for a depressed patient, for example, to respond to one SSRI after being unresponsive or unable to tolerate a number of others.

Regardless of what model formulary is selected, employers should insist that the health plan or PBM:

- Use evidence-based prescribing principles in making formulary decisions.
- Focus on a medication's ability to improve health, (rather than on price and rebate).
- Ensure that therapies called for in clinical guidelines issued by government agencies and medical societies (both for prevention and treatment of serious illness) are covered.
- Ensure that productivity concerns, including a drug's impact on employees' ability to get to work and function effectively, are addressed.

Clinical Interventions

Disease management

(See disease management worksheet in Section B of Appendices.)
Less than optimal use of pharmaceuticals, primarily among those with chronic disease, costs an estimated \$76 billion a year, and is believed to be the cause of nearly 30% of all hospitalizations.²

Programs designed to ensure that the chronically ill receive proper care, education, and support and comply with a safe and effective treatment and self-care regimen should be a crucial part of any corporate health benefit package.

Health plans, PBMs, and specialty vendors are the primary providers of disease management programs, but pharmaceutical firms, local healthcare facilities, and the staff of in-house corporate health departments sometimes offer programs as well. It's not the source that's crucial, however, but the focus. Because disease management programs can drive up drug use through enhanced compliance, for example, a vendor that promises or is expected to lower Rx costs will be hampered in its ability to be effective. The corporate objective and the goal of the program administrator—which should be to maintain health, boost productivity, and drive down overall medical costs—must be in alignment.

The Disease Management Association of America (DMAA) provides the following definition of a full-fledged program: "Disease management is a system of coordinated healthcare interventions and communications for populations with conditions in which patient self-care efforts are significant."

Any disorder with high prevalence and high direct and/or indirect costs is an obvious target for a disease management program. But there are additional criteria to consider. The ideal candidate is a condition with widely accepted clinical guidelines that define appropriate treatment, yet one where there is considerable variation in practice patterns and poor patient compliance with treatment. Acute flare-ups, which adherence to therapy can avert, are also part of the clinical picture. The potential for relatively short-term savings also makes a disease attractive for disease management strategies. ¹¹

Key features of a comprehensive disease management program include:

• A process of population identification and collection of baseline health status data;

- Patient-specific assessment and recommendations;
- Evidence-based guidelines that are provided to physicians;
- Collaborative practice models that include doctors and other providers;
- Patient education in self-management and support, e.g., a nurse line;
- Ongoing case management and coordination with doctors and patients;
- Process and outcomes measurement, evaluation and management;
- Routine reporting/feedback to patient, physician, health plan, and other providers;
- Tracking and guaranteeing cost savings/quality improvement.

The association classifies less comprehensive programs as disease management "services," but in some cases, a more limited program is well suited to a company's needs. Even programs that do not include every component should provide regular reports with measurable outcomes—a reduction in ER visits among asthmatics who participate, for example.

The DMAA offers tips for employers to consider in settling on a disease management program and selecting a vendor. The patient education features should be carefully evaluated. Programs with strong behavior change components, for example, are more effective than those that provide educational materials alone. The extent and frequency of data reporting are also crucial. Programs that do not provide timely access to information such as nurse support line utilization and Rx claims data, according to the DMAA, are unlikely to yield the best results.

The association also suggests considering a disease management program that focuses not just on one disease but on multiple conditions, a new approach that's well-suited to the needs of an older and sicker population. This is similar to the case management services that some PBMs offer as part of their utilization management, although the pharmacy-based programs typically focus on medication compliance alone.

Outsourced or in-house

Which disease management services or programs are best suited to an in-house program? Which should be outsourced?

Again, the DMAA weighs in: An outside vendor is likely to be a better choice than an in-house program for a company with no previous experience in disease management, it suggests. For companies with more experience, however, there are other considerations. ¹²

One is staffing. Does the organization have an occupational health

department with the resources to conduct a full-fledged disease management program or the ability to determine which services would yield the biggest payoff?

Another is the nature of the illness being targeted. Employees may be reluctant to participate in an on-site program involving a disorder that has a perceived stigma, such as depression or bipolar disease. ¹² It should be recognized that employee assistance programs have effectively dealt with these issues in many organizations.

Many employers have had success in conducting in-house health management programs, a variation on the disease management theme. Features may include Health Risk Appraisals and follow-up reports, on-site screening, smoking cessation classes, stress relief, exercise, and nutrition and weight management, with participation often boosted with a reward or incentive. With studies repeatedly showing that the vast majority of healthcare costs are incurred by a small fraction of the population, programs that help employees get healthy—or stay healthy—are a sensible and profitable investment.

Any internal health-related program requires strict adherence to measures to ensure employee confidentiality, with personal health information accessible only to those with a legitimate need to know in keeping with new federal privacy rules. Companies that conduct HRAs, for example, typically use an outside vendor to tally the results and issue a report revealing findings only in the aggregate. Many states have

enacted their own privacy regulations as well; some are stricter than those issued under HIPAA (the Health Insurance Portability and Accountability Act), and should be reviewed to ensure compliance. ¹³

Predictive modeling

Technology is at the heart of predictive modeling, a newer and broader approach to disease management whose aim is to prospectively identify at-risk individuals and intervene before a catastrophic illness strikes or chronic disease fully develops. Also known as population health management or care enhancement, it involves the use of mathematical models to comb myriad sources of data—pharmacy claims, reports from primary care providers and specialists, input from employee self-appraisals, for example—in search of opportunities for timely intervention. Predictive modeling vendors use historical claims data to generate relative risk scores for beneficiaries, providing employers with forecasts of future cost drivers as well as the opportunity to develop programs to mitigate the risk. 14, 15

Here, as with a more traditional disease management service, the program providers are in touch with physicians. But in this newer model, the focus is likely to be on the application of the latest research findings and on pointing out patients who are potential candidates. While some doctors may resent the intrusion, others appreciate the opportunity to speed the time it takes to put newly proven applications into practice.

While the verdict is still out on the return on investment, there are signs

that many organizations view this as a valuable and cost-effective approach. An outcomes verification project is underway at Johns Hopkins University. The Federal Employee Health Benefits Program and Medicaid both have pilot predictive modeling programs with one vendor. A Boston-based vendor cites such giants as Aetna, Cigna, Pfizer Health Solutions, and Pitney Bowes as users of its predictive modeling software products as well. 15, 16

Case management and compliance

Typically offered by PBMs and health plans as part of their efforts to manage drug utilization, case management/compliance programs include some but not all of the components of disease management. Such services generally target enrollees with one or more chronic conditions and feature refill reminders, identification of patients who are underutilizing medication or have stopped taking it entirely, and intervention, as needed, with patient and physician.

Here, too, matching the service to the needs of those covered is key.

An older, sicker workforce or group of retirees will benefit from a case management approach focused on age-related conditions and treatments, for instance. For a young, healthier population, a compliance campaign might target childhood immunization instead. Three out of 10 children enrolled in commercial HMOs do not receive the recommended chicken pox vaccine. ¹⁷ In addition to the health risk that poses, productivity suffers when parents miss work to stay home with kids who contract the disease.

Utilization management

(See drug utilization worksheet in Section B of the Appendices.)

On a broader level, drug utilization review (DUR) is an assessment of the appropriateness of Rx drug use and prescribing patterns that can occur at various points in the process.

Concurrent review, for instance, takes place at the time the drug is dispensed: The electronic system that connects all the pharmacies in the network flags the pharmacist if a newly prescribed medication has the potential to interact dangerously with another product the patient is taking. Retrospective review may include drug edits to verify that physician prescribing patterns are appropriate.

Assuring that the proper dosage is prescribed and screening for therapeutic duplication occurs at the point of sale as well. Some prior authorization measures—utilization management strategies that aim to balance cost effectiveness and clinical efficacy are discussed below—are applied at this point as well.

Summary

Not all of the tools described in this chapter will be applicable to or appropriate for all employers. In the appendix several other tools and disease management resources are highlighted. There is also a list of commonly used terms and definitions. It is important to remember that whatever tools are chosen will only be useful and effective in the context of a solid program of employee education.

II. ENGAGING EMPLOYEES

n the quest to effectively manage a prescription drug benefit, it is important not to lose sight of the fact that it is not just about benefit design. It's no secret that education can play a crucial role in helping workers become more cost-conscious healthcare consumers or that ensuring that those with chronic conditions receive the proper treatment and follow a daily self-care regimen—the premise of disease management—can bring a reduction in acute episodes. Similarly, a clear explanation of what their health and pharmacy benefits cover, how to file appeals, if necessary, and other related details can help employees better negotiate the system. Yet this is one component of employee education that benefit managers tend to overlook.

A Harris Interactive poll of more than 4,000 adults, conducted in 2000 for the National Pharmaceutical Council, highlights Americans' understanding of and attitudes about employer-sponsored drug coverage—and provides glaring evidence of a communication gap.¹

Respondents were not at all confused about their need for more information: Eight in 10 said they wanted details about which drugs were on a health

plan's preferred list before enrolling in it. Nearly nine out of 10 wanted to know what was preferred before their doctor selects a particular drug and more than nine out of 10 wanted to know what was preferred before going to the pharmacy to fill the prescription.

The most obvious lapse: Nearly two out of three of those polled were unfamiliar with the word "formulary." After hearing an explanation, however, six respondents in 10 said they thought that their pharmaceutical plan uses one. While most believed that reliance on preferred drugs is a money-saving measure, nearly half feared that formulary medications are less effective.

Information about the appeals process is in even greater demand: Fully 97% wanted to be told what steps to take if they received notification that a particular drug had been denied, and 98% sought assurance that any appeal they filed would be decided on by independent reviewers.

On a more positive note, roughly nine out of 10 respondents agreed that medication had improved their own lives or the life of someone close to them and had helped prevent the development or worsening of a serious illness. Close to nine out of 10 expect prescription drugs to extend their own life or the life of someone they care about as well.

Notably for employers, eight respondents in 10 recalled a time when a prescription drug helped them or someone close to them get back to work

INFORMATION GAPS

- ~2/3 are unfamiliar with the term "formulary;
- Almost half suspect that formulary drugs are less effective;
- 8/10 want information on "preferred" list prior to plan enrollment:
- Almost 9/10 want to know what is "preferred" before their physician selects a drug;
- >9/10 want to know which drugs are "preferred" before going to the pharmacy;
- Nearly all want information on the appeals process. Source: Harris Survey

sooner and be more productive, and nearly two out of three said drugs had helped them or a loved one hold on to a job. No wonder consumers have strong feelings about their ability to get the medication they need when they need it at an affordable price.

Six in 10 said they would certainly or very likely complain to their health plan if their out-of-pocket costs for prescription drugs were significantly increased. But that doesn't let plan sponsors entirely off the hook: More than half would also take their complaints to their employers and look to switch to another employer-sponsored plan.

What most would not do is jeopardize their health by tampering with their medication.

Higher out-of-pocket Rx costs would prompt nearly one in 10 to consider a change in jobs, a factor that employers planning an increase in copays would be wise to take into account. Nonetheless, recent findings suggest that would-be job seekers in search of a more generous drug benefit are not likely to find it. Nationwide, Rx copays are increasing.

Not surprisingly, the Harris poll found that consumers feel strongly about other strategies aimed at cost control as well. While respondents were about as likely to favor as to oppose a strategy calling for the pharmacist to contact the patient's doctor before filling a prescription for a nonformulary drug, they plainly objected to the use of financial incentives to encourage doctors to use preferred products. Some seven in 10 also opposed the increasingly prevalent

MOST EMPLOYEES WOULD NOT "TAMPER" WITH THEIR MEDICATION

- 87% would not settle for a less expensive drug
- 90% would not reduce the dosage or take the drug less frequently to make it last longer
- 92% would not stop taking the drug
- 73% would not be amenable to a lower priced, less convenient drug

ENGAGING EMPLOYEES

- Provide a list of "preferred" drugs for each plan.
- Describe features of the company Rx benefit plan and the rationale.
- Provide access to HEDIS data.
- Ensure that plan documents are comprehensible to all employees.

practice of requiring enrollees to pay more for non-formulary medications, which at least 40% of firms with 500 or more employees now do.

However, with Rx spending continuing to surge, that finding is not likely to deter employers bent on switching to a multi-tier benefit design. But other opinions expressed by those surveyed can and should be heeded, particularly the plea for being kept better informed. Their responses are vivid reminders that in crafting brochures, comparison charts, or other written material and in planning the content to cover at employee meetings, nothing should be taken for granted.

