

## SPECIAL ARTICLE

# Unintended Consequences of Caps on Medicare Drug Benefits

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## ABSTRACT

**BACKGROUND**

Little information exists about the consequences of limits on prescription-drug benefits for Medicare beneficiaries.

**METHODS**

We compared the clinical and economic outcomes in 2003 among 157,275 Medicare+Choice beneficiaries whose annual drug benefits were capped at \$1,000 and 41,904 beneficiaries whose drug benefits were unlimited because of employer supplements.

**RESULTS**

After adjusting for individual characteristics, we found that subjects whose benefits were capped had pharmacy costs for drugs applicable to the cap that were lower by 31 percent than subjects whose benefits were not capped (95 percent confidence interval, 29 to 33 percent) but had total medical costs that were only 1 percent lower (95 percent confidence interval, -4 to 6 percent). Subjects whose benefits were capped had higher relative rates of visits to the emergency department (relative rate, 1.09 [95 percent confidence interval, 1.04 to 1.14]), nonelective hospitalizations (relative rate, 1.13 [1.05 to 1.21]), and death (relative rate, 1.22 [1.07 to 1.38]; difference, 0.68 per 100 person-years [0.30 to 1.07]). Among subjects who used drugs for hypertension, hyperlipidemia, or diabetes in 2002, those whose benefits were capped were more likely to be nonadherent to long-term drug therapy in 2003; the respective odds ratios were 1.30 (95 percent confidence interval, 1.23 to 1.38), 1.27 (1.19 to 1.34), and 1.33 (1.18 to 1.48) for subjects using drugs for hypertension, hyperlipidemia, and diabetes. In each subgroup, the physiological outcomes were worse for subjects whose drug benefits were capped than for those whose benefits were not capped; the odds ratios were 1.05 (95 percent confidence interval, 1.00 to 1.09), 1.13 (1.03 to 1.25), and 1.23 (1.03 to 1.46), respectively, for subjects with a systolic blood pressure of 140 mm Hg or more, a serum low-density-lipoprotein cholesterol level of 130 mg per deciliter or more, and a glycosylated hemoglobin level of 8 percent or more.

**CONCLUSIONS**

A cap on drug benefits was associated with lower drug consumption and unfavorable clinical outcomes. In patients with chronic disease, the cap was associated with poorer adherence to drug therapy and poorer control of blood pressure, lipid levels, and glucose levels. The savings in drug costs from the cap were offset by increases in the costs of hospitalization and emergency department care.

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PAYING FOR PRESCRIPTION DRUGS IS A challenge in the United States.<sup>1,2</sup> As costs escalate, public and private payers are increasing how much patients pay for prescription drugs.<sup>3-6</sup> Many employers and Medicare+Choice health plans have implemented caps on annual prescription-drug benefits or have eliminated benefits altogether. Drug-benefit caps require patients to pay the full price of drugs consumed after their spending exceeds the cap amount. To date, there has been little information on how such caps affect clinical and economic outcomes.

In theory, increasing the share of costs paid by patients creates an incentive for more efficient use of care.<sup>7-9</sup> Drug-benefit caps could encourage efficiency if patients and their physicians made judicious choices about drug therapies. Alternatively, these incentives could create barriers to care, especially for patients requiring long-term drug therapy.<sup>10-12</sup> Reduced access to drugs is of particular concern when there is strong evidence that a drug is cost-effective.<sup>13,14</sup> Previous studies indicate that limiting drug coverage has adverse effects in non-Medicare populations.<sup>15-17</sup> Surveys also suggest that Medicare beneficiaries reduce their drug consumption because of cost sharing.<sup>18,19</sup>

In a prepaid integrated-delivery system, we investigated the effects of a \$1,000 cap on annual drug benefits in Medicare+Choice beneficiaries 65 years of age or older by comparing them with a concurrent control group whose benefits were not capped because their former employers supplemented their Medicare benefits. We examined drug consumption, hospitalizations, visits to the emergency department, office visits, mortality rates, and medical costs in 2003. We also examined drug adherence and physiological outcomes associated with drug therapy among patients receiving therapy for hypertension, hyperlipidemia, and diabetes mellitus. This information can help us understand the effect of the new Medicare Part D drug plans, in which many patients pay in full for annual drug costs between \$2,250 and \$5,100.

## METHODS

### SETTING

Kaiser Permanente–Northern California provides comprehensive medical care, including prescription drugs. Within this system, Medicare+Choice

(now Medicare Advantage) members had either employer-supplemented or individual insurance. Members with employer-supplemented insurance generally had drug benefits without annual limits. Members with individual insurance had an annual cap of \$1,000 for drugs in 2002 and 2003. The cap applied to 95 percent of outpatient prescriptions; some classes of drugs, such as those used for chemotherapy, were exempted from the cap.

### POPULATION

The study population included all Medicare+Choice beneficiaries who were at least 65 years old on January 1, 2003, and who were enrolled in a two-tier drug plan (with copayments of \$10 for generic drugs and \$15 to \$30 for branded drugs) with either a \$1,000 cap or no cap on annual drug costs. We excluded subjects whose copayment status or membership in a plan with a cap as compared with a plan without a cap changed during the year (less than 1 percent of subjects) or who had Medicaid insurance (also less than 1 percent of subjects).

