

SPECIAL ARTICLE

The Effect of Incentive-Based Formularies on Prescription-Drug Utilization and Spending

Haiden A. Huskamp, Ph.D., Patricia A. Deverka, M.D., Arnold M. Epstein, M.D., Robert S. Epstein, M.D., Kimberly A. McGuigan, Ph.D., and Richard G. Frank, Ph.D.

ABSTRACT

BACKGROUND

From the Department of Health Care Policy, Harvard Medical School (H.A.H., R.G.F.); the Department of Health Policy and Management, Harvard School of Public Health (A.M.E.); and the Section on Health Services and Policy Research, Department of Medicine, Brigham and Women's Hospital (A.M.E.) — all in Boston; and Medco Health Solutions, Franklin Lakes, N.J. (P.A.D., R.S.E., K.A.M.). Address reprint requests to Dr. Huskamp at the Department of Health Care Policy, Harvard Medical School, 180 Longwood Ave., Boston, MA 02115, or at huskamp@hcp.med.harvard.edu.

N Engl J Med 2003;349:2224-32.
Copyright © 2003 Massachusetts Medical Society.

Many employers and health plans have adopted incentive-based formularies in an attempt to control prescription-drug costs.

METHODS

We used claims data to compare the utilization of and spending on drugs in two employer-sponsored health plans that implemented changes in formulary administration with those in comparison groups of enrollees covered by the same insurers. One plan simultaneously switched from a one-tier to a three-tier formulary and increased all enrollee copayments for medications. The second switched from a two-tier to a three-tier formulary, changing only the copayments for tier-3 drugs. We examined the utilization of angiotensin-converting-enzyme (ACE) inhibitors, proton-pump inhibitors, and 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitors (statins).

RESULTS

Enrollees covered by the employer that implemented more dramatic changes experienced slower growth than the comparison group in the probability of the use of a drug and a major shift in spending from the plan to the enrollee. Among the enrollees who were initially taking tier-3 statins, more enrollees in the intervention group than in the comparison group switched to tier-1 or tier-2 medications (49 percent vs. 17 percent, $P < 0.001$) or stopped taking statins entirely (21 percent vs. 11 percent, $P = 0.04$). Patterns were similar for ACE inhibitors and proton-pump inhibitors. The enrollees covered by the employer that implemented more moderate changes were more likely than the comparison enrollees to switch to tier-1 or tier-2 medications but not to stop taking a given class of medications altogether.

CONCLUSIONS

Different changes in formulary administration may have dramatically different effects on utilization and spending and may in some instances lead enrollees to discontinue therapy. The associated changes in copayments can substantially alter out-of-pocket spending by enrollees, the continuation of the use of medications, and possibly the quality of care.

INCENTIVE-BASED FORMULARIES ARE AN innovation designed to curb the increasing costs of prescription drugs.¹ An incentive-based or tiered formulary provides financial incentives (i.e., lower copayments) for enrollees to choose drugs that are preferred by the payer.^{1,2} In contrast to closed formularies, which specify a limited number of drugs that are available for coverage in each class, incentive-based formularies are intended to preserve choice for patients and physicians by providing some level of coverage for most drugs while encouraging patients and their physicians to select the drugs that are more cost effective for the plan. At the same time, the use of incentive-based formularies results in increased bargaining power for plans to negotiate rebates with drug manufacturers by promising an increased volume of prescriptions for the preferred drugs.³

There is wide variation in the design of incentive-based formularies, with varying numbers of tiers, different drugs assigned to each tier, and a range of copayments required. A three-tier formulary, now the most common type, typically requires the lowest copayment for generic drugs (the first tier), a higher copayment for the brand-name drugs that are preferred by the organization (the second tier), and the highest copayment for brand-name drugs that are not preferred by the organization (the third tier). As of spring 2002, 57 percent of workers in the United States who had drug benefits were enrolled in plans with a three-tier formulary.²

Previous studies have found that the adoption of an incentive-based formulary and the accompanying changes in copayments resulted in lower aggregate utilization of and spending on drugs.⁴⁻¹⁰ However, there have been few studies investigating whether patients who have been using medications that are typically used to treat chronic illness continue to use their previous medications and pay higher copayments, switch to lower-cost medications, or stop using their prescribed drugs entirely.^{5,11} To examine this question, we studied responses to the introduction of two different incentive-based formularies used by a large health plan and a national pharmacy benefits manager.