In addition to defining the components of the formulary (the drugs on the "preferred list"), it is important for employers to clearly describe each feature of the Rx benefit plan, providing the rationale for including it as well as the definition whenever possible. Enrollees who understand, for instance, that a brand drug and its generic equivalent have the same chemical structure and safety profile are more likely to opt for

generic substitution than those who aren't sure exactly what generic means. Recognizing that cost is the only major difference between the two products should make employees more amenable to a financial incentive program that requires a substantial copay—or the full differential—for a brand drug with a generic equivalent as well.

If employees have a choice of health plan, it is incumbent on the employer to provide the details they need—the drugs on formulary, for starters—to make an informed selection. That includes access to HEDIS (Health Plan Employer Data Information Set) reports, whenever possible, and details on how to compare plans' scores on a range of clinical and service-related performance measures. (See Quality Metrics in Chapter III.)

Benefit managers charged with preparing written material about health and drug coverage would also do well to heed a warning issued by the Employee Benefit Research Institute. For the estimated 42 to 90 million Americans who function at low literacy levels and for those for whom English is a second language, plan documents and other explanation of benefits—which even sophisticated readers tend to find confusing—are apt to be incomprehensible. 19

The move to a consumer-driven, patient-centered healthcare marketplace depends on employers' ability to present vital information about employee benefits in terms that all workers can understand. That translates into plain language, relatively short words, and a lack of jargon and employer purchasers' willingness to engage employees in the quest for quality.

(See cost-sharing and prior authorization worksheets in Section B of the Appendices.)

NAIC MODEL LEGISLATION

Consumer concerns about managed care and increasingly about pharmacy benefit management practices often draw the attention of insurance regulators. Many of these concerns are addressed in a new model regulation soon to be released by the National Association of Insurance Commissioners. This model, which at least some states expect to adopt, can be found on the web-site of www.naic.org by clicking on the link for "Draft Model Acts" on the bottom of the home page and then selecting "Health Carrier Prescription Drug Benefit Management Model Act." Various cogent provisions of the model are referenced throughout this paper. The model certainly establishes a number of the standards relative to disclosure of information to employees, including disclosure in member handbooks about the use and design of formularies, prior authorization, step therapy, and other pharmacy benefit management practices. In addition, there are requirements to make information available to current and prospective members, about the drugs subject to formulary restrictions or other benefit limitations. Last, plans and PBMs are required to notify members and physicians 60 days in advance of deleting a drug from a formulary or imposing a new benefit requirement or limitation, in order to give the member time to appeal.

The federal Dept of Labor has also recently issued regulations, which outline requirements to notify beneficiaries, whenever a claim is denied, of the basis for the denial and their rights to appeal. It also establishes standards and timelines for appeal processes. As part of the ERISA requirements, this regulation affects all employer-sponsored health plans, whether self-insured or fully insured.

III. CHOOSING AND MANAGING A PBM

hether an Rx benefit plan is administered by a pharmacy benefit manager or health plan, a thorough evaluation of the program and the features offered is in order. Regardless of whether a benefit manager is investigating a new vendor or assessing the performance of one with whom there is an ongoing relationship, the question is the same: What evaluation criteria should be used?

So is the answer: Clinical analysis, data collection and reporting, access to pharmaceutical products, member services, and purchasing strategies all require close scrutiny.

Quality metrics

When dealing with a health plan, it's important to look beyond its experience in managing prescription drugs, seeking evidence of its ability to manage health and overall health costs.

HEDIS (Health Plan Employer Data and Information Set) report cards provide standardized measures that score managed care plans on their compliance in dozens of clinical and non-clinical areas. They range from cesarean delivery rate to follow-up care after heart attack, access to primary and preventive care, immunization rates, and breast cancer screening. Accreditation by NCQA, the organization that issues the report cards and conducts patient satisfaction surveys, is a mark of quality as well.

Employers should take these metrics into account and employees should have the opportunity to review HEDIS scores and NCQA accreditation during open enrollment.

Formulary decisions

Queries should reveal whether clinical measures or manufacturer discounts and rebates are the key determinants of which drugs are added to the preferred list. It is crucial to find out how decisions are made and who makes them. Benefit managers should review the credentials of the clinicians who determine both the formulary make-up and the outcome of appeals. These decision makers typically have an advanced degree, such as a PharmD, a background in drug evaluation, and experience on Pharmacy & Therapeutics committees.

NAIC Model Act
The National Association
of Insurance
Commissioners' (NAIC)
model act on pharmacy benefits
requires that a P&T committee must
include physicians and pharmacists with
current knowledge of clinically appropriate
prescribing, and must base their clinical
decisions about formularies and the use of
other benefit limitations on scientific and
medical evidence.

Benefit managers should ask specifically how new drugs are handled and how soon they're considered for formulary placement. Decisions regarding non-formulary status or prior authorization should be made before a drug goes on the market; if no such limits are implemented at that point and the new medication is readily accessible, limits imposed at a later date may create clinical problems and cause personal distress. A checklist of prior authorization provisions is also a worthwhile

evaluation tool, in part to ensure that the plan administrator does not make the processes so onerous that they become a virtual guarantee of denied access.

Benefit managers may want to request:

- A list of drugs for which step therapy applies;
- *The average turnaround time for authorization;*
- A systematic review of all denials;
- Provisions for emergency approvals or Rx supplies;
- The previous year's generic dispensing rate;
- The top five drugs requiring prior authorization in the previous year and the approval rate for each.

Requiring a systematic assessment of any prior authorization program included in the Rx plan design is an effective way to monitor its effects. The approval rate is a key criterion, and the following rule of thumb has been suggested as a guide: If it exceeds 80%, chances are the administrative costs outweigh any potential benefits.²

Concurrent review, retrospective review, and compliance programs are other utilization management functions that should be assessed, with targeted questions to determine which features are offered and whether they can be tailored to specifications. Data reporting is crucial, too, so questions about what information is available and how it's reported are also in order. If the plan administrator tracks late refills and no refills, for instance,

are those numbers included in quarterly reports? Are comparison data provided to help assess whether or not a compliance program is yielding results?

Customer service

A pharmacy benefit plan should also offer a wide range of member services, addressing such specifics as customer service support for enrollees who are hearing-impaired or don't speak English, the extent and capabilities of the retail pharmacy network, and the turnaround time for Rx orders placed by mail. Benefit managers should delve into the issue of member access with questions to determine which formulary options and administrative procedures are used.

In assessing any pharmacy benefit, a direct line of questioning is the best way to ensure that the plan administrator's goals and those of the employer are aligned—that clinical evidence takes priority over discounts and rebates in determining which medications are added to the formulary. HMOs often outsource pharmacy management functions. If that's the case with the plan being considered, it is important to request information about the subcontractor as well. Another means of measuring the effectiveness of existing health and pharmacy benefit plans is to survey employees to gauge their satisfaction with member services.

(See the pharmacy request for information worksheet on page 56 and the drug utilization review program checklist on page 53 for additional details.)

IV: UNDERSTANDING THE PHARMACEUTICAL "FOOD CHAIN"

At the onset we recognized that the nature of this section necessitated a level of expertise beyond that resident within our working advisory committee. We therefore requested that PricewaterhouseCoopers (PWC), as a core contributor to Wye River Group on Healthcare, provide insight into the marketplace dynamics underlying the cost of drugs. The information in this chapter of the guide was authored by and reflects the sole experience of PWC. PWC has referenced publicly available documents wherever possible. We recognize that percentages and dollar amounts will likely vary from one part of the market to another. No funding was provided to PWC for this valuable contribution and we are grateful for their expertise.

nderstanding the pricing of prescription drugs is a challenge to most corporate benefit managers due to the variety of ways a given drug price may be represented from a manufacturer or distributor. Additionally, different health care entities measure drug purchase prices in a number of different ways making it difficult for payers and consumers to pin point a fixed value for a drug product. Unlike other industries, the pharmacy industry doesn't use terms such as "suggested retail cost" and "wholesale cost" in a way that is easy for most consumers to understand. Instead the pharmacy industry uses different terminologies derived from routine publications by "price distributors" that convey a purchase price that is not equal to the net price to the end user.

A price distributor is a company in the business of providing drug pricing information and other related clinical data to a variety of users throughout the pharmacy industry. Included in this user group are community pharmacies and Pharmacy Benefit Mangers (PBMs). These price distributor companies routinely survey wholesalers and manufacturers to determine the most current and accurate price for a given product.

The price assigned to the drug by the drug manufacturer is compiled by commercial organizations such as Red Book, First DataBank and Medi-Span for use by the pharmaceutical community 1. Information obtained by these companies is date stamped and stored in a database, which is prepared for distribution to their network of users. Users subscribe to these pricing services and receive current price information on thousands of drug products. Users also have an option to receive the pricing information daily, weekly or monthly. PBMs typically receive electronic data feeds from these companies on a daily basis.

Drug purchase costs communicated from the pricing distributors to the user groups are expressed as "Average Wholesale Price" (AWP). The AWP is the best known of the pricing terms. It is comparable to a sticker price on an automobile where the manufacturer suggests a certain price but almost everybody pays something different from that price.2 The AWP however is neither "average" nor "wholesale"; it is simply a number assigned by the products manufacturer³. The AWP is often described as a "list price", "sticker price" or "suggested retail price" reflecting that it is not necessarily the price paid by the purchaser or a consistently low or "wholesale" price.4

Practically speaking, AWP is really nothing more than a standard or a baseline that is used in understanding drug costs during the purchasing process. It really has nothing to do with the term "wholesale" as we know it. To that end, pharmacies, wholesalers and distributors do not actually purchase drugs at AWP nor do they all purchase drugs for the same price. Drug prices vary between industry channels and even between pharmacies. Therefore, there really is no reasonable way of actually determining a "true" drug cost because of the variability in the discounts offered to each delivery channel purchasing the products. Simply put, pharmacies purchase drugs at some number below AWP. In other words, AWP is discounted by the wholesaler, distributor and manufacturer to the community

CHANNELS OF DISTRIBUTION FOR PRESCRIPTION DRUGS

MANUFACTURER

WHOLESALER

Retail Hospital Hospital Hospital HMO's Clinics 26%

15%

Mail Order Pharmacies 10%

SOURCE: Congressional Budget Office based on Micky Smith, Pharmaceutical Marketing Strategy and Cases (New York: Pharmaceutical Products Press, 1991), Chapter 3; Boston Consulting Group, The Changing Environment for U.S. Pharmaceuticals (Boston: Boston Consulting Group, April 1993); and Pharmaceutical Research and Manufacturers of America, 1997 Industry Profile (Washington, D.C.: PhRMA, March 1997), p. 31.

NOTES: Figures in parentheses represent shares of the prescription drug market in 1996, calculated as a percentage of total U.S. sales at manufacturer prices. HMOs = health maintenance organizations.

- a. Some chain-store pharmacies buy directly from the manufacturer.
- b. Some mail-order pharmacies go through a wholesaler.

pharmacy at the point of purchase. Discount levels below AWP that are achieved by pharmacies vary and depend on a variety of factors, which include size of purchase and speed of payment.

Historically, pharmacists used AWP as their basis for pricing. However, they would usually purchase drugs from wholesalers or manufacturers at some percentage discount from AWP and could thus retain the difference between what they paid for the drug and the cost basis for reimbursement as an additional profit.⁵

What do pharmacies actually end up paying for drugs?

There are a variety of factors, which influence a pharmacy's net purchase price. These factors include purchase volume and timeliness of payments. A 2000 report by the U.S. Department of Health and Human Services estimates that retail pharmacies purchase brand name products at approximately AWP minus 18%. A study conducted in 1999 by the Office of the Inspector General (OIG) indicated that pharmacies purchased brand name drugs at an estimated average of AWP minus 21.8% for calendar year 1999.6 The OIG reviewed thousands of invoices from pharmacies participating in the Medicaid Program and reported their findings in a publication titled "Medicaid Pharmacy-Actual Acquisition Cost of Brand Name Prescription Drug Products" dated August 10, 2001.

A similar report on generic drugs titled "Medicaid Pharmacy-Actual Acquisition Cost of Generic Prescription Drug Products" issued on March 14, 2002 indicated pharmacies were purchasing generic drugs with an average discount of AWP minus 65.9%.⁷

What factors can influence the value of AWP in my contract with our PBM?