### STUDY DESIGN

We used a prospective cohort design to examine the effects of drug-benefit caps on various outcomes in 2003. In the overall cohort, we compared consumption of drugs subject to the cap, rates of use of medical services (hospitalizations, emergency department visits, and office visits), mortality rates, and medical costs between the group of subjects whose benefits were capped and the group of subjects whose benefits were not capped, with adjustment for individual characteristics. We also examined adherence and physiological outcomes among patients who received drug therapy in 2002 for hypertension, hyperlipidemia, or diabetes mellitus. Eighty-nine percent of the subjects receiving antihypertensive drugs in 2002 were in the Kaiser Permanente hypertension disease registry (84 percent) or had documented elevated systolic blood pressure but were not in the registry (5 percent) during the study period. We observed the subjects until they left Kaiser Permanente or died, or to the end of 2003, whichever occurred first. For the long-term drug classes examined, there was strong evidence from trials demonstrating efficacy according to physiological and clinical outcomes. The Kaiser Permanente institutional review board approved the study.

The study was designed and the data analyzed

by the authors. The Agency for Healthcare Research and Quality, the National Institute on Aging, the Alfred P. Sloan Foundation, and Kaiser Permanente had no role in the design, analysis, or interpretation of the study or in the decision to submit the manuscript for publication.

#### OUTCOMES

We measured drug expenditures according to the prices Kaiser Permanente members had to pay after exceeding the \$1,000 cap. For other medical costs, we obtained data from Kaiser Permanente's cost-accounting system as well as claims data for out-of-system visits. Medical costs (i.e., for hospitalizations, office visits, and emergency department visits) included all direct and ancillary costs associated with the visit, such as laboratory costs. We made no adjustments for subjects for whom less than 12 months of data were available (7 percent); sensitivity analyses using cost extrapolation for these subjects yielded similar findings.

To assess long-term adherence to drug treatment, we calculated the proportion of days covered in 2003, defined as the percentage of days in the year for which the subject received drugs within the therapeutic class, allowing for carry-over of the remaining drug supply from 2002.<sup>20,21</sup> The drug-related physiological outcomes measured were systolic blood pressure, low-density lipoprotein (LDL) cholesterol, and glycated hemoglobin. Office visits, hospitalizations, and visits to the emergency department included both those occurring inside and those occurring outside the Kaiser Permanente system, and mortality figures included deaths identified from California state death certificates.

#### COVARIATES

For all analyses, we adjusted for age (three categories), sex, race or ethnic group (including an "unknown" category, which accounted for 12 percent of the subjects), years of membership in Kaiser Permanente, copayments for emergency department and office visits, and medical center. We assessed race or ethnic group using a combination of automated health-system data and self-reports from routine patient surveys. To adjust for coexisting disorders, we used the prospective diagnostic-cost-group (DxCg) score, which is similar to the method used by the Centers for Medicare and Medicaid Services for Medicare risk adjustment.<sup>22</sup> We also used a binary neighbor-

hood socioeconomic status indicator based on 2000 U.S. Census block groups and residential addresses, which are defined as neighborhoods of lower socioeconomic status if at least 20 percent of residents have household incomes below the federal poverty level or at least 25 percent of residents 25 years of age or older have less than a high-school education.<sup>23</sup> In sensitivity analyses, we used a five-level indicator for socioeconomic status, which did not alter our estimates of the cap effect. In the analyses of physiological outcomes, we adjusted for baseline physiological levels, using the first available physiological value obtained in 2002 or 2003 after the subject started drug therapy (initial value) to predict all subsequent values in 2003.

#### STATISTICAL ANALYSIS

To assess drug and medical costs in 2003, we used a two-part model consisting of logistic regression of the probability of any costs and linear regression of costs for subjects with costs. Because relative costs are more broadly interpretable, we used estimated coefficients from the two-part model to construct a cohort relative cost, which was calculated as the ratio of the predicted cost for all subjects as if their benefits were capped to the predicted cost for all subjects as if their benefits were not capped. We estimated standard errors for relative costs using the delta method.<sup>24</sup> All analyses used Stata software (version 8.2) or SAS software (version 9.1.3). All reported P values are two-sided.

To increase our understanding of the temporal dynamics of drug consumption and adherence during 2003 among subjects with and those without caps on their benefits, we estimated monthly population-averaged means or proportions using generalized-estimating-equation methods with models including interactions between cap and month that allowed each comparison group to have its own profile over time. To examine monthly differences in drug consumption and adherence before and after the cap was exceeded, we identified the month in which a subject exceeded the \$1,000 annual cap amount and examined up to six months before and after that month.

To examine differences in adherence to treatment and physiological outcomes in 2003 between subjects with and those without benefit caps who used long-term drugs in 2002, we used generalized-estimating-equation methods (xtgee binomial family with logit-link in Stata 8.2).<sup>25</sup> In the models, we included monthly terms for overall

**Table 1. Characteristics of the Study Population.\***

Characteristic	All (N=199,179)	Benefits Capped (N=157,275)	Benefits Not Capped (N=41,904)	P Value
Person-years of follow-up in 2003	192,165	151,180	40,985	
Age (%)				<0.001
65–74 Yr	55	55	52	
75–84 Yr	35	35	39	
≥85 Yr	10	10	9	
Female sex (%)	59	60	54	<0.001
Race or ethnic group (%)				<0.001
White	68	67	72	
Black	4	3	6	
Hispanic	6	7	4	
Asian	7	8	7	
Other	3	3	3	
Unknown	12	13	10	
1st year of Kaiser Permanente membership (%)				<0.001
2002 or later	9	10	4	
2001	7	8	2	
2000 or earlier	84	82	94	
1st year of membership in plan with cap on drug benefits (%)				
2003	NA	10	NA	
2002	NA	17	NA	
2001	NA	70	NA	
2000 or earlier	NA	2	NA	
Residence in a low-socioeconomic-status neighborhood (%)	18	19	15	<0.001
Had a regular primary care provider in 2003 (%)	99	99	99	<0.001
Mean comorbidity (DxCg score) in 2002†	0.89	0.88	0.91	<0.001

difference (secular trends), and interactions between cap and month for monthly differences. We also compared the effect of the cap on physiological outcomes stratified according to whether the subjects exceeded the cap amount in 2003.

