Cost Containment Strategies For Prescription Drugs: Assessing The Evidence In The Literature

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March 2005

Acknowledgements

The author would like to thank Andrea Kastin, a graduate student in Georgetown's Graduate Public Policy Institute, for her extensive help in searching the literature for this project and for drafting several sections of this report. Her contributions have considerably improved the quality and completeness of this report. Deb Ashner also made valuable contributions to searching and organizing the literature. In addition, the author would like to thank the staff at the Foundation for their help in designing this project and for their insightful comments on various drafts. Finally, thanks go to many professional colleagues who made suggestions about topics and articles to include and contributed ideas that improved the report.

Table of Contents

5. Education Strategies

    a. Education of consumers and physicians on the benefits of generic drugs
    b. Education of consumers and physicians on the appropriate use of particular drugs
    c. Counter detailing or academic detailing
    d. Development of unbiased information on the appropriate use of certain drugs

Pricing Strategies

6. Pricing Approaches Available to All Payers

    a. Use of purchasing pools
    b. Higher rebates through market leverage
    c. Requirements to make prices and rebates transparent
    d. Lower dispensing fees to the pharmacy
    e. Use of restricted pharmacy networks
    f. Use of discount cards
    g. Defined contribution approaches

7. Lower Transaction Costs

    a. Incentives for increased use of mail-order pharmacies
    b. Mandatory mail order for maintenance medications

Regulatory Strategies Available Only to Government

8. Pricing Approaches

    a. Expanded access to Medicaid rebates or changes to the rebate formula
    b. Direct price regulation
    c. Expanded access to the federal supply schedule

9. Direct Regulatory Approaches

    a. Broader availability of generic drugs through changing patent protection laws
    b. Broader authority to move drugs to over-the counter status
    c. Increased regulation of direct-to-consumer advertising
    d. Reduced restrictions on importation of drugs from other countries

Appendix A. Literature Reviewed

Overview

Persistent double-digit annual increases in prescription drug costs have generated considerable interest in strategies to control growth in drug spending. As the recent Medicare prescription drug debate demonstrated, there are numerous options available to public and private actors interested in moderating drug prices, although deep divisions exist within the policy community and the public over the appropriate roles for and balance between market forces and government regulation. This report was developed to assist policy makers and others in understanding better the various options available to address drug spending growth and how private and public payers are currently using these options in different settings.

Concern over rapidly rising drug prices is likely to continue for some time to come – actuaries at the Center for Medicare and Medicaid Services project that prescription drug spending will rise on average by more than 10 percent per year over the next decade, faster than any other health care service and far outstripping growth in inflation. Both public and private policy makers are striving to find strategies that will work to slow drug spending growth. In doing so, they hope to move beyond anecdotal evidence or a belief that a particular cost-containment strategy will save money to finding systematic evidence on the use of a strategy. The research underlying this report suggests that a limited literature is available on the range of cost-containment strategies, but that literature is hardly adequate to make choices for the many different settings through which Americans get their drug benefits. The challenge remaining for both the research and policy communities is to sponsor and conduct more studies on the effectiveness of cost-containment strategies.

How To Use This Report

This report provides detailed descriptions of over 30 specific cost control strategies, organized under three broad themes. The first, "Utilization Strategies," describes a variety of market-based approaches intended to affect which and how many drugs patients use. These strategies range from direct limits (such as excluding specific drugs from coverage or limiting the quantity covered), to rules on utilization (such as formularies, preferred drug lists, step therapy, and prior authorization requirements), to methods to influence how much the patients pays (such as tiered copayments or reference pricing). The second, "Pricing Strategies," discusses market-based approaches intended to reduce the price of drugs, including restricted pharmacy networks, use of mail-order pharmacy, and manufacturer rebates. A final theme, "Regulatory Strategies," discusses ways of using government authority to contain costs, including direct price regulation, changing patent-protection laws, and transferring drugs to over-the-counter status.

The report looks at each cost-containment strategy separately, with a description of how the approach works, examples of how the approach is being used by private or public payers, and, when available, a discussion of known evidence (with citations to relevant literature) regarding the effectiveness or cost-savings potential of the approach. These descriptions are independent from one another; readers are free to look at just a few approaches that are of interest or may wish to review the entire document for a thorough review of cost-containment options.

The information presented here was obtained through a literature review performed by the author, with the help of two research assistants, between mid-2002 and mid-2004. A fuller discussion of the methodology is presented in Appendix A. Readers should note that the evidence relating to cost-effectiveness in particular has important limitations. There are relatively few peer-reviewed studies looking at the impact of different cost-containment strategies. Several approaches, such as tiered cost sharing, have been the subject of a number of studies, but many other strategies have not been studied extensively. In some cases, evidence of effectiveness has been reported – often in quite general terms – in various industry newsletters or in reports produced by different industry organizations (e.g., the large pharmacy benefit managers). In the discussions below, we label carefully the source of the available evidence. Although peer-reviewed studies are clearly preferable, decision-makers can make cautious use of other evidence. Readers should draw their own conclusions about how much weight to give to the non-peer-reviewed evidence. Additional discussion of the use of evidence from the literature is included in Appendix A.

1. Utilization Strategies: Direct Limits

These strategies limit utilization directly. Some strategies, such as limiting the maximum number of prescriptions per month, are applied without regard to the circumstances of specific patients or specific providers. These decisions may be subject to an exceptions or appeals process, but otherwise patients who wish to receive the limited drug generally pay the entire cost out of pocket. Other strategies may restrict coverage because of patient-specific factors. The latter often relate to patient safety factors, such as avoiding adverse drug reactions or drugs that are inappropriate for patients of a certain age.

a. Exclusion of specific drugs or drug classes from coverage
b. Exclusion of over-the-counter drugs from coverage
c. Dispensing limits (quantity limits) for a particular drug or prescription
d. General limits or caps on the quantity of drugs covered
e. Concurrent (prospective) drug utilization review

1a. Exclusion of Specific Drugs or Drug Classes from Coverage

Plan sponsors may choose to exclude certain drugs or classes of drugs from coverage. Often, these exclusions represent a design decision of what types of services plan sponsors want in their health plan. Thus, they may exclude weight loss products, birth control pills, or life-style drugs. These exclusions of course reduce the overall cost of a drug benefit. One Pharmacy Benefit Manager (PBM) advises its clients that all the typical classes of drugs excluded collectively represent about 5 percent of all drug costs (Medco). However, only about one-fourth of its clients totally exclude oral contraceptives and vitamins, the two largest classes among those that are sometimes excluded. The PBM advises clients that a typical set of exclusions may yield savings in the range of 1 percent of drug costs. In at least some cases, plan members may purchase excluded drugs at the plan's discount, and the plan will conduct checks for health and safety considerations.

One consultant suggests that Medicare might consider excluding various classes of drugs (Fox). "Quality of life" drugs such as those preventing or reversing hair loss or topical drugs that promise to result in clearer skin do not improve medical outcomes or reduce overall health costs. Policies affecting some drugs in this category become complicated, especially because benefit designs are not always carefully drawn, resulting in coverage of new drugs that they really did not intend to cover. For example, when Viagra was introduced to treat erectile dysfunction, it did not fall in an excluded class for many plans. Plans wishing to exclude it from coverage had to revise their benefit design at the next opportunity. Nonsedating antihistamines for allergies may be viewed by some as improving quality of life, but not medical outcomes – but may be especially important for a worker who operates complex machinery. Fox also suggests that some drugs that are expensive and marginally effective or whose indications for use are unclear could be candidates for exclusion from coverage. Alternatively, coverage could be limited to individuals with specific health problems (e.g., Cox-2 inhibitors could be made available only to people with documented gastrointestinal problems).

Medicaid by statute allows states to exclude coverage for several classes of drugs: drugs for anorexia, weight loss, or weight gain; infertility treatments; drugs for cosmetic purposes or hair growth; drugs for symptomatic relief of cough and colds; smoking cessation products; vitamins and minerals; nonprescription drugs; barbiturates; and benzodiazepines. In practice some states choose not to take advantage of these exclusions. While a majority of states, according to the December 2003 Kaiser Commission on Medicaid and the Uninsured survey, excluded certain classes (cosmetic, hair-loss drugs, fertility or sexual dysfunction drugs, and weight-control drugs), a smaller number of states chose to exclude smoking cessation drugs (Crowley et al.). The Medicare Modernization Act generally follows the Medicaid statutory exclusions as opposed to actual state practices, but it does require coverage of smoking cessation drugs.

In the private sector, according to a 2002 survey, 72 percent of employers were excluding drugs for weight loss, 57 percent excluded smoking cessation drugs, 51 percent excluded fertility treatments from coverage, while a considerably smaller number excluded such classes as growth hormones or oral contraceptives (PBMI). The proportion of employers excluding injectable drugs and oral contraceptives has been dropping modestly since 2000. Instead, some previously excluded drugs are now covered but placed in a coverage tier with a substantial copayment or are

covered only under prior authorization or as part of some other type of utilization management program. In still other cases, drugs might be covered only for certain categories of patients (e.g., growth hormones where there is documentation that a child has a medical syndrome causing him or her to grow too slowly) or in conjunction with certain programs (e.g., appetite suppressants for a patient who meets with a nutritionist on a regular basis).

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Fox, Peter D., "Prescription Drug Benefits: Cost Management Issues for Medicare," *Health Care Financing Review* 25(2): 7-21, Winter 2003-2004.

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1b. Exclusion of Over-the-Counter Drugs from Coverage

The Food and Drug Administration (FDA) designates when a drug can be dispensed only with a prescription. In other cases, drugs can be dispensed over-the-counter (OTC) without a prescription. Health plans may choose not to cover OTC drugs or to cover them in only limited circumstances. Nearly all private employers (95 percent) completely exclude OTC drugs from coverage, although the recent move of some highly used drugs to OTC status is creating exceptions to this general policy (PBMI/2003). Otherwise, the exceptions were firms that provided coverage of certain products (e.g., aspirin or ibuprofen) either as part of a disease management program or as the first level in step therapy. For example, one New York managed health plan covered nonprescription H2 antagonists (Tagamet HB, Pepcid AC, Zantac 175). The article reporting this cited the plan's claim of a nearly 50 percent reduction in its budget for prescription versions. The plan had not yet reviewed whether there was any change in use of more expensive brand-name drugs like Prevacid (Sica).

State Medicaid programs are somewhat more likely to cover OTC drugs than are private firms, but states vary substantially. In 2003, 39 of 43 responding states reporting covering at least some OTC drugs. Some states cover all OTC drugs, while others cover them only in certain circumstances. For example, Washington covers OTC drugs when they are less costly than the competing prescription drug, while Illinois requires that a prescription be obtained for the OTC drug (Crowley et al.). According to a 2001 survey, classes of OTC drugs most commonly covered were cough/cold medications and diabetic supplies. Least commonly covered were smoking cessation drugs, contraceptives, and feminine products (Schwalberg et al.).

The FDA's decision in 2002 to allow the sale of Claritin on an OTC basis has brought attention to this issue. According to news accounts, some insurance companies responded by making it difficult for patients to obtain competing prescriptions once a drug in its class becomes available over-the-counter. Some large insurers responded to this change by moving competing drugs (Allegra and Zyrtec) to non-formulary status, requiring patients to get prior authorization before getting these drugs covered. Where closed formularies are in use, Allegra and Zyrtec will require prior authorization; where open formularies are used, prescriptions for the alternatives to Claritin are covered at the highest copay level. In other cases, insurers require proof that a patient has tried Claritin before allowing a person to receive coverage for a competing drug.

One news account reported Medco's estimate that its clients could save over $500 million (about 40 percent of the total amount spent on non-sedating antihistamines in 2002) in the first year of Claritin's availability as an OTC drug, often as a result of dropping coverage for competing drugs. Presumably some of this savings will be a cost shift to patients who will pay the full cost of Claritin out of pocket. As generic alternatives to Claritin become more widely available, the new costs to patients may become less.

The FDA decided in June 2003 to approve over-the-counter sales of another popular prescription medication, Prilosec – a proton pump inhibitor (PPI) for certain gastrointestinal problems. One health plan decided to cover Prilosec OTC since it has the same active ingredient and dose as generic Prilosec by prescription, but with a large cost difference. The plan noted that Prilosec OTC cost less than $1 per tablet, compared to $3 for generic Prilosec, and chose to cover it on

that basis as long as it is prescribed by a doctor. In doing so, the plan did not modify its general rule against covering OTC medications, arguing that the Prilosec situation is unique. Other plans did not immediately change their rules, but considered higher cost sharing or additional prior authorization requirements for competing drugs in the same class.

A 2003 survey found evidence of some overall change in plan sponsors' attitudes toward coverage of OTC drugs. About 10 percent of plans were covering OTC Claritin, while 12 percent of plans were excluding other non-sedating antihistamines from coverage. About 4 percent of plans were covering OTC Prilosec. The lower coverage level in this case may have reflected both the more recent date of the move to OTC status for Prilosec and the fact that stronger doses of Prilosec remained available by prescription (PBMI/2004).

One published study looked at the decision of a state employee health plan to add coverage for Prilosec OTC. It found that within two months, about 60 percent of claims for drugs in the PPI class were for Prilosec OTC. The state realized savings of as much as 50 percent of total costs for the PPI class, despite a modest increase in the use of such drugs. Plan enrollees also realized savings based on lower copayments, and savings may increase beyond the scope of this short-term study if more enrollees switch away from prescription products (Harris et al.).

Cost tradeoffs can sometimes create a rationale for covering an OTC drug. If a plan covers prescription pain medications, but does not cover aspirin or ibuprofen, it is more difficult for the pharmacy benefit manager (PBM) to recommend substitution of the nonprescription medication. In some cases (e.g., aspirin), the total cost might be lower than the copayment on an expensive alternative like a Cox-2 inhibitor. But in cases like Claritin, the cost of the OTC drug is considerably higher; in fact, it may be cheaper for a person to spend a $10 copayment on a competing drug than to spend $1 per pill on OTC Claritin (Neergard). A peer-reviewed study in 1995 showed that people with prescription coverage are more likely to choose prescription medications over OTC alternatives when the price of the OTC drug is greater than the after-insurance cost of the more expensive prescription medication (Stuart and Grana).

There do not appear to be any studies of how well coverage of OTC drugs by Medicaid has worked. Where OTC drugs are covered, it increases the cost to the state. Where OTC drugs are not covered and a drug like Claritin is shifted to OTC status, it will either increase costs to beneficiaries or deny access to those drugs for reasons of affordability.

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1c. Dispensing Limits (Quantity Limits) for a Particular Drug or Prescription

Some health plans make specific provisions to establish how much of a drug is covered by limiting the quantity of pills or the number of days a prescription may cover. For example, a plan might limit the plan member to a certain number of migraine medications per month. Some groups refer to this as managed drug limitation. One issue is that a month's supply of some drugs is not well defined and depends on patient circumstances. A migraine medication that is used "as needed" for migraine headaches may be required just once or twice a month for some patients and a dozen or more times for others. One variation on quantity limits is a trial prescription program, where the prescription is dispensed in two parts – a seven-day supply and then the balance, after a follow-up phone call to assess side effects and compliance.

Under Medicaid, nearly all states have some type of limit on prescriptions. The most common is a limit on the amount of medication per prescription (e.g., 30 days, 34 days, or 100 units). Some states also limit the number of refills, for example, to 4 within 6 months (Crowley et al.).

One PBM, Medco Health, states in its *Drug Trend Report* that plan exclusions — including both specific drug limits and general limitations (section 1d) — can save up to 1 percent of drug spending. Medco asserts that large savings are available in certain cases, citing that limits on a medication for severe acute pain (Toradol) yielded a 45 percent reduction in claims (Medco/2002; Medco/2004).

A 2001 peer-reviewed study looked at whether the length of a prescription could be a factor in increasing drug costs (Walton et al.). The study looked at the potential for drug wastage when physicians make changes to patients' prescriptions while the patient still has a supply of the medication. According to the study, about three-fourths of the prescriptions studied (in a VA system) were for 90 days, with the rest for 30 days, and about 15 percent of each type were changed during the term of the prescription. The researchers found that the total unnecessary cost for unneeded drugs was lower for the 90-day prescriptions, with the additional dispensing costs outweighing the greater amount of medication wasted. The authors acknowledge numerous limitations on the study, but suggest that their model can be used in other situations.

Two peer-reviewed studies looked at the effect of monthly coverage limits on migraine medications (triptans such as Imitrex). One examined a provision by a managed-care plan that limited coverage to dosages appropriate for four migraines per month. If a patient exceeded the quantity limit, the prescription was denied pending an appeal to the plan. Looking at utilization before and after the limit was imposed, the researchers found that the plan saved money – based on a decrease in the use of these medications. They found that there was an increase in the number of patients taking prophylactic therapy, and small changes in utilization of hospitalizations and physician visits. The overall level of cost savings, according to the study, was $12.25 per member per month (Culley and Wanovich).

The measure analyzed in the second paper included a monthly milligram limit without allowing for medical exceptions or system overrides. The program resulted in a 29 percent reduction in direct drug costs and a 40 percent decline in related medical services. There was no

accompanying increase in any other medication category, although changes in use of over-the-counter medications were not studied (Hoffman et al.).

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1d. General Limits or Caps on the Quantity of Drugs Covered

One of the simplest means to control costs is to limit the amount of drugs for which payment is provided by the health plan. This strategy may take the form of a quarterly or annual limit on the amount of coverage. Thus, a benefit may cover up to $300 worth of covered drugs per quarter or $1,000 per year. Alternatively, this strategy may take the form of a limit on the number of prescriptions covered, such as no more than five prescriptions per month. These provisions may have a large effect in limiting a plan's or payer's costs, but may have less effect on overall drug costs and almost certainly will raise the costs to consumers. When enrollees exceed the cap, they may still have access to the plan's discounted retail prices, although paying the entire cost out of pocket. But availability of discounted prices varies by the specific arrangements made by plans, pharmacy benefit managers (PBMs), and pharmacies.

One issue where caps or other quantity limits are used is how spending is counted to determine whether the limit is reached. Typically, plans calculate expenditures based on the negotiated contract prices at the retail pharmacy, less the enrollee's copayment. But this contract price does not factor in manufacturer rebates, although these may help to lower overall plan premiums. Another issue is that claims data may no longer be accumulated after a cap is reached, especially if the enrollee does not present the insurance card or goes to a non-network pharmacy. In the absence of claims data, utilization review functions cannot be performed.

General quantity limits are not a popular cost containment approach in the private market. One PBM, Medco Health, notes that general annual benefit maximums or caps are "among the less desirable ways to share costs with members." While these limits can provide a quick fix to lower drug spending, the PBM indicates that it penalizes plan members who are the sickest and most in need of medications. The result may be that these members skip essential medications and incur higher overall medical costs (Medco).

Although quantity limits or caps seem unpopular with private purchasers, they are far more common with public purchasers. In Medicaid, a growing number of state plans have limits on the number of refills per prescription and the number of prescriptions a beneficiary can have at one time before the state requires prior authorization (Crowley et al.). In addition, quantity limits have become increasingly popular is Medicare+Choice. In 2003, only 2 percent of plans, weighted by enrollment, had unlimited coverage for both brand and generic drugs – down from 22 percent in 1999. Among enrollees with some drug coverage, about 41 percent had coverage only for generic drugs. When coverage is available for both generic and brand-name drugs, about 63 percent faced a cap of $1,000 or less per year (Achman and Gold). The increased use of $500 or $1,000 annual caps means that many beneficiaries reach them each year. There is also an increase in the use of semi-annual, quarterly, or even monthly limits (Draper et al.).

The impact of quantity limits has been considered in several peer-reviewed studies. Stephen Soumerai and his colleagues have conducted a series of studies looking at the impact of monthly limits on prescriptions as imposed by state Medicaid programs. In particular, studies focused on a three-prescription monthly limit posed by New Hampshire in 1981 before switching to a copayment in 1982. New Jersey Medicaid was used as a comparison state. Soumerai and his colleagues found a sustained reduction in the number of prescriptions filled after the cap was

imposed. The reductions occurred both for essential and less essential drugs, but the drops were lesser for essential drugs and for relatively high-cost drugs. The overall result, according to the study, was a 19 percent reduction in spending for the state, but at the expense of reduced use of appropriate medications (Soumerai et al. 1987). A second study showed that the reduced drug use resulted in increased nursing home admissions (Soumerai et al. 1991), and a third study showed resulting increases in visits to community mental health centers and sharp increases in the use of emergency mental health services and partial hospitalization (although no increase in hospital admissions) for patients with schizophrenia (Soumerai et al. 1994). A closer look at chronically ill patients showed an average 34 percent drop in the use of essential medications (Fortess et al.).

Other peer-reviewed studies have looked at the effect of capped benefits in Medicare+Choice. One study by a researcher at a managed health plan found that from 17 percent to 25 percent of Medicare beneficiaries exhausted their capped benefits in 1998, well before the substantial growth in the use of capped benefits by plans (Rector). In these cases, beneficiaries were more likely to disenroll from the plan, with potential consequences for continuity of care. Another study by researchers at a PBM found that beneficiaries at risk for reaching their prescription cap take various steps to reduce costs (Cox et al.). Some steps, such as getting samples from physicians, might be considered prudent behaviors, while others, such as discontinuing prescribed drugs or taking less than prescribed, might place the patient at risk.

Another peer-reviewed study looking at 2001 claims of Medicare beneficiaries aged 65 years and older with high medication costs and enrolled in a Medicare+Choice plan that imposed annual dollar limits found that as many as 22 percent of beneficiaries exceeded the caps with resulting higher out-of-pocket costs (Tseng et al. 2003). A further study by the same researchers found that 18 percent of patients exceeding these caps used less prescribed medication than Medicare beneficiaries in a control group (10 percent). While 8 percent of both groups of beneficiaries stopped taking their prescribed medications altogether, those exceeding the cap were more likely to call pharmacies to find the best price for their drug (46 percent versus 29 percent), switch medications (15 percent versus 9 percent), and use samples (34 percent versus 27 percent). Sixty-two percent of those who exceeded their plan's cap had difficulty paying for prescriptions compared with 37 percent of beneficiaries in the control group (Tseng et al. 2004).

Another peer-reviewed study surveyed beneficiaries with chronic illnesses who enrolled in eight Medicare+Choice plans with a capped drug benefit. About one-third of enrollees reported not filling a prescription or reducing the prescribed dosage because of their out-of-pocket costs. The result was under-use of needed medications, especially for those with lower incomes or poorer health (Rector and Venus).

A somewhat different angle on the latter question was addressed in a peer-reviewed study of how Medicare beneficiaries chose among capped and uncapped drug benefit plans. It found that beneficiaries choosing the capped plans were less likely to have high expenses, suggesting that they anticipated their needs correctly before choosing a plan (Andrade and Gurwitz).