Many employer/PBM contracts define AWP as the average wholesale price listed for the National Drug Code (NDC)⁸ submitted by a nationally recognized pricing source on the date that the prescription is billed. Contracts may even delineate a difference in the AWP definition as it pertains to retail and mail order claims. Often AWP for retail claims will be defined as the NDC for the package size billed, whereas mail order claims will be for the NDC for the same product based on package sizes of 100's for tablets and capsules and 480ml's for liquids. Product package size is an important issue for employers to understand because it has a direct effect on the AWP of the product. In other words AWP may vary for any one product as a function of how that product is packaged. PBMs use these sizes of 100's or 480's as standards because they typically purchase products in bulk and dispense them in smaller quantities. However employers should know the smaller the bottle size (100's or less) the more expensive the unit AWP is for the drug. For many drugs, the product unit cost to the employer will be more if the PBM uses the AWP of a bottle size of 100 then it would be if they priced the drug using the AWP of a bottle size of 500 or 1000 or higher.

The chart above illustrates the cost differences for a given product as a

Drug Name / Strength	Package Size	Unit Cost ⁹	Difference Per 100 Units	Percent Difference
Product A (Calcium Channel Blocker) 5mg	90	1.4511		
Product A (CCB) 5mg	300	1.42207	\$2.90	2%
Drug Name / Strength	Package Size	Unit Cost 10	Difference Per 100 Units	Percent Difference
Product C (ACE Inhibitor) 20mg	100	1.18325		
Product C (ACE Inhibitor) 20mg	3000	1.15987	\$2.34	2%
Drug Name / Strength	Package Size	Unit Cost ¹¹	Difference Per 100 Units	Percent Difference
Product D (SSRI) 20mg	100	2.6681		
Product D (SSRI) 20mg	1000	2.5347	\$13.34	5%

function of package size for some commonly prescribed products. 9, 10, 11

The AWP discount that a PBM or health plan offers is also a key concern of plan sponsors. The extent of the discount is influenced by a number of variables, including client size, plan design, regional factors, competition, and the pharmacy plan's marketplace clout, but it's generally in the range of 12 to 16% for brand name drugs in retail pharmacy and 18 to 23%¹² for brand name drugs in mail order.

The retail brand discounts cited above are consistent with discounts reported in "Report to the President on Prescription Drug Coverage" issued by the Department of Health and Human Services (HHS). The HHS Researchers interviewed industry experts that estimate the retail brand discounts to be between AWP minus 13% to AWP minus 15%. ¹³

An August, 2000 study by David Kreling at the University of Wisconsin School of Pharmacy cites research published by Wyeth-Ayerst that found the Average Retail Brand Discount in 1998 was AWP minus 13.2%¹⁴. In addition 22% of the respondents to the Wyeth survey indicated that they receive brand name discounts of 15% or more ¹⁵.

Some PBMs choose to offer discount arrangements based on Average AWP, which has a direct effect on the net discount. Average AWP isn't as redundant as it sounds. It is in fact a means of reimbursement that considers averages of certain doses and package sizes in determining the net cost to the employer.

The Medco Health Consultant Website identifies this practice as one that intrinsically distorts the whole concept of AWP and any discount associated with it making comparisons between AWP's even more complex and misleading ¹⁶. In fact, this technique actually is a way of inflating the AWP, so that any discount then associated with it may appear to be greater than it is. Since the employer may be focusing more on the discount number and not on what they are actually paying, they can be easily misled and may be

enabling the PBM to pocket the difference ¹⁷.

The reimbursement rates between the PBM and the retail pharmacies are a result of on-going negotiations between the PBMs and the pharmacy providers and are often based on the anticipated number of patients geographically available to any given provider. Therefore, participating pharmacies are often reimbursed at variable rates even for one single employer.

How do contracted pharmacies make money under these reimbursement arrangements?

It is difficult for pharmacies to thrive in today's competitive market. Successful pharmacies rely on a high volume business backed with strong purchasing discounts. Consider the following simple example. Using the acquisition cost numbers cited earlier from the 1999 OIG Report we can estimate the profit of a pharmacy for a brand name drug with an AWP of \$100.00.

If the full AWP of the drug reimbursed is \$100.00 and the pharmacy has a net purchase discount for that same drug at AWP minus 22%, and assuming the PBM is reimbursing the pharmacy at AWP minus 13%, using the Kreling figure, with a \$2.00 dispensing fee and \$10.00 co-payment the following will illustrate the transaction model and the pharmacies rate of profit:

What About AWP on Generics?

Understanding AWP as it relates to generics is a little more complicated then understanding AWP's for brands. Competition between generic companies on products they mutually produce is fierce. The report on

SAMPLE PRODUCT AVERAGE AWP/UNIT

\$.4916
\$.4864
\$.6216
\$.5930

But, lowest AWP/unit available on market is \$.3945

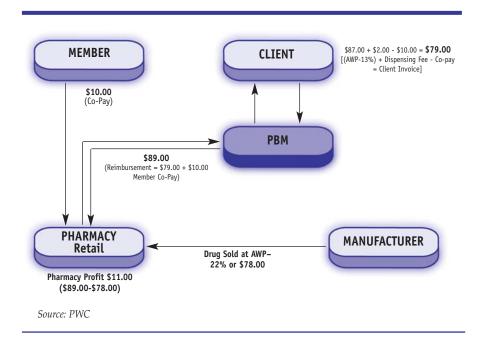
Impact of average AWP on drug spend could be as much as 25%

Source: Medco Health Consulting Website, January 2002

generic drugs titled "Medicaid Pharmacy-Actual Acquisition Cost of Generic Prescription Drug Products" issued on March 14, 2002 indicated pharmacies are purchasing these products at an average discount of AWP minus 65.9% Additionally, since generic drugs are relatively inexpensive, pharmacies have an opportunity to buy these products in bulk. Often, the larger the bulk purchase the steeper the discount offered to the pharmacy.

As a result of the competition and the variability in purchase price for generics reimbursement for these products on the retail level tends to be even more complicated then brands. When reimbursing generics PBMs often use pricing limits known as Maximum Allowable Cost (MAC). For generic drugs about three fourths are reimbursed using limits known as MAC¹⁹. These limits are established by PBMs based on the lowest estimated acquisition cost for any of the generic equivalents of a given drug. The MAC tends to be 50-60% below AWP²⁰. The remaining one-forth of generics are reportedly reimbursed like brand name drugs at AWP minus 13-15% 21.

MAC Pricing allows the PBM to set reimbursement on a product specific basis without regard to which manufacturer NDC was purchased or used in the billing process. Therefore MAC Pricing eliminates the inherent variability in generic product AWP's. Also, each PBM has a separate and proprietary means of establishing MAC. Therefore no two PBM's will have the same reimbursement for a single generic drug. This is an important issue to employers when selecting a PBM because the



differences between one PBMs MAC and the other could be significant.

Lastly, not all generics have MAC prices. MAC inclusion is based on a variety of factors including but not limited to product availability, product ratings and amount of time the product is on the market. This is why generic drugs not priced as MAC are often priced with the same discount the PBM uses for brand name drugs²². The, number of products included on the MAC list should therefore be equally as important to the employer as the value of the MAC discount offered by the PBM.

When considering or comparing MAC reimbursements among PBM's employers should focus on the overall generic discount (MAC & Non-MAC generics) and the overall value that brings to the pricing quote.

What Are Rebates?

Rebates are moneys returned by a seller to a purchaser that are delayed from the sales transaction, and can be considered a negotiated price discounting strategy targeted to drug manufacturers. Manufacturers pay a rebate based upon the amount of the firm's products that are dispensed by the pharmacies providing prescription service to beneficiaries or enrollees. The rebates usually are a percent of the value (at the manufacturers transaction price) of a drug dispensed and occur separate from the claims submission/payment cycle as an after market arrangement. PBMs often negotiate and administer the rebates for drug plan sponsors and charge a fee or percent of the rebate for administering the rebates, although some sponsors (e.g., HMOs) may engage directly in the rebate process. They ultimately reduce drug program costs for sponsors 23.

What is the extent of savings from rebates and discounts?

In the HHS report on prescription pricing,24 manufacturers' rebates to FEHBP plans were estimated to range from 2 to 21 percent of acquisition price and as high as 35 percent for selected drugs. Rebates may occur merely because the PBM (or health plan or program sponsor) represents a volume purchaser of a manufacturers product. Rebate arrangements also may have some purchase volume or market share requirements associated with them, giving credence to the notion that the discount truly reflects a volume difference. Market share stipulations associated with rebates often are connected to incentives such as formulary inclusion or pharmacist and patient incentives

to influence market shares of rebated products ²⁵.

According to Kreling, rebates are intended to reduce net drug program costs and their impact can be substantial. However, some advise caution about focusing on maximizing rebates when the emphasis should be on minimizing total costs. For example, a 20% rebate may seem very attractive, yet if that is applied to a \$50.00 brand name drug prescription (approximate average brand name drug prescription price), the net price would be \$40.00, considerably more than what might occur if a generic drug was dispensed (with an approximate average price of \$17.00). If rebates detract from the potential of the overall best cost-effective drug choices, they may lead to false economies 26.

Kreling believes that rebates as cost control strategies can produce savings for overall program costs. However, since rebates generally are associated with newer, brand name drugs, they continue to foster a new drug mind set that serves to keep a focus on newer, typically more expensive brand name drugs as our primary therapeutic agents and may lead to less emphasis on overall more cost effective therapies. However according to a study by Frank Lichtenberg never drugs tend to lower all types of non-medical spending, resulting in substantial net reduction in the total cost of treating a given condition.²⁷

What percentage of the savings is being passed on to my company? Rebates may be expressed as a per

Rebates may be expressed as a per claim rebate, a per brand claim rebate

or a per rebateable claim rebate. Each type of rebate is different from the other. The easiest one to understand is the per claim rebate. A per claim rebate means the employer is going to receive the designated rebate value for each claim (brand and generic) billed to the PBM. A per brand rebate means that the employer will receive a designated rebate value only when a brand name drug is dispensed. A per rebateable claim means that the employer will receive a designated value only when a formulary drug is dispensed.

When a PBM is quoting on a per brand or per rebateable basis a calculation needs to be performed to determine what the per claim basis would be. Often the per brand and per rebateable quotes are considerably larger then the per claim quote and therefore appear to be the better offer. This not always true.

Consider choosing between a \$6.00 per rebateable claim offer and a \$3.00 per claim offer. Looking at the numbers it would be hard to believe that the most advantageous offer of the two is the \$3.00 offer. The reason is simple. The universe of eligible claims gets reduced considerably with the \$6.00 offer. You can reasonably assume 38 to 40% of the claims gets thrown out because they are generics and therefore are excluded from the rebateable claim population. Out of the remaining brand name claims an additional 25% gets dropped because they are non-formulary, non-rebateable products. Once you reduce the original \$6.00 number by the designated percentages your net rebate value becomes \$2.70 therefore making the \$3.00 offer more favorable.

Mail order rebates are even greater due to the higher number of units dispensed per claim and the PBMs ability to switch non-preferred medications to the preferred medications. It is not unusual to see mail order per claim rebates at two to three times the amount of retail per claim rebates.

What is the criteria for formulary placement?

Formulary inclusion is a decision made by an independent board of pharmacists and physicians retained by the PBM on a consulting basis. This board is commonly referred to as a Pharmacy & Therapeutics Committee (P&T). The P&T Committee typically meets quarterly to review current formulary products and make additions and deletions to the existing formulary based on new product availability, drugs going off patent and other related matters.

The role of the P&T committee is to decide the amount of control and form the formulary will take as well as to design and coordinate all other aspects of the system. The P&T committee also is the communications link between the MCO's medical staff and the pharmacy providers ²⁸.

Before a product is included on the formulary the P&T Committee will meet and debate on several issues related to the product. The P&T Committee will consider the products clinical efficacy, cost effectiveness, relative market share and potential for rebates as well as other relevant information prior to making a recommendation. If the P&T Committee concludes the sum of these considerations support the

products formulary inclusion they will recommend the product be designated as preferred.

The underlying intent of a formulary, simply a list of covered or reimbursable drugs, is to improve prescribing and drug use quality. Formularies target drug use decision-makers, including both prescribers and consumers, and can be considered a benefit structure component intended to control or influence utilization by specifying which drugs can be used. They can be established by PBMs, health plans, sponsors, hospitals, and others and take several forms. They are labeled in various ways to reflect the breadth of drugs included and/or ease of access to drugs not listed. An open formulary includes all drugs. A closed or restricted formulary only includes or covers listed drugs. Closed formularies may vary in breadth, ranging from including only one select drug within a therapeutic category or drug group to including multiple drugs within a therapeutic category.