METHODS

STUDY POPULATION

We studied the use of prescription drugs by employees and their dependents who had health care cov-

erage from two large employers that contract with a large health insurer. The insurer subcontracts with Medco Health Solutions for the management of its pharmaceutical benefits.

In 2000, both employers made major changes to their pharmaceutical benefits that involved the implementation of a three-tier formulary. Employer 1 made a relatively dramatic change in benefits, moving from a one-tier formulary (requiring the same copayment for any drug) to a three-tier formulary and increasing the levels of copayments for all tiers (Table 1). Employer 2 made a more moderate change from a two-tier formulary (involving one level of copayment for generic drugs and a second level for brand-name drugs) to a three-tier formulary that involved increases in the copayments only for the nonpreferred brand-name drugs that were assigned to tier 3 (Table 1). In both cases, the list of drugs available for coverage did not change, just the copayments required for specific drugs. The assignment of specific drugs to different tiers was the same for both employers (Table 2).

We compared the patterns of utilization and spending for Employers 1 and 2 before and after these changes in policy with patterns in a comparison group of enrollees covered by the same insurer who were not affected by the policy changes. This approach enabled us to control for trends in drug utilization that were unrelated to changes in the formulary. For each employer that adopted a three-tier formulary, we used a comparison group representing a similar population of enrollees whose health plan had similar characteristics.

SELECTION OF COMPARISON GROUPS

We identified two comparison groups of enrollees for Employers 1 and 2 from a pool of more than 1000 employer-clients of the insurer. Separate comparison groups of enrollees covered by employers that had a two-tier formulary that was stable throughout the study period were identified for Employers 1 and 2 with the use of the JMP clustering algorithm (SAS Institute). This method is similar to propensity-score matching, in which an exact match on each item is not required.¹² Matches were made on the basis of overall similarity with regard to the following characteristics: the type of medical benefits (both preferred-provider-organization and point-of-service plans for Employer 1 and point-of-service plans only for Employer 2), the copayment levels for the first and second tiers (\$8 and \$15,

Table 1. Summary of Changes in Pharmaceutical Benefits.*

| Employer No. | Characteristics of the Company† | Old Design of Pharmaceutical Benefit | New Design of Pharmaceutical Benefit |
|--------------|---|--|---|
| 1 | Large firm with mostly hourly workers | One-tier benefit: Retail — \$7 generic or brand-name Mail order — \$15 generic or brand-name | Three-tier benefit: Retail — \$8 generic, \$15 preferred brand-name, \$30 nonpreferred brand-name Mail order — \$16 generic, \$30 preferred brand-name, \$60 nonpreferred brand-name Three-tier formulary structure plus across-the-board increase in copayments |
| 2 | Large firm with mostly salaried workers | Two-tier benefit: Retail — \$6 generic, \$12 brand-name Mail order — same as for retail | Three-tier benefit: Retail — \$6 generic, \$12 preferred brand-name, \$24 nonpreferred brand-name Mail order — same as for retail Three-tier formulary structure only |

* Typically, an enrollee receives a 90-day supply of a drug when purchasing it through a mail-order program, as compared with a 30-day supply when purchasing it in a retail setting.

† We do not provide additional details about the characteristics of the employers in order to protect their anonymity.

respectively, for Employer 1 and \$6 and \$12, respectively, for Employer 2), age and sex distribution, and geographic distribution.

DATA

We used eligibility files and pharmacy data obtained from Medco Health Solutions for the three-year period beginning January 1, 1999, and ending December 31, 2001. We studied persons who were enrolled continuously during this period. The study period began more than one year before the policy changes were made for each employer and ended more than one year after these changes. (We do not reveal the exact implementation date for each employer in order to protect the employers' anonymity.)

