Effect of Prescription Benefit Changes on Medical Care Utilization in a Medicare HMO Population

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Objective: To examine the impact of 2 cost-containment efforts in prescription benefits in successive years that included changes in copayment and coverage levels, expanded generic coverage, and brand name prescription drug limit-of-coverage in a Medicare health maintenance organization (HMO). The benefit changes included moving to a drug benefit with increased total coverage and higher copayments in the first year (1998) and to one with brand name limit-of-coverage and unlimited generic availability in the second year (1999).

Study Design: A repeated-measures analytical design with enrollee follow-up before and after introduction of the 2 policies.

Patients and Methods: A cohort of 2411 older adults continuously enrolled in a Medicare HMO since 1998 was followed up for 1 year pre-post for healthcare service utilization and costs; 259 patients enrolled since 1997 were available to test the effects of the first policy change.

Results: Bivariate and multivariate analyses found a significant decrease of 27% in prescription costs, a 4% decrease in physician visits, and a 6% decrease in total costs associated with the change in prescription benefit in the second year (1999). The policy change in the first year (1998) resulted in a 29% increase in prescription costs and 38% increased total costs for the HMO.

Conclusions: Introduction of a prescription benefit that included substantial brand name limit-of-coverage and generic drug coverage expansion was associated with significantly reduced prescription costs. In addition, this change did not seem to increase nonprescription-related healthcare service use in the population.

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Because traditional Medicare does not include provisions for outpatient drug coverage, many Medicare managed care plans that cover prescription drugs are likely to be faced with the prospect of increased medication use by the elderly. Many managed care organizations, underestimating the potential benefit of prescription drug coverage in the long run (improvement in patient health outcomes with improved medication compliance), have opted to place restrictions on prescription drug coverage to curtail the high healthcare costs associated with the elderly enrollee.[1] A few studies[2-4] have individually examined the impact of cost-sharing strategies (such as copayment level changes and prescription expenditure caps) on changes in healthcare service utilization in managed care plans with elderly enrollees (age ≥65 years).

A study by Johnson et al[2] of 2 insured Medicare risk groups showed that small increases in drug copayments had no significant effect on exposure to or the cost of therapeutic drugs. However, large increases in copayments resulted in a significant reduction in exposure to drugs, which could have contributed to the observed decline in the health of the elderly.[2] A more recent study by Popovian and colleagues[3] focused on the effect of drug payment capitation on healthcare expenditures of Medicare enrollees and showed that patients with capitated pharmaceutical reimbursements were more likely to have increased pharmacy expenditures as well as increased nonprescription-related healthcare utilization and costs. The authors, based on the study find-

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ings, raised serious doubts about using policies limiting access to drugs as a means of decreasing healthcare costs.[3]

A comparative study by Soumerai and colleagues[4] examined the effects of restricting reimbursement of drug payments on the rate of admission of the elderly population to hospitals and nursing homes. Results showed a significant increase in admissions to nursing homes for elderly patients enrolled in a restrictive Medicaid plan and no significant change in hospitalization rates.[4]

Although it is tempting to deduce that curtailing access to medications via cost-control mechanisms can adversely affect other health costs and increase total healthcare service utilization, the findings from these studies are mixed. Additional studies are needed to compare and contrast different cost-sharing strategies in similar populations to examine the relative impact of each strategy on healthcare costs in Medicare managed care plans.

To curtail unsustainable financial losses, a large Medicare health maintenance organization (HMO) in the southeastern United States changed its coverage policy twice in 2 years. The 2 prescription benefit changes consisted of moving to a drug benefit with increased total coverage and higher copayments in the first year (1998) and to one with brand name limit-of-coverage and unlimited generic availability in the second year (1999). The second change, in particular, was strongly influenced by a thorough examination of the weight of existing evidence in the literature by the HMO's Pharmacy and Therapeutics Committee. Other than the change in the prescription benefits, no other interventions were undertaken that would affect medical resource utilization in this population.

