The Effect of a Copay Increase on Pharmaceutical Utilization, Expenditures, and Treatment Continuation

Brenda R. Motheral, PhD; and Rochelle Henderson, MPA

Abstract

Objective: **No research has evaluated the impact of an increase to a copay that is reflective of today's healthcare market. This study examined the effect of an increase from a $10 to $15 copay for brand drugs on key pharmaceutical utilization measures, including participation rates, treatment continuation, and expenditures, in an adult population.**

Study Design: **A quasi-experimental, pre-post design with control group was used.**

Patients and Methods: **Two different employer plans implemented an increase from $10 to $15 for brand copays in January of 1997. The utilization and expenditures of these plans were compared with those of a control group with a constant brand copay of $10 for 6 months preceding and 6 months following the copay increase.**

Results: **When other predictor variables were controlled for, the copay increase was not associated with a statistically significant difference in overall utilization compared with the control group, although brand utilization was significantly lower in the copay group. Savings to the payer were substantial, and resulted primarily from cost-shifting, reduction in brand utilization, and an increase in the generic fill rate. The rates of continuation with chronic medications in the 6 months following the copay increase were not reduced in the copay group compared with the control group.**

Conclusion: **A copay increase can provide substantial savings to a payer without being a major deterrent to overall utilization or resulting in discontinuation of chronic medications.**

(Am J Manag Care 1999;5:1383-1394)

A commonly used tool in pharmacy benefit management is the copay, which is a fixed dollar amount per prescription (in contrast to coinsurance, which is a fixed percentage of ingredient cost, typically 20%, plus the dispensing fee). A primary purpose of a copay increase is to maintain member cost-sharing levels. If copay levels do not keep pace with the rising cost of medications, a disproportionate share of the costs is incurred by the payer. The Consumer Price Index (CPI) for prescription drugs grew 12.2% between 1993 and 1997,[1] whereas the average wholesale price (AWP) per prescription rose 36.6% during the same time period.[2] A national survey of 333 employer plan sponsors showed that despite the rapidly rising AWP ingredient cost, retail prescription copays for brand medications did not keep pace with the increased ingredient costs and rose 6.6% between 1995 and 1997.[3] Consideration only of changes in the CPI may lead to the conclusion that copay levels have indeed kept pace with prescription prices in recent years. However, the CPI can be misleading for the purpose of tracking cost-sharing levels, because it takes into account only increases in the price of drugs already on the market and does not reflect the introduction of new drugs or increases in the quantity filled per

From the University of Arizona College of Pharmacy, Tucson, AZ (BRM); and Express Scripts, Inc. Bloomington, MN.(RH).

Address correspondence to: Brenda R. Motheral, PhD, University of Arizona College of Pharmacy, 1703 E. Mabel, Tucson, AZ 85719. E-mail: Motheral@pharmacy.arizona.edu.

prescription, both of which are included in the AWP cost per prescription. (Although few health plans actually pay AWP, the discount off AWP has not changed significantly in recent years.)

Copays may also be used to deter unnecessary or marginal utilization. According to economic theory, if individuals are required to pay a portion of the prescription cost, they will use prescriptions more prudently and will assess the need for the medication and also the availability of a less-expensive substitute (eg, a generic equivalent). Accordingly, the number of prescriptions should fall as the price increases, if other factors are unchanged. This assertion is based on Grossman's derived demand model, which contends that the demand for medical care, of which prescription drugs are one component, flows from an underlying demand for health.[4] When health is "depleted," a patient desires to restore the "stock of health" through the consumption of one or more inputs (ie, physician visits, pharmaceuticals, etc).

Previous research has invariably found higher copays to be associated with modestly lower utilization.[5-7] Demand appears to be inelastic, or less than an absolute value of 1, which indicates that individuals are not very sensitive to changes in the price of medications.[8] Many of these studies have involved Medicaid and Medicare populations, which may have a greater medical need than the general adult population. Thus, although it is expected that people with higher incomes, on average, will also show an inelastic demand for prescription medications, it is difficult to predict whether their demand will be more or less elastic than that of lower-income people, because high income people's medical need may not be as great.

The effect of the copay amounts currently charged in the market is unknown. The highest copays examined were $8 in a nonexperimental study and $5 in a quasi-experimental study,[9] but the average brand copay in 1997 was $10.33, and 36% of plans surveyed had brand copays that exceeded $10.[3] Other researchers have called for an examination of higher copays,[5] expressing concern that "high fees . . . may be associated with different patterns of use than have been observed in studies with low fees."[8] This concern has drawn the attention of the popular press as well.[10]

Although the small number of prescription cost-sharing studies have produced some consistent findings, many gaps in knowledge remain. One study found a copay increase to have a greater impact on the utilization of discretionary drugs rather than on essential drug use; other studies, however, have not shown this to be the case.[6,11] Furthermore, research has not provided any consistent results regarding the relationship between higher copays and medication compliance, overall medical costs, or quality of life.[12-16]

The objective of this study was to examine the effect of an increase in brand copay on utilization, expenditures, and medication continuation within a general population. Two employer plans that received prescription benefits through Express Scripts, a pharmacy benefit manager, implemented a copay increase, which provided a natural experiment in which the effect of a copay increase could be examined.

