Annals of Internal Medicine | ARTICLE

The Effect of the Medicare Part D Prescription Benefit on Drug Utilization and Expenditures

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Background: Information about the effect of the Medicare Part D Prescription Drug Benefit on drug utilization and expenditures is limited.

Objective: To estimate changes in prescription utilization and out-of-pocket expenditures attributable to Part D among a sample of persons eligible for the benefit.

Design: Generalized estimating equations were used to estimate changes in expenditures and utilization among beneficiaries. A control group was included to control for secular trends unrelated to the Part D benefit.

Setting: National pharmacy chain representing approximately 15% of all U.S. retail pharmacy sales.

Participants: Persons age 66 to 79 years (those eligible for Part D) and a control group of persons age 60 to 63 years (those ineligible for Part D). The final sample represented approximately 5.1 million unique beneficiaries and 1.8 million unique control individuals.

Measurements: Prescription utilization (measured in pill-days) and out-of-pocket expenditures, as determined from pharmacy claims from September 2004 to April 2007.

Results: During the penalty-free Part D enrollment period (January 2006 to May 2006), average monthly drug utilization increased by 1.1% (95% CI, 0.5% to 1.7%; $P < 0.001$) and out-of-pocket expenditures decreased by 8.8% (CI, 6.6% to 11.0%; $P < 0.001$). After enrollment stabilized (June 2006 to April 2007), average monthly drug utilization increased by 5.9% (CI, 5.1% to 6.7%; $P < 0.001$) and out-of-pocket expenditures decreased by 13.1% (CI, 9.6% to 16.6%; $P = 0.003$). Compared with eligible nonenrollees, enrollees had higher out-of-pocket expenditures and utilization at baseline but experienced significantly larger decreases in expenditures and increases in utilization after enrollment.

Limitations: Analyses were limited to claims within 1 pharmacy chain. The effect of the "doughnut hole" and the effect of changes on clinical outcomes were not evaluated.

Conclusion: The Medicare Part D prescription benefit resulted in modest increases in average drug utilization and decreases in average out-of-pocket expenditures among Part D beneficiaries. Further research is needed to examine patterns among other beneficiaries and to evaluate the effect of these changes on health outcomes.

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The Medicare Modernization Act Prescription Drug Benefit (Part D) established a prescription drug benefit for all 43 million Medicare beneficiaries in the United States. This is the largest change to Medicare since the program began several decades ago (1).

The prescription benefit has increased the proportion of Medicare enrollees with prescription drug coverage (2), and the Centers for Medicaid & Medicare Services report that among seniors eligible for Medicare, Part D enrollees save on out-of-pocket expenses compared with those not enrolled in Part D (3, 4). Previous reports also have examined enrollment and used surveys to examine beneficiaries' beliefs and experiences (5–7).

Although these reports and others (8, 9) point to positive effects of the Part D benefit, several questions remain unanswered about its overall effect on prescription utilization and expenditures. This is because studies have tended to focus only on beneficiaries who have enrolled in a Medicare Part D plan. Changes in drug utilization or expenditures measured in these studies could represent Part D coverage, trends in prescription drug use unrelated to Part D, or differences between beneficiaries who enrolled in Part D and those who did not.

A 2004 projection suggested that the Medicare drug benefit would reduce average out-of-pocket expenditures by about 14% among elderly persons with Medicare coverage and by about 47% among elderly persons without preexisting drug coverage, resulting in an overall increase in total drug spending of about 6% (10). This prediction was mainly driven by the fact that almost three fourths of elderly persons in the United States already had some kind of drug coverage and that Medicare Part D would have a small effect on their expenditures and utilization. Yet with the exception of 1 recent study (11), little work has been done to empirically estimate the effect of the Part D benefit on prescription drug utilization and expenditures.

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Context

In 2006, Medicare inaugurated a drug benefit for older adults.

Contribution

Using data from a random sample of pharmacy customers who were beneficiaries of the program after the enrollment deadline, the authors estimate that the drug benefit saved people about $9 a month and gave them an extra 14 days of pills, on average.

Caution

The authors did not examine effects of the doughnut hole and did not look at specific drugs or drug classes.

Implication

The Medicare drug benefit has led to modest decreases in expense and increases in drug use for older adults.

—The Editors

We sought to address these limitations by analyzing pharmacy claims from a national pharmacy chain accounting for approximately one eighth of the market share of prescription medicines in the United States. Although this sample may not be nationally representative, it offers an opportunity to study the effect of Part D on a broad and heterogeneous population that accounts for a substantial portion of the entire Medicare population. Our analyses compare the effect of Part D on prescription drug utilization and expenditures among persons eligible for the benefit who enrolled in a Part D plan, persons eligible for the benefit who did not enroll, and noneligible persons. We also distinguish between the overall effect of Part D during the penalty-free enrollment period and the post–penalty-free period, when enrollment was stable, to determine the steady-state effect of Part D, independent of enrollment dynamics.

METHODS

Sample and Measurements

We selected a 5% random sample of unique pharmacy customers who filled at least 1 prescription during both the 2005 and the 2006 calendar years through the Walgreens pharmacy chain, whether at a retail store or by mail order. For each person in our sample, we obtained claims data for every prescription filled between 1 September 2004 and 31 April 2007.