We examined the impact of these 2 policy changes in prescription benefits on total healthcare service utilization and costs in cohorts of continuously enrolled Medicare HMO enrollees 1 year before and after the policy changes.

··· METHODS ···

Study Population

The study population comprised older adults enrolled in a Medicare managed care plan in the southeastern United States. This managed care plan has been operational since late 1996 and is the sole provider of medical care to enrollees ("lock-in" risk benefit plan). Availability of a discount even while filling prescriptions after the monthly coverage limit was exhausted enabled us to accurately capture prescription refill rates before and after introduction of the new prescription benefit.

A cohort of 2411 older adults continuously enrolled in the Medicare HMO from January 1, 1998, who had completed a comprehensive baseline risk assessment on enrollment in the plan and were receiving the drug benefit was followed up for healthcare service utilization and costs 1 year before and after introduction of the new prescription benefit effective January 1, 1999 (population A). Because the HMO began operation only in late 1996, we were restricted to a small sample of 259 patients who could be followed up for healthcare service utilization and costs 1 year before and after introduction of the new prescription benefit effective January 1, 1998 (population B). The study design is represented in the **Figure.**

Prescription Policy Changes in the Medicare HMO

The initial prescription benefit policy (1997) had a $500 *annual* coverage limit, with a $6 copayment for generic drugs and a $12 copayment for brand name drugs. This policy changed on January 1, 1998, to a $200 *quarterly* coverage limit, with a $7 copayment for generic drugs and a $15 copayment for brand name drugs. Based on recommendations in the existing literature on adverse reports of increased cost sharing on use of chronic medications, there was a second policy change on January 1, 1999, to unlimited coverage of generic drugs, with a $5 copayment, and a restriction of brand name drugs to $25-per-month coverage, with a $15 copayment.

Analytical Methods

We compared changes across the 2 years in populations A and B using bivariate and multivariate techniques. For the multivariate estimations, we used a random-effects modeling technique, adjusting for person-specific differences across time and baseline differences across enrollees.[5] (In a panel, the intercept could vary according to different cross-sectional units [eg, in this case, individual participants or time periods]. Use of the random-effects model in this case, instead of ordinary least squares regression, reduces the need for several extra dummy variables to account for different cross-sectional units by having an overall intercept and an error term with 2 components: the traditional error term unique to each observation and an error term that represents the extent to which the intercept of a particular cross-sectional unit differs from the overall intercept. This composite error term allows for esti-

mation of the model using estimated generalized least squares.) We used the Lagrange multiplier to determine whether there were unobserved person-specific differences across time, warranting the necessity of this approach.[6] In addition, we used the specification test proposed by Hausman[7] to examine whether these unobserved individual effects were systematic or nonsystematic to determine whether the fixed-effects or the random-effects model was more appropriate. The results of these tests conducted on the 2 total healthcare cost regressions ($\chi^2 = 4.61$, $P = .10$ for population A and $\chi^2 = 2.75$, $P = .26$ for population B) led to the conclusion that the random-effects technique was appropriate in these estimations.