We defined drug adherence as having received enough drug supply to cover at least 80 percent of total days in 2003. The physiological-outcome thresholds were a glycated hemoglobin level of at least 8 percent, an LDL cholesterol level of at least 130 mg per deciliter (3.3 mmol per liter), and a systolic blood pressure of at least 140 mm Hg. In sensitivity analyses of physiological outcomes, we examined the effect of the benefits cap on all values by using logistic regression with random patient effects (xtlogit, random-effect option in Stata 8.2), only the last 2003 value, the last value

adjusted for the first 2003 value, and other thresholds for poor physiological outcomes. We also examined adherence and physiological values as continuous outcomes. We calculated adherence and poor physiological outcomes for subjects with and those without caps on their benefits by using the coefficients from the model to predict outcomes for all subjects as if their benefits were capped and as if their benefits were not capped.

To estimate the adjusted relative rates of use of medical services, we applied Poisson regression analyses with gamma-distributed random patient effects to patients' repeated monthly counts (xtpoisson, random-effect option in Stata 8.2). We modeled secular trends with terms for month within year. To assess the effect of the cap on

**Table 1. (Continued.)**

Characteristic	All (N=199,179)	Benefits Capped (N=157,275)	Benefits Not Capped (N=41,904)	P Value
Drugs received in 2003 (%)				
Any prescription drug	92	92	94	<0.001
Any antihypertensive drug	65	64	67	<0.001
Any lipid-lowering drug	34	34	36	<0.001
Any antidiabetic drug	13	13	13	0.067
Care for hypertension				
Any antihypertensive drug in 2002 (no. of subjects)	122,939	96,313	26,626	
At least 1 blood-pressure measurement in 2003 (%)	88	88	90	<0.001
Initial blood-pressure measurement in 2002 or 2003 and at least 1 additional measurement in 2003 (%)	85	85	88	<0.001
Mean initial systolic blood pressure (mm Hg)	142.3	142.5	141.8	<0.001
Care for hyperlipidemia				
Any lipid-lowering drug in 2002 (no. of subjects)	59,017	45,882	13,135	
At least 1 LDL cholesterol measurement in 2003 (%)	86	85	88	<0.001
Initial LDL cholesterol measurement in 2002 or 2003 and at least 1 additional measurement in 2003 (%)	80	79	83	<0.001
Mean initial LDL cholesterol level (mg/dl)‡	112.4	112.8	111.0	<0.001
Care for diabetes				
Any antidiabetic drug in 2002 (no. of subjects)	24,916	19,837	5,079	
At least 1 glycated hemoglobin measurement in 2003 (%)	89	88	91	<0.001
Initial glycated hemoglobin measurement in 2002 or 2003 and at least 1 additional measurement in 2003 (%)	86	85	88	<0.001
Mean initial glycated hemoglobin level (%)	7.7	7.7	7.6	<0.001

\* The table shows the percentages of subjects with each sociodemographic and clinical characteristic, as well as the level of coexisting illnesses, as measured by the mean diagnostic cost group (DxCg) score. The initial physiological measurement is defined as the first available measurement taken in 2002 or 2003 after the patient started drug therapy. In our models of physiological outcomes, we included subjects with an initial measurement plus one subsequent measurement in 2003. The first year of membership in a plan with a cap on drug benefits is defined as the first year of having 12 months of a cap in 2000, 2001, and 2002. Subjects whose first year of membership in a plan with a cap on drug benefits was 2003 may have been members for less than 12 months if they died or left the Kaiser Permanente system. Among subjects receiving any antihypertensive drugs, 89 percent were also in the Kaiser Permanente hypertension registry (84 percent) or had documented elevated systolic blood pressure but were not in the registry (5 percent); similarly, 100 percent of the subjects receiving any antidiabetic drugs were also in the Kaiser Permanente diabetes registry. All P values are two-sided. NA denotes not applicable.

† The DxCg score ranges from 0.1 to 10.2, with higher scores indicating a greater severity of coexisting illnesses.

‡ To convert the values for LDL cholesterol to millimoles per liter, multiply by 0.02586.

death rates, we used exponential and Cox proportional-hazards models (streg with exponential distribution and stcox in Stata 8.2). We calculated the rates of use of medical services by subjects with and those without benefit caps by using the coefficients from the model as previously described.

As a guard against functional form misspecification, we also examined propensity scores (of having a cap on benefits), estimated by using a logistic model and observable covariates; we used this predicted probability as a covariate in our

analysis.<sup>26</sup> We also repeated all nonmortality analyses on continuously enrolled subjects. We found that all analytic approaches yielded similar results.

## RESULTS

There were 199,179 subjects in January 2003; 79 percent had a \$1,000 cap on their drug benefits, and 21 percent had no limit (Table 1). Among subjects whose benefits were capped, 13 percent exceeded the \$1,000 cap during 2003.

Among subjects who had been receiving long-term drug therapy since 2002, consumption of antihypertensive drugs in 2003 was 15 percent lower (95 percent confidence interval, 11.4 to 18.1 percent) for subjects whose benefits were capped than among those whose benefits were not capped, consumption of lipid-lowering drugs was 27 percent lower (95 percent confidence interval, 23.1 to 30.4 percent), and consumption of antidiabetic drugs was 21 percent lower (95 percent confidence interval, 14.3 to 26.6 percent) (Table 2). Drug spending among subjects whose benefits were capped was 31 percent (95 percent confidence interval, 29.1 to 32.5) lower for all drugs applicable to the cap than it was among subjects whose benefits were not capped (Table 3).