···METHODS ···

Study Design and Subjects

The copay group included 2 commercial plans that increased the copay for brand drugs from $10 to $15 in January 1997. The copay for generic drugs increased from $4 to $5 for Plan A and from $5 to $7 for Plan B. The control group was a commercial plan that had a $10 brand copay and a $5 generic copay throughout 1996 and 1997. None of the plans had deductibles, prescription caps, or other formulary-type distinctions in 1996 or 1997. Additionally, the selection criteria required that no other changes in plan design that could potentially affect the results (eg, an increase in office visit copay) occurred during the study period.

A pretest-posttest control group design was used.[17] This design measured the dependent variable in the post-copay increase period (termed the post-period) after controlling for the pre-copay increase period (termed the pre-period) score and compared the post-period measure across the copay and control groups. This was equivalent to comparing the change from the pre-period to the post-period across study groups. The inclusion criterion for the copay group was continuous enrollment from January 1, 1996, to December 31, 1997. The control group consisted of randomly selected age- and gender-matched samples of continuously eligible members drawn from the control plan. Employees, their spouses, and dependents were considered for study inclusion; however, the results from only the adult population (18 years and older) are presented in this study because analyses indicated an interaction between age and copay. Overwhelming differences in baseline utilization and expenditures across

copay and control groups for the children made interpretation difficult.

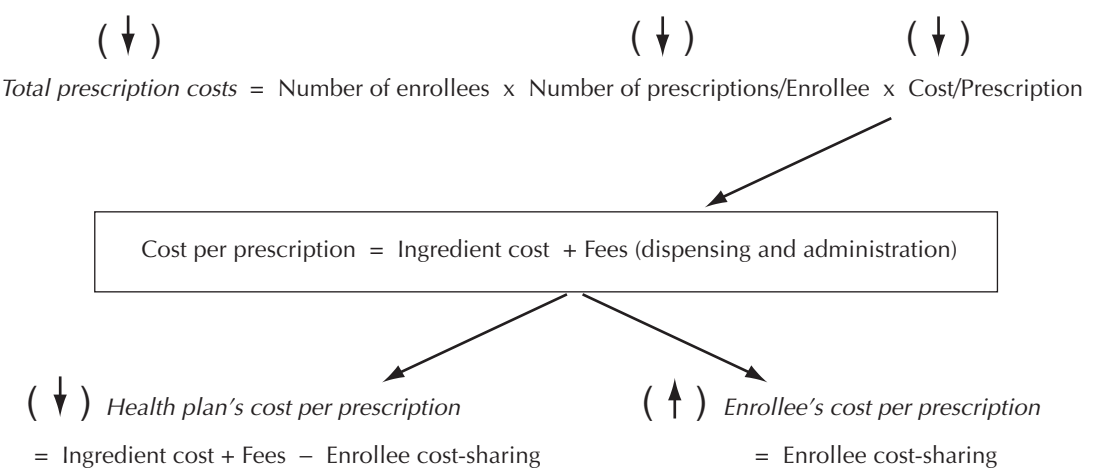
The observation period for the study was a total of 12 months, 6 months in the pre-period (ie, before the copay change) and 6 months in the post-period (ie, after the copay change). The pre-period began on February 1, 1996, and ended on July 31, 1996. The post-period began on February 1, 1997, and ended on July 31, 1997. The decision was made a priori not to include the first month after the copay change in order to avoid the anticipatory demand that may have occurred in late 1996 and resulted in artificially low utilization in the beginning of 1997. A 1-month period was chosen because approximately 90% of claims across all groups were for a 1-month supply or less. However, subsequent examination of the data showed no evidence of anticipatory demand. The pre-period dates were chosen to exactly parallel the time frame of the post-period, thereby avoiding any seasonality differences. Claims for growth hormones, injectable fertility, cancer, organ transplant, and AIDS medications were excluded from the analysis because of their substantial expense and low frequency.

Measures

As shown in Figure 1, total prescription drug expenditures in a given time period are a function of the number of enrollees, the number of prescriptions per enrollee, and the cost per prescription. Cost per prescription is the sum of the ingredient cost and any dispensing and administration fees. Although the objective of the study was to examine how each of these components was affected by the copay increase, the number of enrollees was not relevant because it remained fixed for this investigation; also, dispensing and administration fees were not considered because they were unrelated to the copay change.

Dependent variables. Dependent variables were selected to assess the effect of a copay increase on (1) utilization and expenditures, (2) compliance with chronic medications and (3) whether the effect of the copay increase varied with the type of medication. In addition, total prescription costs were disaggregated into the amount paid by the health plan and the amount paid by the enrollee because the effect of the copay increase on each of these constituencies was of interest.

Figure 1. Hypothesized Effect of a Prescription Copay Increase on the Components of Prescription Costs*



*Arrows in parentheses indicate the hypothesized effects.