STATISTICAL ANALYSIS

For each employer, we conducted two types of analyses. First, we conducted descriptive analyses of the rates of switching from one drug in a class to another or terminating the use of all drugs in the class within six months after the policy change took effect. Second, we conducted multivariate analyses of the use of drugs in the classes we studied and, among enrollees who used these drugs, the level of spending for the drugs by the plan and the enrollee, as well as the total spending, over a 33-month study period beginning April 1, 1999. We focused on three classes of commonly used medications: angiotensin-converting-enzyme (ACE) inhibitors, proton-pump inhibitors, and 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitors, or statins.

Descriptive Analyses of Changes in Medications and Terminations of Treatment

We studied enrollees who filled at least two prescriptions for a given class of drugs during the six months before each employer's policy changes took effect and determined whether enrollees who used only tier-3 drugs (i.e., those who faced the largest increases in cost sharing) continued to use tier-3 drugs, switched to drugs of a lower tier, or stopped using any medication in the particular class of drugs during the six-month period after the changes were adopted. Because the withdrawal from the market of cerivastatin in August 2001 occurred approximately one year after both employers implemented their policy changes, this withdrawal should have little effect on the results with regard to statins. We also examined whether enrollees who stopped taking tier-3 drugs switched to alternative classes of medications (beta-blockers, calcium-channel blockers, H₂-receptor blockers, or other cholesterol-lowering agents, such as cholestyramine, gemfibrozil, or niacin).

Multivariate Analyses of Utilization and Spending

In analyzing trends in utilization and spending for each class of drugs, we first examined raw data. Since clear breaks in trends were apparent at the time the policy changes were implemented, we estimated the effect of these changes by including a dummy variable to denote the prechange and postchange periods. In the multivariate analyses of spending, we compared changes in the interven-

Table 2. Drugs Available in Each Tier.*

| Class of Drugs | Tier 1 | Tier 2 | Tier 3 |
|------------------------|--------------------------------|--|--|
| ACE inhibitors | Captopril Enalapril maleate | Accupril (quinapril) Capoten (captopril) Lotensin (benazepril) Prinivil (lisinopril) | Aceon (perindopril erbumine) Altace (ramipril) Mavik (trandolapril) Monopril (fosinopril) Univasc (moexipril) Vasotec (enalapril maleate) Zestril (lisinopril) |
| Proton-pump inhibitors | None | Nexium (esomeprazole), after 11/01 Prilosec (omeprazole) | Aciphex (rabeprazole) Nexium, before 11/01 Prevacid (lansoprazole) Protonix (pantoprazole) |
| Statins | Lovastatin | Baycol (cerivastatin), after 10/00 Lipitor (atorvastatin) Pravachol (pravastatin) Zocor (simvastatin) | Baycol, before 10/00 Lescol (fluvastatin) Mevacor (lovastatin) |

* ACE denotes angiotensin-converting enzyme.

tion group with changes in the comparison group in order to control for general trends in use and spending.¹³

We estimated two-part models because of the large number of enrollees who were not using each class of drugs.¹⁴ We first fit a logit model of the probability that an enrollee would obtain a prescription for a drug in a particular class during a given month. Then, among the enrollees who used a particular drug in a given month, we estimated three regression models of spending on drugs in that class (spending by the plan, spending by the enrollee, and the sum of the two, or total spending). The person-month was the unit of analysis. We considered an enrollee who filled a 90-day mail-order prescription to have used the drug for the subsequent 3 months, with spending spread out over the 3-month period. A logarithmic transformation of the level of spending was used to address skewness in the distribution of the spending measures.

The key independent variables were an indicator for the period after the policy changes, an indicator for the intervention group (relative to the comparison group), and the interaction between these two variables. We included several covariates: the age at the end of the study and its square, the month of the study and its square to account for secular trends in the dependent variable, sex, and indicators of employee or spouse status ("dependent" was the omitted category). The squares of age and month were included to address potential non-linearity in the effect of these variables on the study

outcome. We used Huber–White corrections to adjust the standard errors for the clustering of multiple observations for each enrollee.^{15,16}

RESULTS

CHARACTERISTICS OF THE ENROLLEES

Table 3 provides descriptive information regarding the enrollees in each group. There were small differences in most of these measures between the enrollees covered by each employer and the comparison group with which they were compared.