Differences in monthly drug consumption between the two groups increased over the year

(Fig. 1 and 2). Moreover, among subjects whose drug expenditures exceeded the cap amount, differences between the two groups in drug consumption were greater in the months after the cap was exceeded than in earlier months. There were similar trends for monthly adherence to drug therapy (see the Supplementary Appendix, available with the full text of this article at [www.nejm.org](http://www.nejm.org)).

Table 2 also shows the odds ratios of nonadherence to long-term drug therapies and of having poor physiological outcomes (for subjects whose benefits were capped as compared with those with no cap). Among subjects whose benefits were not capped who were prescribed an antihypertensive, lipid-lowering, or antidiabetic drug, 15 percent, 27 percent, and 21 percent, respectively, were non-adherent. As compared with subjects whose ben-

**Table 2. Drug Consumption, Adherence to Drugs, and Physiological Outcomes in Subjects with Hypertension, Hyperlipidemia, or Diabetes Mellitus among Subjects with and Those without a \$1,000 Cap on Drug Benefits.\***

Variable	Benefits Not Capped	Benefits Capped	Relative Cost (95% CI)
	<i>percent</i>		
<b>Drug consumption in 2003†</b>			
Antihypertensive drugs	NA	NA	0.85 (0.82–0.89)
Lipid-lowering drugs	NA	NA	0.73 (0.70–0.77)
Antidiabetic drugs	NA	NA	0.79 (0.73–0.86)
<b>Drug nonadherence in 2003 among subjects receiving drugs of the same class in 2002</b>			<b>Odds Ratio (95% CI)</b>
Antihypertensive drugs	14.6	18.1	1.30 (1.23–1.38)
Lipid-lowering drugs	26.5	31.4	1.27 (1.19–1.34)
Antidiabetic drugs	21.2	26.2	1.33 (1.18–1.48)
<b>Poor physiological outcomes in 2003 among subjects receiving drug therapy in 2002</b>			
Systolic blood pressure $\geq$ 140 mm Hg in 2003 among subjects receiving antihypertensive drugs	38.5	39.5	1.05 (1.00–1.09)
LDL cholesterol $\geq$ 130 mg/dl in 2003 among subjects receiving lipid-lowering drugs	19.6	21.3	1.13 (1.03–1.25)
Glycated hemoglobin $\geq$ 8% in 2003 among subjects receiving antidiabetic drugs	17.0	19.7	1.23 (1.03–1.46)

\* The table shows drug consumption, measured as a relative cost for subjects with a drug-benefit cap as compared with subjects without a cap, estimated by a two-part model. The table also reports the odds ratios for monthly drug adherence and poor physiological outcome (on the basis of all test results obtained in 2003), estimated by regression models that allow for repeated measures. All analyses are adjusted for age, sex, socioeconomic status, race or ethnic group, coexisting disorders, years of enrollment in Kaiser Permanente, level of cost sharing for visits to the emergency department, level of cost sharing for office visits, and medical center. The analyses of physiological outcomes are also adjusted for the first available measurement obtained in 2002 or 2003 after a subject began drug therapy. We defined drug adherence as having received enough drugs to cover 80 percent of total days in 2003 among subjects receiving the drug in 2002; there were 122,939 subjects who received antihypertensive drugs, 59,017 who received lipid-lowering drugs, and 24,916 who received antidiabetic drugs. The physiological outcome models include subjects who were prescribed drug treatment and received the drug in 2002, who underwent at least one initial physiological measurement in 2002 or 2003 after starting drug therapy, and who underwent at least one subsequent physiological measurement in 2003; there were 104,948 subjects receiving antihypertensive drugs whose systolic blood pressure was measured, 47,084 receiving lipid-lowering drugs whose LDL cholesterol was measured, and 21,321 receiving antidiabetic drugs whose glycated hemoglobin levels were measured. The lower bounds of the 95 percent confidence intervals for all odds ratios (benefits capped vs. benefits not capped) were greater than 1.0, including the odds ratio for systolic blood pressure above 140 mm Hg. CI denotes confidence interval, and NA not applicable.

† Drug consumption is measured in dollars.

efits were not capped, subjects whose benefits were capped had higher odds of nonadherence to antihypertensive drugs (odds ratio, 1.30; 95 percent confidence interval, 1.23 to 1.38), lipid-lowering drugs (odds ratio, 1.27; 95 percent confidence interval, 1.19 to 1.34), and antidiabetic drugs (odds ratio, 1.33; 95 percent confidence interval, 1.18 to 1.48).

Among subjects whose benefits were not capped, 38 percent of those receiving antihypertensive drugs had systolic blood-pressure values of 140 mm Hg or more, 20 percent of those receiving lipid-lowering drugs had LDL cholesterol levels of 130 mg per deciliter or more, and 17 percent of those receiving antidiabetic drugs had glycated hemoglobin levels of 8 percent or more (Table 2). As compared with subjects whose ben-