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1e. Concurrent (Prospective) Drug Utilization Review

Concurrent or prospective drug utilization review (DUR) strategies (sometimes referred to as point-of-sale DUR) restrict filling a prescription based on factors such as duplication, interactions with other drugs, excessive dosage or duration, or diagnostic appropriateness. Unlike other types of utilization review that may look at overall patterns of utilization (sections 4a, 4c), concurrent DUR focuses on the particular prescription that has been presented. It may look at whether the patient has a current prescription for the same drug or another drug for the same condition. It may also look at factors that could adversely affect the patient's health, such as interactions with other prescribed drugs, whether the dosage or duration of the prescription is greater than recommended guidelines, or whether a particular drug is contraindicated based on the patient's age, sex, or other characteristics. Concurrent DUR typically generates a flag for the pharmacist, who can override the flag either based on his or her own assessment or after consultation with the prescribing physician.

One pharmacy benefit manager (PBM) for example, AdvancePCS, applies several types of reviews to new prescriptions: (1) drug-drug interaction, (2) drug-age conflict, identifying drugs that should be used with caution based on the age of the patient, (3) drug-disease conflict, (4) drug-allergy conflict, for drugs to which a patient may have sensitivities, (5) drug-gender issue, (6) drug-pregnancy warning, for drugs that should be avoided during pregnancy, (7) excessive controlled substance utilization, (8) overuse or excessive duration of a prescription, (9) high dose warning, (10) ingredient duplication, and (11) therapeutic duplication. In 2001, AdvancePCS reported issuing safety-related alerts on 7 percent of all claims. High dose warnings and drug-drug interactions were the alerts that occurred most commonly. Nearly 10 percent of those alerts resulted in a changed prescription. Ingredient or therapeutic duplication and high dose warnings were the alerts that were most likely to lead to the "reversal" of a prescription. Between 20 percent and 25 percent of the reversals in certain categories occurred based on prescriptions filled at different pharmacies – a situation that could not be observed and corrected by the pharmacist at a single pharmacy (AdvancePCS).

Concurrent DUR is one of the more universal cost containment approaches, being increasingly regarded as a basic element of electronic claims processing. It is used by a substantial majority of private plans, and all state Medicaid programs by law are required to have DUR programs for outpatient drugs. According to a 2002 survey, 81 percent of private employers reported that their plans have implemented concurrent DUR programs (PBMI/2003). Nearly all states use automated DUR systems and contract with outside agencies to run these systems. Some states use active systems where the review agency must intervene to override an alert; others use passive systems that provide the information to the pharmacist, but do not prevent the prescription from being dispensed (Crowley et al.).

Two peer-reviewed studies looked at the response of physicians and pharmacists to concurrent DUR alerts. One, conducted by researchers at a large PBM examined 43,000 alerts triggered by their DUR program in one year. In over half of these alerts, the PBM was able to contact a physician and saw a change to a more appropriate drug in one-fourth of those cases (Monane et al.). The other study found that pharmacists did not intervene for all DUR messages, but they

found those related to medication overuse and drug interactions most useful. The most common response was to telephone physicians or talk to patients (Armstrong and Markson).

Another study focused on the introduction of prospective DUR in Medicaid and found no evidence that the DUR programs had any measurable effect on reducing the frequency of drug problems, or on lowering spending or utilization of either drugs or other health services. Despite these results, the evaluators do not conclude that the DUR programs are wasted efforts, but raise the possibility that the particular DUR models studied may not have been the most promising (Kidder and Bae). A 2004 review article reports that a growing body of literature indicates numerous problems with respect to the quality of DUR criteria and alerts and the response of health care professionals to these alerts. Problems ranged from technical issues (e.g., duplicate messaging from in-store and on-line systems) to those involving how pharmacists interpret and respond to the alerts. The article included recommendations on both sets of issues, including more validation of criteria through evidence-based studies, performance standards for pharmacists, and payment to pharmacists for time spent identifying and addressing drug therapy problems (Fulda et al.).

Two case studies also indicate the types of savings that purchasers might expect for the use of concurrent DUR. In one case study of the use of utilization management by a medium-sized company, concurrent DUR was used to look for potentially inappropriate drug use, such as use of products containing aspirin for patients with ulcers, use of certain anti-depressants for patients with Parkinson's disease, and certain combination cholesterol therapies that can have unwanted side effects. When these situations were flagged, two clinical pharmacists reviewed case histories and where appropriate recommended a change in therapy to the prescribing physician. The company estimated that it was able to reduce its overall drug spending for the year by 2.3 percent compared to what it would have spent otherwise (PBMI/2002).

Another case study involved reviews for duplicative therapies for a municipality with 17,000 covered lives. Interventions were triggered in cases where different drugs with an identical or similar therapeutic profile were prescribed within the same 30-day period. Therapeutic classes that received particular attention were anti-depressants, anti-histamines, nasal sprays, non-steroidal anti-inflammatory drugs, and proton pump inhibitors. In an eight-month period, duplicate prescriptions were identified for 105 patients, generating an estimated savings of $8,810 (PBMI/2002).

Finally, another peer-reviewed study showed the potential represented for savings if the inappropriate use of drugs by older people were reduced. The study found that about 20 percent of patients (seniors living in the community) used one or more drugs considered inappropriate. This inappropriate use persisted over time (Hanlon et al.).

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2. Utilization Strategies: Utilization Management Approaches

These utilization management approaches are focused on particular prescription events. While reviews may be triggered at the point of sale, they generally require some type of interaction with the physician. Unlike direct limits (section 1), these utilization strategies are mostly aimed at substituting a different drug for that originally prescribed. Patients who prefer the originally prescribed drug may be required to pay some or all of the cost out of pocket, to apply for an exception, or to file a formal appeal. Cost sharing approaches (listed as a separate category, section 3) are often used as an incentive mechanism in conjunction with utilization management approaches.

a. Prior authorization requirements
b. Step therapy or fail-first requirements
c. Therapeutic substitution or therapeutic intervention
d. Closed formulary
e. Preferred drug list or open formulary
f. Mandatory generic substitution
g. Management of specialty drugs
h. Provider financial incentives
i. Payments to pharmacies as incentives
j. Other coverage management approaches

2a. Prior Authorization Requirements

Under prior authorization, the health plan or pharmacy benefit manager (PBM) must authorize a particular prescription before it can be filled. Prior authorization may be required for drugs in certain classes in order to limit use of drugs in that class to patients with certain medical conditions or histories. In other cases, this strategy is used as a means of enforcing a formulary or preferred drug list (section 2e). Drugs off the formulary or preferred list might be available with prior authorization in contrast to a formulary that is enforced by incentives such as different levels of copayments. Prior authorization also may be used in conjunction with a step therapy system (section 2b), so that a patient might be required to try a less expensive drug before receiving authorization to receive the drug originally requested.

Prior authorization is used by about three-fourths of private employers (PBMI). One PBM (Medco Health) suggests that savings are accomplished more easily and more effectively when prior authorization programs are applied at the time when a drug is first introduced rather than later, after patient prescribing patterns have been established.

Most state Medicaid programs also make at least some use of prior authorization, typically targeting certain classes of drugs (e.g., growth hormones, impotence agents, and anorexia drugs). States may also require prior authorization for more common medications, such as non-steroidal anti-inflammatory drugs (NSAIDs) or anti-ulcer medications. By law states that include a prior authorization for their Medicaid programs must have a process for responding within 24 hours to authorization requests and must provide a 72-hour emergency supply of any drug on the prior authorization list (Crowley et al.). More recently, several states (e.g., Michigan) have created preferred drug lists that use prior authorization as a means of enforcing the list.

In April 2004, a federal appeals court rejected a challenge by the pharmaceutical industry that Michigan's use of prior authorization for drugs not on preferred drug lists forced patients to accept inferior drug alternatives. The court's decision stated that "... the available data confirmed that in practice the prior authorization requirement has proved neither burdensome nor overly time-consuming" (Pear).

Some state Medicaid programs have relatively simple prior authorization processes. According to a 2003 study on prior authorization requirements for five state Medicaid programs, Georgia requires prior authorization for 25 categories of drugs and contracts with a PBM to conduct the reviews. Physicians must document medical necessity in order to get the drug authorized. Pharmacists can override the authorization requirement. By contrast, Washington state has a complicated system that combines prior authorization for certain drugs with another type of review for beneficiaries that are prescribed at least four brand-name prescriptions in a month or are prescribed non-preferred drugs in any of certain therapeutic classes. The biggest complaints raised about the use of prior authorization included delays in getting needed prescriptions, multiple trips to the doctor or to the pharmacy, insufficient information for beneficiaries about the process (e.g., appeal rights), and administrative burden for doctors. Oklahoma includes in its procedure a random call back to people who have been denied a prescribed drug; the state found no adverse outcomes (Tilly and Elam).

A 2001 literature review of studies of prior authorization found six studies that looked at the effects of a prior authorization program on specified drugs. The authors found generally that the studies lacked a randomized, controlled design and had severe methodological flaws. The studies concluded that prior authorization programs had an impact on reducing costs, but generally they did not examine the impact on outcomes or satisfaction (MacKinnon and Kumar).

Among the peer-reviewed studies considered for that review was a 1995 paper that looked at a prior-authorization policy for non-generic NSAIDs in the Tennessee Medicaid program (Smalley et al.). Overall, expenditures for NSAIDs fell by 53 percent, as a result of increased use of generic NSAIDs and a decrease in overall NSAID use. The authors found no accompanying increase in other medical expenditures. Another paper looked at the use of prior authorization in Georgia, finding savings of $8 to $20 million annually across all 46 drugs in the program (Kotzan et al. 1996). The same research team earlier reported on savings specific to the use of NSAIDs (Kotzan et al. 1993).

A 2001 peer-reviewed study by PBM researchers (at AdvancePCS) looked at strategies for managing Cox-2 drugs (Celebrex, in particular), comparing four different approaches used by different client companies (Tucker et al.). The study showed that prior authorization was the second most effective of the four (in terms of percentage savings). The other utilization management approaches tested were step therapy (most effective), a form of reference pricing (third), and three-tier copayments (least effective). In another study published in the *Journal of Managed Care Pharmacy*, prior authorization for Cox-2 inhibitors in a 3-tier copay plan proved effective in managing pharmacy costs (Stacy et al.). This concurs with an Express Scripts presentation (not peer reviewed), which asserts that drug expenditures were significantly lower under prior authorization for nearly all therapy classes studied. The cost savings may be associated with significantly lower utilization for the drug classes studied (Motheral et al.).

Finally, another peer-reviewed study used 2001 drug claims data from a national PBM to look at the effect of various plan design features on drug use and spending for people age 65 and older with private employer-based coverage. Prior authorization programs were categorized based on how frequently they deny prescriptions. Savings were shown for plans with stronger prior authorization controls for certain drug classes (anti-obesity drugs, blood products, and central nervous system drugs). Prior authorization is generally used in combination with other strategies, and the study was not able to examine its effect alone (Thomas et al.).

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2b. Step Therapy or Fail-First Requirements

Step therapy, also referred to as a fail-first requirement, is a program where payment for a drug is restricted unless certain other drug therapies have been tried first. For example, coverage of Cox-2 inhibitors (e.g., Celebrex) for arthritis would be available only to patients who do not respond successfully to less costly non-steroidal anti-inflammatory drugs (NSAIDs). Thus a patient might first be treated with a non-prescription NSAID like ibuprofen. If that treatment is not satisfactory, coverage for a prescription dose of ibuprofen might be approved, followed by a drug like naproxen sodium. Only if those drugs have been tried and deemed unsuccessful would coverage be approved for a Cox-2 inhibitor. These programs are sometimes referred to as fail-first requirements since a certain drug (e.g., Cox-2 inhibitor) cannot be prescribed until other therapies have been tried first and failed.

According to private-sector employer surveys, step therapy was used in 2003 by 28 percent of employers, up from 22 percent in 2000 (PBMI). There is some evidence that interest in this strategy will continue to grow: a 2002 survey reported that one-third of employers were very or somewhat likely to require use of step therapy edits in the next three years (Hewitt). Employers may find this strategy useful if it limits use of an expensive drug that protects against a serious but rare side effect. But they also worry about the need for extra physician visits or calls to the plan to get approval of a particular drug (Wye River Group on Healthcare). For example, one pharmacy benefit manager (PBM) adopted an alternative step-therapy strategy, which employs category-specific programs with the goal of making step therapy a more employee-friendly cost containment mechanism. For up to five selected drug classes, coverage is limited to the preferred drug unless the physician determines that it is not successful. Then the non-preferred medication is automatically covered based on the presence of a prior claim for the preferred drug. Clients can opt into these programs, and specific savings from programs are estimated at $4 to $9 per member per year depending on utilization (Drug Cost Management Report).

Among state Medicaid programs, 27 states and the District of Columbia had a step therapy (fail first) requirement on one or more drugs in 2003, up substantially from three years earlier. Several state Medicaid programs have specifically targeted NSAIDs or Cox-2 inhibitors for their fail-first requirements. Other states have targeted drugs for gastrointestinal conditions, especially proton-pump inhibitors (Prilosec, Prevacid), typically requiring that H2 blockers (Tagamet, Zantac) must be tried first. Others drugs targeted for step therapy include Xenical, non-sedating antihistamines, and hypertension medications (Crowley et al.).

A peer-reviewed study by PBM researchers (at AdvancePCS) looked at strategies for managing Cox-2 drugs (Celebrex, in particular), comparing four different approaches used by different client companies (Tucker et al.). The study showed that the highest percentage savings came from step therapy (74 percent savings from what would have been paid without step therapy in effect). The other approaches tested were prior authorization (second), a version of reference pricing (third), and three-tier copayment (least effective). In this version of step therapy, the Cox-2 drug claim was paid only if the patient had used one of several therapies in the previous 90 days – specifically, previous use of Cox-2 drugs or use of certain gastrointestinal drugs. This study has two apparent limitations. The first, noted by the authors, was that the plan using step

therapy was a relatively small plan. The second is that the plan allowed use of gastrointestinal drugs to qualify as evidence that other therapies would be ineffective.

An older study, published in *JAMA*, also tested step therapy for the use of NSAIDs (Jones et al.), requiring a trial of either ibuprofen or indomethacin before a prescription can be filled for a more expensive NSAID. In this controlled trial, costs were reduced by 30 percent in the two sites using step therapy, compared to a 5 percent decrease in a site that used a computer cost-prompt when a prescription for the more expensive NSAID was presented and to a 2 percent increase where there was no intervention.

Other evaluations conducted internally by PBMs (and not peer reviewed) also support the effectiveness of step therapy. An internal study by Express Scripts researchers found a 12 percent savings within the NSAID therapy category, although fewer than 1 percent of plan members were affected (Cox et al.). Medco Health found that when a client used step therapy more broadly to encourage more use of generic drugs, the rate of generics dispensed rose from a little over 50 percent to nearly 90 percent in just twelve months. In this case, the cost per day of therapy dropped from a little over $1.60 to just under $1.00 (Medco).

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2c. Therapeutic Substitution or Therapeutic Intervention

Therapeutic substitution is a program designed to switch a patient from one medication to another that is on a preferred drug list or formulary. Some specify the term "therapeutic intervention" rather than "therapeutic substitution" to emphasize the fact that the pharmacist or pharmacy benefit manager (PBM) can only intervene with the physician to get a new prescription as opposed to substituting an alternative drug without a new prescription. By contrast, pharmacists generally can use generic substitution (section 2f) when there is a generic alternative to the prescribed brand-name drug.

In the retail setting, the pharmacist may be required to contact the physician at the point of sale to see if the physician will authorize a switch to the preferred drug. In some cases, the initial prescription would be filled, and the potential substitution would be researched prior to the refill prescription. In the mail-order setting, the timing allows therapeutic substitution to work more easily. The pharmacist has the time available to contact the prescribing physician, since the patient is not waiting to get the product.

Physicians are generally not supportive of this approach or others that cause changes in their prescription decisions. Although they retain the final decision on which drug the patient receives, they are concerned about both the loss of clinical autonomy and the reasons why certain drugs end up on the preferred list. Physicians may contend that certain patients respond better to a particular drug from a given class or that a drug's status on the preferred list or formulary may have more to do with the availability of a larger rebate than clinical criteria.

In the private sector, about half of employers use therapeutic substitution as part of their arsenal of utilization management (PBMI). Its popularity has declined in recent years because it is viewed as aggressive, especially in the retail setting, requiring a relatively heavy-handed approach compared to other techniques such as prior authorization or step therapy. Because it requires the pharmacist or PBM to contract the prescribing physicians at the point of sale, it can create delays for the patient in getting a drug. Tiered cost sharing has also become an alternative that places the choice (and financial consequences) of staying with the original prescription in the hands of the patient.

In a recent variation, one health plan (Humana) introduced a system where the plan reviews drug claims for which a lower-cost brand or generic drug is available. Through a computerized interactive voice response system, the patient receives a call explaining that he or she can save money by taking a substitute drug. Humana estimated that 19 percent of the calls prompted patients to move to a lower-cost drug (Trude and Grossman).

One PBM (AdvancePCS) has suggested that it can obtain savings of 1 to 5 percent through use of therapeutic substitution, but few peer-reviewed studies have been identified that evaluate the effectiveness of this strategy. One such study looked at hypertension treatment in a VA Hospital. Patients were converted from one calcium channel blocker drug to another less-expensive but equally effective drug in the same class. The researchers were surprised to discover that the total cost of drug therapy was higher after patients were converted. Average blood pressure readings were lower, and there were no changes in the use of other health

services. The difference seemed to be more total prescriptions filled, possibly explained by larger doses of the new medications than expected or higher patient compliance (Mamdani et al.). Conversely, a retrospective analysis of the VA Pittsburgh Healthcare System found that six months after switching patients with gastrointestinal ailments from nizatidine to cimetidine, the Pittsburgh system generated $7,260 monthly in pharmaceutical cost savings without increased healthcare resource utilization (Good et al.).

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2d. Closed Formulary

A formulary is a list of drugs selected by the health plan or its contracted pharmacy benefit manager (PBM) as drugs that are most useful in patient care, based on both clinical effectiveness and cost considerations. The term "closed formulary" generally refers to a formulary where a relatively limited number of drugs are included and coverage by the plan is only permitted for drugs that are on the formulary list. Enforcement of the closed formulary may be absolute, with no payment for drugs not on the list, except by appeal, or enforcement may be accomplished through prior authorization or some other exceptions process. Where an exception is granted, it may be permitted for an extended period of time, for example, several years or the duration of the time when the enrollee has the drug benefit.

Formularies are a tool for price negotiation. By placing a drug on its formulary, the PBM or health plan may have increased leverage with manufacturers. By creating the ability to steer utilization toward a particular drug, the plan can offer higher volume in exchange for a lower price or a higher rebate from the manufacturer. A tighter formulary or stronger incentives will increase this leverage.

Decisions about which drugs to include on a formulary are typically made by a committee of experts referred to as pharmacy and therapeutics (P&T) committees. Made up of physicians, pharmacists, and other clinical experts, these committees review clinical evidence for all drugs in a given therapeutic class. The formulary may exclude some drugs in a class, for example, older drugs that have been replaced in practice with safer, more effective alternatives.

Where multiple drugs in a class are considered generally equivalent, the committee may narrow the list of alternatives based on clinical or cost factors (Health Policy Alternatives). There is some literature addressing factors influencing formulary adoption decisions. For example, at least two studies have found that visits by manufacturer representatives increase the likelihood that a particular drug will be on the formulary (Chren and Landefeld; Dranove et al.). According to a 2001 study of formulary use in California, health plans rated quality of care, managing costs, and maximizing rebates as the most important factors in designing their formularies, while employer and physician satisfaction were rated least important. Among the national PBMs, quality of care and managing costs were also listed as the two most important factors – followed by member satisfaction (William M. Mercer).

A recent trend is to take a more systematic approach to bringing scientific evidence to bear in the decision of what drugs to include in a formulary (Neumann). Regence Blue Shield (based in Seattle, Washington), for example, started asking drug manufacturers to present a dossier of clinical and economic evidence in support of their drugs before they are reviewed for inclusion on the formulary. The state of Oregon requested reviews of scientific literature before making decisions on what drugs to include on a preferred drug list (see section 5d for more discussion of the development of unbiased information on the effectiveness of drugs). One PBM that used a pharmacoeconomic approach to developing formulary guidelines for depression prescription drug therapies saw a 25 percent increase in drug therapy compliance, while overall medical costs dropped by 10 percent (White).

In the private sector, few employers (3 percent) have retained the use of closed formularies (PBMI). Their declining popularity resulted directly from plan enrollees expressing a strong preference for plan designs that offer more choice. Many physicians also oppose restrictive formularies because of their limitation on prescribing practice and physician authority (Levy and Cocks). Employers have shifted to tiered copayment schemes, typically based on an open formulary (sections 2e and 3b). In these arrangements, plan members can obtain any drug by paying a higher copayment, and the plan does not need to be in a position of denying coverage. This trend has occurred even though PBMs tend to believe that substantial savings (as high as 15 percent) are available with a closed formulary (AdvancePCS).

Medicaid programs that participate in the Medicaid drug rebate program are not permitted by law to have a closed formulary. States must cover all drugs (other than the specific class exclusions, noted in section 1a) that are made by any manufacturer that participates in the rebate program. States typically used prior authorization (section 2a) or a preferred drug list (section 2e) in lieu of a closed formulary. For the 30 states that used formularies before passage of the 1990 law banning them, the availability of drugs increased significantly, according to a study published in 1996. Some of the drugs that became more widely available were of questionable therapeutic value, according to a panel of physicians consulted in the study. In addition, the researchers found an increased use of prior approval requirements (Walser et al.).

In Medicare, however, closed formularies have become more common. In 2002, about 89 percent of enrollees with drug coverage through Medicare+Choice were in plans that used a formulary, and about 37 percent had closed formularies that covered only drugs on the formulary (dropping to 34 percent in 2003) (Achman and Gold; personal communication). And there is some evidence that plans use tighter formularies for M+C than for commercial business, with one plan executive reporting that the plan eliminates about 10 percent of high-cost drugs from its M+C formulary. Some plans even used a closed formulary without an exceptions process (Draper et al.).

Another major public-sector use of closed formularies is the Veterans Affairs National Formulary, which has closed a subset of drug classes, limiting coverage to one or two drugs in those classes unless a waiver is obtained from a physician. The Institute of Medicine (IOM) found that this formulary affected utilization, prices, and market share of drugs in closed and preferred classes compared to the drugs in open classes (Blumenthal and Herdman). The IOM estimated that the market share for covered drugs rose between 35 percent and 80 percent, with the highest shift occurring for proton pump inhibitors. Overall, the VA saved $100 million over the 2-year span after which the formulary was implemented, which is about 15 percent of expenditures in the six analyzed drug classes. A peer-reviewed article assessed the impact of the VA formulary on market share, drug prices, and drug spending. Where a class of drugs was closed, 85 percent to 97 percent of the market went to the on-formulary drug (up from 16 percent to 47 percent before the class was closed). By contrast, use of the preferred drug in another class, where the formulary was not closed, rose from 15 percent to only 23 percent (Huskamp et al.).