DRUG UTILIZATION

Employer 1

Table 4 shows the predicted change in the probability of the use of a drug in each class by enrollees in the intervention group after we had accounted for any changes in the probability of use by the comparison group; these predictions are based on the logit models. The policy change adopted by Employer 1 resulted in a significantly slower rate of growth in the probability of the use of any drug in a given class than the rate in the comparison group (a difference of 24 percentage points for ACE inhibitors, 34 percentage points for proton-pump inhibitors, and 24 percentage points for statins; $P < 0.001$ for all three comparisons between groups).

Table 5 shows changes in utilization patterns among enrollees in the health plan offered by Employer 1 and the corresponding comparison group who used only tier-3 drugs during the six months

Table 3. Characteristics of the Study Population.*

| Characteristic | Employer 1 | | | Employer 2 | | |
|--|-------------------------------|-----------------------------|---------|-------------------------------|-----------------------------|---------|
| | Intervention Group (N=55,567) | Comparison Group (N=55,951) | P Value | Intervention Group (N=11,653) | Comparison Group (N=27,051) | P Value |
| Age as of 12/31/01 (yr) | 29.6±16.7 | 33.5±17.2 | <0.001 | 37.5±17.6 | 34.8±17.1 | <0.001 |
| Male sex (%) | 54 | 52 | <0.001 | 47 | 47 | 0.99 |
| Employee status (%) | | | | | | |
| Employee | 36 | 41 | <0.001 | 52 | 47 | <0.001 |
| Spouse | 25 | 23 | <0.001 | 20 | 22 | <0.001 |
| Dependent | 39 | 36 | <0.001 | 28 | 31 | <0.001 |
| ACE-inhibitor use (no.) | 2231 | 2596 | | 659 | 1087 | |
| Average monthly probability of use in 6 mo before policy changes (%) | 2.2 | 2.2 | 0.99 | 3.1 | 2.2 | <0.001 |
| Enrollees who bought medications only through retail outlets before policy changes (%) | 83.6 | 88.3 | <0.001 | 85.4 | 96.3 | <0.001 |
| Proton-pump-inhibitor use (no.) | 3547 | 3850 | | 837 | 1822 | |
| Average monthly probability of use in 6 mo before policy changes (%) | 2.5 | 2.3 | 0.02 | 2.7 | 2.5 | 0.13 |
| Enrollees who bought medications only through retail outlets before policy changes (%) | 91.9 | 92.7 | 0.10 | 96.0 | 99.1 | <0.001 |
| Statin use (no.) | 2608 | 3391 | | 933 | 1513 | |
| Average monthly probability of use in 6 mo before policy changes (%) | 2.2 | 2.5 | <0.001 | 4.1 | 2.7 | <0.001 |
| Enrollees who bought medications only through retail outlets before policy changes (%) | 80.7 | 88.9 | <0.001 | 89.8 | 96.7 | <0.001 |

* The total number of enrollees in each group includes those who were enrolled continuously from January 1, 1999, through December 31, 2001. Plus-minus values are means ±SD. ACE denotes angiotensin-converting enzyme.

before the policy change. Many enrollees in the intervention group switched to a drug of a lower tier with lower copayments after the policy changes (41.6 percent of the enrollees taking ACE inhibitors, 35.1 percent of those taking proton-pump inhibitors, and 49.4 percent of those taking statins). A lower proportion of enrollees in the comparison group who used a tier-3 drug switched to medications of a lower tier (4.2 percent, 1.5 percent, and 17.3 percent, respectively; $P < 0.001$ for all three comparisons between groups). A sizable proportion of the enrollees in the intervention group who had used tier-3 drugs before the policy change continued to use a tier-3 medication (42.3 percent for ACE inhibitors, 32.9 percent for proton-pump inhibitors, and 29.2 percent for statins).

Perhaps most important in clinical terms, enrollees covered by the health plan of Employer 1 who had used a tier-3 drug before the policy changes were significantly more likely than enrollees in the comparison group to stop using a drug in the class ($P < 0.001$ for the comparison between groups in the use of ACE inhibitors and proton-pump inhibitors; $P = 0.04$ for the use of statins). In the case

of ACE inhibitors and statins, enrollees covered by Employer 1 were twice as likely as their counterparts in the comparison group to discontinue the use of drugs in the given class altogether.