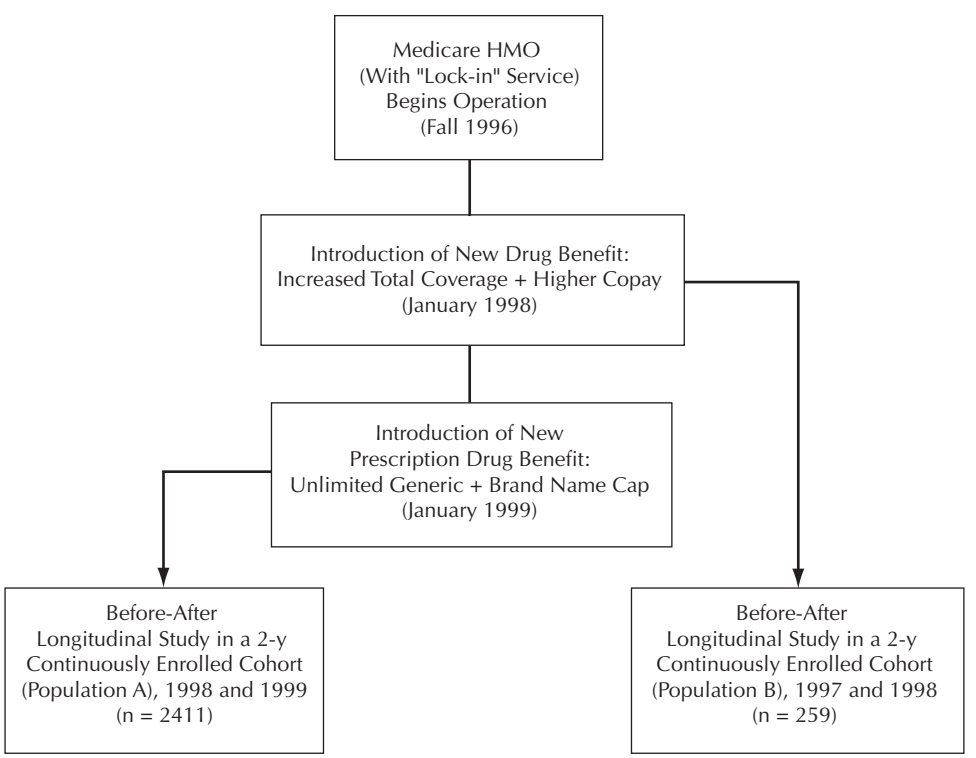
The dependent variables in the regression analyses were healthcare services (inpatient admissions [including emergency department] and outpatient facility [including physician office] visits) and healthcare costs (prescription costs and total annual costs). Because the distribution of the dependent variables was skewed, the natural logarithm of the dependent variables was used for all regressions. The multivariate regressions controlled for baseline differences in study patients.

The basic model that was estimated was as follows:

$$\textit{Natural Log (UTILIZATION/COSTS)} = \beta 0 + \beta 1\ \textit{Year Dummy} + \beta 2\ \textit{Baseline Demographics} + \beta 3\ \textit{Baseline Health Status Measurements} + \beta 4\ \textit{Baseline Medication Use} + \varepsilon$$

The parameter estimates obtained from regressing log-transformed costs on covariates were interpreted using the correction proposed by Halvorsen and Palmquist,[8] with a modification by Kennedy.[9] We accounted for zero values (<5% in the case of inpatient admissions, no zero values of outpatient visits/charges) by including a small value (0.01) instead of zero in the regressions. We also conducted additional tests suggested by Manning[10] to determine if the log-transformations caused any heteroskedasticity problems (variance of the error terms correlated with one or more explanatory variables), and we used generalized least squares to

Figure. Description of the Study Design



HMO = health maintenance organization.

obtain efficient regression estimates. All analyses were conducted using Stata statistical software.[11]

Because the study was conducted from a payer perspective, we used the costs reimbursed by the HMO in our calculations. We also examined changes in prescription refill rates for 5 of the most commonly used medication classes (angiotensin-converting enzyme inhibitors, 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitors, calcium channel antagonists, β-adrenergic blocking agents, and selective serotonin reuptake inhibitors) in this population. Baseline control variables included the Charlson comorbidity severity index score,[12] demographics, medication type variables (chronic medications are defined as those with ≥2 refills in 6 months), and baseline health status (measured at the time of enrollment using a comprehensive health risk assessment questionnaire battery).[13,14] A dummy variable for year was used in the models to estimate changes in the dependent variables across the 2 years after adjusting for person-specific differences at baseline and across the years. The variables in the regressions, which varied with time, were age and the year dummy. All the costs in the study were adjusted using the healthcare component of the Consumer Price Index to reflect 1998 costs.[15]

··· RESULTS ···

The baseline characteristics of the 2 study populations are outlined in **Table 1**. Nearly 73% of the overall population were women, and although the average comorbidity severity score was <2 on the Charlson index, 17% to 24% of enrollees reported being in poor health. Populations A and B had similar values for many study variables.