A preferred or partially restricted/ closed formulary specifies the drugs covered, but allows exceptions to the list, usually with increased cost sharing (sometimes labeled incented formularies) or administrative effort (e.g., prior authorization). Drugs in a preferred formulary often are specified as the formulary drug because of a rebate arrangement with the drug's manufacturer (although clinical parameters are, or are claimed to be, the primary determinants of potential formulary selection and status)²⁹.

Employers need to educate themselves to both the benefits and limitations of their drug discounts and rebates as well as other aspects of the pharmacy benefit programs. There are many common employer strategies used by PBMs in an attempt to control cost where the cost to the employer sometimes out weighs the benefits. The challenge is a difficult one but the pay off in savings could be significant to the employer.

CHAPTER IV REFERENCES

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V. EVALUATING OUTCOMES

egardless of the type of healthcare and pharmacy benefit an employer provides, it is crucial to ensure that it's effective. The key questions here are:

- What measures can the company use to determine its value?
- Do employees have access to the treatment they need?

Direct healthcare expenses, for medical claims and pharmaceuticals, are the place to start. Although these costs reveal only part of the picture, they're a means of detecting changes and patterns. Increases in Rx costs for treatment for a condition in the year after a disease management or compliance program was introduced, for instance, may be offset by a decline in medical claims.

While pharmaceutical spending is unlikely to decline, the PBM or the health plan providing the Rx benefit should conduct drug edits to assess and report on—the appropriateness of the medications prescribed for patients with the most prevalent and costly conditions. Quarterly reports, which should include such information as the generic dispensing rate, the percentage of prescriptions that involved requests for drugs requiring priorauthorization, and the approval rate, are a valuable source of outcomes analysis as well. An approval rate of >80% or persistent requests for a particular type of non-formulary drug, or both, could indicate a need to reconsider the product's placement to ensure that employees have greater access.²

Disability and disease management data

While HIPAA privacy regulations may impose new challenges for employers disability data should be carefully dissected as well. In addition to looking at the overall cost of short-term disability, benefit managers should request a report on the number of claimants, broken down by disease category and duration, from the company's short-term disability (STD) and workers' compensation carriers. If they don't keep such details in the records, such detailed reporting can be added as a requirement in the Request For Proposal. Determining the ratio of medical claimants who file STD claims for a particular condition—and comparing the ratio with that of previous years—is a valuable measure of whether efforts to manage it are effective. In addition STD relapse rates vary for chronic diseases. This is another important reason to consider disease management programs which focus on medication compliance and persistence.

Administrators of disease management programs should provide detailed reports as well, with outcomes measures—number of inpatient stays, trips to the emergency room, and doctor visits, for example, as well as Rx and medical claims costs. ¹¹ Other vendors, including the Employee Assistance Program, behavioral health/substance abuse carveout, and sponsors of health promotion or wellness programs, should be expected to provide similar data as well.

VI. RX AND THE WORKFORCE

or employers that want to be more proactive in assessing and managing healthcare costs, including prescription drug benefits, further analysis is necessary.

No matter how well informed they may be about the factors driving up drug costs nationally, it is impossible for employers to make sound decisions about healthcare spending without knowing where their own biggest expenses lie. Companies should attempt to identify their most significant cost drivers, health information analysts from The MEDSTAT Group advise, and use the findings to develop a targeted strategy to bring costs in line.²⁰

MEDSTAT has published a list of the top 10 most costly conditions the business community faces, with findings derived from claims representing some 4 million workers at more than 60 large companies. Overall, coronary artery disease is the most expensive physical illness on the list, followed by GI disorders, hypertension, childbirth, and arthritis. In the mental health arena, bipolar disease tops the chart. But every organization is different, and the problems that plague the companies in the MEDSTAT database aren't necessarily the same ones affecting every workforce. 20

Employee demographics, particularly age and gender breakdown, as well as regional differences, are among the myriad factors that determine a firm's unique health profile. Type of industry plays a key role as well. For example, diseases of the ear, nose, and throat and back problems rank among the

five most costly conditions for firms in the oil, gas, and mining business. In this predominantly male industry, however, childbirth isn't even on the top 10 list.

Pinning down the specifics requires gathering and analyzing as much data as possible. (See Mining the Data on page 32.)

The key questions are:

- Which diseases are most prevalent among the firm's employees?
- Which conditions account for the highest direct medical expenses, including pharmaceutical costs?
- What indirect health-related expenses should be considered to get a complete picture?
- How can positive health behaviors be promoted within the workforce?
- What is the economic impact to a company by increasing the productivity of its workforce?
- What is the (ROI) return on investment of a healthy at-work workforce?

For many employers, however, the answers remain elusive. Claims data, broken down by disease category, is a crucial part of the investigation. But HMOs, in which about a third of individuals with employer-sponsored health coverage are enrolled, are the least likely to be able to produce it.

Important as it is to look at total claims costs, focusing on medical and drug spending alone can also be deceptive. Depending on the size of the workforce or the group represented by the data, an isolated case or several instances of high-risk

pregnancies or premature births, for example, might give the false impression that there's a need for an intensive prenatal care program. In fact, a case management program directed at catastrophic cases might be a more appropriate response.

But even the most finely tuned medical and pharmaceutical claims data present an incomplete picture. Direct healthcare costs alone should never be the sole criterion for decisions about healthcare spending, any more than the cost of a particular drug should. Yet at most corporations, they are the only costs considered, resulting in a serious underestimate of the total burden of a disease. A small but growing number of organizations are attempting to put a price tag on the indirect costs associated with various medical conditions. (See Bank One case study on page 33.)

What are those indirect costs? Some firms focus exclusively on the productivity loss associated with absenteeism and short-term disability (STD). Others include presenteeism, the phenomenon of being at work but not fully functioning. Research leaves little doubt that these indirect disease-related expenses are an enormous drain on the corporate bottom line.

The Institute for Health and Productivity Management estimates that the indirect costs related to chronic conditions typically account for as much as 55% of the total expenditures, and considerably more in some cases.¹⁷

For most companies, though, much of what comprises indirect costs and productivity loss is difficult, if not impossible, to quantify. Disability insurance providers should be able to produce STD claims data, broken down by disease. Similarly, human resources departments should track unscheduled absences and be able to report on patterns, but a lack of disease-specific data is likely to preclude using this as a measure of a condition's indirect costs.

A recent study of diabetic workers at a large firm found that only 70% of their total healthcare costs were related to direct medical expenses—for physician visits, hospitalization, medications, and the like. Fully 30% related to the disability/lost productivity burden. Overall healthcare costs for employees with diabetes were two and a half times higher than those of their non-diabetic colleagues.) ²¹

A study linking medical and short-term disability (STD) claims at a major manufacturing firm identified some conditions—most notably ischemic heart disease and cancer—that have very high medical expenditures but low disability costs and others where the opposite is true: Sprains and strains (excluding back problems) had the lowest ranking in claims costs among the 10 categories studied, for examples, but third highest in disability costs. Together with mental health disorders, another prominent cause of productivity loss, sprains and strains accounted for a quarter of the company's short-term disability days.) ²²

Consider the impact of depression, which has a national health tab estimated at \$30 to \$44 billion a year. While employers often worry about the direct cost of treating the disease, numerous studies suggest that it's a bargain compared to the cost of untreated depression. One study found, for instance, that individuals who are depressed but not receiving care for the condition consume two to four times the healthcare resources of other enrollees. Another revealed that depressed employees take as many as 10 sick days a year because of their depression alone. ²³ Still others showed that patients whose access to psychotropic drugs is arbitrarily restricted often end up hospitalized, exacting a human and economic toll far greater than any savings on medication costs that might have been achieved.) ²⁴

MINING THE DATA

To determine which diseases are most prevalent and which are costing you the most, benefit managers are advised to pull together as much in-house information and data from third party vendors as possible, then turn to additional resources for help in filling in the missing pieces. While some of the facts and figures are likely to be inaccessible, this partial list can help employers get started:

Demographics:

- Number of employees, broken down by age, gender, job category, and locale.
- Number of covered dependents, broken down by age.
- Number of covered retirees, broken down by age and Medicare eligibility.

Absenteeism:

 A tally of unscheduled absences, with year-to-year comparisons and any other information revealing reasons or patterns.

Medical claims data:

- Direct costs, by disease category and number of claimants in each group.
- Separate data on catastrophic cases.

Pharmacy claims data:

- Rx drug costs, grouped according to therapeutic category and number of claimants in each group.
- Prior authorization assessment (if part of the plan), by type of strategy, drug category, number of requests, and approval rate.

Short-term disability:

- Number of short-term disability claimants, by disease category, duration, and by occupational and non-work- related condition.
- Number of workers' compensation claims, by cause and duration of disability.
- Percentage of medical claimants who file STD claims, by disease category.
- Percentage of STD and workers' compensation claimants who go on long-term disability.

Disease management:

- Number of program participants and participation rate.
- Outcomes measures, including a comparison with pre-program medical and Rx claims cost and disability rates.

Behavioral health/substance abuse:

- Claims data, by diagnosis and number of claimants.
- Employee Assistance Program data, including number of users, average number of visits, and percentage who seek additional mental health services.

Additional resources:

- Health Risk Appraisals
- Epidemiological studies, including prevalence data and estimates of direct and indirect disease-related costs (primary sources include the Journal of Health Promotion and the American Journal of Public Health).

Productivity loss because of sub-par performance on the job is even more elusive. It has been tracked by large organizations whose workers is easily quantifiable: Bank One was able to gauge the productivity of customer service representatives, for instance, by measuring the portion of the day they spent in contact with customers and time away from their desks (and therefore not on providing services). 25 A large insurance company conducted a similar study of the productivity of claims processors, this one involving the effects of allergy medication (see box page 38), by tallying the output, or number of processed claims.²⁶

Unless a company's workers perform a particular function that can be easily tracked and counted, however, it's no simple matter to approximate the amount of time they are unproductive. And linking presenteeism to a particular disorder and putting a price tag on it requires more complex calculations than most employer purchasers can manage.

Matching Data and Demographics

What employers can do, however, is use published studies of disease prevalence and indirect health-related costs as a starting point, then adapt the findings to fit their workforce demographics. Bank One's use of epidemiological data as part of its effort to gauge the impact of migraine headache—described in Targeting Disease with Integrated Data on page 33—is a case in point.

Because women are three times as likely as men to suffer from migraines,

the financial institution had to adjust the figures to reflect its predominantly female workforce. Depression, too, strikes disproportionately, affecting some 12% of women but less than 7% of men in the U.S. each year. ²⁷

The Bank One case study also highlights the use of another valuable source of information about employee health, the Health Risk Appraisal. A relatively inexpensive resource available to all but firms so small that employee confidentiality could be jeopardized, HRAs typically address risk factors, such as being overweight and having high blood pressure; lifestyle and behavioral measures, such as smoking and seat belt use; and emotional factors, such as stress and anxiety. Questions about the presence of conditions such as diabetes and migraine headaches can be included as well.

While completing the questionnaire is generally voluntary, the expected response rate (about 20%) is often sufficient to provide a relatively accurate picture of direct and indirect healthcare costs. Not surprisingly, research has found that the drain on productivity correlates with the number of self-identified health risks.²⁵

Other resources can be helpful, too. One notable tool is the NCQA Quality Dividend Calculator. Provided by the committee that accredits health plans nationwide, this online resource (www.ncqacalculator.com) uses demographic and other data you supply about your workforce to estimate the economic value of productivity losses associated with various ailments affecting your

workforce. The calculator accounts for regional differences in both healthcare delivery and disease prevalence.

The calculator focuses on asthma, hypertension, heart disease, depression, diabetes, smoking, and chicken pox, a childhood ailment with high productivity loss because of parental absenteeism an expense that compliance with immunization guidelines could go a long way to eliminate. The NCQA's intent is to emphasize the benefits of contracting with an accredited health plan, but the findings can easily be extrapolated to help employers decide where to focus their healthcare dollars. The calculator gives benefit managers a tool for considering the financial implications of the productivity gains

TARGETING DISEASE WITH INTEGRATED DATA

Bank One's sophisticated health data management system provides the means for analysis of the full range of factors that affect corporate healthcare costs. In addition to demographics and medical and pharmaceutical claims, the computerized database tracks short-term disability, both occupational and non-job related, scattered absences, participation in wellness and disease management programs, employee health risks, and more, providing an accurate picture of the true cost of a disease. Corporate Medical Director Wayne Burton recommends that companies create a matrix with direct costs on one axis and indirect costs on another, then target the conditions with high costs in both places.