Employer 2

For each class of drugs studied, enrollees covered by Employer 2 who had been using a tier-3 drug before the policy changes were more likely than enrollees in the comparison group to switch to drugs of a lower tier ($P < 0.001$ for all comparisons) but, in contrast to the enrollees covered by Employer 1, were not significantly more likely than enrollees in the comparison group to stop using a medication in the same class (Table 5). In fact, enrollees in the intervention group who used ACE inhibitors were significantly less likely to stop using an ACE inhibitor than users of ACE inhibitors in the comparison group (8.3 percent vs. 15.8 percent, $P = 0.03$). There was no statistically significant change in the probability of use of a drug in any of the classes after we had accounted for any changes in the probability of use by the comparison group (Table 4).

Table 4. Effect of Policy Changes on the Probability of Use of Drugs and on Enrollee, Plan, and Total Spending for Prescriptions Filled.*

| Variable | ACE Inhibitors | P Value | Proton-Pump Inhibitors | P Value | Statins | P Value |
|--|----------------|---------|------------------------|---------|---------|---------|
| Employer 1 | | | | | | |
| No. of users | | | | | | |
| Intervention group | 2231 | | 3547 | | 2608 | |
| Comparison group | 2596 | | 3850 | | 3391 | |
| Change in probability of use in intervention group minus change in probability in comparison group (percentage points) | -24 | <0.001 | -34 | <0.001 | -24 | <0.001 |
| Change in spending for prescriptions filled in intervention group minus change in spending in comparison group (percentage points) | | | | | | |
| Total spending | -0.3 | 0.59 | -3.2 | <0.001 | -0.7 | 0.301 |
| Spending by the plan | -58.2 | <0.001 | -15.3 | <0.001 | -13.7 | <0.001 |
| Spending by the enrollee | +141.8 | <0.001 | +148.0 | <0.001 | +117.9 | <0.001 |
| Employer 2 | | | | | | |
| No. of users | | | | | | |
| Intervention group | 659 | | 837 | | 933 | |
| Comparison group | 1087 | | 1822 | | 1513 | |
| Change in probability of use in intervention group minus change in probability in comparison group (percentage points) | -5 | 0.26 | -5 | 0.32 | -2 | 0.69 |
| Change in spending for prescriptions filled in intervention group minus change in spending in comparison group (percentage points) | | | | | | |
| Total spending | +3.1 | <0.001 | -0.4 | 0.66 | +2.0 | 0.03 |
| Spending by the plan | -5.6 | <0.001 | -2.3 | 0.02 | +1.9 | 0.07 |
| Spending by the enrollee | +7.5 | <0.001 | +4.9 | <0.001 | +0.3 | 0.79 |

* The estimated percent changes in the probability of use for each class of drugs are predictions based on logit-model results. For the regression models of total, plan, and enrollee spending for prescriptions filled, we transformed the coefficients from the interaction variable for the postchange-period and intervention-group variables to obtain estimates of the percent change in spending. ACE denotes angiotensin-converting enzyme.

Use of Alternative Drugs

We found no evidence that enrollees in the intervention group who had been using tier-3 drugs and who stopped taking all medications in the class after the policy changes switched to alternative classes of drugs more frequently than the enrollees in the comparison group. For example, of the 19 enrollees covered by Employer 1 who had been using tier-3 statins and who stopped treatment, 2 used another cholesterol-lowering drug before the policy changes were implemented, and 1 did so after the changes were implemented; of the 11 enrollees in the comparison group who stopped using statins, 1 used another cholesterol-lowering drug before the policy changes, and 1 used another drug after the changes.

Sensitivity Analyses

We also estimated logit models of the probability of stopping treatment in the intervention group relative to that in the comparison group, with control for age. The results were consistent with those obtained from the descriptive analyses, so age differences between the two groups were not confounding the results regarding the discontinuation of use of a given class of drugs. Finally, in analyses involving a less restrictive definition of use (i.e., including as a user any enrollee who filled at least one prescription during the six months before the policy changes were implemented), the results were qualitatively similar.