Table 2 outlines the differences in average annual healthcare service utilization, costs, and the number of prescription refills across the 2 years for population A. There was a 4.6% decrease in annual outpatient visits, a 9.6% decrease in the total number of different types of nonchronic medications (chronic medications are defined as those with ≥2 refills in every 6-month time window), and a 36% decrease in prescription costs (all $P < 0.05$) across the 2 years using the *t* test of unequal variances. There were no significant differences across the 2 years for other types of healthcare service utilization and costs or in the average number of refills for the 5 most commonly used therapeutic classes of medications.

Table 3 examines the differences in average annual healthcare service utilization, costs, and the number of prescription refills across the 2 years for population B. There was a 25.2% increase in annual inpatient admissions, a 125% increase in the total number of different chronic medications, and a 43.1% increase in total enrollee costs (all $P < 0.05$) across the 2 years using the *t* test of unequal variances. There were no significant differences across the 2 years for other types of healthcare service utilization and costs or in the average number of refills for the 5 most commonly used therapeutic classes of medications.

The multivariate random-effects generalized least squares

Table 1. Baseline Health Risk Assessment (1997) in the 1998-1999 Study Population (A) and the 1997-1998 Study Population (B)*

Variables	Population A (n = 2411)	Population B (n = 259)
Age, y (1998)†	73.8 (5.9) [65-98]	68.9 (7.7) [65-90]
Proportion female	0.73 (0.45) [0-1]	0.72 (0.45) [0-1]
Proportion heavy smokers (>1 pack per day)	0.14 (0.34) [0-1]	0.14 (0.34) [0-1]
Proportion high alcohol consumers (≥4 drinks per day)†	0.096 (0.30) [0-1]	0.17 (0.38) [0-1]
Proportion >1 fall†	0.084 (0.28) [0-1]	0.10 (0.31) [0-1]
Proportion reporting health worsening	0.16 (0.37) [0-1]	0.17 (0.37) [0-1]
Proportion reporting health poor†	0.24 (0.42) [0-1]	0.17 (0.37) [0-1]
SF-12 general health†	60.18 (24.92) [0-100]	65.52 (23.50) [0-100]
Proportion with depressive symptoms	0.12 (0.33) [0-1]	0.12 (0.33) [0-1]
Proportion sedentary†	0.41 (0.49) [0-1]	0.47 (0.50) [0-1]
Proportion living alone	0.29 (0.45) [0-1]	0.29 (0.45) [0-1]
Charlson comorbidity severity index total score†	1.81 (1.78) [0-12]	1.47 (1.60) [0-9]

*Data are given as mean (SD) [range]. See the "Study Population" subsection for a complete description of populations A and B.
†The difference across the 2 groups was significant at the 5% level using the *t* test of unequal variances for continuous variables and the χ^2 test for categorical variables.

regressions in population A accounted for nearly 34% of the variance in healthcare costs and 19% to 32% of the variance in healthcare service utilization (**Table 4**). We found a significant decrease of 27.4% ($P < 0.05$) in prescription costs associated with the change in prescription benefit in the second year, after accounting for person-specific differences and other potential baseline confounders. There were no significant changes in other healthcare service costs. Overall, annual total healthcare costs significantly reduced by 6.2% in the second year. There were no significant changes in inpatient visits across the 2 years. There was a significant reduction of 4.4% ($P < 0.05$) in outpatient visits in the second year. Other baseline variables that were significantly associated with increased healthcare costs and utilization included increased severity of comorbidity, poor general health reported on the Short Form-12, and the number of different medications for which the patient had refills.