A peer-reviewed study by PBM researchers compared an employer plan that implemented a closed formulary in July 1997 with a control that used an open formulary (Motheral and Henderson). They found that the closed formulary was associated with significantly lower increases in utilization and expenditures, after controlling for differences in age, gender, and chronic disease scores. They also found that those using the closed formulary had a higher use of prior authorization and a reduced rate of continuation with chronic medications in the nine months following its implementation.

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2e. Preferred Drug List or Open Formulary

A preferred drug list, sometimes referred to as an open formulary, is a list of drugs selected by the health plan or its contracted pharmacy benefit manager (PBM) as drugs that are most useful in patient care, based on both clinical effectiveness and cost considerations (see section 2d on closed formularies for a discussion of how formularies are established). By contrast with a closed formulary, the preferred drug list allows use of drugs not on the list. Preferred drug lists are combined with other rules, such as prior authorization or tiered copayments, to create an incentive to use the preferred drugs.

In the private sector, while open formularies are far more popular than closed formularies and were used by 26 percent of employers in 2003, this mechanism has declined in the private sector from 67 percent of employers who reported having open formularies in 1999 (PBMI). Another 71 percent of employers were using "incented" formularies, which refers to open formularies that are linked to tiered copayments. For purposes of this report, open and "incented" formularies are not treated as distinct strategies.

As described in section 2d, state Medicaid programs are not permitted to maintain closed formularies. Preferred drug lists, usually in conjunction with prior authorization requirements, represent a relatively new approach for state Medicaid programs, one that is growing rapidly in popularity. California has had such a system in place for many years, but it was alone in that regard for much of that time. A 2003 survey found that 18 states were implementing some form of preferred drug list (Crowley et al.).

In 2001, Florida created a preferred drug list for its Medicaid program. For a drug to be included on the list, a manufacturer has to agree to make rebate payments to the state in addition to the federal rebates. Drugs not on the list can be obtained only through prior authorization. The state reached an agreement with several manufacturers that their drugs could be included on the preferred drug list based on provision of disease management and health education services instead of supplemental cash rebates. In 2004, the Florida legislature decided to end these alternate programs in 2005, citing that savings were less than accomplished through the rebates.

Later in 2001, Michigan created a preferred drug list that applies to Medicaid and all other state-funded drug programs. The state used a panel to select at least two "best in class" drugs from each of 40 therapeutic classes based on criteria of clinical effectiveness, safety, outcomes, and cost. For drugs not selected for the list, the manufacturer must offer rebates adequate to reduce the price to that of the lowest price among the selected drugs for that therapeutic class.

Early case studies of Michigan and Florida noted some implementation issues (Bernasek et al./2003; Bernasek et al./2002). For example, the Michigan list was found to be more restrictive in the range of drugs included compared to other such lists. Categories of particular concern were cardiovascular, antidepressants, and diabetes medications. By contrast, the Florida list was no more restrictive than that of a large private plan. Also, there were early concerns reported in Michigan that the administrative burden to obtain prior authorization was considerable and might harm beneficiaries. While some of these issues were lessened over time, other administrative problems arose. In Florida, there were initial concerns about whether beneficiaries were given

adequate information on the new procedures. A formal evaluation has been mandated by the Michigan legislature.

Pharmaceutical manufacturers have gone to court to block implementation of some of the state preferred drug lists. To date, the courts have sided generally with the states, allowing the preferred drug lists to stay in place. In addition, if a state designs a more restrictive list, it tends to run into opposition from physician and patient groups as well – especially if the exceptions process is difficult to use.

Most of these state preferred drug lists are too new to have formal evaluations of their impact. An article in *The New York Times* reported that Florida is claiming savings of $200 million per year, while Michigan is saving $45 million (Perez-Pena). Indications are that some of the widely advertised drugs are often excluded from the preferred list in favor of older, less expensive alternatives. Some early reports have suggested that when a manufacturer has a drug excluded from one state's list, it becomes more aggressive to get that drug included on other state lists.

Many of the peer-reviewed studies that consider the effectiveness of formularies focus on the incentives (most often prior authorization or tiered cost sharing) used to steer utilization to drugs on the formulary rather than on the subject of formulary management (see especially sections 2a, 3b, and 3c). For example, one study of health plan design and management features found that features such as prior authorization and formulary management used together with higher copayments tend to be associated with differences in the types and costs of prescriptions that seniors use (Thomas et al.). PBMs assert generally that use of formularies is a major factor in obtaining savings for their clients. Medco Health, for example, states that formulary management in general can save up to 11 percent or more of drug spending (Medco).

One peer-reviewed study focused on the role of formularies for psychotropic drugs (Huskamp). Some evidence suggests that patients tend to respond differently to alternative drugs for mental health conditions (such as depression) more so than for other health conditions (although treatment for hypertension raises some of the same issues). As a result, consumers are less likely to change psychotropic drugs in response to incentives to use drugs on the formulary and are more willing to incur the higher copayments or go through authorization procedures to stay with a drug that has been working for them. Another factor that potentially influences the effectiveness of formularies for psychotropic drugs is that Medicaid is responsible for a large share of all use for these drug classes, meaning that Medicaid decisions can have a disproportionate influence on investment decisions by drug manufacturers. Finally, managed behavioral health care carve-out vendor contracts typically cover only specialty inpatient and outpatient treatments and do not place the vendor at financial risk for psychotropic drugs. As a result, such vendors have no incentive to control psychotropic drug costs.

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2f. Mandatory Generic Substitution

Mandatory generic substitution refers to the policy of a health plan to pay only for a generic drug, unless no generic equivalent is available. Generic drugs are products no longer covered by patent protection and thus may be produced or distributed by multiple drug companies. Most plans adopting this policy make some provision for the patient's physician to specify that the brand-name drug should be dispensed. This policy can be as easy as designating "dispense as written" on the prescription or as difficult as requesting an exception with an indication of why the generic drug is ineffective for the particular patient. Mandatory generic substitution amounts to a special case of a closed formulary (section 2d), where no brand-name drug with an available generic equivalent is listed on the formulary. It is also a case of reference pricing (section 3f), but restricted to generic drug situations only. According to one survey, about 20 percent of covered workers had mandatory use of generic drugs (Kaiser/HRET).

Generally, state laws allow pharmacists to fill a prescription with a generic drug even in those cases where the doctor has written a prescription for a brand-name drug. The specific provisions of state laws vary. For example, in about 40 states, the pharmacist can substitute the generic drug unless the prescribing physician indicates in writing on the prescription "no substitution" or that the brand drug is "medically necessary." In a subset of these states, the law mandates that the pharmacist substitute the generic drug. In most states, the pharmacist must obtain the consent of the patient or at least must inform the patient that a generic drug is being substituted (NIHCM Foundation).

Some state Medicaid programs have increased the steps that a physician must take to insist on a brand-name drug. For example, in November 2001, Massachusetts imposed a requirement that Medicaid beneficiaries receive generic medications in all cases except where physicians demonstrate that a brand-name drug is medically necessary and they get prior approval from the state. This replaced a policy where the pharmacist was required to substitute a generic drug unless the physicians requested a brand-name drug. The suspicion was that many doctors were routinely requesting the brand-name drug, and the new rules increases the steps the doctor must take to request the brand-name drug.

The potential for savings from increased use of generic drugs is substantial. One study, conducted in 2001 by researchers at Brandeis University with funding from the Generic Pharmaceutical Association, found that optimal use of generic drugs could yield significant savings for a Medicare drug benefit. Currently, seniors in managed-care plans use generic drugs at a rate of 38 percent. Should the rate of generic use achieved by the plans with highest generic use (about 51 percent) be met by plans serving all seniors, a 16 percent savings per individual would be generated (Ritter et al.).

One pharmacy benefit manager (PBM) has estimated that it can save up to 4 percent from generic incentives and education, although it does not provide a separate estimate for mandatory generic substitution (Medco). Another PBM (AdvancePCS) estimates savings in the range of 6 to 10 percent when requiring clinically appropriate generic substitution (AdvancePCS).

A 2002 peer-reviewed study looked at mandatory generic substitution along with other benefit designs such as tiered cost sharing by analyzing claims data for 25 private employers for 1997 to 1999 with a total of 55 different benefit packages for a working-age population. Mandatory generic substitution lowered drug costs significantly – by about 8 percent in plans with two-tiered cost sharing. Spending was reduced on both multi-source and single-source brand-name drugs, without any increase in spending on generics (Joyce et al.).

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2g. Management of Specialty Drugs

The term "specialty drugs" most commonly refers to drugs that are administered in a physician's office or in some other situation where the patient needs assistance to administer the drug. The major category of specialty drugs is chemotherapy drugs, most of which are administered by infusion under a physician's supervision. Injectable drugs for diseases such as multiple sclerosis also fall into this category, as do blood products provided to patients with hemophilia and similar diseases.

In Medicare, specialty drugs – specifically, any drug that can normally not be self-administered, plus several other categories provided by law – are the only drugs paid for on an outpatient basis (prior to implementation of the new outpatient drug benefit in 2006). Before 2004, Medicare paid physicians for these drugs at the rate of 95 percent of the average wholesale price (AWP). The Medicare Modernization Act reduced this payment rate to 85 percent of AWP for most of these drugs and substituted a pricing system based on 106 percent of a newly defined average sales price (ASP) in 2005. In 2006, a competitive acquisition program will be established for vendors to bid for contracts to purchase and distribute drugs in regional competitive acquisition areas. Medicare will pay selected vendors directly. Each year physicians will be able to select a contractor through the competitive acquisition program or receive Medicare payments for drugs based on 106 percent of ASP.

Private purchasers have typically used a similar system to Medicare's AWP-based system, although adjustments above or below AWP vary. Specialty drugs tend to be included under a health plan's medical benefit, rather than under its outpatient drug benefit. Some plans have been looking at reducing the payment rate to achieve cost savings. Others have initiated pilot programs to change the method by which specialty drugs are purchased and distributed. For example, they might require physicians to use a designated distributor for specialty drugs, where that distributor uses its increased volume to obtain a lower price from the manufacturer. One health plan worked with a single supplier to provide certain injectable products (especially those for hemophilia), with the goal of both streamlining the distribution process and making claims submission more efficient (MedPAC; NORC/Georgetown).

In other cases, health plans may incorporate specialty drugs into their systems of tiered cost sharing. Humana, for example, has initiated a policy where specialty drugs are on a fourth tier. In contrast to the first three tiers that require a fixed copayment, the fourth tier requires the plan member to pay 25 percent of the cost of the drug up to an annual copayment maximum (see section 3d for a further discussion of four-tiered systems).

Although some private payers suggest they can achieve 10 to 25 percent savings by making changes to the way they pay for specialty drugs and even greater savings if implemented in conjunction with increased utilization review, no published studies document these savings claims.

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2h. Provider Financial Incentives

A growing number of insurers have experimented with programs where providers are offered financial incentives for meeting certain performance incentives. In the drug arena, insurers might offer incentives for increased use of generic drugs or for meeting certain target rates of use for preferred drugs.

A 1991 article in *Benefits Quarterly* describes some of the issues that need to be addressed in requiring physicians to take capitation payments for the cost of drugs and the potential for cost savings under this approach. The author noted that in setting capitation rates, it is important to pay attention to enrollee-related variables and medication-related variables, as well as operational costs. In the end, he asserted that a capitation system has more cost management potential than tradition fee-for-service payment (Lawson). Physicians, however, may be reluctant to accept risk for drug costs. Although they decide whether to prescribe a needed drug, they cannot control either their patients' health conditions or the prices charged for drugs. For this system to work, it would require an accurate approach to risk adjusting the capitated payments and to other operational issues such as sorting out prescriptions written by other physicians treating the same patient.

AdvancePCS reports that large medical groups in California during the mid-1990s assumed financial risk for the prescription drug costs of their patients, leading in turn to more conservative prescribing habits. With the more recent rapid rise in drugs costs, providers have generally renegotiated their risk contracts to eliminate this type of risk sharing. There is some suggestion that future contracts may incorporate more limited risk arrangements (AdvancePCS; William M. Mercer).

No published studies have been identified that have examined the use of financial incentives for providers for meeting certain standards for prescription drug use.

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2i. Payment to Pharmacies as Incentives

Some pharmacy benefit managers (PBMs) have a system of performance-based pharmacy reimbursement. They provide incentive payments to those pharmacies that meet standards for dispensing generic drugs, dispensing preferred brand-name drugs from the formulary, or more generally meeting standards as measured in drug utilization review programs.

In addition, there are various proposals and some testing of programs to reimburse pharmacists for cognitive services for counseling patients on the appropriate use of drugs. One challenge is how to distinguish between the normal services expected of a pharmacist and special services that might justify an extra payment (Fox). The evaluation of one pilot conducted in the Washington Medicaid program found no increase in the use of cognitive services as a result of additional payment (Kidder and Bae).

One peer-reviewed study did report on the use of a tiered reimbursement program that provides incentives to pharmacists for higher rates of generic dispensing. Priority Health, a managed care organization in western Michigan, created an incentive payment that ranged from $0.50 per prescription for a generic dispensing rate of at least 26 percent to $2.50 if the rate was at least 47 percent. Over a five-year period (1992 to 1997), the plan's overall generic dispensing rose from 37 percent to 47 percent, while the national average only grew from 39 percent to 41 percent (both rates were slightly higher in 1995 and 1996 than in 1997) (Keating).

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2j. Other Coverage Management Approaches

There are a variety of other coverage management approaches that do not fit easily in the categories outlined in this section.

For example, dose optimization refers to situations where a single pill of a higher dosage taken once a day can replace lower-strength pills of the same medications taken several times a day. Medco Health describes a plan it implemented for one client for dose optimization. It moved patients on a cholesterol-lowering medication from a dosage requiring two pills a day to a single pill a day and reported that doing so achieved a 21 percent savings for the client (Medco).

A similar approach, which has been gaining in popularity, is pill splitting. In many cases, 50-milligram and 100-milligram pills may cost the same amount, or at least the price of the larger pill is considerably less than double that of the smaller pill, despite containing double the amount of medication. Some health plans have proposed to prescribe the larger pill and have the patient cut them in half to reduce costs. Other plans have preferred not to take this approach, raising patient safety concerns. Manufacturers are typically opposed, also arguing on patient safety grounds that the split pill may not have the correct dosage or that patients will forget and take the entire pill. Frail patients in particular may find pill splitting a burden. In addition, pill splitting can lead to wastage if some pills shatter (Brubaker).

Literature

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3. Utilization Strategies: Cost Sharing Approaches

Cost sharing is both a way to reduce costs for the payer by transferring some of the costs to the patient and a way to influence utilization by providing monetary incentives to patients for reducing the number of prescriptions filled or for shifting to a lower cost drug. These approaches are often used in conjunction with utilization management approaches (section 2), such as a preferred drug list.

a. Copayments as a general strategy
b. Tiered copayments in general
c. Three-tiered copayments
d. Four-tiered or other more complex copayment structures
e. Coinsurance
f. Reference pricing

3a. Copayments as a General Strategy

A copayment is a fixed charge that is paid by patients for each medication they purchase. In general, copayments are used to induce the patient to incur a price for using a medication and thus to consider more carefully whether a medication is useful to him or her. According to economic theory, copayments should control over-utilization by providing an incentive to either discontinue treatment or to decide not to initiate treatment. The goal is to discourage unnecessary utilization, but at least for lower-income patients, it may also have the effect of reducing use of necessary drugs. The critical issue thus is whether a copayment is more likely to deter inappropriate use of drugs or to induce people to reduce their use of needed drugs.

Federal Medicaid statute limits copayments to nominal amounts (defined by the Secretary of Health and Human Services to be from $.50 to $3.00 per prescription) and further specifies that a beneficiary's "inability to pay" cannot prevent him or her from receiving medications. However, according to a peer-reviewed study, elderly and disabled Medicaid beneficiaries who resided in states that implemented a copayment system on prescription drugs have significantly lower drug use than those who reside in states without copayments (Stuart and Zacker). Consistent with these findings, the Center for Studying Health System Change analyzed state Medicaid cost containment strategies such as copayments, dispensing limits, generic substitution, prior authorization and step-therapy protocols and determined that while there may be definite savings with the implementation of such cost containment mechanisms, there may be a reduction of beneficiary access to needed drug therapies (Cunningham).

A study published in 1974 found relatively inelastic demand for drugs and a minimal price effect for copayments (Phelps and Newhouse). A subsequent study published in 1985 measured levels of drug expenditures corresponding to the generosity of an individual's insurance coverage for drugs. It found that individuals with more generous insurance buy more prescription drugs, while the proportion of brand-name drugs purchased in pharmacies was not a function of insurance plan (Leibowitz et al.).

Other studies have found reduced utilization from cost sharing, although the amount varied by the circumstances. For example, there is some evidence of physicians writing prescriptions for fewer drugs to diminish the impact of higher copayments. In a series of studies, researchers looked at the use of drugs by Medicaid beneficiaries in South Carolina after imposition of a 50-cent copayment in 1976. The first study found that patients reduced their use of medications when faced with a copayment (Nelson et al.). In a second study, the same research team found that the effect differed by class of drugs: there was a significant effect of copayments on all drug categories except analgesics and sedative/hypnotic drugs. Long-term effects were clearest for cardiovascular, cholinergic, diuretic, and psychotherapeutic agents. Use of these drugs declined significantly in the long term. The suggested conclusion is that patients were less likely to reduce use of pain medications, sleeping pills, or other drugs for which the effect was relatively immediate and obvious. They were more likely to reduce use of drugs for hypertension or other conditions where the effect of reducing or discontinuing the use of a medication was less obvious to the patient yet significant from a clinical perspective (Reeder and Nelson).

Two other peer-reviewed studies found similar results on reduced spending. In one study, Johnson and his colleagues examined the impact of increased cost sharing on two groups of elderly patients enrolled in Medicare HMOs. Specifically, drug copayments were increased from $1 to $5 for the first group of elderly patients, and coinsurance was increased from 50 percent (maximum of $25) to 70 percent (maximum of $30) per prescription for a second group. These increases resulted in lower annual prescription drug utilization and expenses. However, no consistent changes were observed in either medical care utilization (office visits, emergency room visits, home health visits, hospitalizations) or total medical care expenses (Johnson et al.). Another study found that a change in prescription drug copayments from $3 to $5 for a set of employer groups was associated with a 5 percent decrease in prescription drug utilization, a 10 percent decrease in overall employer prescription drug costs per person and an increase in employee costs of approximately $2 per prescription (Smith).

A peer-reviewed study, published in 2001, focused on increased cost sharing imposed in Quebec. It found that, after imposition of higher cost sharing, patients took fewer drugs identified by the researchers as "essential" and that these same patients experienced an increased use of emergency room visits and admissions to hospitals or nursing homes. There was also a decline in the use of "less essential" drugs, but this change was not associated with an increase in the use of other health services (Tamblyn et al.).

A study published in 2004 looked at the important questions of whether the effect of increased cost sharing has a differential across major classes of drugs (Goldman et al.). The research team found that doubling copayments led to reduced use in eight therapeutic classes, with the largest decreases occurring for non-steroidal anti-inflammatory drugs (NSAIDS) and antihistamines. The smallest reductions were for drugs to treat diabetes, hypertension, and depression. They suggest that the smallest reductions occurred for drugs with greater consequences for missed doses, whereas the largest reductions corresponded to medications taken intermittently to reduce symptoms. This finding is accentuated by looking at those patients receiving ongoing care from a chronic illness, for whom drug use was less responsive to copayment changes. There were also higher responses for drugs that had over-the-counter substitutes and for brand drugs versus generic drugs.

Another study found circumstances where higher cost sharing did not have a consistent effect on the use of drugs based on the financial incentives faced by prescribing physicians. This peer-reviewed study discussed the effectiveness of higher prescription drug copayments in two different physician compensation models: an independent practice association (IPA) and a network-model HMO. Unlike the IPA model where physicians are not at risk for drug costs, the network model placed physicians at financial risk for their prescribing behavior. The results of the study found that higher copayments were associated with lower drug spending in IPA models but had little effect in network models (Hillman et al.).

A variation on the use of copayments is referred to as a benefit-based copay system. This system is slightly different than other copayment or tiered copayment systems in that it takes into account the medical necessity of a prescribed drug along with its actual cost. Patients who have a high potential benefit from a particular drug would have a lower copayment than patients with lower potential benefits. This benefit-based system provides a financial incentive for individuals

to prioritize their out-of-pocket drug expenditures based on the value of their medications, not their price (Fendrick et al.).

Humana introduced a version of this benefit-based approach, where the level of cost sharing is based more on the use of the drug than on the price of the drug. The plan pays the highest amount toward the cost for those drugs that treat acute illnesses (e.g., antibiotics) or those that keep patients out of the hospital. It pays the next highest amount toward maintenance drugs, such as those to treat hypertension, AIDS, or cancer. The plan pays a lower allowance for drugs that the patient can live without but which boost workplace productivity (e.g., allergy medications). It makes the smallest payment toward drugs that have no medical payback, but which improve lifestyle (e.g., drugs for acne, hair loss, or sexual dysfunction) (Drug Cost Management Report).

Medco Health tells clients that cost sharing in general can generate savings of up to 10 percent or more (Medco/2004). It should be noted that in this estimate, they are including other types of cost sharing, such as deductibles and benefit maximums. Their analysis (not peer reviewed) also shows evidence that as member cost share increases, the growth rate for utilization moderates. For example, they suggest that a 2 percent to 5 percent increase in cost sharing slows the rate of spending growth from 8 percent to about 6 percent. A 10 percent or greater increase in cost sharing reduces the spending growth rate to zero. Yet they also show that utilization changes affect both essential and "less essential" medications. For example, when cost sharing is increased by 10 percent or more, the rate of growth in less essential medications drops from about 14 percent to negative growth of 3 percent. At the same time, the rate of growth in essential medications drops from about 7 percent to about 1 percent.

For a privately insured population, Medco Health makes a recommendation that members contribute overall no more than about 25 percent to 35 percent of drug costs, presumably including share of premiums. This recommendation seems to reflect a concern that raising the members' share of costs too high can raise other health costs or impair health (Medco/2002).

Finally, one complication occurs for drugs that sell at a very low price. A *Wall Street Journal* article warned consumers to be careful when purchasing generic drugs under a plan's copayment system. The case example in the article highlighted a consumer who paid $5 for a generic heart medication for which the plan negotiated a $.76 price (Martinez). In many cases, copays are defined as the lower of the plan amount or the actual cost of the drug, but in some cases, the consumer may be charged the copay amount even if it is higher.