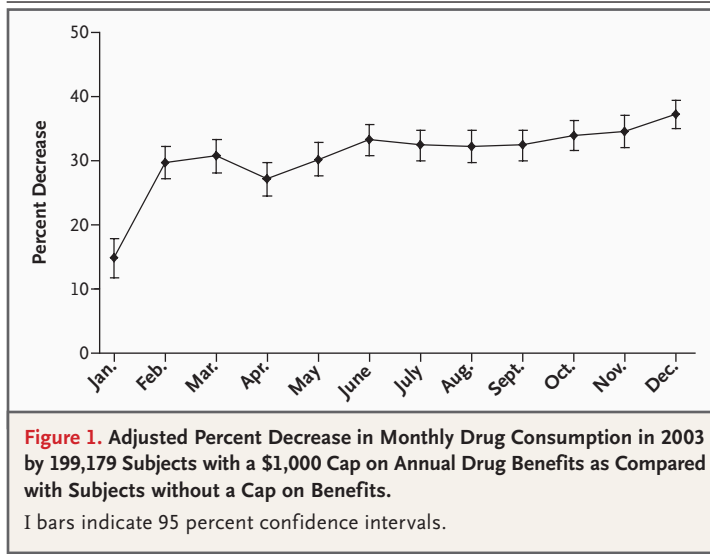
efits were not capped, subjects whose benefits were capped were more likely to have elevated systolic blood pressure (odds ratio, 1.05; 95 percent confidence interval, 1.00 to 1.09), LDL cholesterol (odds ratio, 1.13; 95 percent confidence interval, 1.03 to 1.25), and glycated hemoglobin (odds ratio, 1.23; 95 percent confidence interval, 1.03 to 1.46).

In stratified analyses for each of the three groups of drugs, the magnitude of the effect of the cap on physiological outcomes was greater among subjects who exceeded the \$1,000 cap amount than among those who did not (see the Supplementary Appendix); for example, among subjects whose expenditures exceeded the cap amount, the odds ratio for elevated LDL cholesterol was 1.28 (95 percent confidence interval, 1.05 to 1.56),

**Table 3. Rates of Use of Medical Services, Death Rates, and Relative Medical Costs in 2003 among Subjects with and Those without a \$1,000 Cap on Their Drug Benefits.\***

Variable	Benefits Not Capped	Benefits Capped	Relative Rate (95% CI)
	<i>rate/100 person-yr</i>		
<b>Rate of medical-services use</b>			
Emergency department visits	45.2	49.2	1.09 (1.04–1.14)
Hospitalizations	38.4	39.7	1.03 (0.98–1.09)
Nonelective	16.6	18.7	1.13 (1.05–1.21)
Elective	21.4	20.7	0.97 (0.91–1.03)
Office visits	933.5	902.7	0.97 (0.95–0.98)
<b>Death rate</b>			
	3.05	3.73	<b>Difference (95% CI)</b> 0.68 (0.30–1.07)
<b>Direct medical costs</b>			
			<b>Relative Cost (95% CI)</b>
Pharmacy costs	NA	NA	0.72 (0.70–0.74)
Costs of drugs that apply to the cap	NA	NA	0.69 (0.67–0.71)
Medical (nondrug) costs	NA	NA	1.05 (0.99–1.11)
Emergency department visits	NA	NA	1.09 (1.01–1.18)
Hospitalizations	NA	NA	1.13 (1.01–1.26)
Nonelective	NA	NA	1.14 (0.98–1.33)
Elective	NA	NA	1.13 (0.97–1.32)
Office visits	NA	NA	0.96 (0.93–0.99)
Total 2003 costs	NA	NA	0.99 (0.94–1.04)

\* The table shows adjusted rates per 100 person-years and relative rates of use of medical services, absolute mortality rates per 100 person-years and differences between the two groups, and relative costs for subjects with and those without an annual cap on their drug benefits. Values were estimated by a Poisson regression model with random patient effects, a proportional-hazards model, and a two-part model, respectively. There were 86,223 visits to the emergency department, 31,885 nonelective hospitalizations, 39,081 elective hospitalizations, 1,722,757 office visits, and 7338 deaths among the 199,179 subjects in 2003. The pharmacy costs reflect both drug acquisition and drug dispensation costs. These annual costs do not account for differing lengths of membership. The drug benefit cap applied to 95 percent of outpatient drug prescriptions. The relative rates and costs were adjusted for age, sex, socioeconomic status, race or ethnic group, coexisting disorders, years of enrollment in Kaiser Permanente, level of cost sharing for visits to the emergency department, level of cost sharing for office visits, and medical center. CI denotes confidence interval, and NA not applicable.



as compared with 1.07 (95 percent confidence interval, 0.95 to 1.20) for subjects whose expenditure did not exceed the cap amount.

Table 3 shows adjusted relative rates of use of medical services, mortality rates, and relative medical costs. Subjects whose benefits were capped had higher rates of visits to the emergency department (relative rate, 1.09; 95 percent confidence interval, 1.04 to 1.14), nonelective hospitalizations (relative rate, 1.13; 95 percent confidence interval, 1.05 to 1.21), and death (3.05 percent vs. 3.73 percent; difference, 0.68 percent; 95 percent confidence interval, 0.30 to 1.07 percentage points; relative rate, 1.22; 95 percent confidence interval, 1.07 to 1.38) than subjects whose benefits were not capped. Subjects whose benefits were capped had significantly fewer office visits (relative rate, 0.97; 95 percent confidence interval, 0.95 to 0.98). The rates of elective hospitalization did not differ significantly between the two groups (relative rate, 0.97; 95 percent confidence interval, 0.91 to 1.03). All differences in rates were of similar size and direction among subjects receiving long-term drug therapy.