Companies that lack data that pinpoint indirect costs should consider Bank One's approach to migraines. The condition, which studies have shown to affect about 6% of men but 18% of women, was a major headache for the 80,000-employee corporation, which has a 70% female workforce.

To determine whether the prevalence figures were an accurate measure of the disorder's impact for the company, Bank One sent a Health Risk Appraisal that included the question, "Do you have migraine headaches?" to the 20,000 workers at one of its units. One in five of the nearly 4,000 respondents—more than 23% of the women and nearly 8% of the men—said Yes.

Bank One also used published literature to assess indirect costs, referring to a survey in which migraine sufferers reported missing an average of three days a year and performing poorly for a total of about five days because of their condition. The next step: Using employees' average daily pay to calculate migraines' financial toll on Bank One, which came to well over \$20 million in absenteeism and lost productivity annually. ²⁸

that improved quality of care can be expected to provide, for example.

An updated version of the Quality Dividend Calculator also allows employers to factor in a range of variables, including comorbidities, direct claims costs, employee out-of-pocket costs, health plan premiums, and benefit structure. Its algorithms and parameters can calculate the direct per patient per year cost associated with diabetes, for instance, including the treatment needed to achieve and maintain the recommended level of disease control.

VII. DRUG COSTS IN CONTEXT

Ithough employer purchasers generally track rising prescription drug spending in their health plans, they may not have a solid idea of the impact of Rx costs on their healthcare budgets. Here, two key questions are addressed:

- What portion of the recent double-digit health plan premium increases does the Rx spending surge actually account for?
- What's driving the increase in drug spending?

The answers will help identify ways to manage costs without jeopardizing employee health.

In 2001, the most recent year for which figures are available, the national tab for healthcare climbed to more than \$1.4 trillion, 8.7% more than in 2000. Outpatient drug costs grew by 15.7%. The tally reflects public and private sector spending. That encompasses money spent on drugs for government-sponsored and employer-sponsored pharmacy coverage, and Americans' out-of-pocket expenditures on prescription medicine.²⁹

With this increase, outpatient pharmaceutical spending accounted for just under 10% of the national healthcare tab, about the same as in the early 1960s. The percentage declined steadily throughout the late 1960s and 1970s and then began to rise again throughout the 1980s and 1990s.

Predictions are that prescription drug benefit costs will continue to escalate in the coming years. A Segal Company survey of managed care organizations, national and regional insurers, and PBMs projects an increase in 2003 of nearly 20%. ³⁰ A recent report by the Centers for Disease Control and Prevention (CDC) based on data from a government survey tracking physicians' prescribing patterns since the 1980s, concludes that drug costs will double in the next 5 years. ³¹

But how much of recent premium increases – 12 to 15% for large employers and much more for small companies - is attributable to increased drug spending? Even if medication costs were to account for 15% of a health plan's premiums and those costs rose by 20% per year, that would still amount to just 3 percentage points $(0.15 \times 0.20 = 0.03)$ —about a quarter or less of the latest round of premium increases. It is apparent that other factors are at work. Increased costs for physician services and hospital care, insurer profits and the cyclical nature of premium increases are all contributing factors.

Volume vs Cost

Is increased drug spending a predictable consequence of the surge in pharmaceutical use, which is itself the combined result of a rapidly aging population, an explosion of new and better treatments, and new clinical guidelines? Or is inflation the key culprit? The answer is both, but the specifics of the relative contribution of these factors may vary for specific therapeutic areas and the characteristics of the population.

One large study using paid claims assessed changes in use and cost for seven of the largest or fastest-growing therapeutic categories over a threeyear period in the late '90s. In each category, the researchers found substantial increases in spending ranging from a low of 43% for gastrointestinal drugs to a high of 219% for hormone replacement therapy. Further analysis, with everything affecting cost per day of treatment going into the price column and everything affecting intensity of use and number of users classified as volume, found volume to be the predominant factor in every case. ³²

More recent but unpublished work in a large managed care population by Protocare Sciences corroborated this finding. Its analysis of spending from 1999 to 2001 found 70% accounted for by volume and the rest by higher Rx prices, including changes to newer, more expensive products. A similar study using a PBM database by Brandeis University researchers found that price and volume were equal factors in the rapid growth in drug spending. 33 The increase in price per daily dose came mostly from the shift from less expensive to more costly newer drugs within the same category. A decline in generic use added to the rising costs.

One study of enrollees in a large PBM found, for instance, that while those over 65 represented just 6 % of the participants, they accounted for 20% of drug use and Rx spending. ³³

A landmark diabetes trial completed in the early '90s, found that tighter control of blood sugar can reduce or eliminate many of the disease's most devastating effects, and recently revised national guidelines for cholesterol management that lower the threshold for initiating therapy. New parameters and updated clinical protocols have led to the identification of more patients who need more treatment.

Volume appears to be driven primarily by three factors:

- Demographics
- Expanding medical knowledge
- Disease management

Demographics is a key factor, as the graying of America alone is responsible for a sizeable increase in drug use. As seniors age, more chronic disease becomes almost inevitable. For every one-year increase in average age of the enrolled population, Merck-Medco reports, spending on pharmaceuticals goes up 4%.

These are notable findings for a nation with well over 34 million seniors and nearly 76 million Baby Boomers not far behind. The first wave of Boomers, who comprise nearly a third of the population, turned 55 in 2001. That's about the time when drug use patterns diverge from those of their younger counterparts as age-related chronic diseases develop.

Expanded medical knowledge about particular diseases or conditions, new and more effective multi-drug regimens, and better diagnostic tools have contributed to the surge in drug consumption as well, as treatable diseases are detected and treated earlier.

Disease management programs, typically developed for chronic diseases like asthma, diabetes, and heart failure, boost drug use, too. Indeed, their success lies in convincing people of the importance of following a healthy lifestyle and a regimen of maintenance drugs, fostering compliance, and assuring that those who have not been getting adequate care receive needed treatment.

Older Drugs vs Newer Drugs

Although increases in volume account for much of the surge in Rx spending, questions are frequently raised about the cost and value of newer drugs

A recently published Health Affairs study supports the claim that many newer drugs represent real value. The study classified drugs by FDA approval date, then looked for links between the age of the product and cost, morbidity, mortality, and productivity loss. It concluded that savings associated with use of newer drugs in place of older drugs, due largely to a decline in hospitalization and a shorter length of stay, were more than three times the additional cost of the new medications. 34 Newer drugs also often have fewer side effects, an important issue for some patients.

But when newer drugs are not needed, they can create problems other than cost inflation. For example, the CDC has launched an educational campaign in response to the alarming rise in antibiotic-resistant bacteria. Its focus is twofold: emphasizing to physicians and patients that most upper respiratory infections are viral in nature, and thus antibiotic therapy isn't necessary, and promoting older antibiotics as first-line treatment for many uncomplicated bacterial infections. ³⁵

What about generics? Some pharmacy benefit managers and health plans have begun pushing generics as they scramble to control costs, programs that can save a substantial amount of money. Merck-Medco's Generics First, a program that encourages physicians to alter their prescribing

How much has prescription drug use expanded? In 2000, according to the National Association of Chain Drug Stores, retail outlets dispensed some 2.8 billion scripts, up from 2.1 billion in 1995—a 33% rise.

patterns by handing out generic samples, reportedly accounted for a savings of \$3.5 million in the first six months. Michigan Blue Cross-Blue Shield partnered with pharmacies across the state to encourage greater usage of generics, resulting in savings of some \$3.4 million in the fourth quarter of 2001.

Clearly, generics and older medications can be important components of a balanced and cost-effective pharmacy benefit plan. It's equally clear that many new drugs offer significant benefits over older medications.

The goal should be for each individual patient to have the right medication at the right price—the drug that will appropriately, adequately, and cost effectively address the problem.

In this context, the final factor said to be driving greater volume as well as influencing the use of newer drugs is direct-to-consumer (DTC) advertising. In 1996, pharmaceutical firms collectively spent \$791 million on marketing to consumers. After FDA revised the rules governing broadcast ads in 1997, investment surged, rising to \$2.5 billion in 2000. ³⁶ Whether this is good or bad is a matter of continuing debate and study.

Supporters contend that DTC ads encourage patients who would

EXAMPLE

An example that shows the interplay among the multiple factors driving volume and price relates to asthma. Spending on asthma medications rose by 94% from 1995 to 1998. The main reason: The average number of prescriptions per patient went from nine to 14 per year. Another key factor was the switch to newer drugs. Both the increase in prescriptions per patient and the shift to newer inhaled corticosteroids were likely driven by guidelines issued by the National Heart, Lung, and Blood Institute in 1997 stressing the importance of using inhaled corticosteroids as a maintenance medication. This is a prime example of a case in which focusing solely on the cost of the drug gives an incomplete—and misleading—picture: While the per patient drug cost rose from \$236 to \$460 a year, the rate of hospitalization (averaging \$11,000 per patient stay) fell by 27% and emergency room visits, at \$450 each, declined by 8%, helping to offset the additional drug spend.) \$2.37

otherwise not seek medical treatment for their conditions to do so. However, opponents assert that such advertising prompts demands for high cost medications that may not be necessary and may interfere with the doctorpatient relationship. As this debate continues, it is important that efficient and effective means be sought for physicians to assist patients in evaluating the range of health care information and making informed choices about their health. 47,48

BRAND VS GENERIC?

A study of claims processors taking allergy medicine revealing that the cheaper, older product (a sedating antihistamine) was not a bargain at all highlights the importance of considering side effects that interfere with work performance as well. By measuring the number of claims processed in the weeks after an employee filled a prescription, the researchers found that the newer, more expensive drug (a non-sedating antihistamine) was by far the more cost-effective choice when productivity effects were considered.) ²⁶

VIII. TOWARD PATIENT-DIRECTED HEALTHCARE

he movement toward "patient-directed" financing models for health benefits that give employees more choice and control, as well as more responsibility for decision-making, is widely recognized as a means of making employer costs more predictable and employees more responsible—and is a logical next step. Some benefit managers believe that this approach is ideally suited to prescription drugs.

It's not a single strategy, however, but an array of options that encompasses both commonly understood variations and promising new designs. On the far end of the spectrum is a defined contribution model in which an employer would give each staff member a set amount of money to be used to purchase health coverage, including pharmacy benefits, on the open market. But current tax laws and the individual insurance marketplace will have to change to make that a viable option. In a less radical patientdirected model, the company continues to provide the structure, select the coverage, and bear the risk.

While Medtronic, the medical device manufacturer, stands out as an early adopter, employer interest in following suit is rapidly growing. William M. Mercer reports that nearly half (45%) of the firms it surveyed are interested in defined contribution plans; Towers Perrin finds that four firms in 10 have implemented or are considering adopting a patient-directed benefit, and a Washington Business Group on Health/Watson Wyatt survey suggests that three employers in 10 are likely or very likely to move to a defined contribution strategy in the foreseeable

future. And the Pacific Business Group on Health (PBGH), a purchasing coalition representing some 44 major firms and 3 million employees, recently announced plans to make its own version of a patient-directed benefit available to its members. ³⁹

The appeal of patient-directed healthcare extends beyond the employer community. Many employees welcome the opportunity to have greater control as well. It reflects a consumer empowerment movement, characterized by patients' greater knowledge of preventive measures, heightened awareness of prevalent conditions and their treatment, and increasing insistence on partnering with the physician of their choice. It also addresses the demands of many consumers—the roughly six in 10 Americans with employer-sponsored health coverage foremost among them-who objected strenuously to the controls imposed by HMOs just a few years ago.

While not right for everyone PDHC can work for a large percentage of our population. For those who are unable or unwilling to participate actively in healthcare decisions, additional support will be necessary.

Information technology, which brings the latest studies and journal



Minneapolis-based Medtronic added this type of arrangement in 2001, putting \$1,000 into a spending account for each single employee and \$2,000 for each family who signed on. Enrollees were given a choice of a range of deductible levels, which went as low as \$1,500 for an individual or as high as \$7,000 per family. The monthly premium, based on their selection, also covers a catastrophic policy takes over after the deductible has been met.) 38

articles to the desktop and into the home, is a key reason 21st century healthcare consumers are better informed and more involved than their predecessors. A single Internet search under "consumer health" yields well over 2 million entries, including many web sites developed by leading medical societies and healthcare organizations. ⁴⁰

Magazines and newspapers have responded, too, to the public's seemingly endless quest for news about medicine and health. DTC ads provide targeted information about diseases and treatments and urge Americans to consult with their doctors as well.