The definitions and calculations for each of the dependent variables were based on the post-period experience and are presented below. Eligible subject refers to any subject continuously eligible during the entire study period, and participant refers to any continuously eligible subject with one or more claims during the pre- and post-periods. Dependent variables included the following:

- *Participation* was defined, at the subject level, as having one or more claims during the post-period.
- *Total plan cost per eligible subject* was defined as the sum of the ingredient costs minus the sum of the copays paid by the subject.
- *Total copay per eligible subject* was defined as the sum of all copays paid by the subject.
- Total ingredient cost per eligible subject was defined as the sum of the ingredient costs across all claims and was measured separately for brand and generic drugs. The AWP (as of January 1997) was used as the ingredient cost for brand products; for generic products, 65% of AWP was used as the ingredient cost (First DataBank data). A discount of 35% off the AWP was chosen as the cost for generic drugs because this reflects the typical difference in AWP discount between brand and generic drugs.[3] It was essential to factor in the discount off AWP for brand versus generic products in order to avoid underestimation of the impact of any changes in the generic fill rate on overall costs. We considered only the ingredient cost of the drug and not the dispensing or administration fees as these have no relationship to copay change.
- *Total utilization per eligible subject* was defined as the total number of claims and was measured separately for brand and generic drugs.
- *Mean cost per prescription per participant* was defined as the total ingredient cost divided by the total number of claims.
- *Mean generic fill rate per participant* was defined as the total number of claims for generic medications divided by the total number of claims.
- *Continuation with medications used for chronic conditions.* Subjects who began use of one or more selected medications for chronic conditions prior to January 1, 1997, were followed through July 31, 1997, to determine whether they continued use of the same medication or another medication within the same therapeutic class. Use was defined as at least 2 prescription claims for the medication in the pre-period. The treatment termination date was defined as the last observed fill date plus the number of days for which medication was dispensed. Length of therapy was then calculated as the termination date minus the copay implementation date of January 1, 1997. Only medication classes that are indicated primarily for chronic conditions were analyzed; these included estrogens, oral contraceptives, progestins, antidiabetics, β-blockers, calcium channel blockers, antihypertensives, antipsychotics, and anticonvulsants. The days supply for each therapeutic class in the pre- and post-periods was also determined.
- *Utilization of essential and discretionary medications.* Prescription medications are considered normal goods; that is, demand for medication increases when incomes rise. Furthermore, price elasticity of demand for a particular good or service is influenced by the price of the good relative to total income, the timing and availability of substitute products, and whether the good is considered a luxury or necessity. The last factor has led to the development of the concepts of essential and discretionary medications in the drug benefit policy literature, the hypothesis being that when faced with a higher copay, patients' demand for discretionary medications will decrease to a greater extent than will demand for essential medications. Medications were classified as essential or discretionary based on the definitions of Harris et al.[6] Essential medications included the antihypertensive drugs, cardiac agents (eg, cardiotonics, anti-anginals), antidiabetic drugs, and thyroid medications. Cough and cold remedies, skeletal muscle relaxants, nonsteroidal anti-inflammatory drugs, and analgesics were categorized as discretionary. Utilization and expenditures for essential and discretionary brand medications were examined, as was the fill rate for generic drugs.

Independent Variables. Independent variables included in all multivariate analyses were (1) copay (ie, copay versus the control group), (2) age as of January 1, 1997, (3) gender, (4) chronic disease score (CDS), calculated between February 1, 1996 ,and July 31, 1996, and (5) the pre-period equivalent for each dependent variable. The CDS algorithm used population-based pharmacy data to create a measure of chronic disease status that was predictive of subsequent hospitalizations and mortality.[18] A higher CDS score indicated a greater number of different chronic illnesses.

Statistical Analysis

For the bivariate analysis, the nonparametric Mann-Whitney test was used to compare changes in the dependent variables from the pre-period to the post-period across groups. In the multivariate analyses, participation rates were examined using logistic regression, whereas the remaining dependent variables were analyzed using linear regression.

Compliance with assumptions (eg, linearity, normality, homogeneity of variance) was assessed with various specificity tests. With the exception of the generic fill rate, the variables had highly skewed distributions and many subjects had values of 0; therefore, the data required log transformation in order to meet the assumptions of a regression model. Because a value of 0 cannot be log transformed, a constant of 0.1 was added to each of the dependent variables before log transformation so that all subjects could be included in the analyses. Similarly, with the exception of the generic fill rate, the pre-period equivalent for each dependent variable was also log transformed. Cox regression was used to analyze medication continuation, and utilization and expenditures for essential and discretionary medications were examined with the nonparametric Mann-Whitney test because the data violated the assumptions of linear regression. The significance level for all statistical analyses was set at a *P* value less than .05.

Sensitivity Analysis

Six sensitivity analyses were conducted. The first sensitivity analysis was conducted to examine the effect of the copay increase among subjects who had prescription claims in the post-period. In other words, a 2-equation model divided the sample into those who did and those who did not have any prescription claims during the post-period because a large percentage of the sample did not have any claims. This approach, which is identical to that used in the Rand Health Insurance Experiment (HIE), allowed examination of the effect of the copay within a group of utilizers and was therefore of interest.[19] To address the possibility of regression to the mean, a second sensitivity analysis evaluated only those patients whose pre-period costs fell at or below the 75th percentile in terms of cost. A third sensitivity analysis compared the control group to Plan B only because baseline utilization and expenditures for Plan A were substantially different from those of the control group. For the same reason, a fourth sensitivity analysis of the Cox regression of compliance excluded Plan A. In the fifth sensitivity analysis, we considered the family as the unit of analysis because it could be hypothesized that purchasing decisions are made at the family level. The final sensitivity analysis of the linear regressions included all subjects who were continuously eligible during the study period and not just those subjects who were continuously eligible and matched.