Table 5. Drug Utilization after Policy Changes among Enrollees Who Used Tier-3 Drugs before the Changes.*

| Drug Class | Continued Use of Tier-3 Drug | | | Switched to Drug of Lower Tier | | | Discontinued Use of All Drugs in Class | | |
|------------------------|------------------------------|------------------|---------|--------------------------------|------------------|---------|--|------------------|---------|
| | Intervention Group | Comparison Group | P Value | Intervention Group | Comparison Group | P Value | Intervention Group | Comparison Group | P Value |
| | no./total no. (%) | | | no./total no. (%) | | | no./total no. (%) | | |
| Employer 1 | | | | | | | | | |
| ACE inhibitors | 238/563 (42.3) | 421/471 (89.4) | <0.001 | 234/563 (41.6) | 20/471 (4.2) | <0.001 | 91/563 (16.2) | 30/471 (6.4) | <0.001 |
| Proton-pump inhibitors | 108/328 (32.9) | 219/275 (79.6) | <0.001 | 115/328 (35.1) | 4/275 (1.5) | <0.001 | 105/328 (32.0) | 52/275 (18.9) | <0.001 |
| Statins | 26/89 (29.2) | 75/104 (72.1) | <0.001 | 44/89 (49.4) | 18/104 (17.3) | <0.001 | 19/89 (21.3) | 11/104 (10.6) | 0.04 |
| Employer 2 | | | | | | | | | |
| ACE inhibitors | 79/156 (50.6) | 154/222 (69.4) | <0.001 | 64/156 (41.0) | 33/222 (14.9) | <0.001 | 13/156 (8.3) | 35/222 (15.8) | 0.03 |
| Proton-pump inhibitors | 44/68 (64.7) | 111/141 (78.7) | 0.03 | 12/68 (17.6) | 3/141 (2.1) | <0.001 | 12/68 (17.6) | 27/141 (19.1) | 0.79 |
| Statins | 14/33 (42.4) | 22/25 (88.0) | <0.001 | 16/33 (48.5) | 2/25 (8.0) | <0.001 | 3/33 (9.1) | 1/25 (4.0) | 0.45 |

* For each class, the analysis includes only the enrollees who filled at least two 30-day prescriptions for tier-3 drugs only in the class in question during the 6 months before the adoption of a three-tier formulary (i.e., a small number of enrollees who had used drugs from multiple tiers before the policy changes were excluded). The rates of continued use of a tier-3 drug, switching to a drug of a lower tier, and discontinuation of use of all drugs in the class apply to the six months after the policy changes. If an enrollee switched to a different drug in tier 3, this was counted as continued use of a tier-3 drug. ACE denotes angiotensin-converting enzyme.

SPENDING ON DRUGS

Employer 1

Table 4 shows the percentage changes in spending for enrollees in the intervention group who filled a prescription as compared with the levels of spending in the comparison group. The estimate of the percentage change is a transformation of the coefficient for the interaction between the variable for the period after the policy changes and the variable for the intervention group from the regression models. In terms of total spending on a given class of drugs for those who filled a prescription, the policy changes had either no statistically significant effect (for ACE inhibitors and statins) or a significant but very small negative effect (a decrease of 3 percent for spending on proton-pump inhibitors, $P<0.001$) (Table 4). However, the changes had a large effect on the distribution of spending between the plan and its enrollees. After changes in monthly spending by the health plan for enrollees in the comparison group had been accounted for, there were decreases in monthly spending by the health plan for enrollees covered by Employer 1 of 58 percent for ACE inhibitors ($P<0.001$), 15 percent for proton-pump inhibitors ($P<0.001$), and 14 percent for statins ($P<0.001$). Conversely, after changes in monthly spending by enrollees in the comparison group

who filled a prescription had been accounted for, there were increases in monthly spending by enrollees in the intervention group who filled a prescription (of 142 percent for ACE inhibitors, $P<0.001$; 148 percent for proton-pump inhibitors, $P<0.001$; and 118 percent for statins, $P<0.001$).