Patient-directed healthcare also supports Americans' growing interest in alternative medicine: Typically, consumers are free to use the money in their accounts to pay for the services of non-traditional practitioners and, often, for contact lenses and procedures like laser vision correction that more traditional plans don't cover.

This increasingly popular approach, which typically allows unused funds to roll over to the following year, gives employees an incentive to take cost into consideration. That freedom prompts employers with a stake in keeping their workers healthy to ask: How can a company be sure its workforce will get the care—and the medications—they need?

Arming employees with information, including the price and relative value of prescription drugs and other medical services and treatments, will help ensure that the decisions they make are truly value-based. With that in mind, patient-directed benefits need to be paired with information and support.

IX. LOOKING TO THE FUTURE

ging Baby Boomers, said to be the most savvy group of healthcare consumers our nation has ever had, rapid increases in our understanding of disease states, and Americans' insistence on the most innovative medical treatments, are some of the factors driving the ever-growing demand for more and better prescription drugs. The supply side is keeping pace, with pharmaceutical companies unceasingly pursuing new products based on groundbreaking scientific knowledge and capabilities.

These realities—including the fact that elderly Americans take three times more prescription drugs than the rest of the population—have already led to a sizeable increase in the use of medication. ⁴¹ The number of retail prescriptions dispensed in the U.S. went from 2 billion in 1994 to 2.5 billion in 1998 and 2.9 billion in 2000. Of the \$100 billion spent on prescription drugs in 1998, more than a third covered drugs introduced since 1991. ⁴²

As the promise of genomics is fulfilled, drugs will play an even greater role in the maintenance and management of Americans' health. In addition to evaluating and redesigning their pharmacy benefit plan now, employers nationwide need to look toward the next 10 to 15 years in anticipation of the changes and adjustments ahead.

The mapping of the human genome has opened the door to the day when pharmaceutical companies offer customized drugs. Clinical trials involving the use of genetic markers to predict patients' responses to

particular medications are already under way and genetically based custom therapies are close at hand. At the same time, researchers have stepped up the study and identification of human protein function—known as proteomics—which has the potential to have a major effect on drug development as well.

With the vision of customized drugs as the primary focus, many pharmaceutical companies are spending billions of dollars in their quest to bring genetic therapies to market—a development Americans are sure to embrace. Indeed, surveys attest to their keen interest in medical innovation.

In one study, for instance, seven in 10 of those polled expressed a positive attitude toward genetic testing to predict disease—and six in 10 expected to be tested themselves. ⁴³ Another found that U.S. adults have a greater interest in technological advances than their European counterparts. Not only do they want everything medicine has to offer, the survey found, but about half of those polled rejected the notion that a private or public sector purchaser might not be able to pay for it. ⁴⁴

The nation's health has already improved in many ways, and Americans can look forward to living longer and remaining healthier longer than their parents did—and longer than they could have hoped for even a decade ago. Yet significant problems remain. In addition to getting older, the U.S. population is growing fatter and more sedentary. The same consumers who push for new and

MANAGING INJECTABLES

More than 117 biotechnology, or biotech, drugs are on the market today, with 75% of them having been approved by the Food and Drug Administration (FDA) within the past 6 years. Currently 30-40% are chemotherapeutic or cancer-related agents. More than 350 new entities are in the pipeline undergoing clinical trials targeting over 200 diseases, from Alzheimer's to AIDS, cystic fibrosis to rheumatoid arthritis and diabetes to multiple sclerosis. These injectable products are a rapidly growing force to be reckoned with.

Biotech drugs have provided hope and given relief to people suffering from some rare and devastating disorders. But the price tag is high because of the more sophisticated technology used to develop and manufacture them. Many specialty injectables are administered in the physician's office or the home, with the drugs coming directly from the physician. Thus, until now, they have remained virtually hidden from view, their costs and coverage imbedded in medical claims and the risk largely shouldered by physicians and medical groups.

Now the explosive growth in these high-tech entities is causing doctors to demand relief—and health plans and PBMs to face the need to manage the escalating cost of these high-cost products in a way that balances employer and employee needs.

As injectables move from the medical to the Rx side of the healthcare budget, they are a cost driver employers cannot afford to overlook. Purchasers should ask their health plan or PBM how these costs are being managed and request their help in determining which drugs will provide benefits that outweigh their costs. 45, 46

better treatments often fail to take responsibility for their own health or for the financial consequences of the healthcare decisions they make.

In the face of this dichotomy, employers must take a leadership role. There is clearly a need to continue to offer effective Rx coverage, but judicious use of innovative therapies demands greater consumer involvement. Employee education focusing on clinical information and quality data and the knowledge consumers need to conduct their own cost-effectiveness and trade-off analyses-becomes a key benefit management tool. But convincing Americans that they must shoulder more of the cost and responsibility for the technological advances they value so highly may be employers' biggest benefit management challenge.

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APPENDICES

Appendix A

Reviewing Coverage for Retirees

Rx spending is especially high for those age 65 and over. The drug cost alone has led to a steady decline in the number of employers offering retiree coverage, which wraps around Medicare benefits. FASB 106, the 1992 accounting rule that forced companies to recognize the cost of retiree coverage on their balance sheets, also interfered with employers' ability to continue to provide benefits. In 2001, only 23% of large employers—defined as those with 500 or more workers—offered health insurance to Medicare-eligible retirees. In 1995, 35% did. 1

The number of employers offering health benefits for retirees under 65 continues to shrink as well, going from 41% in 1995 to 29% in 2001. That same year, per retiree costs for health and pharmacy benefits for early retirees averaged \$6,642, according to the most recent data from Mercer Human Resource Consulting, compared to \$2,717 per Medicare-eligible retiree.

Companies that still offer retiree coverage are advised to carefully review their expenditures, an important step in considering whether there are ways to mitigate retiree health costs. Decisions to drop or scale back coverage—by increasing copays, adding deductibles, and capping drug expenditures, for instance—in the absence of contractual agreements precluding any such change, should be carefully reviewed for both legal and financial ramifications.

Private HMOs, once seen as a viable way for the government and employer purchasers to save money and offer seniors a comprehensive package that included Rx benefits, have withdrawn from the Medicare market in record numbers so the stability of a Medicarerisk HMO should be investigated carefully before adding it as a coverage option. There are hidden factors to consider before making any changes in coverage as well, not the least of which is the fact that delayed retirement is a likely consequence of not offering health benefits to early retirees.



Appendix B
Worksheets



Member Cost Sharing Worksheet

Aligning Pharmacy Benefit Member Cost Sharing with Objectives

Plan Design Option	Objective	Issues to Consider	Impact on Employer/ Member Cost ¹
Use one- or two-tiered copay Example: One tier: \$10 for all prescriptions Two tier: \$5 (generic) and \$10 (brand)	 Maintain employee satisfaction Maximize drug choice and access Minimize administrative hassles Simplify benefit design 	 A single copay for all drugs provides no incentives for members to use generics or more cost effective brand drugs. Member cost share erodes over time with flat dollar copays. To encourage employees to change behavior, for a two-tier plan the differential between 1st and 2nd tier should be at least \$8 to \$10. When cost share changes are > 10 percentage points (e.g., 20% to 30%)₃ essential medication utilization drops.³ 	• Each \$1 increase in copays saves the plan 1 to 2% but costs members 7 to15% more for average utilization of a typical family
Move from 2-tier to 3-tier copay Example: Move from \$5 (generic) and \$10 (brand) to \$5 (generic), \$10 (formulary brand) and \$25 (non-formulary brand)	Increase employee share of costs Increase awareness of costs among drug choices and incent use of less costly alternative	 This is the most prevalent plan design. * Expect some employee dissatisfaction; good communication is key to success. Employers and their medical directors should carefully review drug preferences to ensure that access is maintained for patient and physician drug choices. A differential of at least \$15 between 2nd and 3rd tier is generally considered by PBMs and health plans to be effective in incenting members to utilize generic and formulary brand name drugs. Setting copay levels too high has been shown to impact essential medication use. 	 Cost savings to employers generally range from 2 to 4% depending on plan design and breadth of the formulary Cost increase to members generally ranges from 13 to 24% depending on plan design and breadth of the formulary

Estimates of savings and costs developed using Mercer proprietary data. It is important to assess the cost impact on both the employer and the member when evaluating plan design changes.

Express Scripts, Inc. 2001 Drug Trend Report

The Merck-Medco Drug Trend Report, 2001

Mercer 2002National Survey of Employer-sponsored Health Plans

Plan Design Option	Objective	Issues to Consider	Impact on Employer/ Member Cost ¹
Add a fourth tier copay Example: Members pay a high level of coinsurance (50%), or 100% of the negotiated discounted price for select drugs	Maintain employee satisfaction by offering coverage of some drugs for conditions not otherwise covered e.g., for cosmetic purposes Align member cost sharing with employer's health care strategy	 Drugs assigned to the 4th tier are most often for otherwise non-covered conditions, e.g., hair loss treatment, contraceptives, infertility treatment. Expansion of 4th tier drug list to include other medications could have negative impact on essential medication use. Expect some employee dissatisfaction; good communication is key to success 	The impact on plan and member costs depends on the breadth of the 4th tier and on how these drugs would otherwise have been covered under the plan.
Mail order for maintenance drugs Example: Members have the option to use a mail order pharmacy instead of a retail pharmacy and can generally receive a larger supply of medication (e.g. 90 days) per prescription Option possible to require patients to use mail order after three 30-day scripts filled at retail pharmacy	 Lower costs due to purchasing efficiencies, more frequent switching to alternative therapies and formulary enforcement Increase employee satisfaction by providing additional means for filling prescriptions which may be more convenient and reduce copays 	Requires a strong communication plan for members to understand how the benefit works and accept any benefit changes. Mail order copays must generally be at least two times that of retail in order to provide cost savings to the plan. "Requirement" to use mail order plans can be difficult to administer (e.g. definitions of maintenance drugs can vary from vendor to vendor)	 Mail order generally provides plan savings of 1 to 6%, depending on pricing, demographics and plan design. Members generally pay less at mail order than retail for an equivalent supply of a drug.
Establish/dcrease out-of-pocket (OOP) maximums for drugs Example: After members pay \$1,000, additional prescriptions are covered by the plan at 100% with no member copay.	 Limit financial exposure for members with severe or multiple medical conditions resulting in high drug spend 	 An OOP maximum maintains access to essential medications Many plans do not have an OOP maximum for pharmacy benefits. The OOP feature may be applied only to drug spend or integrated with medical OOP. It can be difficult to administer an integrated medical/Rx OOP maximum particularly if the pharmacy benefit is carved out to a PBM 	 The cost increase to the plan will vary depending on the OOP maximum, utilization patterns and plan design. Only a minority of members will pay less if this design feature is implemented A \$1,000 per member OOP max could increase plan sponsor costs by 1 to 3% and provide savings to 2 to 3%of members. Costs will vary by plan.
Add an Rx deductible Example: Members must pay the first \$100 in pharmacy expenses each year	Lower costs to the plan by requiring members to cover initial dollar amount prior to beginning employer coverage Increase awareness of costs among drug choices and incent use of less costly alternative	Deductibles have the potential to negatively impact compliance rates with important therapies especially in lower paid workforces. Employers and their medical directors should consider the potential impact of non-compliance on overall medical costs and workplace productivity It is possible that payments for noncovered drugs may not be counted towards the deductible.	 Savings will depend on the deductible level, use patterns, and plan design. As an example, a \$100 per member deductible could save the plan sponsor 9 to 12% in plan costs and will increase costs for 75 to 90% of members.