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3b. Tiered Copayments in General

Tiered copayments are used to vary cost sharing based on the type of drug being purchased. The simplest form of tiered copayments is the use of two different copayments for generic and brand-name drugs. Other forms of tiered copayment may add separate tiers for preferred and non-preferred brand-name drugs. The purpose is to steer consumers away from more expensive non-preferred drugs to lower-cost preferred medications.

In the private sector, tiered copayments have become the norm. In 2004, 65 percent of covered workers faced 3-tier copayments, 20 percent faced 2-tier copayments, and 3 percent faced 4-tier copayments (Kaiser/HRET). Only 10 percent were not subject to tiered copayments. Workers in small firms were somewhat less likely to face tiered copayments than those in large firms. Workers in conventional plans were considerably less likely to face tiered copayments in conventional insurance arrangements than in HMOs, PPOs, or point-of-service plans. Average copayments were $10 for generic drugs, $21 for preferred drugs, and $33 for non-preferred drugs. Oftentimes plans with multi-tiered copayment structures have other cost saving mechanisms in place, such as mail-order programs.

As noted in section 3a, federal Medicaid statute limits copayments to nominal amounts. Within these limits, there are about ten state Medicaid programs where copayments for brand-name drugs were higher than for generics, according to a 2003 survey (Crowley et al.). Some additional states have higher copays for higher-cost drugs. In Medicare+Choice plans, tiered copayments have become the norm. Generally, plans have a similar structure as for their commercial counterparts but often with higher copayment amounts (Draper et al.). Most frequently, copays for generic drugs are $10 or less, while those for brand-name drugs are at least $20, with a typical ratio between the copays of between 2:1 and 3:1 (Achman and Gold).

Results for other benefit surveys were quite consistent, allowing for differences in how the surveys were designed and reported. However, one report that looked at patterns in California suggested that the adoption of three-tier schemes was occurring more slowly in that state, perhaps because more plans there used closed formularies and that employees were reasonably satisfied with their current arrangements (William M. Mercer Inc.).

The impact of tiered copayments on drug utilization has been the subject of several studies. One peer-reviewed study of people enrolled in employer-sponsored insurance found that members in a plan with a single $5 copay for all drugs used drugs the most, with an average annual per member spending of $725. Use of a $10 copay reduced the annual average drug cost for the plan to $563 per member. For two-tier plans, doubling copayments from $5 for generics and $10 for brand drugs to $10 and $20 reduced plan costs from $678 to $455. Adding an additional copayment of $30 for non-preferred brand drugs to a two-tier plan ($10 generics; $20 brand) lowered overall drug spending by 4 percent while requiring mandatory generic substitution in a two-tier plan reduced drug spending by 8 percent. Doubling copayments in a two-tier plan increased the share that beneficiaries' paid out-of-pocket from 18 percent to 26 percent. Overall, increased copayments or adding a new level of copayments reduced plan expenditures for working aged people enrolled in employer health plans. The reduction mainly benefited health insurance plans because of increased beneficiary out-of-pocket costs (Joyce et al.).

Two other recent peer-reviewed studies showed that tiered cost sharing led to more use of the preferred drugs. One study, published in 2004, found that tiered plans are associated with the utilization of specific types of drugs for hypertension. The likelihood of receiving more expensive therapies was lower among enrollees in two-tier plans with the highest copayment differentials than for those in single-tier plans with the lowest copayments (Kamal-Bal and Briesacher). Another study, published in 2003, found that tiered copayment systems were associated with a significant shift from non-preferred to lower-cost preferred brand prescription drugs (Rector et al.). Other studies emphasize that, while tiered copays provide consumers with a wider choice of prescriptions (compared to the use of closed formularies) and plans are saving money, consumers have increased cost burden under tiered cost sharing (Mays et al.).

A two-year review of 8.1 million people in 246 three-tier plans found that 70 percent of the plans' total drug spending was for preferred drugs in a system that one pharmacy benefit manager (Advance PCS) refers to as a guide to drugs in select therapeutic categories that are more cost effective than other drugs for its members – but not a formulary. The implementation of a three-tiered copayment system saved these plans $1.62 billion in 2001. Members' costs per month grew by 4.5 percent during 2001 compared with the national trend of 13 to 17 percent (AdvancePCS).

The Congressional Budget Office, in its 2002 review of design issues for a Medicare drug benefit, suggests that tiered copayments may offer health plans the greatest opportunity to save money where a therapeutic class includes only a few distinct drugs, all of which are protected by patents. In this situation, the pharmacy benefit manager can allow manufacturers of the therapeutically equivalent drugs to bid for preferred status by offering rebates; the confidentiality of the rebate amounts should encourage stiffer competition compared to the more public approach of reference pricing. The degree of savings, according to CBO, will depend on the tiered copayment rates, number of tiers, and the breadth of the therapeutic classes. If broader therapeutic classes are established, more drugs are placed into competition with each other and classes are more likely to include drugs with generic alternatives. For example, if Cox-2 inhibitors are placed in competition with other non-steroidal anti-inflammatory drugs, a pricing system can create more incentives to avoid the more expensive Cox-2 drugs. But others argue that this situation is more likely to reduce incentives for pharmaceutical research and development (CBO).

One question in the Medicaid context is whether small differences (say $1 for generics versus $3 for brand-name drugs) provide a meaningful incentive to the beneficiary to choose the generic drug. No studies have been located that test the effectiveness of this small copayment difference, although one peer-reviewed study suggests that "even very small Medicaid copayments deter drug use" by reducing the likelihood that beneficiaries fill any prescriptions during the year. The authors of this study also found that beneficiaries in less than very good health in copay states filled fewer prescriptions on average than in non-copay states (Stuart and Zacker).

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3c. Three-Tiered Copayments

Three-tiered copayment arrangements usually refer to systems where the insurer or purchaser creates one copayment amount for generic drugs and two different amounts for brand-name drugs based on whether they are on a formulary or preferred drug list. In some cases, the second and third tiers are divided between brand drugs where a generic is available (multi-source drugs) and those for which no generic is available. Most private purchasers use tiered copayments (see section 3b for specific estimates of use of three-tier copayments in private plans).

The pharmacy benefit managers (PBMs) that implement different cost sharing mechanisms generally estimate (from non-peer-reviewed studies) that switching from a two-tier copayment system to three-tier copayments yields savings between about 5 percent and 15 percent. Express Scripts, for example, cited that adding a higher third tier to the two existing tiers could save between 7 percent and 8 percent of overall drug costs for a health plan. AdvancePCS claimed savings of 16 percent in the cardiovascular class and 10 percent in the psychotherapeutic class. Various analyses have suggested that the largest source of savings is from the higher copayments themselves, with lesser savings coming from the use of lower cost drugs or possibly higher rebates. IMS data show that savings in three-tiered copayment plans were only slightly greater than those in two-tier plans, while doubling copayments in plans with multiple tiers reduced average drug spending by 33 percent (Long).

A 2003 peer-reviewed study compared claims data from two employer-sponsored health plans that changed their formulary structures. The first plan changed from a one-tier to a three-tier formulary and increased copayments for all covered medicines. The second plan switched from a two-tier to a three-tier formulary changing only the tier-3 copayment. Plan one experienced a significant decrease in the probability of the use of any drug in a given class and the cost burden shifted to the enrollee compared with those enrollees in plan two. While some enrollees in plan one switched to cheaper tier-1 or tier-2 alternatives, the study showed that some stopped taking medications in these classes altogether (Huskamp et al.).

According to some experts, the effectiveness of a tiered copayment system lies in the relative prices of each tier. To affect utilization, tiered copayments must be structured in multiples, such as X for generic drugs, 2X for formulary brands, and 3X or 4X for non-formulary brands; put another way, differentials between tiers must be closer to $15 than $5 (Darves; Segedin).

Two studies conducted by PBM researchers have been published in peer-reviewed journals. Researchers at Express Scripts looked at the experience of a PPO population in a single midwestern state over a 24-month period from 1997 to 1999. The test group added a three-tier copay ($8/$15/$25) at the 12-month mark of the study. Payer costs dropped 17.1 percent, with 9.9 percent attributed to the absolute increase in copayments, 5.3 percent to reduced utilization, and 1.9 percent to the lower cost of the substituted drugs. The authors estimated that if the lower two tiers had remained at the pre-change level (thus, only adding the third tier) savings would have been reduced to 6.4 percent. There was no evidence of adverse health effects (Motheral and Fairman). Another (unpublished) study by Express Scripts researchers found that aggressive copay changes yielded even higher savings. An important factor that goes into the effectiveness of a three-tiered copayment system is the price level at which the copayments are set between

each tier. They found that greater differences between tier-two and tier-three copay amounts were associated with greater decreases in utilization of non-preferred drugs (Roe et al.).

Researchers at another PBM (AdvancePCS) looked at strategies for managing Cox-2 drugs (Celebrex, in particular), comparing four different cost-management approaches used by different client companies. The study found three-tiered cost sharing to be the least effective approach (17 percent savings from what would have been paid otherwise). The other approaches tested were step therapy (most effective), prior authorization (second), and a version of reference pricing (third). This particular plan used a $7/$15/$25 set of copayments, with Celebrex priced at the $25 level (Tucker et al.).

Two other peer-reviewed studies have examined the impact of three-tier copayments. One, looking at implementation of new arrangements in one HMO, found that implementation of a three-tier copayment system may cause some shifting of medication costs to tier two medications. Generic use increased by 6 to 8 percent, and the use of formulary brand-name products increased by 3 to 5 percent. Non-formulary use appeared to decrease only for members who changed from a two-tier to a three-tier structure (Nair et al.). Another peer-reviewed study, which examined the effect of three-tier cost sharing for those enrolled in retiree plans, found that higher copayments and three-tier models cut back on overall expenditures. The cost burden, however, falls mainly on the consumer (Thomas et al.).

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3d. Four-Tiered or Other More Complex Copayment Structures

Some payers have moved to four-tiered systems. In the simplest case, the middle tier, which represents preferred brand-name drugs, is divided into two. The first of these would include lower-cost preferred drugs or preferred drugs with better predicted outcomes. The other would include higher-cost drugs or those with less certain outcomes. In other applications, the fourth tier may be reserved for specialty drugs (e.g., self-administered injectable drugs or biotechnology treatments) or drugs needed for symptomatic relief. In some cases, the fourth tier represents drugs where the consumer is required to pay the entire cost, perhaps at a discounted rate negotiated by the pharmacy benefit manager (PBM) or insurer. According to one survey, approximately 3 percent of plans have moved to four-tier cost sharing, where the fourth tier may be used to increase enrollees' sensitivity to the high cost of certain drugs or to drugs primarily intended for relief of symptoms for conditions that are unlikely to have life-threatening consequences (e.g., allergies or sexual dysfunction) (Kaiser/HRET).

Because of increased costs for prescription drugs, Humana found that two-tier and three-tier systems were not extremely effective in curbing costs. With the implementation of a four-tier system, Humana hopes to make its members more aware of the actual costs of prescription drugs by making out-of-pocket expenses closer to the price of the prescribed drug. Humana's goal is to curb the demand and current expenditure for expensive brand-name drugs (Perlstein).

Some state prescription drug programs also utilize four and five-tiered copayment systems. For instance, New York's Elderly Pharmaceutical Insurance Coverage (EPIC) program recently reduced its tiered copayment structure from a five-tiered to a four-tiered system to prompt members to use generic drugs, instead of expensive brand-name drugs. A report by the National Governors Association highlights that although multi-tiered copayments are often used in state pharmaceutical assistance programs, they contribute administrative complications, which in turn may restrict access to needed prescription drug therapies (NGA).

Medco Health in 2002 stated it had more than 25 plans actively pursuing variations of the four-tier formulary design. For one client, it was testing a value-based program for a four-tier formulary. Lower copayments were established for drugs used for more serious conditions. Thus proton pump inhibitors were placed in the second tier when prescribed for severe, erosive esophagitis; but they were in the third tier (with a higher copayment) when used for mild forms of heartburn. Similarly, cholesterol-lowering drugs had a lower copayment when prescribed for patients with a high near-term risk for heart attack. Medco generally projects savings of from 5 to 10 percent or more when a plan moves to a four-tier formulary, but no peer-reviewed study has been published to date (Medco).

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3e. Coinsurance

In contrast to copayment systems, where a flat dollar amount (or series of different amounts based on tiers) is established for a drug claim, a coinsurance system establishes a percentage of the allowed drug cost as the patient's responsibility. The Medicare Modernization Act established a coinsurance system for the new Medicare Part D benefit. According to a 2003 survey of employers, the percentage using coinsurance increased from 22 percent in 2001 to 30 percent in 2003. Some plans use coinsurance only for second-tier or third-tier drugs, while using a flay copayment for the generic drugs in the first tier. In addition, some plans cap the amounts for the coinsurance-based cost sharing (PBMI).

Tiered coinsurance rates are sometimes established for brands and generics or for preferred and non-preferred drugs. The copayment and coinsurance approaches differ in that coinsurance amounts are automatically larger for more expensive drugs. The Kaiser/HRET survey of employer health benefits found average coinsurance rates of 20 percent for generic drugs, 26 percent for preferred drugs, and 31 percent for non-preferred drugs (Kaiser/HRET).

One advantage for payers of a coinsurance approach over copayments is that it is designed to require that beneficiaries pay a higher share of more expensive drugs, thus making them aware of these higher costs and more interested in considering less costly alternatives. Also, some plan managers choose this approach because coinsurance increases automatically as the cost of drugs increases. This allows them to avoid adjusting cost sharing amounts upward over time, a step that leads to enrollee discontent.

An issue with coinsurance is that it is likely to be based on a price that may not be the final transaction price. Coinsurance is based on the retail transaction price before any rebates are taken into effect. If the final amount paid is reduced by rebates or other considerations outside the retail transaction, then the beneficiary's share of the payment is actually higher than the nominal coinsurance amount. In addition, coinsurance may be less popular for patients because the amount owed is unpredictable. However, an Express Scripts presentation asserts that there is no evidence that coinsurance, compared with a flat copay, provided any advantage in promoting greater use of generic drugs, greater use of less expensive brand drugs, or slowed growth in overall drug utilization (Motheral et al.).

One pharmacy benefit manager (PBM) reported that nearly 40 percent of its clients had at least some members using coinsurance-based cost sharing (Medco Health). It expected that more clients would adopt this approach in the years to follow. They recommended that a typical coinsurance structure would charge 20 percent coinsurance for preferred drugs and 40 percent for non-preferred drugs.

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3f. Reference Pricing

Reference pricing is a system that establishes a base price as a basis for reimbursement. Any amount charged above the reference price is the responsibility of the individual user of the drug. In one common application, the reference price is set based on the cheapest drug among those competing within a particular class of drugs. In other applications, one drug is selected out of a broader class of drugs for treating a particular condition, based on some combination of clinical and price considerations. The selected drug – or any drug that is priced lower than the selected drug – is fully covered by insurance (or covered with a modest copayment). The amount by which any other drug is more expensive is fully the responsibility of the patient. The patient is thus exposed to the full price difference between the non-preferred drug and the selected drug.

Use of reference pricing is not common in the United States, but in 2004, Wellpoint Health Networks introduced a reference pricing approach for some of its clients. This plan has different levels of pharmacy benefits based on the average price of a drug within a specific class of drugs. Wellpoint asserts that this structure will give members more value, choice, and control in selecting and purchasing their prescriptions. The plan has four copayment or coinsurance levels. Level 1 includes generic drugs that cost less than the reference price, level 2 includes brand-name drugs that cost less than the reference price, level 3 includes generic or brand-name drugs that cost more than the reference price, and level 4 includes self-injectable drugs. Members must take the plan's prescription drug guide to their doctors in order to discuss which drug best meets their needs based on clinical need and cost (WellPoint Press Release).

Although no estimates have been located for the use of reference pricing in the private sector, there is some evidence that it is being used as a payment basis for multi-source brand-name drugs where a generic is available. Among employers, 38 percent required enrollees to pay the total difference in cost between the generic and the higher-priced brand-name drug, as opposed to simply charging a higher copayment (PBMI). Similarly, some state Medicaid programs have used a reference pricing approach to encourage the use of generic drugs (Schwalberg et al.). According to the 2003 survey, 26 states pay only the generic rate for brand-name drugs, double the number of just three years earlier (Crowley et al.). Even if the brand-name drug is dispensed, the state only pays the pharmacy the lower amount.

There is little research looking at the use of reference pricing in the U.S. setting, in part because its use has not been extensive. A peer-reviewed comparative study by researchers at one pharmacy benefit manager (PBM) looked at strategies for managing Cox-2 drugs (Celebrex, in particular), comparing four different approaches used by different client companies. The study showed that reference pricing (referred to in this study as therapeutic buy-up) was the third most effective of the four (with savings of about 37 percent). The other approaches tested were step therapy (most effective), prior authorization (second), and three-tier copayment (least effective) (Tucker et al.). The authors acknowledge that a potential limitation of this study is that the plan adopting step therapy was the smallest of the four, making the estimate potentially less reliable.

Reference pricing has been used more widely in other countries, including Germany, Netherlands, Denmark, Sweden, Canada (British Columbia), Australia, and New Zealand. Peer-reviewed studies have looked at the introduction of reference pricing for several classes of drugs

in British Columbia. One looked at reference pricing for ACE inhibitors (a common medication for hypertension). Residents were fully covered for the least expensive ACE inhibitors up to a maximum amount per month. In this particular application, the reference price was set at $27 per month, without regard to the dosage, and those using other ACE inhibitors were responsible for any higher costs. Exemptions were provided for frail elderly patients or for demonstrated failure of particular medications. In the study, those who switched to the medication not subject to cost sharing were compared to those who continued use of their original ACE inhibitor. The researchers found a steep decline in the use of higher-priced ACE inhibitors after implementation of the policy. After a transition, the utilization rate for all ACE inhibitors was 11 percent below projected use rates, although overall use of anti-hypertensive drugs was unchanged. They estimated savings of $6.7 million (Canadian) in one year's expenditures (Schneeweiss et al./CMA Journal). Older patients and low-income patients were more likely to switch medications. In a second report from this same study, the researchers found little evidence that patients stopped treatments or that health care utilization or costs increased. One issue raised by the authors is that there are fewer pharmacologic differences among the drugs in this particular class (Schneeweiss et al./NEJM). A separate study looked at reference pricing for H2 antagonists (a class of drugs used to treat ulcers). This study found no worsening of health outcomes as a result of implementing reference pricing in British Columbia (Hazlet and Blough).

More generally, economists have debated the appropriateness of reference pricing in the American setting, especially for Medicare. Huskamp and her colleagues make a case for the use of reference pricing for Medicare, particularly in the context where a single entity (e.g., a PBM) administers the benefit in each geographic area. Kanavos and Reinhardt find reference pricing consistent with efforts to offer a Medicare drug benefit in a competitive environment, although they emphasize the technical complexities and political sensitivities of implementing such an approach in the United States. Danzon and Ketcham, by contrast, raise serious concerns about the implications of using reference pricing, pointing in particular to the potential deterrent effect on pharmaceutical research and development. They argue that in drug classes where there is generic competition, reference pricing will drive prices and revenues down to the point that incentives to develop new drugs in that class will be significantly diminished.

The Congressional Budget Office, in its review of design issues for a Medicare drug benefit, suggests that reference pricing may offer health plans the greatest opportunity to save money where generic versions of at least one drug in a therapeutic class are available. The stiff competition among generic alternatives allows the plan or PBM to set a reference price based on these lower prices (CBO).

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4. Utilization Strategies: General Utilization Review Strategies

General utilization review strategies address utilization in regard to overall prescribing patterns, taking into account the pattern of use for a particular beneficiary or total patterns of use for a particular physician. These approaches are aimed at having the physician conduct a more general review of a set of prescriptions, as opposed to rejecting payment for a specific drug at the point of sale or taking specific steps to cause the substitution of one particular prescription.

a. Retrospective drug utilization review
b. Physician profiling
c. Drug utilization review targeted to high-cost users
d. Disease management

4a. Retrospective Drug Utilization Review

In general, drug utilization review (DUR) refers to any system for monitoring and managing use of drugs. Generally, these programs determine patterns of drug utilization and costs and provide information in some form to payers, prescribers, and pharmacists with the goal of correcting problems. Many such programs also establish some type of standards and then match utilization patterns against those standards. Typically, programs are intended both to improve quality of medical care received and to manage costs by reducing inappropriate use of prescription drugs. Retrospective DUR can refer to any such program where the review is conducted sometime after the prescription as been filled – in contrast to concurrent DUR (section 1d), where a review occurs at the point of sale.

In 2002, 60 percent of employers reported using retrospective DUR programs, slightly down from 69 percent in 2000 (PBMI/2003). About twice as many (71 percent versus 31 percent) employers who managed their own benefits used retrospective DUR, compared to those that contracted out management to an outside vendor (PBMI/2002).

By law, all state Medicaid programs are required to have DUR programs for outpatient drugs. Their purpose is to ensure that prescriptions are appropriate and are not likely to result in adverse medical outcomes. The retrospective DUR program must review claims data to identify fraud, abuse, or inappropriate or medically unnecessary care among physician prescribing patterns. According to a 2003 survey, nearly all states (40 of 43 responding states) monitor trends in utilization, trends in cost (39 of 43), and drug costs per each individual drug (37 of 43). A large majority of states also review drug costs on the basis of brand-name versus generic status (34 of 43) and drug costs by condition (32 of 43) (Crowley et al.).

Some DUR programs focus on the potential for abuse of certain drugs. One Medicaid HMO identifies members who have 10 or more narcotic prescriptions written by three or more doctors and filled by three or more pharmacists in a three-month period. These cases are reviewed to see if the high level of prescribing is appropriate (e.g., a patient with a catastrophic illness or one who is legitimately seeing several physicians). If the use appears inappropriate, the patient is monitored and prescriptions are approved only if written by the patient's primary care physician. The plan estimates that they have identified 250 patients misusing narcotics out of 90,000 members in the plan. Some disenrolled from the plan, while some others entered drug treatment programs (AAHP).

Other programs focus more on patient safety issues. For example, health plans described reviewing such combinations as asthma patients who are prescribed beta-blockers (which can exacerbate asthma symptoms), pregnant women who are prescribed medications known to have the potential to cause fetal abnormalities, or elderly patients who are prescribed medications with long-term effects that can increase the chance of falls (AAHP).

Several peer-reviewed studies of DUR programs have examined programs in outpatient settings. Kreling, in a review of literature, identified two studies that have shown both quality and cost improvements (Kozma et al.; Kreling and Mott) and two others that have shown the impact of interventions targeted toward prescribers or pharmacists (Sleath et al.; Mott and Collins).