Employer 2

By contrast, the policy changes implemented by Employer 2 had smaller effects on the use of and spending on prescription drugs (Table 4). There were small decreases in monthly spending by the health plan for enrollees who filled a prescription relative to the spending levels in the comparison group for ACE inhibitors (5 percent, $P<0.001$) and proton-pump inhibitors (2 percent, $P=0.02$), and there were commensurate increases in spending by enrollees (7 percent and 5 percent, respectively; $P<0.001$ for both comparisons).

DISCUSSION

The use of incentive-based formularies is intended to prompt consumers to opt for more cost-effective drugs or to pay more for the drug they prefer when it is considered by the payer to be less cost effective. Our results show that two different changes in for-

mulary administration had quite different effects on the utilization of and spending on drugs.

The simultaneous switch by Employer 1 from a one-tier to a three-tier formulary and the implementation of an across-the-board increase in copayments resulted in a shift in the distribution of spending from the plan to the enrollee in all the classes of drugs we studied. Although a sizable minority of patients did change to less expensive tier-1 or tier-2 alternatives, our results show that some enrollees stopped taking medications in these classes altogether. In some situations, such as that of treatment with a proton-pump inhibitor for acid reflux, terminating the use of the medication may be clinically appropriate for many patients. However, the observation is worrisome with regard to patients who have been taking statins and presumably require cholesterol reduction on an ongoing basis.

By contrast, the switch by Employer 2 from a two-tier to a three-tier formulary with no increases in cost sharing for drugs in tiers 1 and 2 had little effect on the probability of the use of a drug, the distribution of spending, or the likelihood of the discontinuation of the use of a medication. The difference between the effects of the two policy changes may reflect the fact that the increases in the copayments implemented by Employer 2 were more limited than those implemented by Employer 1. Although it is common for employers to move to an incentive-based formulary at the same time as they increase copayments, many employers choose, like Employer 2, to make more incremental changes to the design of their benefits.

Our results are consistent with a study by Rector et al., which showed that the adoption of a three-tier formulary was associated with shifts by enrollees from tier-3 to tier-2 brand-name drugs; that study did not examine whether patients discontinued the use of medication altogether.¹¹ We have no explanation for the finding that enrollees in the comparison group who used ACE inhibitors were more likely than those covered by Employer 2 to discontinue the use of that class of drugs.

Our study had several limitations. We were unable to incorporate proprietary information on changes in the magnitude of rebates from manufacturers that may have resulted from the changes in the formularies, so our estimates of the effects on spending by the health plan and total pharmaceutical spending are likely to be underestimated. Second, the filling of a prescription does not guaran-

tee that an enrollee continues to take the medication for the specified period. It is also possible that the apparent discontinuation of the use of a drug is attributable in part to the filling of prescriptions under a spouse's benefit by enrollees who maintain dual health care coverage, so any adverse effects on the continuation of the use of medications may be overestimated. Third, our findings may not be generalizable to other groups of employers that contract with different insurers or pharmacy benefits managers. Finally, as compared with Employer 2, Employer 1 employs a larger proportion of hourly workers, who are more likely to have lower incomes and thus to be more sensitive to increases in copayments. We cannot be sure that the groups do not differ in terms of unobservable characteristics, such as income, that could influence the effect of the policy changes.

In conclusion, we found large effects on the continuation of the use of medications and out-of-pocket expenditures for enrollees associated with the switch by one employer from a one-tier to a three-tier formulary involving across-the-board increases in cost sharing. In contrast, there were only small effects on these outcomes with the shift by another employer from a two-tier to a three-tier formulary without similar increases in cost sharing. The discontinuation of the use of medications such as statins and ACE inhibitors that are needed for the treatment of chronic illnesses raises important questions about potentially harmful effects of formulary changes and the associated changes in copayments. The different effects observed in the two groups of enrollees covered by different employers show that, when it comes to efforts to understand the effect of formulary design on the utilization of and spending on drugs, the devil is in the details. As three-tier formularies become increasingly prevalent, we need much greater knowledge about these details in order to reap the advantages in cost savings without causing deleterious consequences for patients.

Supported by a grant from the Robert Wood Johnson Foundation's Changes in Health Care Financing and Organization Initiative, by a grant (1 K01 MH66109) from the National Institute of Mental Health, and by a grant (5 P01 HS10803) from the Agency for Healthcare Research and Quality.