Plan Design Option	Objective	Issues to Consider	Impact on Employer/ Member Cost1
Mandatory generic program Example: The member will pay the difference between the brand and generic drug in addition to the copay if a brand drug is dispensed when a generic equivalent is available. Medical exception process may be available	Lower plan sponsor's costs Increase awareness of costs among drug choices and incent use of less costly alternative.	This provision may only apply to drugs that are on the vendor's Maximum Allowable Cost (MAC) list. This provision can be applied only to brand drugs requested by members or also to brand drugs requested by the physician.	 The average plan can save from 1 to 5% by introducing a mandatory generic program. Relatively few members will pay more under this plan design provision.
Move to percentage copays (coinsurance) Example: Members pay 20% of prescription costs	Increase employee awareness of Rx costs Maintain an even level of member cost share over time	 This plan design can increase the cost burden for members on high cost drugs and could negatively impact compliance Percentage copays can be more difficult to administer at mail order. In many cases, the percentage copay level needs to be set fairly high to produce an equivalent member cost share under a two or three tiered copay plan design. Expect some employee dissatisfaction; good communication is key to success If employer moves from flat copays to a percentage copay, some members will pay less (usually for lower cost generics) while other members will pay less (usually for lower cost generics) while other members will pay less usually more (for more expensive brand name drugs). Employers may use percentage copays along with minimum and maximum copays to increase member copays for low cost drugs and limit member copays for high cost drugs. 	 The cost impact of moving to a percentage copay will vary based on the specific plan design features and utilization patterns. As an example, a \$10/\$20/\$35 copay plan is roughly equivalent in overall member cost share to a 32% percentage copay plan. The cost burden on members for high cost medications could be considerable possibly impacting compliance. The lack of compliance has the potential to increase direct and indirect costs for the plan's sponsor as well.

Prior Authorization (PA) Worksheet

For those employers who wish to consider adopting PA, the following checklist of issues and options may be useful.

- Review Best Practice Expectations and Attributes.
- -. ഗ. ღ. 4.
- Check desired program attributes. Check whether expectation or authorization program. Check whether expectation or attribute is part of current prior authorization program. Compare desired with current program attributes. If they do not match closely, you may want to consider changing the program design.

		Profortod	Current	Current PA Program
	Best Practice Expectations and Attributes	PA Program Attributes	Yes/ Included	No/Not Included/ Not Available
Program Objective	Uses evidence-based coverage criteria			
	Ensures appropriate access to medications including necessary use of high cost drugs			
************	Reduces inappropriate utilization of drugs which have potential for misuse			
	Assures minimal disruption to members, physicians, pharmacists			
General Program	Program is focused on drugs that have the potential for misuse and are typically high cost			
Description	◆ Vendor may offer recommendation for standard PA protocols but will offer to customize.			
	 Vendor has developed, provides and discloses sound administrative and clinical logic for PA (consistent with evidence-based medicine and best practice treatment guidelines) 			
	Vendor provides timely completion of each PA request using predetermined criteria.			
	 Vendor provides appeals and reviews that meet standards for timing and fairness of process. 			
	Vendor offers plan sponsor modeling/decision support tools			
	Vendor offers a rules-based PA program, reducing number of necessary reviews through analysis of eligibility data, Rx claims, diagnosis code on Rx, and medical claims (when available).			
-	PBM provides frequent account-specific reporting detailing:	-		
	Total number of PA requests and number authorized/denied/appealed and top requests			
	 Extent of complaints from members, priyalciaris, priarriadists A single report detailing both fees and drug cost savings 			
	 Estimated total savings in direct healthcare costs and indirect costs 			
	 Report and savings are auditable. 			
Financial Structure	◆ Fees of \$15 - \$30 per PA for clinical Pas are generally seen. No fees for overrides (e.g., early refill)			
	 Savings based on actual cost of denied Rxs and refills. 			
	 Savings from PA program are guaranteed but are not overly aggressive so as to encourage inappropriate denials. 	V MAN		
	Vendor does not retain a share of the savings.		1 1 1 1 1 1	

Drug Utilization Worksheet

Evaluating the features of the DUR program.

To complete the chart:

- Select the type of DUR program(s) being evaluated: Concurrent DUR (on-line, real-time), Retrospective DUR and/or Compliance Programs
- For each column (type), if the plan in question has the feature or service described (i.e., meets the success criterion), circle the number of points corresponding to that feature in the adjacent column. If the plan in question lacks the feature, do not circle the points. 7
- When you have finished going through the features for that DUR type, sum the number of points circled. The closer the sum is to 10 (the maximum number of points), the stronger the DUR program is. რ

	Forms of Drug Utilization Review (DUR)	(DUR)		
Concurrent DUR (on-line, real-time)	Retrospective DUR		Compliance Programs	
Points	Success Criteria	Points	Success Criteria	Points
_	Vendor analyzes claims data at least monthly to identify opportunities	-	Vendor sends out refill reminders by mail or telephone	-
-	Vendor does general mailings to targeted physicians about disease/therapy management opportunities	~	Vendor contacts at least some employees by phone for refill reminder	2
-	Vendor does targeted mailings/faxes to physicians with patient-specific opportunities	2	Vendor offer a program to case manage compliance for high risk patients and coordinates efforts with physicians	င
2	Vendor tracks physician compliance with therapy recommendations and provides reports to clients	2	Vendor offer 24 hour/7 day access to pharmacist to answer questions	-

		Forms of Drug Utilization Review (DUR)	DUR)		
Concurrent DUR (on-line, real-time)	ıl-time)	Retrospective DUR		Compliance Programs	
Success Criteria	Points	Success Criteria	Points	Success Criteria	Points
Vendor offers a program option for an expanded clinical review for mail order Rxs to intervene on Rxs that do not meet best practices	-	Vendor guarantees and reports savings	3	Vendor offers 1-800 number or Web site where employees can access prescription drug information	_
System offers specialized DUR for elderly and pediatric population	_			Vendor offers at least one automated option for mail order refills (e.g., IVR or internet)	-
System can provide information to the physician at the point-of-care (via handheld device/computer)	_			Vendor has DUR edit for late refill, which prompts pharmacist to counsel employee about compliance	-
Vendor guarantees and reports savings	3				
Total Score		Total Score		Total Score	

Cost - Prevalence - Estimated Savings **Disease Management Worksheet**

This worksheet will help define what certain high-cost disease states may cost, as well as provide an estimated savings should disease management programs be implemented.

(if unknown, multiply number of active employees by 2.11) Number of active employees: Number of members:

Disease State	Averaç	Average Cost	Average P	Average Prevalence	Total Estimated Cost of Disease (Multiply no. of members by avg. cost by avg. prevalence)	ost of Disease g. cost by avg. prevalence)
	Source A ¹	Source B ²	Source A	Source B	Source A	Source B
Asthma	\$ 4,405	\$ 4,922	2.07%	2.00%	\$	\$
Coronary Artery Disease (CAD)	\$ 12,350	\$ 16,855	1.36%	1.38%	\$	\$
Congestive Heart Failure (CHF)	\$ 23,729	\$ 5,522	0.27%	0.35%	\$	\$
Chronic Obstructive Pulmonary Disease (COPD)	\$ 11,505	\$ 15,931	0.39%	0.47%	\$	\$
Diabetes	\$ 6,899	\$ 8,431	2.51%	2.62%	\$	\$
Total			%09'9	6.82%	\$	\$

Estimated Savings based on purchase of a disease management package (not individual programs), including programs similar to those listed above	Low End	High End
Cost of the Intervention PEPY ³	\$30	09\$
Savings PEPY⁴		
Low Range	\$33	\$66
High Range	\$75	\$150
Net Savings PEPY (Savings PEPY – Cost PEPY)		
Low Range	\$3	\$6
High Range	\$45	06\$
Total Net Savings (multiply net savings pepy by total number of employees)		
Low Range	\$	\$
High Range	\$	\$
Total Return on Investment (divide net savings PEPY by cost of the intervention)		
Low Range	\$	\$
High Range	€9	
The state of the s		

Ingenix Normative Data: the Ingenix database consists of commercial claims from around the country including inpatient, prescription drug and medical claims. There are a total of

^{1.1} million lives represented, including 379K active employees with an average age of 44. This represents 2000 claims dollars.

Mercer Human Resource Consulting's Health & Productivity Analysis Book of Business: this represents the book of business for 17 completed Health and Productivity Analyses. The employer groups range in size from 2,000 - 50,000 employees; data are from 2000, 2001 and 2002.

³ Cost is specific to population demographics, disease burden and selected conditions for intervention. The ranges supplied in this worksheet are based upon an analysis of several vendors' disease management program costs. ⁴ Low range and high rangePEPY are estimates over a one to three year period based on vendor experience, client experience, and the literature

Pharmacy Benefits Request for Information Worksheet

Please complete this form and return to:

							employers and note which, if any are outsourced and provide the name(s) of the outsource vendor(s).	ed Name(s) of Outsource Vendor(s)													
					:		ch, if any are	Outsourced													1
							employers and note whi	Provided In-house										0			1
Name	Company	Address	Phone	Fax	Email	1. General Program Administration	Please check the services available to		Implementation Assistance	Claims Processing and Adjudication	Retail Network Management	Mail Order	Customer Service	Clinical Programs:	• DUR	 Case Management 	 Disease Management 	 Other (please list) 	Formulary Development	Member Communication Materials	

TDD-TTY services for hearing impaired		website capabilities:		
Language services for non-English speaking		 Prescription refills 		
Braille prescription labels for visually impaired		 Pharmacist querying capabilities 	bilities	
24-hour pharmacist access via toll-free number		 Educational programs/materials 	terials	
Dispute resolution/appeals process		 Pharmacy locator 		
Customer satisfaction surveys		 Formulary drug list 		
		 On-line retail and mail drug history 	g history	
		 Drug cost calculator 		
		 Health assessment tools 		
3. Retail Network				
What percent of your network retail pharmacies is available to members? (Note to employer: you will need to provide the vendor with a zip code list to obtain most of this information)	ilable to m	embers? (<u>Note to employer</u> : you [,]	will need to provi	de the vendor with a zip code list to
Network pharmacies as a percent of all U.S. pharmacies	es		%	
Network pharmacies as a percent of all U.S. pharmacies within member zip codes	es within I	nember zip codes	%	
Percent urban zip code participants with at least one r	etwork ph	east one network pharmacy within 1 mile radius	%	
Percent suburban zip code participants with at least one network pharmacy within 3 mile radius	ne networl	c pharmacy within 3 mile radius	%	
Percent rural zip code participants with at least one ne	twork pha	ast one network pharmacy within 10 mile radius	%	
4. Access to Pharmaceutical Products				
What formulary options do you current offer, and what are the administrative procedures?	are the ac	aministrative procedures?		
 Open/Voluntary – all FDA-approved medications available, subject to coverage limitations (e.g., exclusion for medications for infertility or cosmetic purposes). 	available, a	subject to coverage limitations (e.g	y., exclusion for r	nedications for infertility or
☐ Incentive/Three-tiered – all FDA-approved medications available, subject to coverage limitations (e.g., exclusion for medications for infertility or cosmetic purposes), but higher copays apply to medications not on formulary.	itions avai edications	able, subject to coverage limitation of on formulary.	ns (e.g., exclusio	in for medications for infertility or
☐ Restricted — Preferred drugs on the formulary list are covered. Drugs not on the formulary are not available or must have prior authorization by the plan to be covered.	are covere	d. Drugs not on the formulary are	not available or	must have prior authorization by

What type of member services do you offer? Check all that apply:

2. Member Services

. Drug Utilization Review Programs

For each program, check all that apply:

	Forms and Features	Mandatory	Optional	Tailored at Client Request	Client-specific Reporting Available
	System accesses integrated retail and mail order history				
	Vendor monitors pharmacy compliance with DUR messages				
Concurrent DUR	Vendor offers a program option for an expanded clinical review for mail order Rxs to intervene on Rxs that do not meet best practices				
	System offers specialized DUR for elderly				
	System can apply dosage and duration edits based upon validated prescribing guidelines				
Retrospective	Vendor mails disease/ therapy management information to targeted physicians		:		
DUR	Vendor sends targeted mailings/emails to physicians with patient-specific opportunities				
	Vendor sends out refill reminders by mail/email or phone				
Compliance Program	Vendor offers programs to case manage compliance for high-risk patients and coordinates efforts with physicians				
	Provides 24/7 access to pharmacists				
	Automated option for mail order refills		and the state of t		
	DUR edit to capture late and no refill				

6. Disease Management Checklist

The following checklist is designed to inventory the elements of the disease management program(s) you offer. Review the list of features and indicate the feature(s) that apply to each disease management program listed in the table. Do this by placing the corresponding letter(s) of the feature(s) in the appropriate disease state column. Add disease states or features when necessary. If you are uncertain about a program feature's inclusion within a disease management program, leave the column blank.

	Program Features
∢	Sends disease information to enrolled patients
В	Sends disease information and clinical guidelines to physicians
ပ	C Provides physicians with patient-specific assessment/recommendations
Δ	Offers patients dial-in access to nurses or other clinicians
Ш	Includes ongoing case management and coordination with physicians and patients
ш	Provides patient-specific report cards to patients and physicians
ව	G Collects baseline health status data and tracks improvements over time
I	Tracks and guarantees cost savings/quality improvements

For each disease management program, place the corresponding letter of the program feature in the appropriate column.