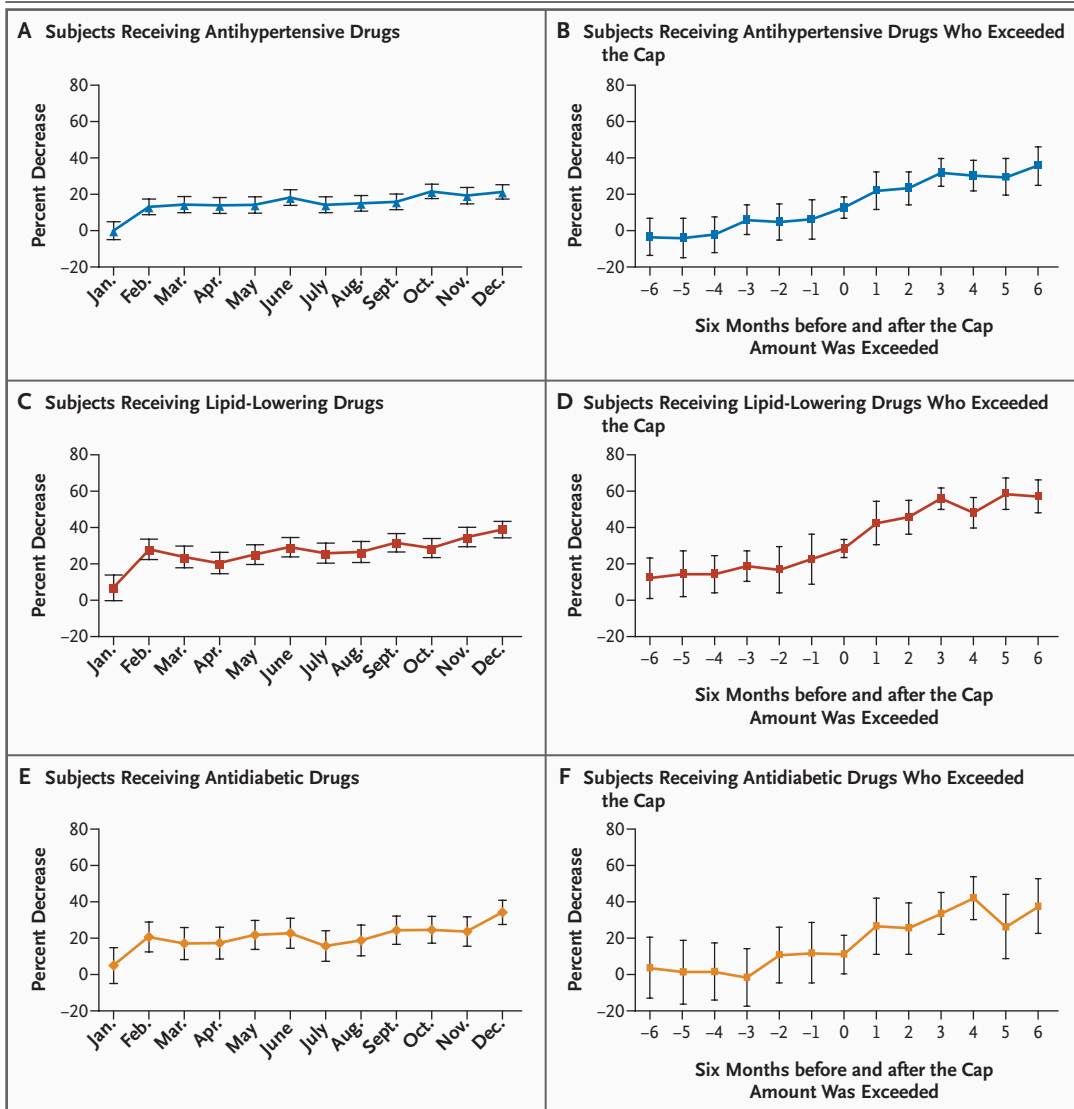
Subjects whose benefits were capped had pharmacy costs that were 28 percent lower (95 percent confidence interval, 25.6 to 30.4 percent) and office-visit costs that were 4 percent lower (95 percent confidence interval, 0.6 percent to 7.0 percent) than those for subjects whose benefits were not capped, but their hospital costs were 13 percent higher (95 percent confidence interval, 1.3 to 26.5 percent) and their emergency department

costs were 9 percent higher (95 percent confidence interval, 1.0 to 17.7 percent). There was no significant difference in annual total medical costs in 2003 between subjects whose benefits were capped and those whose benefits were not capped; the cost was only 1 percent lower for subjects whose benefits were capped (95 percent confidence interval, -4.1 to 5.8 percent).

## DISCUSSION

We examined the effect of drug-cost sharing on clinical and economic outcomes in Medicare beneficiaries. Our findings suggest that limits on drug benefits had consistently negative consequences. Beneficiaries whose benefits were capped used fewer prescription drugs overall and fewer drugs for the treatment of chronic diseases than those whose benefits were not capped. The differences in consumption between beneficiaries with and those without caps on their benefits were substantially larger during the months after the subjects exceeded the cap than during earlier months. Among beneficiaries receiving long-term drug therapy, those whose benefits were capped had lower levels of drug adherence and worse physiological outcomes, results consistent with a lower rate of use of drugs. Overall, subjects whose benefits were capped had higher rates of nonelective hospitalizations, visits to the emergency department, and death. In addition, subjects whose benefits were capped had lower pharmacy costs but higher hospital and emergency department costs, with no significant difference in total medical costs between the two groups.

Our findings are consistent with those of previous survey-based studies.<sup>12,27</sup> Nearly a third of Medicare beneficiaries reported taking fewer drugs than were prescribed in order to save money, and less generous drug benefits were associated with lower rates of drug adherence.<sup>18,19,28,29</sup> In non-Medicare, low-income populations, drug limits increased nursing home admissions.<sup>15</sup> High patient cost-sharing levels in Canada were associated with a lower rate of use of essential drugs and higher rates of visits to the emergency department and hospitalizations.<sup>17</sup> The lack of any drug coverage has been associated with poor outcomes.<sup>28,30-32</sup> In our study, physiological outcomes were worse for those whose benefits were capped than for those whose benefits were not capped; benefit caps were associated with increased rates



**Figure 2.** Adjusted Percent Decrease in Monthly Drug Consumption in 2003 by Subjects with a \$1,000 Cap on Annual Drug Benefits Who Were Receiving Antihypertensive, Lipid-Lowering, or Antidiabetic Drugs, as Compared with Consumption by Subjects without a Cap on Benefits.