Another study, which failed to show an impact for prospective DUR programs, found that retrospective DUR programs in several Medicaid programs achieved their intended effects (Kidder and Bae).

In 1995, Soumerai and Lipton critiqued the use of computer-based DUR programs, raising issues of questionable screening criteria, their failure to examine under-use of drugs, and the risks of denying prescribed drugs (more applicable to use of concurrent DUR). A 2000 peer-reviewed study looked specifically at Medicaid DUR programs, finding average per-recipient savings of 4.9 percent and average total drug savings of 6.9 percent. No significant spillover effect was found for other health expenditures (Moore). Another study of Medicaid DUR, published in 2003, found no reduction in the rate of exceptions after implementing retrospective DUR, nor any effect on hospitalizations (Hennessy et al.).

Overall, pharmacy benefit managers (PBMs) believe that retrospective DUR has the potential to save money. One PBM (Caremark) projected savings of approximately 2 percent to 5 percent. It also noted that the level of beneficiary outreach and education is minimal compared with other cost-containment mechanisms.

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4b. Physician Profiling

Physicians profiling programs focus on the prescribing practices of individual physicians across many patients. For example, a drug utilization review (DUR) program may identify particular physicians who prescribe fewer or more drugs than their peers. Or they may identify how well individual physicians adhere to treatment guidelines. In other cases, profiles may show drug-specific variations, such as when a physician is prescribing a brand-name drug when most area doctors are prescribing the generic version. According to one pharmacy benefit manager (PBM), Caremark, potential savings associated with physician profiling is less than 2 percent.

In these programs, physicians are provided feedback about their own overall prescribing patterns. For example, one health plan sends a quarterly report to top-prescribing physicians. It identifies their top categories of drugs prescribed and potential alternatives that might be less expensive. The general expectation in profiling is that physicians prefer not to be out of line with their peers and will make adjustments, perhaps after seeking out new information about the use of a particular drug or class of drugs. Even in the cases where penalties or mandatory responses are not included, physicians may follow up on information they receive and make changes in their prescribing patterns.

The Arkansas Medicaid program has focused on polypharmacy in nursing homes for several years and has implemented a program of physician profiling. Kansas is also in the process of developing a similar system (Henry et al.).

A peer-reviewed article, published in 2002, reported on the use of profiling for the prescribing of selective serotonin reuptake inhibitors (SSRIs, a major class of antidepressants) in a staff-model managed-care organization. The authors note that earlier research literature has shown only modest effects from the use of profiling, often finding that the cost of providing the feedback does not outweigh the cost of providing the feedback. They also note that much of the profiling literature does not address specifically any impact on prescribing patterns. The use of profiles in this case included both utilization and cost information, and academic detailing (section 5c) was provided for some of the clinics involved. The result was a more rapid decrease in the market share for fluoxetine (marketed under the brand name Prozac) relative to other SSRIs than occurred nationally (a 50 percent drop compared to 31 percent nationally) for an estimated incremental savings of $0.61 per health plan member per year. The authors note that the setting for this study was a staff-model HMO, which may have strengthened the message contained in the profiles and academic detailing (Yokoyama et al.).

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4c. Drug Utilization Review Targeted to High-Cost Users

Spending for prescription drugs is not distributed uniformly across the population. The rule of thumb for general health spending – that 20 percent of the population incurs about 80 percent of the costs – works roughly for drug spending overall. An analysis of spending for 1996 showed that 20 percent of the population accounted for about 84 percent of all drug spending (DHHS). Approximately 2 percent of the population accounts for about one-third of all drug spending, while 5 percent of individuals account for a little over half of expenditures (DHHS; Fairman).

Among those over 65, however, the picture is somewhat less extreme. In this group, 20 percent of the population accounts for about 55 to 60 percent of spending (DHHS, AAA). This less skewed distribution occurs because most seniors have drug claims, usually for a medication taken for a chronic condition and incurring costs for a year's worth of medication.

Drug utilization review can be targeted specifically to high users of prescription drugs. A focus on high-cost users, especially those who are taking many different drugs (polypharmacy), has the potential for both cost savings and quality improvement. Over 4 million older Americans take eight or more drugs; many of them could benefit from a review of their medications (AdvancePCS). With multiple drugs in use simultaneously, the chances are greater that duplicative drugs are being used, and the odds of adverse drug reactions are greater. Drug utilization programs can identify the highest users, allowing follow up by patients and physicians.

For example, Elderplan, a not-for-profit social HMO that serves seniors in New York, has a program of identifying plan members with prescriptions for eight or more medications in a given three-month period. They estimate that about 5 percent of their members meet this criterion. For the members identified, the plan requests that the primary care physician review the patient's drug list for appropriateness. It further recommends that the patient bring in all medications at least once a year for a "brown bag" review. The plan does not dictate any specific steps for changing medications, but depends on the primary care physician to take any necessary steps to reduce utilization and avoid unnecessary hospitalizations that could result from inappropriate use (Arp).

Similarly, North Carolina's primary care case management program has a program to manage drug use for nursing home beneficiaries. The program identifies beneficiaries who take more than eight medications per month or who take certain high-cost drugs. A team that includes both a physician and a pharmacist reviews these patients' medications for potential polypharmacy problems, such as duplicative or inappropriate prescriptions. The team makes recommendations to the prescribing physicians. Preliminary findings indicate that medication changes are made for 37 percent of the patients and that benefits outweigh costs by a ratio of 13 to 1. Savings were estimated as 4.2 percent of patient drug costs (Henry et al.).

A commercial health plan has a program that identifies all elderly patients with 20 or more prescriptions in a given quarter for chronic or high-risk conditions. Once patients are identified, their physicians receive reports with complete information about their medications and are asked to review the medication history to prevent adverse drug interactions (AAHP).

Literature

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4d. Disease Management

Disease management programs generally try to lower the cost of certain chronic conditions through reduced emergency room visits, fewer hospitalizations, and better choices of drugs. Under these programs, health plans identify individuals as having a particular disease or health condition and as potentially high users of health care. Disease management programs may apply outcomes principles or population-based approaches to identify persons at risk. These individuals, whose diseases are expected to be amenable to management, are provided with additional resources and information about their condition and monitored more carefully (Epstein). Key goals are to maximize the effectiveness of drug therapy and minimize the total treatment costs for the disease. Some view disease management programs as a "win-win" situation. Patients learn more about their disease and how to control it, while the payer reaps the rewards in terms of reduced costs. But a key issue is whether it always reduces costs.

Use of disease management is growing. The number of firms reporting that they offer disease management programs to their employees has risen from 14 percent in 1995 to 53 percent in 2002 (PBMI). In Medicaid, 10 states reported a disease management program in 2001 (Schwalberg et al.), and a 2003 study identified 13 states with operational programs (Henry et al.). Most commonly, they cover diabetes and asthma, but a number of other diseases are included as well.

For example, the Virginia Health Outcomes Partnership targets asthma by training both pharmacists and prescribers and identifying patients who are good candidates for intervention. The result, according to a peer-reviewed evaluation, was a 41 percent reduction in emergency room visits for patients of the participating physicians who received feedback reports. At the same time, these patients experienced a 25 percent increase in dispensing recommended asthma drugs. A cost-effectiveness analysis showed direct savings to Medicaid of $3 to $4 for every dollar invested in the program. After this initial success, the program was expanded to address chronic obstructive pulmonary disease, depression, diabetes, gastrointestinal diseases, hypertension, and congestive heart failure (Rossiter et al.).

In Washington's Medicaid program, disease management programs were contracted to outside vendors. One program, operated by McKesson, enrolled a total of about 15,000 patients with diabetes, asthma, or congestive heart failure. Nurse care coordinators maintain regular contact with the patients, advising them on medication management among other things. An evaluation of this program is under way (Henry et al.).

In another example, Blue Cross Blue Shield of Tennessee has a program to manage patients with hepatitis C. It pays for a genotype test (costing $300) to determine which patients need a 24-week regimen and which need a 48-week regimen of interferon with ribavirin. Previously many physicians simply prescribed the 48-week regimen. Based on the test results, some patients can avoid the side effects of the additional weeks of therapy, while the plan estimated savings of $1.9 million in reduced cost of medication (NGA).

One Medicare+Choice plan has tested a predictive modeling approach to identify patients where drug therapy is best able to help avoid negative outcomes. The program initially targeted

osteoarthritis and congestive heart failure. A pharmacist calls patients who are identified, and counsels them on appropriate drug therapies and provides other advice about their disease. It includes nine months of intervention and nine more months of follow-up and outcome measurement.

The ability to achieve savings under disease management has been difficult to document. In part, this is because the comprehensive approach may trade increased spending in one category for savings in another. For example, in the Virginia program, more use of drugs was encouraged to reduce use of other health care services. Increased drug compliance may often be a key goal in disease management. The therapeutic enhancements offered by new drugs may be emphasized, thus increasing the use of these drugs. Critics argue that some programs, especially those sponsored by vendors in the pharmaceutical industry, amount to simply efforts to increase use of certain drugs or that they emphasize a single disease at the expense of attention to multiple comorbidities.

There appear to be few systematic research studies in the literature. In part, this reflects the challenge of measuring the results, for example, whether to compare spending for disease management enrollees with a baseline calculated from prior-year spending versus one calculated from non-participants. Other factors are assessing the long-term effects of measures such as educating providers and patients or sorting out the effect of multiple components implemented simultaneously (Kreling; Wheatley). Vendors of these programs increasingly emphasize enhanced quality rather than savings as the argument for adopting their programs.

In addition to the peer-reviewed study of the Virginia program, noted above, another peer-reviewed article illustrates the difficulties. Researchers reported on a program to manage patients with congestive heart failure. That nurse-directed multidisciplinary program reduced hospital days by 36 percent and readmissions by 44 percent for targeted patients. The study did not look specifically at changes in drug costs, but the authors did report that the targeted patients were in greater compliance with their prescribed medications (Rich et al.).

Finally, another study shows promising results, but conclusions are limited in a non-randomized study without a control group. It examined a program where diabetics covered by self-insured employers' health plans received community-based pharmaceutical care services. The services included education by certified diabetes educators, long-term community pharmacist follow-up, clinical assessment, goal setting, monitoring, and collaborative drug therapy management with physicians. Enrollees' health improved over time while mean medical costs declined for employers (Cranor et al.).

Literature

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5. Utilization Strategies: Education Approaches

Some utilization strategies are aimed at a broader educational approach as opposed to the more coercive approach represented by some of the other categories. The overall idea is that more information in the hands of physicians, pharmacists, or patients may lead to different (and maybe less expensive) patterns of prescribing.

a. Education of consumers and physicians on the benefits of generic drugs
b. Education of consumers and physicians on the appropriate use of particular drugs
c. Counter detailing or academic detailing
d. Development of unbiased information on the appropriate use of certain drugs

5a. Education of Consumers and Physicians on the Benefits of Generic Drugs

Among the various approaches to encouraging greater use of generic drugs, education strategies are the least intrusive. Health plans or the pharmacy benefit managers (PBMs) with which they contract can create a program to provide more information on the benefits of prescribing generic drugs. In some cases, these programs are targeted to consumers; in others, they are targeted to physicians. Campaigns may include broad-based media campaigns, signs or other information provided through pharmacies, direct communications with consumers or physicians, or providing samples to physicians.

The potential effect on drug costs is substantial. According to one study commissioned for Medco Health, 90 percent of patients said they would take a generic drug if it were prescribed, but only half said they remembered that their physician had talked to them about generics (Medco). A report prepared for the Generic Pharmaceutical Association found potential savings of 16.3 percent per individual (for seniors and disabled Medicare beneficiaries) if all benefit administrators achieved the same generic use rate now obtained in the private plans that achieve the best results (Ritter et al.). Finally, a 2003 peer-reviewed study found potential savings of 6.1 percent for Medicaid spending on drugs for which both generic and brand-name forms were available. Overall savings to Medicaid drug costs were estimated at 1.1 percent. Those savings grew to 11.9 percent and 2.1 percent, respectively, if all states adopted the best price available for generic drugs across states (Fischer and Avorn).

Some evidence also suggests that physicians hold some misconceptions about generic drugs. Physicians sometimes believe that pharmacists substitute generic drugs to maximize their profits, and some also believe that generic drug manufacturers may not have to meet the same quality standards as brand-name manufacturers. Although there has been some controversy over the use of certain generic drugs, it seems clear that a better understanding by physicians has the potential to make a difference (Banahan and Kolassa; Murphy).

Several large-scale education campaigns on the use of generic drugs have been undertaken recently. Blue Cross Blue Shield of Michigan (BCBSM) has conducted an extensive campaign to increase awareness of generic drugs. The plan ("Generic Drugs: The Unadvertised Brand") estimated before starting the campaign that members used generic drugs 85 percent of the time when such a drug is available. The campaign included mailing coupons to members to cover the copay for a generic drug, a series of consumer awareness advertisements in newspapers and business journals to dispel myths about generic drugs, and a competition among pharmacies to increase the dispensing rate on generics. The plan invested $1 million in the advertisements and worked on them in partnership with the Michigan Pharmacists Association. The competition among pharmacies saved BCBSM an estimated $13 million in reduced drug costs. They assume even greater savings for consumers, since the campaign will affect use of generics for consumers who are not plan members (BCBSM).

One large PBM, Medco, launched a program known as Generics First in 2000. Several health plans worked with Medco to send letters to providers offering to provide samples of selected generic drugs. Typically, the physicians ordered free samples from four commonly used generic drug categories: anti-hypertension drugs, anti-depressants, gastrointestinal agents, and non-

steroidal anti-inflammatory medications. Medco reported that various actions — including access to generic samples, face-to-face clinical discussions, and use of patient education materials — increased generic dispensing rates by 7.1 percentage points, from about 38 percent to about 45 percent. Among physicians who receive clinical pharmacist visits and have access to generic samples, the campaign generated a 22 percent increase in generic prescribing rates. Medco has also focused on increasing the dispensing of generic drugs in its mail-order programs. It contacts those physicians who write many "dispense as written" prescriptions to ask them to consider prescribing more generic drugs. Medco reports that nine of ten physicians contacted make some changes from brand-name drugs to generic drugs (Medco).

In another variation, a Pennsylvania health plan promotee the use of generic drugs by offering incentive payments to medical practices that use generics. They also send reports to show doctors how they compare with their peers in prescribing patterns for generic drugs.

In 2003, several large California health plans launched a program called Generic Advantage, which used mailings to encourage physicians to discuss with patients the potential use of generic substitutes for drugs used to treat arthritis pain, acid reflux, diabetes, depression, hypertension, and high cholesterol. Physicians can make "$10 off" coupons available to patients, an amount that often has the effect of eliminating the copayment for that prescription (Levin).

One peer-reviewed study looked at a modest program of physician education at an urban public hospital and its satellite clinics. That study included both an educational session with clinic directors and a form that asked the physician to document that at least two generic non-steroidal anti-inflammatory drugs (NSAIDs) had been tried before prescribing a brand-name NSAID. The absence of a form, however, did not prevent dispensing of the drug. The results of this small study was a drop in the rate of prescribing brand-name NSAIDs from 10.5 percent to 6.9 percent, with higher savings where house staff were supervised by attending physicians compared to prescriptions written by community-based primary care physicians (Ahluwalia et al.).

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5b. Education of Consumers and Physicians on the Appropriate Use of Particular Drugs

Purchasers or health plans may use educational strategies to make both physicians and consumers more aware of the availability of alternative therapies or less expensive drugs that are included in a health plan's formulary. Advocates of this approach believe that better availability of information will generally encourage consumers to take more responsibility for their drug use and encourage the selection of the least costly alternatives. Increasingly, this option relies on Internet strategies for making information available in a continuously updated form. Some plans have found that older plan members – although less likely to use the Internet – are generally more knowledgeable about their benefits and more likely to pay attention to educational programs.

In some cases, plans have taken on broad goals, such as promoting appropriate use of antibiotics or encouraging appropriate treatment for certain conditions. In other cases, plans or the pharmacy benefit managers (PBMs) with which they contract have created programs to educate physicians and consumers about their formularies. These programs may include sending a formulary list to network physicians on an annual basis and making it available through the Internet. In some cases, they may arrange for pharmacists to visit with physicians to discuss the formulary or send mailing with specific information about the drugs on the formulary. Some plans organize meetings for enrollees to tell them about the formularies and changes to them. Plans may also target mailings for specific situations, such as when an enrollee is approaching a cap on their benefit. They may also in this situation set up sessions to counsel enrollees on the availability of more cost-effective drugs (Draper et al.). According to a 2001 report sponsored by the California Health Care Foundation, continuing medical education and academic detailing may positively counter the influences of DTC advertising and information from pharmaceutical representatives on physician prescribing practices, thus decreasing spending on expensive brand-name drugs (Protocare Sciences).

Humana has used an online prescription drug management features for its Medicare+Choice plans. It provides both patient-specific information in a secure portion of the website and general information in a public portion of the site. In the secure portion, members can get access to a 24-month history of their pharmacy claims and can find out if a drug is covered (Draper et al.).

Most private health plans have put at least some information on the Internet. A typical plan may allow enrollees to look at the plan formulary, locate participating pharmacies, and order refills for mail delivery. An increasing number of plans have introduced pilot programs for physicians to use hand-held electronic devices to get information about which drugs are on a formulary, verify coverage of a particular drug, learn about cost sharing amounts, and identify dosing precautions and drug interactions. In some cases, these capabilities are combined with the ability to enter the prescription electronically (Draper et al.; AAHP). There are several identified limitations to handheld electronic prescribing devices. Some are unreliable, slow, and can be more time consuming for patients with multiple diagnoses. Overall, use of such devices has not been proven to reduce the amount of medication errors (Lipton).

Another example is focused specifically on educating the physician. The Fallon Community Health Plan makes available guidelines for anti-coagulant management to address the risks

associated with drugs to prevent blood clotting. Significant risks are associated with dosages that are either too high or too low. The plan, which has implemented a computerized flow chart incorporating its recommendations and uses the system to provide multiple cycles of feedback, reports improved results in major measures of performance (AAHP).

Similarly, PacifiCare of Arizona-Nevada claims that its combination of academic detailing and provider education has worked best in curbing unnecessary prescription drug utilization. This strategy helps improve formulary compliance and physician consideration of both cost and clinical effectiveness of a specific drug therapy (Darves).

A program for physician education in the proper treatment of otitis media was evaluated in a 2002 peer-reviewed article. Physicians were offered a continuing medical education program on distinguishing between acute otitis media (AOM) and otitis media with effusion (OME) and presenting consensus recommendations that antibiotics be used for the former, but deferred for the latter. Exposure to the education program increased diagnoses for OME and reduced the number of prescriptions written – with a resulting reduction in drug costs (Pichichero).

Another peer-reviewed study focused on the use of histamine-2-receptor antagonists (drugs, also known as H2 blockers, used to treat ulcers and gastric reflux) based on a program at one health plan that combined physician education, therapeutic reevaluation of eligible patients, and feedback to the physicians. The result was a substantial increase in the use of the preferred drugs, with the annual savings for the health plan exceeding by a wide margin its cost of implementing the program. There was no effect on hospitalizations. The effects were much greater for physicians employed in the health centers (staff model) compared to independent physicians under contract with the plan (Brufsky et al.).

A different education approach is to increase physicians' knowledge of the cost of different drugs. The idea is that, armed with such knowledge, physicians might be more willing to consider costs when writing prescriptions. One study, published in 2003 and based at four teaching hospitals, made available to physicians an interactive teaching conference and a pocket guide that listed the average wholesale prices of over 100 commonly prescribed medications. Over half the physicians consulted the guide and rated it at least moderately useful. The result was a modest increase in physicians' reported awareness of drug costs and concern about the cost of the drugs they prescribed (Korn et al.).

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5c. Counter Detailing or Academic Detailing

Counter detailing, also known as academic detailing, refers to providing alternative information to that provided to physicians by the pharmaceutical manufacturers. Drug company educational strategies (known as detailing) provide drug samples and information about the value of a particular drug marketed by that company with the goal of increasing awareness and use of that drug. In counter detailing, groups such as insurers or purchasers – or groups affiliated with them – can provide alternative messages. For example, they may share with physicians studies showing that a much-advertised brand-name drug is no more effective than a less expensive, older alternative.

An example of this practice is a decision by Massachusetts Medicaid to target a counter-detailing program at physicians who prescribed as many as six psychiatric drugs in the same therapeutic class. If these physicians did not change their practices within three months of receiving letters on the subject, they got visits from state-employed pharmacists to discuss their prescribing behavior. The state's goal was to save $10 million a year from this effort, representing about 2 percent of total spending on psychiatric drugs (Business News of the Week).

Counter detailing may be especially valuable if efforts are focused on medical conditions where the purchaser believes that the alternative treatments are equally effective. A peer-reviewed study of a counter-detailing DUR educational program in Canada found that it was both effective in improving prescribing rates and widely accepted by medical professionals. However, prescribing rate changes and economic impacts differed by therapeutic category (Farris et al.). One potential source of differences is whether the alternative treatment is available as a multi-source drug. Drug companies may no longer be able to justify the cost of detailing on behalf of these less profitable drugs, making it easier for the counter-detailing program to be effective.

In a 1983 peer-reviewed study, researchers implemented an office-based physician education program to reduce excessive use of three drug groups. Prescribers were identified through Medicaid records, and one group was offered educational visits by clinical pharmacists together with mailings about the target drugs. Compared with a control group, these doctors reduced prescriptions of the target drugs by 14 percent, resulting in significant cost savings. No change was seen for a group of doctors who only received the mailings (Avorn and Soumerai). The changes in prescribing persisted for at least nine months after the intervention began. In a follow-up paper, they estimated potential savings to Medicaid (Soumerai and Avorn).

In study published in 2002, academic detailing was used in concert with physician profiling in a Texas staff-model managed-care organization. The result of the combined strategy was a decrease in the use of fluoxetine (Prozac) compared to the use of other selective serotonin reuptake inhibitors for the treatment of depression. On top of a national trend toward less use of fluoxetine, use by physicians in this plan declined more rapidly, leading to annual savings of about $0.61 per member (Yokoyama et al.).

Literature

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5d. Development of Unbiased Information on the Appropriate Use of Certain Drugs

One cost containment strategy is to encourage the development of information on the appropriate use of certain drugs. This strategy is similar to counter detailing (section 5c), which focuses on the dissemination to physicians of accurate information about drugs. The development of unbiased information is a strategy that could be initiated by a single purchaser, but is more likely undertaken by a coalition of purchasers or by the government on behalf of all purchasers.

A number of experts have called for increased efforts to develop unbiased information on the cost-effectiveness of various drugs. A growing number of managed care organizations are implementing the evidence-based and value-based formulary guidelines issued by the Academy of Managed Care Pharmacy. These guidelines urge organizations to request from drug companies a standardized "dossier" that provides information of a drug's effectiveness and safety and also on its economic value relative to alternative therapies (Neumann).