Table 5 presents the results of the multivariate random-effects generalized least squares regressions in population B. These regressions explained nearly 52% to 58% of the variance in healthcare service costs and 51% to 60% of the annual healthcare service use. There were no significant changes in outpatient and inpatient visits with the first policy change in this subsample. However, both prescription and total healthcare costs increased by 29.0% and 37.9%, respectively. Other baseline variables that were significantly associated with increased healthcare service utilization

Table 2. Differences in Average Healthcare Service Utilization in Population A (n = 2411) Across the 2 Study Years*

Variables	Year 1 (1998)	Year 2 (1999)
Total outpatient visits, No.†	11.17 (9.37)	10.68 (9.42)
Total inpatient/emergency department admissions, No.	7.42 (10.31)	7.40 (10.40)
Different chronic medications, No.	0.72 (1.08)	0.74 (1.18)
Different nonchronic medications, No.†	7.22 (5.82)	6.59 (6.35)
Annual costs for prescriptions, $†	404 (381)	297 (399)
Total annual costs for enrollee, $	3365 (7495)	3149 (8116)
Angiotensin-converting enzyme inhibitor refills, No.	1.42 (3.40)	1.38 (3.37)
Calcium channel antagonist refills, No.	1.60 (3.59)	1.54 (3.48)
3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitor refills, No.	1.44 (3.26)	1.36 (3.22)
β-Adrenergic blocking agent refills, No.	1.26 (3.13)	1.29 (3.20)
Selective serotonin reuptake inhibitor refills, No.	0.38 (1.70)	0.36 (1.66)

*Data are given as mean (SD). See the "Study Population" subsection for a complete description of population A.
†The difference across the 2 years was significant at the 5% level using the *t* test of unequal variances.

Table 3. Differences in Average Healthcare Service Utilization in Population B (n = 259) Across the 2 Study Years*

Variables	Year 1 (1997)	Year 2 (1998)
Total outpatient visits, No.	6.73 (12.14)	8.00 (11.79)
Total inpatient/emergency department admissions, No.†	4.17 (7.53)	5.22 (9.46)
Different chronic medications, No.†	0.20 (0.71)	0.45 (1.78)
Different nonchronic medications, No.	4.38 (7.55)	5.13 (7.17)
Annual costs for prescriptions, $	348 (972)	448 (1180)
Total annual costs for enrollee, $†	1731 (4236)	2477 (5670)
Angiotensin-converting enzyme inhibitor refills, No.	0.61 (2.16)	0.81 (2.64)
Calcium channel antagonist refills, No.	0.76 (2.60)	0.90 (2.72)
3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitor refills, No.	0.55 (2.03)	0.76 (2.42)
β-Adrenergic blocking agent refills, No.	0.32 (1.60)	0.42 (1.69)
Selective serotonin reuptake inhibitor refills, No.	0.23 (1.34)	0.42 (1.68)

*Data are given as mean (SD). See the "Study Population" subsection for a complete description of population B.
†The difference across the 2 years was significant at the 5% level using the *t* test of unequal variances.

Table 4. Results of Random-Effects Generalized Least Squares Regressions on the Effects of the Policy Change on Annual Healthcare Costs and Utilization Adjusting for Enrollee-Specific Differences for Population A (n = 2411 x 2 = 4822 person-years)*