···RESULTS ···

Subject Eligibility and Characteristics

The majority of potential subjects were not continuously eligible during the entire study period (Table 1). A higher proportion of subjects in the copay group were not continuously eligible (61%) compared with the control group (37%). An examination of the termination dates for copay group subjects provided no indication that the termination dates were related to the timing of the copay increase. In Plan B, approximately 28% of subjects were not continuously eligible, and their termination dates were evenly distributed over time. In Plan A, approximately 73% of subjects were not continuously eligible; of these subjects, 26% enrolled in the plan after January 1, 1996, 14% terminated the plan on December 31, 1995, 22% terminated on December 31, 1996, and the remaining 33% had termination dates that were distributed evenly over time, indicating that this plan had a high turnover. Furthermore, additional analyses indicated that individuals who terminated before 1997 were not higher utilizers than those who were continuously eligible. The mean CDS, which can range from 0 to 13, was slightly higher in the control group but was not of clinical significance based on the initial validation study.

Table 1. Sample Selection

	Control Group	Copay Group
Enrollees	14,316	4091
Non-continuously eligible	5277	2487
No match	7447	12
Final sample size	1592	1592
Final sample size for adults (age >17 yrs)	1112	1112
Mean age (years)	41	41
Female (%)	48	48
Mean CDS	0.89	0.65

CDS = Chronic disease score.

Bivariate Analyses: Comparison of Changes After Copay Increase

Bivariate data (Table 2) are presented for the copay and control groups, as well as for each of the 2 plans within the copay group. The changes in participation rate, total plan cost, total ingredient cost, total brand cost, total claims, and total brand claims were significantly greater for the control than for the copay group. Specifically, plan cost increased $31 for the control group and decreased approximately $18 for the copay group ($P<.0001$). Total brand claims increased by 0.70 for the control group and decreased by 0.15 for the copay group ($P=.0001$). The change in generic fill rate was significantly greater for the copay than for the control group, as was the change in total copay. Total copay increased $16 for the copay group compared with $3 for the control group.

Logistic Regression Analysis of Participation

Logistic regression analysis (Table 3) indicated that the copay group was associated with a decreased likelihood of being a participant in the post-period ($P<.01$), whereas increasing age, higher CDS, female gender, being a participant in the pre-period, and having a greater number of claims in the

Table 2. Mean Utilization and Expenditures

Variable	Control (n = 1112)			Copay (n = 1112)			Mann-Whitney *P* value (2-tailed)
	Pre	Post	Change	Pre	Post	Change	
Participation rate	0.55	0.59	0.04	0.55	0.54	-0.01	n/a
Plan A (n = 820)				0.61	0.60	-0.01	n/a
Plan B (n = 772)				0.48	0.47	-0.01	n/a
Total plan cost ($)	125.0	155.8	30.8	198.6	181.1	-17.5	.0000
Plan A				268.9	247.8	-21.1	n/a
Plan B				129.4	115.3	-14.0	n/a
Total copay ($)	33.6	36.7	3.1	40.2	56.4	16.2	.0000
Plan A				52.5	70.2	17.6	n/a
Plan B				27.9	42.8	14.9	n/a
Total ingredient cost	158.6	192.5	34.0	238.8	237.3	-1.5	0.0204
Plan A				321.4	317.9	-3.5	n/a
Plan B				157.3	157.9	0.6	n/a
Total brand cost ($)	129.5	163.3	33.8	198.6	192.5	-6.1	0.0056
Total generic cost ($)	29.1	29.3	0.2	40.1	44.8	4.7	0.6949
Total claims	4.62	5.74	0.60	5.88	5.74	-0.14	0.0135
Plan A				7.46	7.36	-0.10	n/a
Plan B				4.32	4.15	-0.18	n/a
Total brand claims	2.98	3.68	0.70	3.79	3.64	-0.15	0.0001
Total generic claims	1.63	1.54	-0.10	2.09	2.10	0.02	0.6304
Mean cost/claim ($)*	32.6	34.4	1.8	37.0	37.4	0.4	0.6507
Plan A				39.4	40.0	0.6	n/a
Plan B				33.8	34.0	0.1	n/a
Generic fill rate*	0.37	0.30	-0.06	0.36	0.37	0.01	0.0030
Plan A				0.36	0.36	0.00	n/a
Plan B				0.36	0.38	0.02	n/a

*The difference was calculated for those subjects who had one or more claims for the variable of interest in the pre-period and the post-period.

pre-period were all associated with an increased likelihood of participation in the post-period.