Drs. Deverka, R.S. Epstein, and McGuigan report having stock options in Medco Health Solutions and Merck, the former parent company of Medco Health Solutions.

We are indebted to Kathryn Trainor, M.S., and Boris Fainstein, M.B.A., for expert programming.

REFERENCES

1. Gabel J, Levitt L, Holve E, et al. Job-based health benefits in 2002: some important trends. *Health Aff (Millwood)* 2002; 21(5):143-51.
2. Kaiser Family Foundation and Health Research and Educational Trust. Employer health benefits: 2002 summary of findings. (Accessed November 13, 2003, at <http://www.kff.org/content/2002/20020905a/3252a.pdf>.)
3. Frank R. Prescription drug prices: why do some pay more than others do? *Health Aff (Millwood)* 2001;20(2):115-28.
4. Description and analysis of the VA national formulary. Blumenthal D, Herdman R, eds. Washington, D.C.: National Academy Press, 2000.
5. Motheral B, Fairman KA. Effect of a three-tier prescription copay on pharmaceutical and other medical utilization. *Med Care* 2001;39:1293-304.
6. Motheral BR, Henderson R. The effect of a closed formulary on prescription drug use and costs. *Inquiry* 1999/2000;36:481-91.
7. Huskamp HA, Epstein AM, Blumenthal D. The impact of a national prescription drug formulary on prices, market share, and spending: lessons for Medicare? *Health Aff (Millwood)* 2003;22(3):149-58.
8. Horn SD, Sharkey PD, Phillips-Harris C. Formulary limitations and the elderly: results from the Managed Care Outcomes Project. *Am J Manag Care* 1998;4:1105-13.
9. Joyce GF, Escarce JJ, Solomon MD, Goldman DP. Employer drug benefit plans and spending on prescription drugs. *JAMA* 2002;288:1733-9. [Erratum, *JAMA* 2002; 288:2409.]
10. Thomas CP, Wallack SS, Lee S, Ritter GA. Impact of health plan design and management on retirees' prescription drug use and spending. (Accessed October 6, 2003, at <http://content.healthaffairs.org/cgi/reprint/hlthaff.w2.408v1.pdf>.)
11. Rector TS, Finch MD, Danzon PM, Pauly MV, Manda BS. Effect of tiered prescription copayments on the use of preferred brand medications. *Med Care* 2003;41:398-406.
12. D'Agostino RB Jr. Propensity score methods for bias reduction in the comparison of treatment to a non-randomized control group. *Stat Med* 1998;17:2265-81.
13. Cook TD, Campbell DT. Quasi-experimentation: design & analysis issues for field settings. Chicago: Rand McNally College Publishing, 1979.
14. Manning WG, Newhouse JP, Duan N, Keeler EB, Leibowitz A, Marquis MS. Health insurance and the demand for medical care: evidence from a randomized experiment. *Am Econ Rev* 1987;77:251-77.
15. Huber PJ. The behavior of maximum likelihood estimates under non-standard conditions. In: *Proceedings of the Fifth Berkeley Symposium on Mathematical Statistics and Probability*. Berkeley: University of California Press, 1967:221-33.
16. White H. A heteroskedasticity-consistent covariance matrix estimator and a direct test for heteroskedasticity. *Econometrica* 1980;48:817-30.

Copyright © 2003 Massachusetts Medical Society.

FULL TEXT OF ALL JOURNAL ARTICLES ON THE WORLD WIDE WEB

Access to the complete text of the *Journal* on the Internet is free to all subscribers. To use this Web site, subscribers should go to the *Journal's* home page (www.nejm.org) and register by entering their names and subscriber numbers as they appear on their mailing labels. After this one-time registration, subscribers can use their passwords to log on for electronic access to the entire *Journal* from any computer that is connected to the Internet. Features include a library of all issues since January 1993 and abstracts since January 1975, a full-text search capacity, and a personal archive for saving articles and search results of interest. All articles can be printed in a format that is virtually identical to that of the typeset pages. Beginning six months after publication, the full text of all Original Articles and Special Articles is available free to nonsubscribers who have completed a brief registration.