Predictor Variables	Dependent Variables			
	Natural Log of Prescription Costs	Natural Log of Total Healthcare Costs	Natural Log of Annual Outpatient Visits	Natural Log of Annual Inpatient Admissions
Year variable	–0.32 (0.023)†	–0.064 (0.032)‡	–0.044 (0.015)‡	NS
Age	NS	NS	0.10 (0.043)‡	NS
Age squared	NS	NS	–0.00069 (0.00028)‡	NS
Male sex	0.12 (0.053)‡	0.17 (0.046)†	NS	NS
Heavy smoker	–0.24 (0.070)†	NS	NS	NS
High alcohol consumer	NS	NS	0.13 (0.042)†	NS
Living alone	0.11 (0.053)‡	NS	NS	0.13 (0.060)‡
Comorbidity severity	NS	0.15 (0.011)†	0.094 (0.0072)†	NS
Perception of worsening health	0.13 (0.062)‡	NS	0.11 (0.034)†	0.099 (0.0098)†
Perception of poor general health	0.23 (0.10)‡	NS	NS	NS
SF-12 general health	–0.0086 (0.0018)†	–0.0059 (0.0015)†	0.00031 (0.00095)†	NS
Number of different chronic medications (baseline)	0.31 (0.015)†	0.077 (0.017)†	0.026 (0.0095)‡	NS
Number of different nonchronic medications (baseline)	0.084 (0.0033)†	0.10 (0.0033)†	0.050 (0.0019)†	.052 (0.0028)†
Constant	6.60 (2.97)‡	9.50 (2.59)†	2.19 (1.62)	1.32 (2.28)
Adjusted R^2	0.34	0.34	0.32	0.19

*Data are given as parameter estimate (SE). The following variables were not significant at the 5% level across all categories: sedentary status, >1 fall, and baseline depressive symptoms. NS indicates not significant even at the 5% level. See the "Study Population" subsection for a complete description of population A.
†Significant at the 0.5% level.
‡Significant at the 5% level.

included increased severity of comorbidity and the number of different chronic medications.

··· DISCUSSION ···

Examination of previous studies on limited drug access policies (drug cost sharing, restricted formularies, etc) most often leads to the conclusion that poor and low-income people, mostly elderly individuals with chronic illness, and disabled people are most adversely affected by implementation of such policies. A couple of ongoing suggestions to minimize such adverse effects, such as providing unlimited drug coverage and cost control at the pharmacy level, could be unrealistic in today's healthcare marketplace. A more plausible solution that has been suggested involves providing a federal-state program to cover poor and low-income people who are ineligible for Medicaid. Other suggestions have included progressive drug copayment (low-income groups pay a lower amount or nothing and higher-income groups share higher amounts of payment), use of comprehensive drug formularies, and cost sharing of these proposed programs by state and federal governments.

A potential contributor to increased drug costs for Medicare HMOs could also be lack of generic substitution, where possible. Many chronic medications used by older adults are available in generic form, which offers comparable therapeutic efficacy at much lower costs. The design of the first prescription benefit took into account costs of medications only. While it increased coverage limits, it increased prescription copayments to contain costs for the HMO. This change was associated with increases in prescription costs and total costs for the HMO. The design of the novel second prescription benefit change took into consideration findings of earlier studies and tried to avoid restricted access to chronic medications by expanding the generic drug cover-

Table 5. Results of Random-Effects Generalized Least Squares Regressions on the Effects of the Policy Change on Annual Healthcare Costs and Utilization Adjusting for Enrollee-Specific Differences for Population B (n = 259 x 2 = 518 person-years)*

Predictor Variables	Dependent Variables			
	Natural Log of Prescription Costs	Natural Log of Total Healthcare Costs	Natural Log of Annual Outpatient Visits	Natural Log of Annual Inpatient Admissions
Year variable	0.26 (0.10)†	0.33 (0.13)†	NS	NS
Age squared	NS	NS	0.00093 (0.00041)	NS
Comorbidity severity	NS	NS	NS	0.11 (0.030)‡
Health worsening perception	NS	NS	0.33 (0.14)†	NS
Number of different chronic medications (baseline)	0.41 (0.093)‡	0.31 (0.12)‡	0.14 (0.039)‡	0.14 (0.044)‡
Number of different nonchronic medications (baseline)	0.27 (0.015)‡	0.32 (0.19)‡	0.12 (0.0063)‡	0.092 (0.0066)‡
Adjusted R^2	0.58	0.52	0.60	0.51