Linear Regression Analyses

In the linear regression analyses, a higher pre-period value was associated with a higher post-period value for every dependent variable, with the exception of the generic fill rate (Table 4). CDS was also associated with a higher post-period value for each of the dependent variables with the exception of generic fill rate. Female gender was associated with a higher post-period value for every variable except mean cost per claim (not significant) and generic fill rate (significantly lower). Similarly, increasing age was

Table 3. Logistic Regression of Participation in the Post-Period

Variable	Exponentiated beta values	*P*
Copay	0.74	<.01
Age	1.02	<.001
CDS	1.17	<.05
Female gender	1.44	<.001
Participant in pre-period*	3.12	<.001
Total no. of claims in pre-period	1.22	<.001

CDS = chronic disease score; n = 2224; model chi square = 909.64; *P* value <.001; cases classified correctly = 78%.
*Participant was coded as 1 if the subject had one or more claims in the period and 0 otherwise.

Table 4. Regression Coefficients From Linear Regression Models

		Predictor					
Dependent Variable*	n	Copay	Age	CDS	Female gender	Pre-period equivalent*	Adjusted R^2
Total plan cost	2224	–0.401§	0.030§	0.317§	0.437§	0.525§	0.44
Total ingredient cost	2224	–0.259†	0.031§	0.304§	0.552§	0.538§	0.44
Total brand cost	2224	–0.343‡	0.032§	0.315§	0.560§	0.515§	0.42
Total generic cost	2224	0.167	0.017§	0.388§	0.255†	0.373§	0.30
Total claims	2224	–0.117	0.018§	0.171§	0.304§	0.572§	0.50
Total brand claims	2224	–0.175‡	0.017§	0.156§	0.294§	0.577§	0.50
Total generic claims	2224	0.099	0.010§	0.209§	0.157†	0.403§	0.32
Mean cost/claim	983	–0.003	0.007§	0.026§	–0.049	0.303§	0.15
Generic fill rate	983	0.070§	–0.003‡	–0.0004	–0.067§	–0.655§	0.34

CDS = chronic disease score.
*All dependent variables represent the post-period, and all have been log transformed, except generic fill rate. Pre-period equivalent (log transformed) of the dependent variable being examined.
†$P < .05$.
‡$P < .01$.
§$P < .001$.

Figure 2. Survival Curves From the Cox Regression Analysis

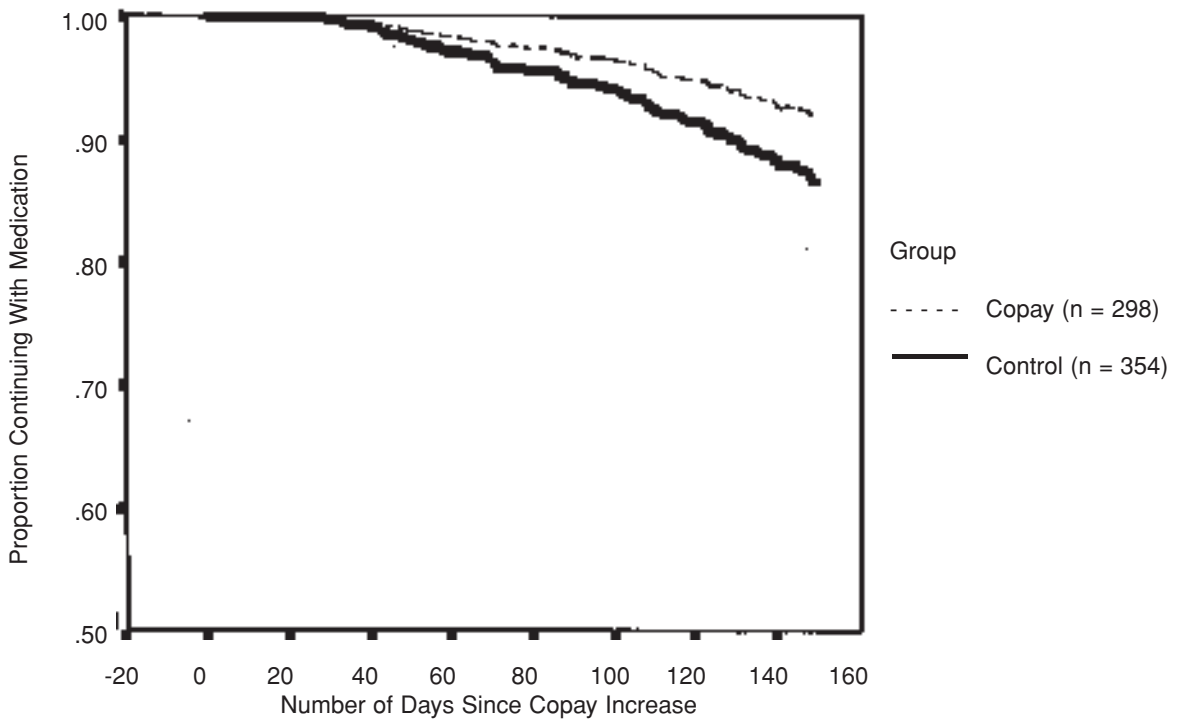


Table 5. Utilization of Essential and Discretionary Medications Among Adults

Variable	Control (n = 1112)	Copay (n = 1112)	Mann-Whitney *P* value (2-tailed)
Change in brand utilization			
Discretionary	0.02	-0.06	0.0703
Essential	0.09	0.03	0.6166
Change in brand expenditures			
Discretionary	1.54	-2.38	0.1588
Essential	10.54	3.60	0.0533
Change in generic fill rate			
Discretionary*	-0.09	0.02	0.0164
Essential†	-0.04	0.04	0.0227

*n = 146 and n = 169 for the control and copay groups, respectively.
†n = 212 and n = 134 for the control and copay groups, respectively.

associated with a higher post-period value for every variable, except the generic fill rate (significantly lower). The copay group had significantly lower total plan costs ($P<.001$), total ingredient costs ($P< .05$), total brand cost ($P<.01$), and total brand claims ($P<.01$), as well as a significantly greater generic fill rate ($P<.001$).