Panels A, C, and E show the percent decreases in consumption of antihypertensive, lipid-lowering, and antidiabetic drugs in each calendar month by subjects who received drugs of the same class in 2002 and whose drug benefits were capped, as compared with those whose benefits were not capped. There were 122,939 subjects who received antihypertensive drugs, 59,017 who received lipid-lowering drugs, and 24,916 who received antidiabetic drugs. Panels B, D, and F show the corresponding data for subjects whose consumption of drugs exceeded the \$1,000 cap amount. There were 21,843 subjects in this group who received antihypertensive drugs, 13,213 who received lipid-lowering drugs, and 6,210 who received antidiabetic drugs. The results are aligned to the month when the cap threshold was exceeded; this month is labeled 0, the six months before are labeled -6 through -1, and the six months after are labeled 1 through 6. I bars indicate 95 percent confidence intervals.

of nonelective hospitalizations, visits to the emergency department, and death, a result that helps quantify the clinical significance of changes in drug consumption; and the higher costs of hospitalizations and visits to the emergency depart-

ment offset much of the savings in pharmacy costs.

In 2003, many Medicare beneficiaries in the United States did not have any drug benefits. Among those with drug benefits, many had ben-

efit limits. In fact, both plans in this study tended to be more generous than other drug-plan options available to individual Medicare beneficiaries.<sup>33,34</sup> In 2004, Kaiser Permanente discontinued the Medicare+Choice benefit caps and switched to a coverage policy limited to generic drugs.

Whether these findings are attributable to the cap on drug benefits or to unrelated differences between the groups is a critical question, given the nonrandomized study design. We believe the differences are attributable to the cap, for several reasons. We found consistent effects on all outcomes. Differences in drug consumption between the two groups also increased over the course of the year; differences were also greater after subjects with a cap lost their drug coverage. These results are consistent with a causal effect of the cap. We adjusted directly for important individual characteristics, including coexisting disorders at baseline and initial physiological outcome levels, and propensity-score methods yielded similar findings. Finally, former employers rather than patients determined whether subjects had uncapped benefits. Nevertheless, despite these consistent and temporal relationships, which agree with clinical-trial data, we cannot rule out the possibility of unmeasured confounders.

Although the ascertainment and timing of physiological measurements were nonexperimental, the majority of subjects underwent measurements, the two groups had similar measurement frequencies, and the analyses adjusted for initial levels. Because 90 percent of subjects whose benefits were capped in 2003 also had a cap on their benefits in 2002, and 99 percent of subjects whose benefits were not capped in 2003 did not have a cap in 2002, these analyses cannot differentiate between clinical effects of the 2003 benefit limits and the cumulative effects of these benefits over a period of two or more years, despite adjustment for years of membership in Kaiser Permanente. These potential cumulative effects may account for the magnitude of the mortality effect. Although the 95 percent confidence interval (0.3 to 1.1 deaths per 100 person-years) is wide, even its lower limit is clinically important.

We could not assess out-of-system drug use and may have underestimated total drug consumption. Telephone interviews, however, suggest that out-of-system use was rare, even after subjects exceeded their cap.<sup>35</sup> The cap-related changes in physiological outcomes were also consistent with little out-of-system drug use. We did not obtain information on any medical-assistance programs, and thus, our findings may underestimate the true cap effect in systems without these safeguards. The high levels of treatment, testing, and physiological disease control in this integrated system may also result in an underestimation of the adverse effects of caps on benefits in other settings. The levels of cost sharing for subjects enrolled in Kaiser Permanente were also less than those for many Medicare beneficiaries in 2003; therefore, for beneficiaries in other settings, the effects of cost sharing might be greater. Finally, we had limited precision when evaluating cost differences between the groups. For example, we did not detect a significant difference in the costs of nonelective hospitalizations (95 percent confidence interval for the relative cost, 0.98 to 1.33), even though we found a significant difference in the rate of nonelective hospitalizations (95 percent confidence interval for the relative rate, 1.05 to 1.21).

The setting of our study is not identical to that of Medicare fee-for-service, nor are these cost-sharing arrangements identical to those in the new Medicare Part D drug plans. Although cost sharing can be substantial under Part D, many beneficiaries might have lower out-of-pocket costs than they did when there was no drug benefit. Cost sharing, however, could increase for retirees who currently have employer-based coverage if their employer discontinues drug coverage. Our findings suggest a need to monitor closely the effects of these new benefits and, possibly, to modify cost sharing for drugs that are effective in treating chronic diseases.