Because the Food and Drug Administration to date has scrupulously avoided looking at cost factors, that agency does not develop such information. Other federal agencies have also tended to proceed cautiously with this line of research because of the potential political fallout if they get too close to making recommendations favoring one treatment or one drug over another. Some have suggested that an independent body, answering neither to government nor industry, could best accomplish this goal (Reinhardt).

A significant initiative in this area comes from the state of Oregon (Oregon Health Resources Commission; Santa). In 2001, the legislature directed the state's Department of Human Services to look at the effectiveness and relative cost of different drugs. The state contracted with the Oregon Health and Science University to conduct evidence-based reviews of published and unpublished studies on drugs in four therapeutic classes: gastrointestinal medications, two types of pain medications, and cholesterol-lowering drugs. Oregon then uses these reviews as input into a process by which a public committee (created by the Oregon Health Resources Commission) draws conclusions, for example, about whether there are differences in efficacy or safety among different COX-2 inhibitors (e.g., Celebrex and Vioxx) or whether there are differences between those drugs and other non-steroidal anti-inflammatory drugs (NSAIDs). In these particular cases, the committee concluded that evidence comparing Celebrex and Vioxx was inconsistent and inconclusive and that evidence does not demonstrate any difference in efficacy among drugs in the larger class of NSAIDs. The state then has the option of deciding whether to use this information to place certain drugs on the Medicaid program's preferred drug list. Information developed through this process is available to both health care professionals and consumers. In fact, AARP has developed summary consumer guides based on the Oregon Commission's work (Douma).

Oregon is one of several states that proceeded with separate procedures for reviewing the literature on drug effectiveness for particular classes of drugs. Some have suggested that this time-consuming process is one that may be best executed if states pooled their resources to create one review that could then be applied to specific state programs. A group of states, led by Oregon, have initiated the Drug Effectiveness Review Project to attempt such collaboration.

A study published in 2004 of early experience with the Oregon preferred drug list reported stakeholder support for the state's approach, including the finding that use of the academic evidence-based reviews enhanced the credibility of the program. Manufacturers, however, were not happy with the decision to use price as a criterion when the evidence suggested that none of the drugs in a class was more effective. Savings targets had generally not been achieved in the brief period being studied, but it may be that the effect of profiling, education, and similar strategies will take longer to have an effect (Bernasek et al.).

In another evidence-based study, findings from the Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT) — a clinical study supported by the National Heart, Lung, and Blood Institute — found that thiazide-type diuretics should be the first step in treatment for hypertension ahead of more expensive drug therapies such as ACE-inhibitors. A subsequent study tracked physician prescribing patterns in the four months following the release of the ALLHAT study. The study showed that published findings significantly influenced prescribing practices in favor of the less-expensive antihypertensive drug therapy. This suggests that physicians may be influenced by clinical evidence despite the cost or brand name of a particular drug (Austin et al.).

Fischer and Avorn, in a 2004 peer-reviewed study, looked at the potential cost savings for health care payers if there was increased adherence to evidence-based recommendations such as those from the ALLHAT study. This study looked at 133,624 elderly enrollees in a large state pharmaceutical assistance program, who were being treated for hypertension in 2001. These patients filled more than 2 million prescriptions at an annual program cost of $48.5 million. The authors found that over 40 percent of the 2 million prescriptions had an alternative regimen that appeared more appropriate according to evidence-based recommendations. Such changes would have reduced the costs to payers in 2001 by $11.6 million. Adherence to evidence-based prescribing guidelines for hypertension could result in substantial savings (about $1.2 billion nationally) in prescription drug costs for the elderly (Fischer and Avorn).

Another peer-reviewed study, published in 2003, concluded that income influenced the use of evidence-based medication by older persons with diabetes who were enrolled in a Medicare+Choice plan in Los Angeles County. Overall, there were lower utilization rates of all evidence-based therapies for Medicare managed care enrollees with incomes less than $20,000 a year (Brown et al.).

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6. Pricing strategies: Pricing Approaches Available to All Payers

These pricing strategies aim at lowering the price paid for drugs, rather than modifying the utilization of drugs. Some focus on the price itself, while other focus on rebates, dispensing fees, or other elements of the overall pricing system.

a. Use of purchasing pools
b. Higher rebates through market leverage
c. Requirements to make prices and rebates transparent
d. Lower dispensing fees to the pharmacy
e. Use of restricted pharmacy networks
f. Use of discount cards
g. Defined contribution approaches

6a. Use of Purchasing Pools

Some organizations have chosen to band together and form purchasing pools. Under these arrangements, organizations aim to increase their purchasing power through higher volume and shared expertise.

At the federal level, the U.S. Departments of Defense (DOD) and Veterans Affairs (VA) have worked together to achieve larger discounts. In 2002, the two agencies spent about $4.7 billion on drugs. They contract jointly to purchase certain drugs from manufacturers, with estimated annual savings of $170 million per year. A study by the Congressional Commission on Service Members and Veterans Transition Assistance in 1999 recommended that the VA and DOD conduct joint procurement of all drugs and use a single clinically based formulary. The Congressional Budget Office, in its March 2003 budget options report, said that these initiatives would save about $600 million over five years and $1.7 billion over ten years (CBO).

Some states have formed purchasing pools for different programs they operate. For example, Massachusetts, in 2000, created a program to combine various programs (senior pharmacy assistance program, Medicaid enrollees, state workers, uninsured and under-insured individuals) into a single purchasing pool. Georgia implemented a program, starting in 2000, to combine management of its drug benefit for Medicaid, state employees, and other public programs. The program covers about 2 million state residents. Through use of a single pharmacy benefit manager (PBM) and a single preferred drug list, Georgia reduced its pharmacy cost growth trend from 26 percent in FY 2001 to 16 percent in FY 2002. Alabama, California, Illinois, Iowa, Maine, Nevada, New Mexico, Texas, Vermont, and Washington are among the other states that have set in motion cross-agency purchasing programs, some of which explicitly exclude Medicaid (NCSL; NGA; Silow-Carroll and Alteras).

A variety of efforts are also under way to combine efforts across states to get better drug prices. West Virginia, working with four other states (Delaware, Missouri, New Mexico, and Ohio) through RXIS (Rx Issuing States), entered into a contract with Express Scripts in July 2002 to manage their drug benefits jointly for state employees and certain other state programs (excluding Medicaid). RXIS uses preferred drug lists and rebate negotiations to lower the cost of prescription drugs through combined market power of about 700,000 lives. West Virginia realized net savings of $7 million in the first year and estimates it will save $25 million (5 percent of costs) over three years by being a part of this common effort (NCSL; Silow-Carroll and Alteras).

The National Medicaid Pooling Initiative was created by Michigan to operate as a multi-state pool, with participation initially by Medicaid programs Alaska, Michigan, Nevada, New Hampshire, and Vermont (joined later by Hawaii and Minnesota). The pool negotiates a matrix of prices and rebates based on the number of pool participants and the exclusivity offered for a particular drug in each state. Each state establishes its own separate contract with the common PBM and makes its own decisions about preferred drugs. In April 2004, DHHS approved this purchasing pool for a total of over 900,000 persons with Medicaid. With this approval, the states estimated the following savings for 2004: Michigan, $8 million; Vermont, $1 million; Nevada, $1.9 million; Alaska $1 million; New Hampshire $250,000; and Minnesota $11 million –

amounts that may represent savings of 25 to 50 percent beyond levels obtained previously with individual preferred drug lists (NCSL; DHHS; Silow-Carroll and Alteras).

There are other multi-state initiatives as well. The National Legislative Association on Prescription Drug Prices, with nine states (Connecticut, Hawaii, Maine, Massachusetts, New Hampshire, New York, Pennsylvania, Rhode Island, Vermont) and the District of Columbia, is working with the Heinz Family Philanthropies to explore options for a common PBM. The Minnesota Multistate Contracting Alliance for Pharmacy (with 41 participating states) is seeking to standardize and consolidate state requirements for pharmaceuticals, supplies, and services, and to develop cooperative contracts. The program reports average savings of 23.7 percent below the published average wholesale price (AWP) for brand-name drugs and 65 percent below AWP for generics (NCSL; NGA).

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6b. Higher Rebates Through Market Leverage

Typically, price discounts in the form of rebates are provided by the manufacturer to public or private health plans or their contracted pharmacy benefit manager (PBM) based on the quantity of the manufacturer's drugs purchased by plan enrollees over a designated period of time. As a cost-containment strategy, higher rebates have the potential to lower the net price paid per prescription. PBMs and health plans may use various strategies to obtain higher rebates. Mostly, these involve measures to increase compliance with a formulary.

Under the common arrangement where the plan or PBM does not actually take possession of the drugs, rebates are paid directly to the plan or PBM often on a quarterly basis. Specific information on rebate agreements and rebate amounts are generally viewed as proprietary information, and they may be based on total sales of a specific drug by a plan's enrollees or on the market share of that drug compared to other drugs in a therapeutic class. In some cases, they are based on changes in the share of drugs, rather than the absolute share. Rebates may also be based on inclusion of a drug on a restrictive formulary. Because of the nature of this market, more generous rebates are likely to be available for drugs that treat conditions for which an alternative brand-name treatment is available. They are less likely to be offered for a new or breakthrough drug, for generic drugs, or for brand-name drugs when generics have been available for a long period of time.

Rebate negotiations with manufacturers may be based on the overall business a plan or PBM does with the company, rather than a separate negotiation for each line of business. Some rebate negotiations are based on an individual drug, while others may be based on a set of drugs produced by the same manufacturer. There is some sense that manufacturers prefer to negotiate on a bundle of drugs, using their breakthrough drugs as leverage to get others on formularies, while plans prefer a drug-by-drug negotiation (Draper et al.).

Industry analysts cite some evidence that PBMs may receive non-cash benefits from manufacturers or cash rebates that are not tied to a particular drug (DHHS). These may be based on agreements about the content of communications to physicians from the PBMs about particular drugs, or plans that operate their own pharmacies or mail-order operations may receive additional price discounts there. Also, some experts have suggested that PBMs may receive support for disease management or research programs in lieu of rebates.

PBMs vary in how they treat rebates in contracts with health plan or purchaser clients. Some PBMs pass rebates on to their client and get their revenue through an additional fee (sometimes called an administrative rebate) from the manufacturer. Other PBMs divide the rebate between themselves and the client. In other cases, negotiations occur separately between the PBM and the manufacturer and between the PBM and the client, with the PBM keeping the net difference between the negotiated net prices (Health Policy Alternatives). According to a 2003 survey, about equal numbers of employers receive rebates as a percentage of all rebates collected versus a guaranteed dollar amount per prescription. But the trend has been toward the guaranteed dollar amount (PBMI).

Average savings achieved through rebates are hard to determine because they are viewed as proprietary. One study by the GAO of plans participating in the Federal Employees Health Benefits Program (FEHBP) estimated that Blue Cross Blue Shield achieved an average discount of 5 to 6 percent in rebates from manufacturers. Through the use of formularies, PBMs encourage doctors and patients to use preferred drugs, which in turn allows PBMs to receive rebates from specified manufacturers. The FEHBP plans that used these PBMs received $113 million collectively from manufacturer rebates, which accounted for 2 to 21 percent of total savings achieved through formulary use (GAO). Industry representatives report that rebate savings can be much higher (35 percent) on selected drugs. HCFA's Office of the Actuary, in estimating net 1997 private insurer drug expenditures for the National Health Expenditure series, assumed average rebates from manufacturers in the range of 7 percent.

Some have argued that rebates, while lowering the price for specific favored drugs, may fail to contain overall costs by encouraging the use of more expensive brand-name drugs. PBMs traditionally look to rebates as an important source of income, which is not always shared fully with their clients. Because rebates are typically unavailable for generic drugs or older brand-name drugs, some believe that PBMs are more likely to include the more expensive brand-name drugs on their formularies because these drugs generate rebates for the PBM.

Consultants typically advise purchasers that they should have a method for forecasting and auditing the rebates they receive from PBMs, since errors leading to incomplete collections are not uncommon. They also suggest that purchasers seek a guaranteed rebate amount in their contracts and remain actively involve in the formulary decisions that often drive rebate amounts. In some cases, purchasers maintain control over what drugs are on the formulary (Nee; Tauber). According to a 2003 article, some managed-care organizations are moving to manage their drug rebate processes in-house because it affords them a higher level of control over the drug utilization of their plan enrollees, improves collection of rebate payments, and avoids the need to share rebates with the PBM (Drug Cost Management Report). One PBM (Express Scripts) has even moved to stop accepting rebates from manufacturers for promoting specific products to physician and patients, although it would continue to accept rebates for increasing drugs sales and market share (Drug Benefit Trends).

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6c. Requirements to Make Prices and Rebates Transparent

Among the key components of an efficient market is complete information on product quality and price. The U.S. market for prescription drugs generally fails to meet this market condition, since complete information on drug prices is unavailable. In particular, manufacturers and their customers view the specific information on rebate agreements and rebate amounts as proprietary.

This absence of price information limits the ability of purchasers (whether public programs or private firms) to ensure that they are getting the best price for drugs. In particular, purchasers may be uncertain whether pharmacy benefit managers (PBMs) choose particular drugs for formularies or preferred drug lists because the drug is most cost effective for consumers or because it generates the highest rebate for the PBM. Pharmacists and physicians charged with making decisions about which drugs to include on a formulary are denied access to accurate price information. The absence of accurate price information also makes it difficult for consumers to shop for the best value at the pharmacy.

Some experts have argued that price transparency would improve economic efficiency in the prescription drug market, empower buyers to negotiate more effectively, give policymakers and researchers access to actual price information, and make pharmaceutical firms more accountable for the prices they charge (Schondelmeyer). From this perspective, one result of greater transparency might be higher prices for certain purchasers that have achieved large discounts, but the overall market price would be more competitive and probably lower. In particular, cash-paying customers (typically those without insurance) should gain access to a lower price. From the perspective of drug manufacturers, however, price transparency is not required in other market sectors and it would not necessarily reduce overall costs for drugs. Industry representatives maintain that keeping rebate arrangements proprietary allows them to negotiate favorable deals with their best customers, whereas making these deals public would hamper negotiations.

There has been some recent shift away from keeping rebate payments secret. According to a 2003 newsletter article, several PBMs developed business models that reflect the increasing demand for transparency. Under these new arrangements, they typically either pass through to the client all money paid by the manufacturer or identify amounts retained by the PBM. Other characteristics of these new products are the identification of rebates received at a drug-specific level and the elimination or identification of any other fees paid by pharmaceutical manufacturers. Many PBMs are reluctant to adopt these new models because it usually results in the elimination of some revenue sources, which in turn leads to higher administrative fees. However, those adopting these arrangements find that the savings from increased PBM transparency should at the very least offset the higher administrative costs (PBMI).

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6d. Lower Dispensing Fees to the Pharmacy

A dispensing fee is a fee paid to the pharmacist in recognition of services provided in connection with filling a prescription. In some pricing methods, the pharmacist is reimbursed separately for the cost of the drug itself and for dispensing the drug. In some cases, the same dispensing fee is paid for all prescriptions, but more often a higher dispensing fee is paid for generic drugs than for brand-name prescriptions. This differential provides more incentive for the pharmacy to dispense a generic drug when one is available. Average dispensing fees in 2001 were $2.29 for brand-name drugs and $2.58 for generic drugs (AIS; Health Policy Alternatives). One consultant observes that there is a difference between the nominal dispensing fee and the true dispensing fee. If the pharmacy can acquire a drug for less than the reimbursement the PBM or insurer pays them for the ingredient cost of the drug, the difference effectively gives them a high dispensing fee – or vice versa. In some contracts, health plans may lower the payment for ingredient costs, which will tend to lower the effective dispensing fee – but may result in less competition and higher market share for the pharmacies that accept the deal (Fox).

In Medicaid, states are allowed to pay the pharmacist a "reasonable" dispensing fee. Some states set a fixed dispensing fee for all drugs; others set separate fees for brand-name and generic drugs or for different types of pharmacies (independent versus chains). According to a 2003 survey, the dispensing fees paid by the states vary widely. Most are in the range of $3.00 to $5.00 per prescription. But the dispensing fee for a retail pharmacy is as low as $2.00 and as high as $44 (for dispensing total parenteral nutrition in Minnesota) (Crowley et al.). States may pay a lower dispensing fee to pharmacies where the higher volume results in lower unit costs. Some states have lowered the dispensing fee as a cost savings measure, but this can lead to political problems. For example, Massachusetts in 2002 tried to lower its dispensing fee only to meet with a decision by large drug store chains to withdraw from participation in the program. The standoff was eventually settled, so that the chains continued in the program.

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6e. Use of Restricted Pharmacy Networks

Plans can lower costs by defining the list of retail pharmacies participating in the plan. Some plans or pharmacy benefit managers (PBMs) also argue that they can improve quality with a restricted network. Pharmacy networks can be restricted on an exclusive basis, that is, prescriptions will not be paid if obtained out of network. Or they can be restricted on a preferred basis, where out-of-pocket costs for enrollees are higher if non-network pharmacies are used. Plans may use restricted pharmacy networks to lower dispensing fees, to get better results from efforts such as generic substitution, or to improve quality because of the availability of automatic DUR programs.

Pharmacies face mixed incentives in accepting lower reimbursements to be included in the network. Their income per transaction is reduced, but inclusion in the network should offer them a higher volume of customers, which increases both revenues for the pharmacy business and foot traffic and sales volume in other parts of the store. In some states, "any willing provider" laws may require plans to accept any pharmacy that agrees to the terms in the standard network contract. If most pharmacies join the network, the ability to achieve either large discounts or increased sales will be weakened.

According to one survey, the proportion of employers with full network access increased from 79 percent in 1995 to 89 percent in 2001 (PBMI). The remaining employers had "limited-access" pharmacy networks. While the survey report does not define these terms, it seems clear that the distinction is between plans where enrollees can go to any pharmacy and those where some pharmacies do not participate in the network. Networks for the larger PBMs typically include about 95 percent of the retail pharmacies across the country (Health Policy Alternatives).

The use of restricted pharmacy networks is often cited by private plans and PBMs as a significant source of cost savings, but there is little agreement on the magnitude of such savings. Because specific discounted rates are treated as proprietary information, it is difficult to get firm numbers on the potential for savings in this area. In a 2003 study of Medicare+Choice plans, plan respondents claimed discounts ranging from 13 to 16 percent for brand-name drugs through restricted networks (Draper et al.). But another report observes (without documentation) that savings are in the range of 1.4 percent of overall costs and attributes the rise in unrestricted pharmacy networks at least in part to the limited savings. This report suggests that plan members tend to rate unrestricted pharmacy access as important to their satisfaction with the plan, creating a disincentive to use this approach (PBMI). One PBM (Medco) states that plans can save up to 4 percent of the usual discounted price by limiting retail pharmacy networks, while another (AdvancePCS) places the level of savings at 2 to 10 percent. Medco advises its clients that they can narrow the network of pharmacies by raising the minimum access requirement, for example, from one mile to three miles. Such a change will increase the ability of the PBM to negotiate discounts without a significant impact on member satisfaction (Medco).

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6f. Use of Discount Cards

Prescription drug discount cards are a relatively recent approach to providing consumers with lower-cost outpatient prescription drugs, an approach that has gotten increased attention since the establishment of the Medicare-approved drug discount card in the Medicare Modernization Act (MMA). These programs target consumers with little or no prescription drug coverage, such as elderly Medicare beneficiaries. Specific arrangements vary by region, sponsor, and the drugs on which the discount will apply. Drug card sponsors range from pharmacy benefit managers (PBMs), insurance companies, third party administrators, and manufacturers, to nonprofit organizations and state governments. Those who meet specific eligibility criteria must sign up for the card and, often times, pay an enrollment fee. Once receiving the card, beneficiaries can receive discounts at specified retail or mail-order pharmacies.

According to the General Accounting Office, PBM-administered cards offer a price that is 10 to 15 percent below either a standard reference price or the retail pharmacy's price, depending on which is lower. Manufacturer-sponsored cards usually provide lower drug prices than PBM-administered cards because they offer either a larger discount off a lower reference price or a flat price ($10 or $15) (GAO).

The GAO noted that regional drug price variability was a main factor in overall cost savings. In Washington, D.C., for example, where drug prices are relatively high, cards provided the highest median savings. Median savings after using a PBM-administered card ranged from $2.09 to $20.95 for a 30-day supply of the nine drugs the GAO examined, while the card savings in North Dakota for these drugs ranged from $0.54 to $7.72.

A 2002 study sponsored by the Kaiser Family Foundation highlighted issues consumers confront when shopping for a program that will generate the most cost savings. These include lack of standardization of drug cards' benefit descriptions, restriction of discounts to specific drugs only, use of undisclosed prices from which discounts are derived, inconsistency of prices, and availability of mail-order prices only. In some cases, the discounted price can only be obtained from a pharmacy in the program's network, and the availability of that price varies from store to store and over time (Health Policy Alternatives/2002).

According to data compiled by the National Conference of State Legislatures as of late 2004, 22 states had either established or authorized prescription drug discount programs targeted toward lower-income people who do not qualify for Medicaid (NCSL). While some programs extend assistance to disabled populations, more than half restrict eligibility to those over the age of 65. Cards endorsed by pharmaceutical company or PBMs also provide assistance to similar populations. Available card programs vary considerably, as illustrated by the following list of eligibility requirements for several discount cards:

- California and Florida both have discount programs designed to give Medicare beneficiaries access to the same low prices available to Medicaid beneficiaries.

- The AARP MemberRx Choice discount card is offered to AARP members for an annual fee of $19.95 (after paying an additional AARP membership fee). Drug discounts vary by

prescribed drug. AARP states that annual savings in the first year of enrollment is approximately $189 or about 19 percent.

- TogetherRx is a discount card collaboratively created by several pharmaceutical companies such as Abbott Laboratories, AstraZeneca, Aventis, Bristol-Myers Squibb Company, GlaxoSmithKline, Janssen Pharmaceutica, Novartis, and Ortho-McNeil Pharmaceutical. Discounts are extended to those who are enrolled in Medicare with an annual income less than $28,000 for singles and $38,000 for couples. Eligible enrollees must not have any other source of prescription drug coverage.

Although the number of discount card programs continues to grow, one report discusses retail pharmacists' discontent with such programs because cost savings may be generated by pharmacy concessions on drug prices and dispensing fees. Participating pharmacies try to compensate for lost revenue by increasing prescription volume and sales of other items in their stores. PBMs usually require participating pharmacies to serve all of their clients, including insured groups, individuals, and enrollees in discount card programs. When drug card programs shift business to mail-order companies, retail pharmacists lose money from both prescription drug purchases and other items purchased at the time of prescription pick-up (Health Policy Alternatives/2002).