Continuation With Medications for Chronic Illnesses

The percentages of subjects using the selected chronic medications were 32% and 27% for the control and copay groups, respectively. The mean length of use in the pre-period were similar for the 2 groups, at 324 and 315 days, respectively. There were differences across groups in the percentage of subjects with claims in many of the therapy classes. For example, 4.5% of subjects in the control group had utilized progestins compared with 7.5% of copay subjects. Although the desired approach was to compare compliance within each therapy

class, the sample size was insufficient for such an analysis, and we therefore aggregated across each of the therapy classes for the Cox regression analysis. Across all therapeutic classes examined, the likelihood of continuing therapy was actually higher for the copay group after controlling for age, gender, CDS, and previous length of therapy (Figure 2). However, the observed difference may not have any meaningful implication, because at 4 months after the copay increase, at least 90% of subjects in both groups were still continuing with their medication. The results within therapy classes for days supply were similar to those for length of therapy (data not shown).

Use of Essential and Discretionary Medications

No statistically significant differences were observed across study groups for utilization of or expenditures for essential or discretionary brand medications (Table 5). The change in generic fill rate was significantly greater for the copay than for the control group for both essential ($P<.05$) and discretionary medications ($P<.05$).

Sensitivity Analyses

In the 2-part model, the copay group was associated with significantly lower total plan cost and brand claims and significantly higher generic cost, total claims, generic claims, and generic fill rate (Table 6). When patients exceeding the 75th percentile of costs ($174) were removed from the analysis, the mean pre-period cost was $30 for the control group and $26 for the copay group. The only noted difference from the baseline analysis was that total claims were significant. The same held true when Plan A was excluded from the regression. When the Cox regression analysis of length of therapy was conducted without Plan A, results were robust. Similar results were observed when analyses were conducted at the family level (Table 7). In the sensitivity analysis that included all continuously eligible subjects, results were generally consistent, with the exception that the copay group was not associated with a statistically significantly

Table 6. Linear Regression Coefficients for Copay Variable From Sensitivity Analyses

	Model		
Dependent Variable*	**Two-Part Model**	**Plan A Removed**	**Upper Quartile Removed**
Total plan cost	-0.202†	-0.672§	-0.591§
Total ingredient cost	0.099	-0.502§	-0.452‡
Total brand cost	-0.242	-0.578§	-0.519§
Total generic cost	0.535§	-0.048	0.002
Total claims	0.089†	-0.252‡	-0.211‡
Total brand claims	-0.144†	-0.283§	-0.239§
Total generic claims	0.312§	-0.033	-0.004
Mean cost/claim	-0.003	-0.067	-0.125
Generic fill rate	0.070§	0.090§	0.090‡

*All dependent variables represent the post-period, and all have been log transformed except generic fill rate.
†$P<.05$.
‡$P<.01$.
§$P<.001$.

Table 7. Change in Utilization and Expenditures at the Individual and Family Level

	Individual as Unit of Analysis	**Family as Unit of Analysis**
Change in total ingredient cost ($)		
Control	34	36
Copay	1.50	2.80
Change in total brand claims		
Control	0.70	0.73
Copay	-0.15	-0.30
Change in generic fill rate		
Control	-0.06	-0.07
Copay	0.01	0.01

lower ingredient cost or brand cost, although the coefficients were negative.

···DISCUSSION ···

This study found that for an adult population, an increase in brand copay from $10 to $15 was associated with reduced brand utilization and expenditures, reduced overall expenditures, and increased generic utilization without a reduction in continuation with chronic medications.

Several approaches were used to rule out plausible alternative explanations for our findings. Plans were selected that had comparable pharmacy benefit designs and no changes in other medical benefits between the pre- and post-periods. Although statistical regression to the mean could be a concern because of the substantial difference in baseline costs between Plan A and the control group, the patterns of change for Plans A and B were consistent relative to the control group; and in a sensitivity analysis that included only Plan B, results were robust. The possibility that selection bias or inherent differences in the treatment and control groups could somehow explain the study findings was addressed by careful selection of study groups as discussed above, control of other potential demographic confounders through matching and statistical control, and by a sensitivity analysis that included only those patients with comparable baseline costs. The representativeness of the control group is evidenced by its observed drug trend. Without any intervention, we would have expected both groups to experience significant increases in drug costs between 1996 and 1997 because published data shows that plans' expenditures for drugs increased an average of 16% between 1996 and 1997.[2] We would, therefore, have been concerned about the comparability of the control group if its drug costs had not increased from 1996 to 1997. However, the control group's ingredient cost grew a comparable 21% during this same time period, suggesting that this plan's drug cost trends were fairly representative of a typical plan.