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#### REFERENCES

1. Newhouse JP. How much should Medicare pay for drugs? *Health Aff (Millwood)* 2004;23(1):89-102.
2. Soumerai SB, Ross-Degnan D. Inadequate prescription-drug coverage for Medicare enrollees — a call to action. *N Engl J Med* 1999;340:722-8. [Erratum, *N Engl J Med* 1999;340:976.]
3. Freemantle N, Bloor K. Lessons from international experience in controlling pharmaceutical expenditure. I: influencing patients. *BMJ* 1996;312:1469-71.
4. 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.]
5. Tseng C-W, Brook RH, Keeler E, Mangione CM. Impact of an annual dollar limit or "cap" on prescription drug benefits for Medicare patients. *JAMA* 2003;290:222-7.
  6. McArdle FB, Neuman P, Kitchman M, Kirland K, Yamamoto D. Large firms' retiree health benefits before Medicare reform: 2003 survey results. *Health Aff (Millwood)* 2004;Suppl Web Exclusives:w4-7-w4-19.
  7. Phelps CE. *Health economics*. New York: HarperCollins, 1992.
  8. Rubin RJ, Mendelson DN. Cost sharing in health insurance. *N Engl J Med* 1995;333:733-4.
  9. Zweifel P, Manning WG. Moral hazard and consumer incentives in health care. In: Culyer AJ, Newhouse JP, eds. *Handbook of health economics*. New York: Elsevier, 2000:409-59.
  10. Goldman DP, Joyce GF, Escarce JJ, et al. Pharmacy benefits and the use of drugs by the chronically ill. *JAMA* 2004;291:2344-50.
  11. Piette JD, Heisler M, Wagner TH. Cost-related medication underuse among chronically ill adults: the treatments people forgo, how often, and who is at risk. *Am J Public Health* 2004;94:1782-7.
  12. Mojtabai R, Olfson M. Medication costs, adherence, and health outcomes among Medicare beneficiaries. *Health Aff (Millwood)* 2003;22(4):220-9.
  13. Mayes R, Hester B. Value-based drug rationing. *Health Aff (Millwood)* 2004;23(2):282.
  14. Morgan S, Bassett K, Mintzes B. Outcomes-based drug coverage in British Columbia. *Health Aff (Millwood)* 2004;23(3):269-76.
  15. Soumerai SB, Ross-Degnan D, Avorn J, McLaughlin T, Choodnovskiy I. Effects of Medicaid drug-payment limits on admission to hospitals and nursing homes. *N Engl J Med* 1991;325:1072-7.
  16. Soumerai SB, Avorn J, Ross-Degnan D, Gortmaker S. Payment restrictions for prescription drugs under Medicaid: effects on therapy, cost, and equity. *N Engl J Med* 1987;317:550-6.
  17. Tamblyn R, Laprise R, Hanley JA, et al. Adverse events associated with prescription drug cost-sharing among poor and elderly persons. *JAMA* 2001;285:421-9.
  18. Rector TS, Venus PJ. Do drug benefits help Medicare beneficiaries afford prescribed drugs? *Health Aff (Millwood)* 2004;23(4):213-22.
  19. Tseng CW, Brook RH, Keeler E, Steers WN, Mangione CM. Cost-lowering strategies used by Medicare beneficiaries who exceed drug benefit caps and have a gap in drug coverage. *JAMA* 2004;292:952-60.
  20. Valenstein M, Copeland LA, Blow FC, et al. Pharmacy data identify poorly adherent patients with schizophrenia at increased risk for admission. *Med Care* 2002;40:630-9.
  21. Steiner JF, Koepsell TD, Fihn SD, Inui TS. A general method of compliance assessment using centralized pharmacy records: description and validation. *Med Care* 1988;26:814-23.
  22. Zhao Y, Ellis RP, Ash AS, et al. Measuring population health risks using inpatient diagnoses and outpatient pharmacy data. *Health Serv Res* 2001;36:180-93.
  23. Krieger N, Gordon D. Re: "Use of Census-based aggregate variables to proxy for socioeconomic group: evidence from national samples." *Am J Epidemiol* 1999;150:892-6.
  24. Oehlert GW. A note on the delta method. *Am Stat* 1992;46:27-9.
  25. Liang KY, Zeger SL. Longitudinal data analysis using generalized linear models. *Biometrika* 1986;73:13-22.
  26. Rosenbaum PR, Rubin DB. Reducing bias in observational studies using sub-classification on the propensity score. *J Am Stat Assoc* 1984;79:516-24.
  27. Stuart B, Simoni-Wastila L, Chauncey D. Assessing the impact of coverage gaps in the Medicare Part D drug benefit. *Health Aff (Millwood)* 2005;Suppl Web Exclusives:w5-167-w5-179.
  28. Steinman MA, Sands LP, Covinsky KE. Self-restriction of medications due to cost in seniors without prescription coverage. *J Gen Intern Med* 2001;16:793-9.
  29. Cox ER, Jernigan C, Coons SJ, Draugalis JL. Medicare beneficiaries' management of capped prescription benefits. *Med Care* 2001;39:296-301.
  30. Federman AD, Adams AS, Ross-Degnan D, Soumerai SB, Ayanian JZ. Supplemental insurance and use of effective cardiovascular drugs among elderly Medicare beneficiaries with coronary heart disease. *JAMA* 2001;286:1732-9.
  31. Lurie N, Ward NB, Shapiro MF, Brook RH. Termination from Medi-Cal — does it affect health? *N Engl J Med* 1984;311:480-4.
  32. Baker DW, Sudano JJ, Albert JM, Borawski EA, Dor A. Lack of health insurance and decline in overall health in late middle age. *N Engl J Med* 2001;345:1106-12.
  33. Kaiser Family Foundation and Hewitt Associates. Current trends and future outlook for retiree health benefits: findings from the Kaiser/Hewitt 2004 survey on retiree health benefits. Menlo Park, Calif.: KFF/Hewitt, 2004.
  34. Achman L, Gold M. Are the 2004 payment increases helping to stem Medicare Advantage's benefit erosion? New York: Commonwealth Fund, 2004. (Publication no. 795.)
  35. Reed M, Fung V, Brand R, et al. Care-seeking behavior in response to emergency department copayments. *Med Care* 2005;43:810-6.

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