Determining exact consumer cost savings is difficult because of the many factors involved, such as quantity and type of a prescription needed. Although card sponsors receive drug rebates, the ultimate effect of these rebates is highly variable, as highlighted in the GAO report on discount cards (GAO).

The MMA allows Medicare beneficiaries the opportunity to obtain drug discount cards beginning in June 2004 through the end of 2005 (until the Medicare Part D drug benefit goes into effect in 2006). The Medicare-approved drug discount cards cost beneficiaries no more than $30 per year, and qualifying low-income beneficiaries receive annual transitional assistance subsidies of $600 on the card. According to one study, savings on a market basket of drugs ranged from 17 percent to 24 percent from retail prices at selected Maryland pharmacies (Health Policy Alternatives/2004). Despite the availability of savings (especially for those eligible for the $600 subsidies), enrollment has been lower than expected, due in large part to confusion by beneficiaries who typically must choose among at least 34 cards.

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6g. Defined Contribution Approaches

In defined contribution or consumer-directed health plans, the employer contributes a fixed dollar amount toward health benefits and shifts the responsibility for those dollars to the employee. In addition to making costs more predictable, employers look to decrease administrative burdens and increase health care choices while empowering employees to take control of their health care spending in order to reduce the employer's responsibility for plan management decisions. Defined contribution products in the market typically include the following features: consumer health spending accounts, a major medical or other kind of insurance policy, and reliance on the Internet to support consumer decision making (Christianson et al.; Draper and Claxton; Trude).

In the case of drug spending before the deductible is met, the patient usually pays 100 percent of the negotiated rate for the prescription, drawing either from their health spending account or out of pocket. Once the deductible is met and the insured benefit commences, the pharmacy benefit may become more controlled using standard approaches used by pharmacy benefit managers (PBMs). The idea is to familiarize patients with the high cost of drugs beyond what can be achieved when paying a copay for each prescription and thus to create a greater incentive to seek cost-effective alternatives. In a few cases, certain drugs that are seen as critical to preventing hospital stays or other high-cost treatments may be covered by the plan prior to the deductible being met.

The pharmacy benefit provided by a defined-contribution product may be integrated with the medical deductible or carved out as a stand-alone card program run by a pharmacy benefit manager. When the pharmacy benefit is included with other medical services, a PBM may still provide management services, for example, applying clinical edits such as those for adverse drug interactions. Access to a network of discount pharmacies is usually provided, although a patient may select any pharmacy he or she chooses (typically at a higher cost).

Cost-savings options, such as using generics, are advised but not required since the consumer controls the funds and suffers the consequences of higher spending. One company claims its generic substitution rate is higher than the national average, citing an example of one plan where the generic substitution rate (among drugs where a generic equivalent is available) went from 89 percent to 92 percent (Managed Care Week). There is also some anecdotal evidence of higher mail-order use under these arrangements. Most companies offering defined contribution or consumer-directed products provide a website through which patients can check the cost of the drug they have been prescribed and compare the price with that of generic options. Other cost-effective brand-name drug alternatives may be suggested, but not required, as there is usually an open formulary.

A 2003 newsletter article argued that one of the key components of defined contribution plans is to reduce drug utilization. An expert in PBM marketing and sales stated that the decreased utilization prompted by such plans, to a certain extent, worries PBMs. While some encourage the use of generic and lower-cost products, few PBMs have addressed issues confronted by decreased utilization to the same extent (Inside Consumer-Directed Care).

Humana recently launched a plan that utilizes the defined contribution approach outside of a fully implemented defined contribution health plan. Depending on the drug category, Humana's plan caps the amount it will contribute toward the cost of a prescribed drug, leaving the consumer with the remainder of the cost. The goal of this plan design is to get consumers engaged in the process of choosing prescription drugs based on their value. Plan enrollees can choose any prescription drug and Humana will pay one of four different allowances for the drug depending on its category. Whatever costs are not covered by the allowance will fall on the consumer. The four categories of drugs are: Group A (for which Humana will pay a $40 allowance): drugs that treat acute illness; Group B ($30 allowance): maintenance drugs such as those for high blood pressure, AIDS, and cancer; Group C ($20 allowance): drugs such as allergy medications, which patients could live without, but which boost workplace productivity; and Group D drugs ($10 allowance): lifestyle drugs such as those for acne or sexual dysfunction. Once a member pays $1,500 out of pocket, Humana pays 100 percent of the remaining drug costs for the year. Also, any leftover allowance money goes into the enrollee's flexible spending account, to be used for other needed prescriptions or medical services (Drug Cost Management Report).

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7. Pricing Strategies: Lower Transaction Costs

Some strategies aim at lowering the actual transaction costs for dispensing the drug and thus the price paid for the drug. Mail-order strategies may also facilitate other types of utilization management, for example by allowing time to contact the physician and request a revised prescription before the drug is dispensed.

a. Incentives for increased use of mail-order pharmacies
b. Mandatory mail order for maintenance medications

7a. Incentives for Increased Use of Mail-Order Pharmacies

Most plans include the option of obtaining prescriptions through mail order in addition to through retail pharmacies. For example, 85 percent of the Medicare+Choice plans that offered drug benefits in 2003 included a mail-order option (Achman and Gold). Typically, use of mail order is voluntary. Plans generally offer some financial incentive to use mail order in the form of reduced copayments for a 90-day supply of a medication obtained through the mail, often the equivalent of the retail copayment for two 30-day supplies. They may also emphasize the convenience factor to plan members.

Use of mail order remains limited. Average mail-order utilization among private-sector plans, measured as the proportion of mail-order prescriptions out of all prescriptions, increased from 13 percent in 2001 to 16 percent in 2002 (PBMI). But Medicare+Choice plans estimate that fewer than 6 percent of all prescriptions are filled by mail. Plan officials suggest that this rate of use may exceed that of commercial members because Medicare beneficiaries use more maintenance drugs (Draper et al.).

Plans or pharmacy benefit managers (PBMs) believe that use of mail-order pharmacies (or home delivery pharmacies) has the potential to lower costs and improve quality. They are able to obtain larger discounts through greater formulary compliance and to impose more safety controls. One PBM finds that use of home delivery pharmacies can save up to 10 percent of retail costs for maintenance drugs dispensed by mail — although this estimate may not capture additional savings through easier application of other cost management features (Medco).

One analysis details some of the economics of using mail order. First, the cost of drugs obtained through mail order is lower. For example, the reimbursement rate for mail-order sales of brand-name drugs was 79.6 percent of the average wholesale price (AWP), compared to 85.5 percent for retail sales. This is a savings equal to 6 percent of the list price; the difference goes up when dispensing fees (higher for retail) are taken into account (PBMI). Second, generic drugs may be dispensed more frequently. The overall rate of dispensing generic drugs is higher for mail order, but this reflects the types of maintenance medications for which patients choose to use mail order. Experts believe that, for the same drugs, mail order leads to more generic substitution.

Several factors are involved in achieving savings through use of mail order. One factor is the efficiency obtained in the mail-order operations, including lower administrative overhead and more ability to purchase medications in bulk and repackage them in larger orders (typically three-month supplies). In addition, the time lag of several days inherent in the mail-order environment where the patient is not waiting for the prescription to be filled allows more effective use of techniques such as generic substitution, therapeutic substitution, formulary compliance, and prior authorization. These can be accomplished because the physician can be contacted about revising a prescription during this additional time. Typically, this means that more prescriptions are filled with the PBM's preferred drug. In the ideal situation, this drug is both more appropriate for the patient and less costly.

Medco, for example, has found that generic substitution programs are more effective in the mail-order environment. When a generic version of Prozac first became available, prescriptions filled

through mail order were dispensed at a 90 percent generic rate within one week of availability. By contrast, retail dispensing of the generic was only about 60 percent at that same point in time, rising to about 80 percent after six weeks. Similarly, when Vasotec went off patent, mail order achieved a 90 percent generic dispensing rate after the first month, while retail pharmacies dispensed only 50 percent in generic form in the same time and only 60 percent after 3 months (Medco).

Use of mail order may have less desirable consequences. For example, some consultants suggest that the mail-order environment reduces the patient's access to the advice offered by a pharmacist. Some also suggest that there is a drop-off in compliance because the system of reminders is less effective. Finally, others point to the potential safety risks around the physical and chemical stability of mailed drugs.

Retail pharmacies often find it difficult to compete with discounts offered by mail-order pharmacies. Recently, Walgreens Health Initiatives, the PBM serving Walgreens retail drug stores, allowed members to purchase 90-day supplies of maintenance medications in Walgreens retail pharmacies. While discounts offered by this program decrease the amount customers would pay if they purchased only a 30-day supply, it is still more cost effective for persons to order 90-day supplies from mail-order programs (Drug Cost Management Report).

Some experts have also raised concerns about whether the promised savings will be achieved (Fox, Kreling, Managed Care Week). One expert points out that at least some of these savings could be offset by waste resulting from the larger size prescriptions that are typically filled and from the lower copays. In general, the payer or health plan must determine whether the higher plan share of the payment that results from reduced copayments is offset by efficiencies in filling the prescriptions or by increased numbers of prescriptions switched to cheaper generic drugs. Some purchasers have found that the mail-order benefit actually increases their costs (McDonough and Chandor; William M. Mercer Inc.; PBMI). A recent study presented at the 2004 meetings of the International Society for Pharmacoeconomics and Outcomes Research found that the revenue lost from lower copayments charged for mail-order sales might not be matched by the reduced cost of ingredients and lower dispensing costs (Carroll). This study, not yet published in a peer-reviewed publication, has been soundly criticized by pharmacy benefit managers as not representative of other experience with mail order. Concerns about the absence of savings may lead some plans to increase cost sharing for mail-order prescriptions.

Higher rebates may be one source of savings at mail order, but some suggest that the savings obtained through larger rebates do not always benefit the purchaser or patient, since some rebates are retained by the PBM. To some consumers, home delivery by mail may be a substantial convenience. In other situations, the loss of an immediate fill for a prescription can be a drawback. Still, surveys have suggested that those using mail-order prescriptions are satisfied with the services they receive (Johnson et al.).

A peer-reviewed study that used 2001 PBM drug claims data to look at the effect of various plan design features on drug use and spending for people age 65 and older with private employer-based coverage found a large variation in the proportion of prescriptions filled by mail (from none to more than half). The generic use rate is lower in mail order than retail, but that finding

(consistent with previous studies) may reflect plan members' decisions of when it is worth using mail order. The study found savings from mail order, both for members (lower copayments) and the plan (lower prices), with the savings most apparent for brand-name medications. The average price difference was about 20 percent, and although the enrollee reaped some of that savings through the lower copayment, considerable savings were typically available to the plan (Thomas et al.).

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7b. Mandatory Mail Order for Maintenance Medications

Most plans include the option of obtaining prescriptions through mail order in addition to through retail pharmacies. Most commonly, use of mail order is voluntary, but in some cases, plans may mandate that members obtain certain maintenance medications via mail order. One survey in 2002 found that 78 percent of employers were using or implementing use of mail order for refills of maintenance drugs on at least a voluntary basis, while 11 percent required its use. Another 27 percent of employers said they were considering mandatory use of mail order (Hewitt). Another survey reports that on average 16 percent of prescriptions were dispensed by mail order in 2003, up from 13 percent in 2002. That survey also found that where mail order is mandatory for refilling maintenance prescriptions, 27 percent of prescriptions were dispensed in that manner compared to 14 percent of prescriptions in a voluntary mail-order plan (PBMI). Some observers have suggested that mail-order use rates may be higher for retirees (Fox; Cook et al.).

Some plans may use a stick by limiting coverage at the retail pharmacy for the original prescription to one refill (or sometimes to three refills) and to require that further refills be obtained by mail order. Other plans use a carrot, for example, by offering a financial incentive to use mail order in the form of reduced copayments for a 90-day supply of a medication obtained through the mail, often the equivalent of the retail copayment for two 30-day fills. They may also emphasize the convenience factor to plan members.

Estimates of the potential for savings generally fall in the range of between 5 and 10 percent of costs for those drugs obtained via mail order (Fox; Medco). These are estimates based on the experience of experts in the field, not on scientific studies (see section 7a or more discussion of savings for mail order). In one example, where retail coverage for a client was limited to three refills, Medco reported that mail-order volume increased from nearly 45 percent to nearly 60 percent of total days dispensed, while the trend in per member per month costs dropped by 16 percentage points (Medco).

Many benefit managers view mandatory mail order as a strategy that may generate complaints from their enrollees. The experience in one case study suggested, however, that complaints subsided after a few months (Drug Cost Management Report). Mandatory mail order is increasingly generating political opposition. Retail pharmacies often have the clout to force action in the legislature, especially where mail-order operations are out of state. Some states have banned provisions for mandatory mail order, while others have limited the ability of plan designs to reduce copays for 90-day prescriptions.

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8. Regulatory Strategies Available Only to Government: Pricing Approaches

Some regulatory approaches address prices directly in ways that only government as regulator, not individual payers, can do. Section 9 includes other regulatory approaches available to the government, focusing on those approaches that do not directly regulate the prices paid by different purchasers.

a. Expanded access to Medicaid rebates or changes to the rebate formula
b. Direct price regulation
c. Expanded access to the federal supply schedule

8a. Expanded Access to Medicaid Rebates or Changes to the Rebate Formula

In the Omnibus Budget Reconciliation Act of 1990, the Congress established a rebate paid by the manufacturer to states for drugs purchased under Medicaid. This had the effect of lowering net costs for the state without interfering directly in the transactions between manufacturers (and intermediaries such as wholesalers) and pharmacies. The rebate system imitated a similar rebate system that had evolved in private market transactions (section 6b). States only receive federal matching payments for the cost of drugs produced by manufacturers that have entered into rebate agreements with the Secretary of Health and Human Services. In return for this rebate agreement, states are required to cover all drugs to which such agreements apply.

The amount of the Medicaid rebate is set by statute. For brand-name drugs, the basic rebate is set at a minimum of 15.1 percent or the difference between the average manufacturer price (AMP) and the manufacturer's "best price" for the drug. Additional rebates apply where the AMP for the drug grows more quickly than the consumer price index. The latter provision was designed to eliminate any incentive for manufacturers to offset the rebate with higher prices for drugs already on the market. On average, it is estimated that states save about 20 to 21 percent on their drug spending each year as a result of the rebate (CBO; Cook/1999; Cook/2001). States must ensure that rebate payments are collected from the manufacturers, and states can determine whether the funds are returned to the Medicaid program or retained for the state's general fund.

The best price provision is designed to ensure that Medicaid pays no more for drugs than do other large private-sector purchasers. Using a rebate rather just mandating a lower price mimics the private sector, where rebates are commonly used as a way of effectively lowering prices to different purchasers based on their ability to move market share between similar drugs. It also simplifies the system where purchasers do not buy drugs directly from the manufacturers. The mandatory rebate used by Medicaid provides a lower price without any guarantee that the manufacturer's market share will be higher – although Medicaid's benefit increases overall sales by making it possible for low-income beneficiaries to afford to obtain prescribed drugs (Cook/1999).

Through a provision of the law, California operates a supplemental rebate program and receives additional amounts in return for not placing drugs on its prior authorization list. As of 2003, 9 states (of 43 responding to the KCMU survey), had created supplemental rebate programs, usually in conjunction with a preferred drug list or system of prior authorization (Crowley et al.). Additional states have enacted supplemental rebates since the completion of that survey.

Maine and Vermont recently obtained Medicaid Section 1115 waivers to make the price reductions created by the Medicaid rebate available to certain low-income non-Medicaid beneficiaries. Maine also created a program (Maine Rx) that allows any state resident to enroll in a program entitling him or her to obtain drugs at a discounted price. Under this program, which the Supreme Court in 2004 decided not to invalidate, the state will collect rebates from participating manufacturers in amounts based on negotiations. Some other states have taken steps to collect rebates, similar to those collected for Medicaid, for other state drug purchases, such as for state employee benefit programs or state pharmaceutical assistance programs.

Some proposals have been advanced to increase Medicaid's rebates, either by simply changing the percentage of the price difference or some other element used in the formula. If the rebate amount grows, it may influence the best prices available to private purchasers. There is evidence that the best price provision already hampers the ability of some private purchasers to get larger discounts. Similarly, if use of the Medicaid rebate were extended to other populations such as Medicare beneficiaries, it would lower the net price paid for their drugs, but would have a potential effect on the private market. Manufacturers might give fewer discounts, thus raising private-sector prices. Such a policy might still be viewed as desirable to some if it created more level pricing across purchasers (CBO, Cook/1999).

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8b. Direct Price Regulation

Government has the power to set directly the price paid for drugs. It has chosen, however, not to regulate pricing in the private sector. As a purchaser of drugs under Medicaid and in certain other government programs (e.g., the Veterans Administration, community health centers), the government does exercise price-setting authority (see section 8c, in addition to the discussion here). In Medicare, the federal government has used some price regulation for the relatively few drugs it purchases under Medicare Part B. But for the Medicare outpatient drug benefit created under the Medicare Modernization Act, the federal government has chosen not to exercise its regulatory authority. By contrast, governments in some other nations have chosen to take a more active role in regulating prices. Although a full discussion of price regulation in other countries is beyond the scope of this report, this section discusses price regulation briefly.

In Medicaid, federal law places a ceiling on the payment for brand-name drugs. The ceiling is set at either the drug's estimated acquisition cost (EAC) plus a dispensing fee or the usual and customary charge for the drug. In most cases, states use the average wholesale price (AWP) to establish the EAC. States then set their payment amount as a subtraction from AWP, such as AWP minus 10 percent, plus a dispensing fee. There is a different method used to set the price for multisource drugs. Some states have considered reducing the price, by calling for a greater reduction below AWP. As a separate issue, there is the possibility of using a different benchmark than AWP. AWP is a "price" set by manufacturers, but does not represent amounts actually used in sales transactions.

Under Medicare Part B, the government is responsible for establishing prices for certain physician-administered drugs. In recent years, Medicare has paid physicians for these drugs at 95 percent of the AWP. The Medicare Modernization Act reduced the payment rates for most drugs purchased under Part B, with the goal of moving away from reliance on the AWP, which does not reflect the actual acquisition costs incurred by physicians. The MMA also calls for implementation of a system of competitive bidding to obtain these drugs at a lower market-based price and thus moves away from direct regulation of these drug prices (section 2g).

Pharmaceutical price regulation plays a substantially greater role in several other nations. In Canada and France, for example, the government negotiates directly with manufacturers to determine the payment level for most drugs. A price is typically established after marketing of a drug is approved but before it reaches the market. The manufacturer's proposed price is reviewed and compared to prices charged in other countries. In addition, the government must approve all price increases. In Germany (as well as in the Canadian province of British Columbia), the primary approach is reference pricing for all drugs for which there is either an exact or close substitute on the market (section 3f). In addition, Germany uses a system of budgets whereby physicians are at financial risk for their prescribing behavior. Finally, in the United Kingdom, the primary regulatory approach is the regulation of manufacturer profits. A target rate of return is set for each country on its brand-drug sales to the national health plan. Actual prices are not regulated, but any price increases require government authorization (Stuart et al.).

Some policymakers have proposed to regulate drug prices more generally in the United States, for example by limiting annual price increases or by denying certain tax advantages to manufacturers that raise prices by amounts greater than inflation. A peer-reviewed article in 1995 reviewed literature on price regulation in the public utility industry and found that under conditions of rapidly changing demand and a short product life cycle, price caps could be manipulated. Applying that model to the pharmaceutical industry, Abbott found that the wide variety of product forms (different packages and dosages) makes drug price regulation difficult. The author also simulated the behavior of pharmaceutical firms in reaction to regulation, showing that they would set launch prices 50 percent higher than in an unregulated market. The benefit to consumers occurs only after a product has been on the market about seven years, at which point the unregulated price would be higher than the regulated price off of a higher launch price. The specifics of this analysis and its underlying model may have limited applicability, but it points out the complexity of predicting a response to price regulation (Abbott).

Danzon has written extensively on the impact of price regulation, drawing on cross-national experiences. In a working paper for the National Bureau of Economic Research (supported by Astra Zeneca Pharmaceuticals), she and her colleagues looked at the launch of new chemical entities in 25 countries (Danzon, Wang, and Wang). Of the 85 new drugs studied, the countries with the most launches in the 1994-99 period were those that did not require price approval before launch, including the United States. Nations with a higher expected price also saw more drug launches. On this basis Danzon and her colleagues concluded that price regulation negatively affects the timing and occurrence of the launch of new drugs. In a 2000 peer-reviewed article, she looked at drug prices in seven nations, considering whether different regulatory approaches affect competition and prices – focusing on both drugs with generic competitors and those with potential therapeutic substitutes (Danzon and Chao). The analysis suggests that price competition between generic competitors is more significant in those markets that are less regulated – fewer generic products, less price competition between generics, and less competitive late entrants to the generic market. The authors conclude "regulation thus undermines the potential for significant savings on off-patent drugs." The evidence in this study for therapeutic substitutes is inconclusive.

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8c. Expanded Access to the Federal Supply Schedule

Prices paid to drug manufacturers by the Department of Veterans Affairs (VA) and certain other federal agencies are set by the Federal Supply Schedule (FSS). Under the Veterans Health Care Act of 1992, manufacturers must make drugs available to covered entities at the FSS price as a condition for having their drugs covered by Medicaid. The VA negotiates FSS prices with manufacturers under the condition that it be no higher than the lowest contractual price charged by the manufacturer to any nonfederal purchaser under similar terms and conditions. The General Accounting Office has calculated that average FSS prices are more than 50 percent below average prices to nonfederal purchasers (GAO). There are other rules that sometimes provide lower prices to the VA and Department of Defense compared to certain other purchasers with access to the FSS, particularly some public hospitals and community health centers.

There are several reasons why the FSS price is so much lower than the prices charged to other purchasers. One is the small share of the market (less than 2 percent) that federal purchasers represent. Others include the effectiveness of the VA as a price negotiator and the interest that manufacturers may have in making sure that their drugs are available to federal facilities and agencies, including VA hospitals that train a large number of the nation's physicians. The VA sometimes negotiates separately for even lower prices by including a drug on its formulary and creating strong incentives for prescribing these drugs (DHHS).

Some have advocated providing broader access to FSS prices, such as giving Medicaid or Medicare beneficiaries access to these prices. FSS prices are excluded from the best price provision used in Medicaid, a provision that determines the size of rebates manufacturers must give the program. This exclusion was added shortly after the creation of the Medicaid program in 1990 after some manufacturers raised their price to the VA in order to reduce their required Medicaid rebates. Veterans' advocates convinced Congress to add the exclusion and set separate pricing rules for federal purchasers.