The copay evaluated in this study was higher, even after accounting for inflation, than copays examined in previous research, yet subjects were not very sensitive to the copay increase. The $5 increase in brand copay was associated with 17.5% lower brand utilization relative to the control group. On the basis of these figures, the price elasticity is –0.35, which compares well with the range of –0.10 to –0.30 found in previous research and indicates that demand for prescriptions is relatively inelastic, even at a $15 copay level.[8] Although there may be a threshold copay amount at which individuals become substantially more sensitive to the price of medication, $15 does not appear to be that threshold.

In addition to lowering payer costs, the copay appears to lower total ingredient and brand cost as well, even when high-cost subjects are not considered. As expected, the sensitivity analysis demonstrated that the reduction in plan costs was not as great when only subjects with utilization in the post-period were considered. Regarding the question of whether persons alter their medication utilization habits to decrease their out-of-pocket costs beyond merely decreasing use, there was evidence that individuals facing a higher brand copay had a higher generic fill rate. These findings contrast with the Rand HIE results, which found no relationship between the level of cost-sharing and the percentage of prescriptions filled with generic drugs.[19] Possible explanations for this inconsistency include changes over time in the type and number of generic drugs available, individuals' preference or willingness to use generic medications, and the relative costs of generic and brand medications. Another difference from the HIE was that patients were not reimbursed or compensated for any out-of-pocket prescription costs incurred; furthermore, in the HIE, the coinsurance for drugs was combined with coinsurance for office visits.

The utilization of essential and discretionary medications would be expected to increase over time in the control group in the absence of any change in plan design. Furthermore, one could anticipate a smaller increase in a plan experiencing a copay increase; the change could be zero or even negative for certain drug groups such as the discretionary medications. Our findings followed this logic, but the results did not reach statistical significance. Several factors may explain why the copay increase did not have a greater effect on the utilization of discretionary compared with essential medications. First, the sample size in this study was considerably smaller than in a previous study that found a differential impact. Second, the therapy class may have little impact since subjects were not sensitive overall to the price of any medications. Furthermore, it is possible that Grossman demand model assumptions of consumer sovereignty and full information are incorrect, that the research definition of essential and discretionary medication does not coincide with patients' perceptions, or that patients do not share a consistent view about which

medications are essential and which are discretionary. Because the finding of a differential effect for essential versus discretionary medications across several studies has been inconsistent,[20] and because a multivariate analysis was not possible in this study, the issue warrants further exploration.

Beyond the actual magnitude of prescription savings, the question of interest to researchers, payers, and consumers is whether such a copay increase has undesirable consequences. Although we were unable to examine overall medical costs or quality of life, this is the first study that actually examines the effect of a copay increase on continuation with chronic medications. This is an important consideration because continuation of medication is the link, if one exists, between copay changes and overall medical costs; because at least for chronic conditions, an increase in overall medical costs resulting from a higher copay must arise from patients discontinuing essential chronic medications.

Our study shows that the higher copay did not result in adverse health effects or future cost consequences—subjects experiencing a higher copay were as likely to continue with their chronic medications as were subjects with a lower copay, at least for the medical conditions studied. This finding is consistent with previous research. Several studies have examined the relationship between copay increases and overall medical costs, but none has found a consistent and convincing relationship.[15] Johnson et al did find greater decreases in health status among patients who had experienced increases in prescription cost-sharing, but the authors made no link between decreased health status and decreased use of essential medications. Equally important, the health status measure used was not based on patient surveys or medical records but on claims information. The claims-based algorithm, which was developed by the study authors, had not been validated.[11] In addition, in a separate article that examined the same population, Johnson et al found no consistent pattern between cost-sharing increases and changes in overall medical costs over a 5-year period.[5] In the HIE, no definitive and meaningful relationship was observed between higher cost-sharing levels and reduced health status,[21] and the study results did not support the notion that patients with less generous insurance substitute physician visits for medications. The small sample size in our investigation necessitated aggregation across therapy classes for the compliance analysis; future research should examine the effect of cost-sharing on compliance with chronic medications by individual therapy class.

Limitations of the Study. The length of the study was shorter than desired. To better account for underlying trends, Soumerai et al recommend use of a time-series approach, which requires a substantially longer analysis period than was available for this study.[14] We concur with Soumerai's recommendation, but it is becoming increasingly difficult to identify plans that do not experience major changes in plan design on a yearly basis and that have a sufficient number of subjects who are continuously enrolled over multiple years. Soumerai et al also advocate at least 2 years of follow-up to assess whether patients learn to overcome policy changes with time. The fact that our study found the copay increase to be associated with a higher generic fill rate suggests that subjects were already exhibiting a learning effect. Because this analysis used a population of continuously enrolled adults who primarily received their health insurance through their place of employment, it is not known whether a copay increase of this magnitude is a significantly greater or smaller deterrent to utilization in other subpopulations, such as lower- income, more severely ill, noncontinuously eligible individuals, the elderly, or children.