*Data are given as parameter estimate (SE). The following variables were not significant at the 5% level across all categories: age, male sex, heavy smoker, high alcohol consumption, living alone, perception of poor general health, SF-12 general health, sedentary status, falls >1, baseline depressive symptoms, and constant. NS indicates not significant even at the 5% level. See the "Study Population" subsection for a complete description of population B.
†Significant at the 5% level.
‡Significant at the 0.5% level.

age benefit. Very little changes in overall healthcare service utilization were observed in the entire population. There was a significant decrease in prescription costs for the HMO associated with this second change in prescription benefit. There were no significant decreases in refill rates of major classes of medications.

In results not shown, we found an increase of 10% in the total number of prescriptions filled and a 20% increase in generic drug utilization in 1999. The decreased costs associated with the substitution of many brand name drugs by available cheaper generic substitutes could have been one of the factors contributing to the significant reduction in prescription costs, as well as the increases in the quantity of medication used by the population in the second year. One point to note is that many medications in the 5 most commonly used classes were brand name drugs. This also highlights another potential cost-shifting phenomenon in the population. It is likely that monies saved by the newly expanded generic drug availability were channeled by enrollees into the increased out-of-pocket expenses associated with the brand name drugs. This could potentially explain why prescription refills in these 5 major medication categories did not significantly change across the 2 years. The overall increased drug availability (due to expanded generic coverage) could have also potentially contributed to the significant reduction in physician visits in the second year.

A major policy implication of these findings is the importance of the use of evidence-based formulary decision making. The second drug benefit design change, in particular, carefully considered the weight of the existing evidence that pointed to a dramatic compromise in patient health outcomes because of capitating prescription coverage limits or increasing out-of-pocket expenses. The implemented new drug benefit increased generic availability and substitution while capitating brand name drug expenditures, thereby decreasing expenditures for the HMO.

Limitations and Generalizability

Use of the random-effects modeling approach helps us generalize our results to similar older HMO-enrolled populations.[5] However, we acknowledge the limitations of being able to collect only limited demographic, clinical, and utilization-related data because of data privacy constraints. We also recognize the limitations of administrative claims data in the ability to capture complete healthcare service utilization; however, the study HMO had lock-in ben-

efits, and the population would have been very unlikely to obtain additional healthcare coverage. It is also unlikely that patients switched to other plans, as disenrollment rates (other than due to mortality) were very insignificant (<5%). Analysis of these patients has shown that they did not differ in healthcare service utilization in the period before disenrollment from patients included in the study. The response to the health risk assessment was nearly 100% for patients who remained continuously enrolled. Our study criterion probably excluded much of the end-of-life healthcare service utilization. However, the rates of disenrollment due to mortality were not different across the 2 years. We were also limited to a small sample size in population B because of the fact that the plan had started operations only in late 1996. Finally, the observational study design prevents us from treating the effect of the prescription benefit change as a causal factor.

··· CONCLUSION ···

The introduction of the new prescription benefit that included substantial brand name limit-of-coverage and a generic drug coverage expansion was associated with significantly reduced prescription and total healthcare costs for the Medicare HMO. An earlier prescription benefit change that increased limits-of-coverage on prescriptions but also increased prescription copayments was associated with higher healthcare costs. Both changes, however, did not seem to affect prescription refill rates for major therapeutic classes. In both study populations, there was no association of either of the prescription benefit changes with nonprescription-related healthcare service utilization. The increased use of generic drugs was likely to be associated with the slight reduction in physician visits, and both these factors were probably associated with the slight decrease in overall healthcare costs in this population. Further research examining the issue of increased generic substitution in the wake of brand name prescription curtailment in greater detail is needed to generate evidence-based policies encouraging generic substitution of essential chronic medications, where possible.

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