Although advocates of wider use of FSS prices point to the potential for large savings, others contend that manufacturers would no longer agree to the same low prices in their negotiations with the VA. The relatively small market share of the purchasers currently eligible for using FSS prices would be expanded substantially under most such proposals. The Medicaid experience in the early 1990s appears to lend support to this argument (Cook).

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9. Regulatory Strategies Available Only to Government: Non-Price Approaches

These regulatory approaches, also available only to government, modify current regulatory practices in ways designed to reduce costs broadly across all payers. This section includes only those regulatory approaches that do not directly regulate the price of drugs; section 8 includes regulatory approaches that address prices directly.

a. Broader availability of generic drugs through changing patent protection laws
b. Broader authority to move drugs to over-the counter status
c. Increased regulation of direct-to-consumer advertising
d. Reduced restrictions on importation of drugs from other countries

9a. Broader Availability of Generic Drugs Through Changing Patent Protection Laws

In order for pharmaceutical companies to embark on risky research and development ventures, they must know that such ventures will have a positive effect on their profit margin. It is difficult to protect intellectual property from utilization by competitors unless a patent protects it. Conversely, controlling the cost of drugs can be addressed by dispensing generic drugs that use patented research and development. Although patents are effective for a 20-year period, drug companies do not financially benefit from this period in full since the patent period begins at the early stages of research and development prior to the drug entering the market.

The Drug Price Competition and Patent Term Restoration Act of 1984, or Hatch-Waxman Act, was enacted in response to industry concerns about the shortened patent period and consumer demand for more affordable prescription drug therapies. The main provisions of the law include:

- a 5-year extension to drug patent holders, a limit of a two-year extension for drug compounds already in clinical trials or under pre-market review by the Food and Drug Administration (FDA);

- market exclusivity that prevents generic manufacturers from using brand manufacturers' data in their Abbreviated New Drug Applications (ANDAs) for five years for new compounds and three years for new uses of existing compounds;

- a standardized and streamlined process for generic drugs to achieve FDA marketing approval.

According to pharmaceutical manufacturers, the share of drugs sold by generic drug makers since the inception of the Hatch-Waxman bill has increased from 19 percent in 1984 to 47 percent in 2000. Every state allows pharmacists to replace virtually all prescribed brand-name drugs with their generic substitutes without prior authorization from the prescribing physician. Physicians are allowed, however, to indicate that there is not an appropriate generic substitution for the specific patient (section 2f).

Since 1984, both brand-name and generic drug manufacturers began engaging in activity that adversely affects the availability of cheaper prescription drugs. Brand-name drug companies have found ways to extend the patent period of their profitable drugs, for example, by patent variations of a drug about to go off patent (e.g., a time-release formulation), or by delaying listing patents in the Orange Book in order to block generic drug companies' access to patented formulas.

The *Wall Street Journal* highlighted the practices of AstraZeneca, maker of Prilosec, in a series of articles on drug pricing. In preparation for its patent expiration in 2001, AstraZeneca prevented generic competition through a series of lawsuits and peripheral patent claims. In addition, the company spent $500 million a year to push consumers from Prilosec to its new patented drug, Nexium, which some critics suggest has little therapeutic advantage over Prilosec (Harris). Some brand-name drug manufacturers also create anti-competitive agreements with generic manufacturers to delay or eliminate specific generic drugs from entering the market,

while generic companies also seek anti-competitive agreements in order to eliminate generic competitors to a specific drug (Strongin).

During the next few years, research-based companies will face a number of patent expirations for top-selling drugs, as generic manufacturers ready themselves up for rapid market entry. Between 2000 and 2005, 150 drugs with $50 billion in sales in 1998 were scheduled to go off patent (Lau). These patent expirations may lead to decreased brand-name sales, since 27 percent of 2001 drug expenditures in top therapy classes would go to generics in the next five years (Frear; Schroeder and Papas). A report by researchers at the University of Maryland highlights the likely scenario that the number of patent expirations will have a tempering effect on the rate of increase for prescription drug spending while fueling demand for cheaper drugs. This supports assertions that increased demand for cheaper drugs will lead to increased generic drug competition and market entry (Mullins et al.).

In June 2003, the FDA finalized regulations intended to speed the marketing of generic versions of drugs whose basic patent has run out. The regulations limit to one the number of 30-month stays that a brand-name drug manufacturer can receive while it claims that the generic would infringe on add-on patents that have not expired. At the same time, the FDA announced that it was increasing the staffing of its generic unit by a third in order to facilitate quicker generic drug approval (Moskowitz).

Title XI of the Medicare Modernization Act included several provisions aimed at remedying some of the issues identified with the Hatch-Waxman legislation (McDermott, Will & Emery). Some of these provisions wrote into law the decisions contained in the June 2003 FDA regulation. The law included provisions to:

- Permit only one automatic 30-month stay on each new application for approval of a generic drug and otherwise limit some of the legal steps that might be used to delay marketing of the generic drug.

- Require that a generic applicant notify the brand-name manufacturer within 20 days after the FDA has filed the ANDA containing a patent challenge.

- Clarify that a generic company has a right to seek a declaratory judgment that marketing its generic drug would not violate the patent rights of the brand-name drug, thus accelerating the generic company's ability to enter the marketplace.

- Modify the trigger for the 180-day marketing exclusivity period available to the first generic applicant, including the possibility that multiple companies may qualify for 180-day exclusivity if they all file applications on the first day of eligibility.

The Congressional Budget Office estimated that these changes to the Hatch-Waxman bill would increase availability of generic drugs and would lower total drug spending within the United States by $7 billion over ten years. Of that total, estimated savings for existing mandatory federal programs would be $750 million (CBO).

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9b. Broader Authority to Move Drugs to Over-the Counter Status

The Food and Drug Administration (FDA) designates when a drug can be dispensed only with a prescription. In other cases, drugs can be dispensed over-the-counter (OTC) without a prescription, provided the FDA concludes that the OTC drug is effective when used without the supervision of a health care professional. In some cases, the FDA may require new clinical trials to evaluate evidence on this question. For some OTC drugs, a prescription may still be required for certain dosages or certain clinical indications. Total spending on OTC drugs was at least $17 billion in 2002, according to the Consumer Healthcare Products Association.

The criteria that the FDA must use before approving OTC marketing of a drug include whether: (1) patients generally can recognize the condition for which the drug is an approved treatment, (2) patients can understand the information on the product label in order to use the drug properly, (3) the drug is effective when used without supervision by a health professional, and (4) the drug is safe when used as instructed (Brass). More than 700 products available over-the-counter today include ingredients that were available only by prescription less than 30 years ago.

Removing the requirement for a prescription can save time for both the patient and the health care professional. It can increase access to effective drugs while decreasing health care costs by requiring fewer visits to physicians. Some studies have shown that use of certain drugs has increased dramatically after becoming available over-the-counter; however, evidence on lower costs is hard to evaluate because there are many confounding factors. Some would argue that the long-term use of OTC aspirin for preventing cardiac disease demonstrates the potential value of having treatments available without a prescription. In addition, lower overall health costs may be accompanied by higher out-of-pocket costs for consumers who lose insurance coverage for purchasing drugs that switch to OTC status (section 1b).

The use of OTC drugs can raise questions of safety, the prime consideration in the FDA's decisions. Without the supervision of a doctor or nurse, some patients may not be able to use OTC drugs appropriately for certain health conditions or in high-risk situations. Patients may not diagnose themselves accurately, leading to delayed or suboptimal treatment of serious conditions, but evidence to support this idea is lacking. The availability of OTC drugs can also lead to unnecessary use of drugs with potential adverse side effects, and the exclusion of them from the drug utilization lists (if no insurance transaction occurs) may cause drug-drug interactions to be missed (Brass; Harrington and Shepherd).

Requests to allow OTC sale of some drugs have been rejected. In 1994, OTC status for oral acyclovir, used to treat genital herpes, was rejected on the grounds that its overuse could hasten development of viral and accelerated microbial resistance. Two cholesterol-lowering drugs were rejected in 2000 for OTC status because the FDA believed consumers could not use them safely and effectively without a physician's involvement (Harrington and Shepherd).

Health plans may choose not to cover OTC drugs or to cover them in only limited circumstances (section 1b). Recently, the FDA decided to allow several high-volume drugs, including loratadine (Claritin) and omeprazole (Prilosec), on a non-prescription basis. These decisions have brought attention to the issue of covering OTC drugs. The switch of loratadine was unusual

because a health plan initiated the request by a petition to the FDA. Initially the manufacturer opposed the petition, raising both legal and clinical issues. Schering-Plough later dropped its objections, in part because Claritin was going off patent and because it decided to push Clarinex, a newly approved replacement drug.

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9c. Increased Regulation of Direct-to-Consumer Advertising

Over the last two decades, the target audience for prescription drug advertising made a notable shift from medical professionals to consumers. Direct-to-consumer (DTC) advertising emerged as an effective mechanism used by pharmaceutical manufacturers to promote products that face competition with generic substitution, formulary restrictions, and other managed care cost containment strategies.

Since its inception in 1985, DTC advertising has succeeded in increasing consumer demand for drugs advertised via television, radio, written publications, and, most recently, the Internet. About 91 percent of respondents saw or heard an ad for prescription medications in the year 2000, opposed to 39 percent in 1993 (Frank et al.). Proponents of DTC advertising assert that such campaigns educate consumers about specific drug therapies, in turn prompting them to discuss ailments and specific advertised prescriptions with their physicians. However, some fear that since pharmaceutical companies are ultimately looking to DTC advertising to boost demand and increase profits, they are not a reliable source for educational tools on which consumers should rely (Hollon).

DTC advertising does have a marked effect on consumer demand. According to IMS Health data, approximately 43 percent of surveyed physicians reported seeing an increased number of requests for brand-name drugs, the most common (in 2001) being Claritin, Viagra, Celebrex, Vioxx, and Allegra. IMS Health data also showed that almost 90 percent of consumers learn about brand-name drugs through manufacturer ads (IMS Health).

In responses to a survey in 2001-02, physicians reported mixed feelings of the impact of DTC advertising. More than 70 percent agreed that the ads helped educate patients about available treatments, and nearly as many agreed that ads helped them have better discussions with their patients. But about 80 percent thought the ads do not provide balanced information and encourage patients to seek treatments they do not need. Physicians reported prescribing the advertised drugs in about 40 percent of the visits that were generated by the ads, but they also recommended that their patients make lifestyle changes and consider other treatments. Nearly half the time, the physicians thought that the advertised drug was the most effective one available, but in another half of the cases they prescribed the advertised drug even though others might be as effective. In about 5 percent of the situations, they prescribed the advertised drug to accommodate the patient's request, despite thinking that another drug or treatment option would be more effective (Weissman et al.).

The impact of DTC advertising on sales is modest overall, but dramatic on some of the most highly advertised drugs. According to one analysis, DTC advertising was responsible for about 12 percent of the overall growth in drug spending between 1999 and 2000 (Rosenthal et al./2003). But DTC advertising is focused primarily on certain drugs. By one estimate, the 25 products with the most DTC advertising have the highest growth trend at 42 percent, while other drugs that have DTC advertising grew at 16 percent. Drugs not advertised directly to the consumer grew at 10 percent. Because of the strong correlation between DTC advertising and increased product growth, annual spending on DTC advertising for prescription drugs tripled between 1996 and 2000, when it reached nearly $2.5 billion (Rosenthal et al./2002). According

to a news report, Nexium (a drug newly introduced in 2001 to treat gastroesophageal reflux disease) saw its sales soar by 275 percent in 2002 as a result of heavy DTC advertising (Vaczek).

With increased prescription drug demand comes increased demand for other medical services such as physician visits and laboratory tests (Wilkes). A report by IMS Health found that after a year of the DTC campaign for Fosamax, physician visits for osteoporosis evaluation nearly doubled. With increased funds going toward DTC advertising, it can be inferred that increases in health system utilization will continue. While initially this may be expensive, further utilization of health services may lead to increased preventive care and early diagnosis of disease. In the long run, this may save the health system money in treatments of advanced diseases.

A potential issue with increased DTC advertising and health system utilization is how well doctors can meet increased consumer demand for new prescription drugs. Doctors' training in pharmacology in relation to increased consumer demand and escalated drug development is questionable. Although the number of people reliant on prescriptions therapies has increased over time, education has arguably not kept pace with such expansion (Hunt). There is also concern that DTC advertising may mislead both consumers and health care providers. Some ads seem to make consumers think a drug therapy is more effective than it actually is. Incomplete or skewed information about a drug potentially misguides both consumers and providers into deducing false information about a new product.

Overall, the General Accounting Office found in a 2002 study that oversight of DTC advertising by the Food and Drug Administration (FDA) is effective at stopping the dissemination of misleading advertisements (GAO). However, some believe that recent changes in FDA's procedures for reviewing draft regulatory letters have reduced the agency's ability to enforce compliance with its regulations. While DTC advertising is here to stay, its potential negative effects may be curbed by increased regulation that may ultimately save consumers and medical providers time and money currently spent after exposure to misleading or inappropriate DTC advertisements.

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9d. Reduced Restrictions on Importation of Drugs from Other Countries

Federal law restricts the importation of drugs from other countries to the United States, even in cases of reimportation, where the drug was originally manufactured in the United States. In practice, the Food and Drug Administration (FDA) does not recommend enforcement of this law in cases of importation of small quantities of drugs for personal use (FDA). Because of the lower prices of drugs in Canada and Mexico, people have increasingly exploited this loophole. According to a 2003 survey, 7 percent of Americans (up from 5 percent a year earlier) said they had purchased drugs from Canada (Harris). More generally, there has been considerable interest in broader access to the cheaper drugs in these countries.

The actual price difference between drugs purchased in Canada versus the United States is difficult to measure. Price comparisons are complicated by variations in the prices paid by different purchasers (especially in the United States) and by whether prices are compared at the manufacturer, wholesale, or retail level. A 2003 compilation of several studies showed that retail prices in Canada were anywhere from 30 percent to 72 percent lower, with even more variation in studies of manufacturer prices (Gross).

Congress has twice in recent years enacted laws that would relax the limitations on importation. In each case, however, the Secretary was given the discretion not to implement the law if she or he could not attest to the guaranteed safety of imported drugs. Both Secretary Shalala and Secretary Thompson invoked their right not to implement this law. The Medicare Modernization Act also loosened importation restrictions for pharmacists and wholesalers for less expensive prescription drugs imported strictly from Canada. However, HHS certification of safety and cost savings was again required, and an HHS task force reported in December 2004 that there were continued safety issues. In looking at a different House bill that would not have required certification, the Congressional Budget Office projected potential savings to the federal budget of $4.5 billion over ten years (without taking into account passage of the new Medicare drug benefit) and total savings for all payers of $40.4 billion over ten years (CBO).

Several states and localities have created programs to take advantage of the lower prices in Canada. In 2003, for example, Minnesota established a website for state residents who want to buy drugs from approved Canadian pharmacies at prices negotiated by the state. In addition, the city of Springfield, Massachusetts, created a program in July 2003 where city employees and retirees can fax prescriptions to Ontario pharmacies and receive medications by mail. The long-term fate of these programs in the light of continued objections from the Department of Health and Human Services is uncertain.

Reducing the restrictions on importation as a cost containment mechanism is extremely controversial. Proponents highlight substantial consumer cost savings as the main argument for its implementation. A study by the Fraser Institute, an independent Canadian economic and social research and educational organization, discussed prescription drug prices for highly utilized brand-name drugs in Canada and the United States. While showing that regional price variation in both countries affects potential consumer cost savings, the report asserted that U.S. consumers do save money purchasing their drugs in Canada (Graham and Tabler). According to a 2003 poll by the Kaiser Family Foundation, there is strong public support (68 percent) for

legislation that loosens restrictions on importation of prescription drugs from Canada. When given arguments for and against such legislation, 63 percent of the public continued to express support (Kaiser Family Foundation).

Opponents have viewed legislation to ease importation of prescription drugs as a distraction from the larger issue of insufficient drug coverage for those populations who need it most. Industry groups such as PhRMA and the American Pharmacists Association have aligned with assertions of the FDA that the safety of imported drugs cannot be guaranteed (Gans). In addition, some pharmaceutical companies have reduced the amount of pharmaceutical supplies to certain Canadian pharmacies in order to curb importation of their drugs. Some also raise the concern of whether the FDA can balance a dramatically increased role in prescription drug monitoring in conjunction with all of its other responsibilities.

Another issue raised is questionable product packaging. The FDA oversees the labeling of prescription drugs to allow for maximum drug effectiveness with minimum side effects. This raises further concerns that imported drugs may not have such labeling, thus leading to the misuse of a prescribed drug. On numerous occasions, the FDA has indicated that many imported mail-order drugs stopped at U.S. borders were potentially dangerous. They include drugs that have been withdrawn from the U.S. market, animal drugs never approved for human use, counterfeit drugs, drugs with dangerous interactions, drugs with dangerous side effects, and narcotics.

The FDA is also beginning to crack down on mail-order and Internet pharmacies that mislead customers about the safety of their drugs. In 2000, the GAO identified 190 Internet pharmacies selling prescription drugs directly to consumers, including 25 that did not require a prescription (GAO). This generates fears that an increasing number of patients are purchasing prescriptions online or through the mail without a medical diagnosis or a doctor's prescription. To confound this situation, many of these pharmacies do not disclose drug safety and approval information on their sites, so drug safety and efficacy are questionable. Proposals such as those in Minnesota and Springfield, MA, would try to avoid these problems by establishing working relationships with certain pharmacies in Canada.

It has yet to be determined whether importing prescription drugs into the United States would have a long-term impact on costs incurred by the consumer, primarily because the factors that determine drug prices are varied and interconnected. Although many prescription drugs cost less in Canada than in the United States, the overall amount that could be saved in the long run is uncertain. The lack of consensus on overall cost savings from importation stems from key differences in how studies compare drug prices between countries. Some focus on retail prices while others may look at prices charged by manufacturers (Gross). To further confound calculations of long-run savings, the Canadian government is hearing reports of medication shortages and drug price increases. This is attributed mainly to the rise of Internet pharmacies, but some feel that the increasing cross-border trade has potential to dismantle Canada's price-setting regulatory agency (Voelker). A 2004 issue brief published by the Congressional Budget Office concluded that current legislative proposals to legalize drug importation would yield only a small reduction in costs (CBO).

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Appendix A. Literature Reviewed

A wide-ranging review of literature was completed between mid-2002 and late 2004 by the author with the help of two research assistants. Included in this literature search were peer-reviewed journals, studies published by foundations and government agencies, as well as both industry newsletters and mass-circulation newspapers. This appendix provides additional detail on the search strategies.

Full searches were completed for the years 1993 to 2004 for the following peer-reviewed journals: *Journal of the American Medical Association, New England Journal of Medicine, Health Affairs, Health Services Research, Inquiry, Journal of Health Economics, Milbank Quarterly,* and the *Journal of Health Policy, Politics and Law*. Other journals and newsletters were checked on a less systematic basis, including *Journal of Managed Care Pharmacy, Medical Care*, and the *American Journal of Managed Care*.

A systematic search was also made of studies published by foundations and government agencies. While these studies are not part of the peer-reviewed journal literature, they normally received extensive review by the organizations involved. Foundation-sponsored reports included those supported by the Henry J. Kaiser Family Foundation, the Commonwealth Fund, the Robert Wood Johnson Foundation, and the California HealthCare Foundation. Government studies include those by federal agencies, such as the Department of Health and Human Services, the Congressional Budget Office, the General Accounting Office, the Congressional Research Service, and the Medicare Payment Advisory Commission. State government sources were also consulted, including studies published by the National Governors Association and the National Conference of State Legislatures.

In addition, various industry sources were reviewed, including work presented by pharmacy benefit managers (PBMs), pharmaceutical manufacturers, and insurers. In particular, this project searched for studies published by the larger national PBMs (AdvancePCS, Caremark, Express Scripts, and Medco Health Solutions), the National Pharmaceutical Council, Academy of Managed Care Pharmacy, the Pharmaceutical Care Management Association, and the Pharmacy Benefit Management Institute. Studies by other trade associations or interest groups, such as the American Association of Health Plans (now known as America's Health Insurance Plans) and the AARP. Generally, evidence about the use or effectiveness of cost-containment strategies identified through these sources is distinguished in the text of the report from findings reported in either peer-reviewed journals or the reports of foundations or government agencies. The reader can judge whether or not to discount findings from these interested organizations.

Finally, articles were used from both trade press (e.g., Drug Benefit Trends, Drug Cost Management Report, and Managed Care Week), and mass-circulation newspapers or news services (e.g., Associated Press, CNN, New York Times, Wall Street Journal, Washington Post). Most often, these sources provided descriptive information about specific strategies being used by an organization – but not an evaluation of its effectiveness.

The search strategy included various library databases, such as Medline, Pubmed, PAIS International, LexisNexis Academic, MDConsult, and JAKE. It also included identification of

articles cited in such Internet digests such as the Kaiser Health Policy Daily Report, Medscape Week in Review, Business News of the Week, Government News of the Week, and Benefit News. Where formal search strategies were appropriate, searches used the following key word search terms: prescription drugs, caps, utilization review, prior authorization, preferred drugs, copayments, coinsurance, reference pricing, formulary, cost containment, disease management, generics, generic drugs, purchasing pools, pharmacy networks, discount cards, pharmacy, mail-order pharmacy, rebates, AWP, Hatch-Waxman, over-the-counter, DTC (direct-to-consumer) advertising, reimportation, and pharmaceuticals.

Evidence for Cost-Effectiveness

The evidence relating to cost-effectiveness of many approaches is limited. There have not been a large number of peer-reviewed studies on the impact of different cost-containment strategies. A few key approaches, such as tiered cost sharing, have been the subject of numerous studies, but many other strategies have not been studied extensively. In some cases, evidence of effectiveness has been reported – often in quite general terms – in various industry newsletters or in reports produced by different industry organizations (e.g., the large pharmacy benefit managers). These sources typically do not report peer-reviewed studies, and in most cases lack details.

In the write-ups for the different strategies, we label carefully the source of the available evidence. Although peer-reviewed studies are clearly preferable, decision-makers can make cautious use of other evidence. Readers may draw their own conclusions about how much weight to give to the non-peer-reviewed evidence.

Other limitations relating to the discussion of effectiveness include the many different ways that evidence has been presented. Some studies report on the overall impact of a particular strategy on annual drug cost trends (percentage savings). Other studies report on the dollar savings for a strategy – sometimes in the aggregate and sometimes on a per-person basis. Still others report results in terms of a percentage of spending for a particular category of drug use. No attempt has been made to standardize these different findings, since the necessary information to do so is often unavailable.

Furthermore, the complete context of a particular estimate may not always be available. Ideally, we should have information about characteristics of the population being studied, prior utilization patterns, other cost-containment measures that might be in use, and the time frame. Typically, some of this information is available; but rarely is all such information available. We have attempted to include all relevant information available in the source consulted.

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