Conclusions

Although the growth in overall medical costs has slowed in recent years, pharmacy expenditures are still experiencing double-digit increases. Payers use many techniques to control these costs while trying to encourage the appropriate use of medications. However, overaggressiveness in managing the pharmacy benefit may lead to an increase in overall medical costs or may adversely affect patients' quality of life by deterring utilization of essential medications.[22] Although this study found no relationship between a higher copay and continuation with chronic medications, more research is needed to examine the relationship between copay levels, overall medical costs, quality of life, and patient satisfaction, as evidenced through medication continuation (compliance) patterns. Notably lacking from previous research is a link between compliance and use of other services. Although some studies have found a correlation between copay increases or formulary closures and overall medical costs, no study has provided a causal link by demonstrating, at the patient level, that the increase in overall medical costs is the result of noncompliance or perhaps utilization of inferior or inappropriate medications.

Such a connection would be difficult to demonstrate because even with the availability of full medical claims or quality-of-life data, the adverse consequences of discontinuation may emerge only after several years. Another difficulty would be finding an organization with a meaningful number of patients who could be monitored for a long period of time.

Acknowledgments

The authors wish to thank Kathleen Fairman, MA, and Fred Teitelbaum, PhD, for their suggestions and Andy Parker, MBA, for his assistance on this project. Preliminary results from this study were presented at the 1998 Express Scripts-ValueRx Outcomes Conference held in St. Louis, MO in July 1998.

···REFERENCES ···

1. Bureau of Labor Statistics, 1998. Available at http://stats.bls.gov. Accessed July 21,1999.
2. Teitelbaum F, Parker A, Martinez R. *Express Scripts-ValueRx 1997 Drug Trend Report.* St. Louis, MO: Express Scripts; 1998.
3. *Wyeth-Ayerst Prescription Drug Benefit Cost and Plan Design Survey Report: 1998 Edition.* Albuquerque, NM: PMBI Inc, and Wellman Publishing, Inc; 1998.
4. Grossman M. *The Demand for Health: A Theoretical and Empirical Investigation.* New York, NY: Columbia University Press (for the National Bureau for Economic Research); 1972.
5. Johnson RE, Goodman MJ, Hornbrook MC, Eldredge MB. The effect of increased prescription drug cost-sharing on medical care utilization and expenses of elderly health maintenance organization members. *Med Care* 1997;35:1119-1131.
6. Harris BL, Stergachis A, Ried LD. The effect of drug co-payments on utilization and cost of pharmaceuticals in a health maintenance organization. *Med Care* 1990;28:907-917.
7. Nelson AA, Reeder CE, Dickson WM. The effect of a Medicaid drug copayment on the utilization and cost of prescription services. *Med Care* 1984;22:724-736.
8. Smith DG, Kirking DM. Impact of consumer fees on drug utilisation. *PharmacoEcon* 1992;2:335-342.
9. Smith DG. The effects of copayments and generic substitution on the use and costs of prescription drugs. *Inquiry* 1993;30(2):189-198.
10. Winslow R. Co-payments rise for prescriptions. *The Wall Street Journal*, January 12, 1999:B1.
11. Johnson TE, Goodman MJ, Hornbrook MC, Eldredge MB. The impact of increasing patient prescription drug cost sharing on therapeutic classes of drugs received and on the health status of elderly HMO members. *Health Serv Res* 1997;32:103-122.
12. Reeder CE, Nelson AA. The differential impact of copayment on drug use in a Medicaid population. *Inquiry* 1985;22:396-403.
13. Col N, Fanale JE, Kronholm P. The role of medication noncompliance and adverse drug reactions in hospitalizations of the elderly. *Arch Intern Med* 1990;150:841-845
14. Soumerai SB, Ross-Degnan D, Fortess EE, Abelson J. A critical analysis of studies of state drug reimbursement policies: Research in need of discipline. *Milbank Q* 1993;71:217-252.
15. Levy RA. Prescription cost sharing: Economic and health impacts, and implications for health policy. *PharmacoEcon* 1992;2:219-237.
16. Reeder CE, Lingle EW, Schulz RM, et al. Economic impact of cost-containment strategies in third party programmes in the US (Part I). *PharmacoEcon* 1993;4:92-103.
17. Cook TD, Campbell DT. *Quasi-Experimentation. Design and Analysis Issues for Field Settings.* Boston, MA: Houghton Mifflin Company; 1979.
18. Von Korff M, Wagner EH, Saunders K. A chronic disease score from automated pharmacy data. *J Clin Epidemiol* 1992;45:197-203.
19. Leibowitz A, Manning WG, Newhouse JP. The demand for prescription drugs as a function of cost-sharing. *Soc Sci Med* 1985;21:1063-1069.
20. Lohr KN, Brook RH, Kamberg CJ, et al. Use of medical care in the Rand Health Insurance Experiment. Diagnosis- and service-specific analyses in a randomized controlled trial. *Med Care* 1986;24(suppl 9):S1-98.
21. 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; 251-277.
22. Foxman B, Valdez B. Lohr K, et al. The effect of cost sharing on the use of antibiotics in ambulatory care: Results from a population-based randomized controlled trial. *J Chronic Dis* 1987;40:429-437.