Condition	Mandatory	Optional	Can be Tailored at Client Request	Client-specific Reporting Available
Arthritis				
Asthma				
Cardiovascular (CHF, cholesterol)				
Chronic Obstructive Pulmonary Disease (COPD)				
Depression				
Diabetes				
Low Back				
Migraine				
Osteoporosis				
Ulcer				
Other:				
Other:				
Other:				

Appendix C

Other Tools

Formulary selection tools

While few employer purchasers are personally involved in formulary decisions, many discuss selection strategies with their pharmacy plan administrator. The following tools highlight selection criteria to inquire about:

AMCP Format for Formulary Submissions is an evaluation tool developed to help pharmacists, PBMs, and health plans determine the impact of a drug's inclusion or deletion from a formulary. The evaluation tool aims to reduce "uncertainty in the pharmacoeconomic evaluation process," according to the Academy of Managed Care Pharmacy (AMCP).

The Format asks pharmaceutical firms applying to have a new product added to a formulary to provide evidence well beyond the scope of what the FDA requires. Specifics include quality of life and patient satisfaction indicators, extensive outcomes data, evidence of improvement over existing medications, and other measures that carry significant weight in determining whether to put the new drug on the approved list. Available at www.amcp.org/publications/format.pdf.

A Coverage Decision Grid developed by the Pharmacy Benefit Management Institute offers guidance in factoring clinical findings into formulary decisions. A sample grid lists three possible value measures (significant therapeutic advantage for most patients; significant advantage for some patients; or no significant benefit) and three price levels: more expensive, about the same, or lower than the drug or group of drugs it would replace. There are three options for formulary placement as well: unrestricted, restricted access, or outright exclusion.

In this model, a new drug that offers significant advantages for most patients gets unrestricted coverage, regardless of cost. If it is significantly better for some, access is unrestricted if the drug costs less than other comparable products. If the price is about the same or higher, enrollees have restricted access—which could take the form of prior authorization, higher copay or coinsurance, or, in a step-care model, only after an unsuccessful trial with the alternate drug or class of drugs. A medication found to have no significant advantage gets restricted access if it's priced about the same or lower. If the price is higher, the drug is excluded. More information can be found at www.pbmi.com/tools.asp

Appendix D

Disease Management Resources

High-cost conditions of pressing concern to employers are listed in a variety of publications, some ranked only by direct medical costs and others including indirect costs as well. None will necessarily mirror a specific company's experience, but each will provide guidance regarding diseases and disorders that can be addressed.

How Illness Hammers Productivity and Health Risks Take their Toll, two charts included in a report on a large productivity study (The real measure of productivity. Business & Health. November 1999:49) highlight diseases and risk factors—smoking, inactivity, and psychological distress, for example—associated with a high degree of productivity loss. Each shows a total score, or Worker Productivity Index, reflecting its overall impact. And each is divided up to show where the problem lies: in high rates of absenteeism, lengthy periods of disability, or a lot of time wasted on the job.

Top 10 Physical and Mental Health Conditions, ranked according to total payments based on findings from a multi-employer database with more than 4 million covered lives, focuses on medical costs. A series of charts broken down by industry—finance, insurance, and real estate; government entities; manufacturing; and oil and gas extraction and mining, among them—allows you to zero in on the

kinds of disorders likely to afflict your workforce. See Goetzel, RZ, Ozminkowski, RJ.

Pharmaceuticals: Cost or investment? Journal of Occupational and Environmental Medicine. 2000; 42(4):338, for more details.

Official Disability Guidelines 2002 (7th Ed.) estimates time away from work and productivity loss for high-volume health conditions. The data comes from a number of government sources, with the Occupational Safety and Health Administration (OSHA), the Bureau of Labor Statistics, and the National Health Interview Survey among them. For more information or to purchase the guide, contact Work Loss Data Institute, 500 N. Shoreline Blvd., Suite 1101N, Corpus Christi, TX 78471 or call 800-488-5548 or 361-883-5000. Orders can also be placed at www.DisabilityDurations.com.

Other references on the role of inhouse disease management programs include:

In-House Disease Management Programs

- Diabetes Management Making the Business Case. CDC/WBGH. 1999. (WBGH 202-628-9320, Julie Gonen contact)
- Employers' Managed Health Care Association (MHCA). Diabetes and the Workplace: How Employers Can Implement Change. 2000
- 3. Burton WN, et al. Bank One's Worksite-Based Asthma Disease Management Program. J Occup Environ Med. 2001:43:75-82

- 4. Burton WN, et al. Asthma Disease Management: A Worksite-Based Asthma Education Program. Disease Management. 4(1) 2001 3-13.
- 5. Burton WN and Connerty CM. Worksite-Based Diabetes Disease Management Program. Disease Management. 2002. 5(1) 1-8.
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Appendix E

Defining the Terms

The design of an organization's Rx benefit plan will have a sizeable impact on employee health and productivity and on the corporate bottom line. The choices are increasingly complex, however, as many design elements intersect and overlap.

Not surprisingly, the terms used to describe many of the elements of a pharmacy program overlap as well, and thus may mean different things to different people. In this milieu, even the word "purchaser" may need clarification. It is used throughout the Guide to mean the employer purchaser, but it has also been used to denote the health plan, or payer. The word "payer"—which has been avoided in the Guide—can create confusion, too, since it can apply to the health plan or the purchaser.

The Formulary

At its most basic level, a formulary is a list of prescription drugs that a pharmacy benefit plan recommends or provides reimbursement for.

An open, or voluntary, formulary provides coverage for the vast majority of FDA-approved medications, although specific categories—products used for cosmetic purposes, for instance—may be excluded.

A **closed**, **or mandatory**, **formulary** only covers drugs on the list. If a doctor prescribes a non-formulary

product, the enrollee has to pay entirely out of pocket.

A selective, or restrictive, formulary, like a closed formulary, provides automatic reimbursement only for drugs on the preferred list. The difference lies in the modifications. A selective formulary may have one or a number of exceptions, typically based on evidence of medical necessity. Step therapy is one example. Rather than simply excluding particular drugs or groups of drugs, formularies with step care provisions require evidence of an unsuccessful trial with one (older and lower-priced) therapeutic class of drugs before authorizing coverage of a newer, generally higher-priced treatment.

A financial incentive formulary typically encourages physicians to prescribe preferred drugs and uses differential copays to influence enrollees' choices. In 2001, for example, the average three-tier Rx benefit had a copay for a branded, non-formulary drug set more than three times as high as the one for the purchase of a generic drug.

The Cost Share

Cost-sharing provisions can be based on a fixed amount or a percentage of the total cost of a prescription drug.

Flat dollar copayment, in which an enrollee pays one set amount regardless of the drug, have all but disappeared as drug costs have continued to rise.

Two-tier copays, with one price for generics and another higher price for

branded drugs, and three-tier copays have replaced them. Like two-tier plans, three-tier structures have generic drugs on tier one. But the second tier is reserved for brand drugs on formulary, and non-formulary branded products occupy the third tier. In 2001, three-tier copays averaged \$9, \$17, and \$31, respectively.

Coinsurance, a cost-sharing provision based on a percentage of the actual price, has the advantage of exposing workers to the true cost of drugs—a system employers purport to favor but rarely use.

Utilization Management

An electronic system linking every pharmacy in a network is crucial for effective *drug utilization review* (*DUR*), an assessment of the appropriateness of Rx drug use and prescribing patterns at the point of sale and retrospectively.

Concurrent review is part of the dispensing process: The system flags the pharmacist if a newly prescribed drug has the potential to interact dangerously with another medication the patient is taking. Assuring that the proper dosage is prescribed and screening for therapeutic duplication occurs at the point of sale as well.

Generic substitution may also be part of the concurrent review. It can be voluntary, with different copays for generic and brand versions of a product designed to act as an incentive, or mandatory, which means that any participant who opts for the branded version of a drug available in generic form must pay the full cost differential.

Prior authorization is a more restrictive form of utilization management, often reserved for high cost non-formulary drugs. Examples include requiring confirmation of the diagnosis at the point of sale, physician confirmation of medical appropriateness of a particular drug, or evidence of a failed trial with one or more lower-priced medications (step therapy), and employer approval of medical exception.

Compliance/case management programs go beyond the standard forms of DUR. These services focus on enrollees with one chronic illness or on a patient population with multiple health problems and feature refill reminders, identification of patients who are underutilizing medication or have stopped taking it entirely, and steps to intervene, when necessary, with patient and physician.

Terms Relevant to Pharmaceutical Pricing (from PWC)

Acquisition Cost – The net cost a retail, mail or hospital pharmacy pays a manufacturer, wholesaler or distributor to purchase a drug product.

Average AWP – A reimbursement model used by some PBMs that averages the costs of a single drug entity across dosages and package sizes to determine a pre-discounted starting point.

Average Wholesale Price – (AWP) The published price offered to

industry entities that represents the full undiscounted cost of the prescription drug.

Brand Name Drug Product – 1) A brand product protected by patent and distributed by the innovator manufacturer. 2) A brand product that is no longer protected by patent but is produced and distributed by the innovator manufacturer.

Co-Payment – The members portion of the drug cost that is designated in the Summary Plan Description (SPD). The co-payment is paid to the pharmacy at the point of sale and deducted from the reimbursement by the PBM.

Dispensing Fee – A contracted fee between a PBM and a network or mail order pharmacy that is paid to the pharmacy for the service of dispensing the prescription to the member. Dispensing fees are independent of the cost of the drug but reimbursed as an addition to the discounted drug cost.

First DataBank – A price distributor that is a subsidiary of The Hearst Corporation.

Formulary – 1) An approved list of products covered under a plan. 2) A list of preferred products that are rebateable under agreements between manufacturers and the PBM.

Generic Drug Product – A generic product that is chemically equivalent to the active ingredient to a corresponding off patent brand name drug and is produced and distributed by one or more companies.

Mail Order Pharmacy – A pharmacy facility owned or contracted by a PBM that is in the business of filling prescriptions that are received in the mail or via the internet and shipping the orders to a members address.

Marketshare – A milestone that establishes a products sales frequency that is measured against other products within the same therapeutic class.

Maximum Allowable Cost – (MAC Pricing) A reimbursement limit established by a PBM or government entity that establishes a deep but variable discount across individual generic drug products.

Medi-Span – A price distributor that was once owned by First DataBank.

National Drug Code – (NDC) A unique 11 digit number assigned to a drug product that numerically conveys the manufacturer, dosage/strength and package size of the product. NDC numbers are used by PBMs to identify the AWP on the date of service of the claim.

Net Purchase Discount – The amount discount expressed as a percentage that a pharmacy saves off AWP as a result of a purchasing agreement from a manufacturer, wholesaler or distributor.

Non-MAC Generics – Drug products classified as generics that are not included on a PBMs MAC list due to the products limited availability, or rating. Non-MAC generics typically are reimbursed at brand name rates.

Package Size – Refers to the size of the container the drug product is packaged in. Individual drug products are typically available in a array of sizes. Often each size is associated with a separate AWP unit cost.

P&T Committee – Refers to a Pharmacy & Therapeutics Committee that is made up of typically independent representatives from the physician and pharmacist communities that meet quarterly on behalf of a PBM to discuss matters specific to a formulary.

Pharmacy Benefit Managers – (PBMs) Companies that manage the financial and claims aspects of an employer or payers prescription benefit plan.

Pharmacy Reimbursement Formula – AWP minus (an established discount percent) + dispensing fee minus co-payment.

Price Distributors – Commercial entities that routinely survey manufacturers, wholesalers and distributors for drug prices and report these prices expressed as "Average Wholesale Prices" to entities within the drug industry.

Product Ratings – Refers to such things as a-rated generics, etc.

Rebates – An amount of money that is paid to a PBM from a drug manufacturer for either representing their product on a formulary or committing to move product market share of the product. A percentage of the rebate paid to the PBM is shared with the employer or payer.

RedBook – A price distributor that is a subsidiary of Medical Economics, Inc.

Retail Pharmacy – A chain or independent pharmacy in the retail community that is enrolled in a PBM provider network and services customers within a community.

Unit Cost – Refers to the per unit, per pill per ml cost of the drug that when multiplied by the actual quantity of the prescription will yield the total cost of the drug.

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