For each prescription claim, we obtained data on the claimant's demographic characteristics (age, sex, language preference, ZIP code of residence), insurance characteristics (whether the claim was paid through a prescription drug plan, method of payment), pharmacy characteristics (ZIP code location), prescription characteristics (National Drug Code, therapeutic class, drug dose, number of treatment days, date dispensed, number of refills), and expenditures (amount paid out of pocket, amount paid by third party). We used data on claimants' ZIP code of residence (the residence recorded at the person's first pharmacy claim in 2005) to link the pharmacy claims data to data from the 2000 U.S. Census, including information on the total population, median household income, income per capita, proportion of urban residents, proportion of African-American persons, unemployment rate, and poverty rate within the ZIP code of residence (12, 13).

We also used data from the Behavioral Risk Factor Surveillance System (BRFSS) to compare the characteristics of our sample with those of all Medicare beneficiaries. We used simple descriptive statistics to compare the age and sex distribution of our sample with those of persons age 60 to 63 years and 66 to 79 years in the BRFSS. We also linked BRFSS data to 2000 U.S. Census data to examine whether the ZIP code–level demographic characteristics of our pharmacy sample were similar to those of the nationally representative BRFSS sample in the same age groups, and whether the characteristics of our sample were similar to those of only BRFSS respondents who lived in the same geographic areas as our pharmacy sample.

We excluded persons 80 years of age or older because the proportion of persons in nursing homes is higher among this age group and because changes in the Medicare Modernization Act regarding persons receiving nursing home care and long-term care (14) do not extend to the majority of the Medicare population.

Outcomes

Our 2 outcomes were monthly average out-of-pocket prescription costs and prescription utilization, as measured by the quantity of a prescription medicine sufficient for 1 day of therapy (pill-day). Each person in our sample contributed 32 observations corresponding to 32 months of data. We divided the 32 months into 3 periods: the pre–Part D period (September 2004 to December 2005); the ramp-up post–Part D period, during which seniors could enroll in Part D plans without penalty (January 2006 to May 2006); and the stable post–Part D period, after the deadline for penalty-free Part D enrollment (June 2006 to April 2007).

Because we aimed to estimate the effect of Part D, we sought to compare observed trends in out-of-pocket costs and utilization among seniors eligible for the benefit (the Part D–eligible group, consisting of persons age 66 to 79 years as of 1 January 2006) with predicted counterfactual trends for the same group of seniors had Part D not been enacted. Thus, we sought to estimate the effect of Part D on expenditures and utilization netting out contemporaneous changes to the outcome variable due to factors unrelated to Part D (15, 16). To estimate counterfactual trends, we used the contemporaneous time profile of the corresponding outcomes in a control group of persons age 60 to 63 years who were not yet eligible for the benefit (the Part

D–ineligible group). We dropped persons ages 64 and 65 years as of 1 January 2006 from the sample because they had partial-year Medicare eligibility during the study period. We first confirmed that the trends in outcomes in persons 60 to 63 years of age provided an adequate control for persons in the eligible group during the pre–Part D era (September 2004 to December 2005) by examining both the statistical significance and magnitude of the coefficients in our regression model that represented the differential trends between the Part D–eligible and Part D–ineligible groups during the pre–Part D era. We then used the counterfactual control trends in the ramp-up period and in the stable enrollment period after the Part D enrollment deadline in May 2006 to represent the counterfactual trends in outcomes for the Part D–eligible group assuming Part D had not been enacted.

Statistical Analysis

We estimated trends and generated predictions by using generalized estimating equations (GEEs). We adjusted for sample demographic characteristics (sex, English-speaking status, Medicaid coverage, age), ZIP code–level characteristics (total population, median household income, per-capita income, proportion of urban residents, proportion of African-American persons, unemployment rate, poverty rate), fixed effects for calendar months (January to December), study period (pre–Part D, ramp-up post–Part D, and stable post–Part D), and Part D–eligible group. Moreover, we explored a variety of splines for representing differential time trends between periods; we ultimately used cubic splines because they produced the best fit for both the pre–Part D and the stable post–Part D periods. A linear spline was used for the ramp-up post–Part D period because this period was short. We added up to 3-way interactions between study period and Part D–eligible group fixed effects and the splines over time. We assessed overall model fit by using a variety of goodness-of-test criteria. We used gamma distribution to model out-of-pocket expenditures and negative binomial distribution to model pill-days. All estimators used log-link models. In addition, we explored the correlation structure between monthly observations within participants and used a first-order autoregressive correlation structure for out-of-pocket costs and an unstructured correlation matrix for pill-days.

We had 2 main goals. First, we sought to estimate the policy effect of Part D coverage during both the ramp-up and stable post–Part D periods. These effects represent the mean differences in the monthly outcomes between the observed factual trends and predicted counterfactual trends if Part D had not been enacted over these 2 periods. The **Appendix Figure** (available at www.annals.org) provides details about the specifications of these models and how the counterfactual trends were derived. These overall policy effects provide the average effect on utilization and out-of-pocket expenditures attributable to Part D for all seniors, regardless of enrollment status.

Second, we examined whether the effect of Part D varied on the basis of enrollment status by repeating our analyses after stratifying seniors into those who enrolled in Part D before the enrollment deadline during May 2006, those who enrolled in Part D after the enrollment deadline, and those who did not enroll in a Part D plan. We reasoned that this was important because selection into Part D plans was predicted to significantly mediate the effect of Part D on utilization and expenditures (10). As with our other analyses, these analyses were based on having filled a prescription for a medicine covered through Part D or an alternative source of prescription coverage.

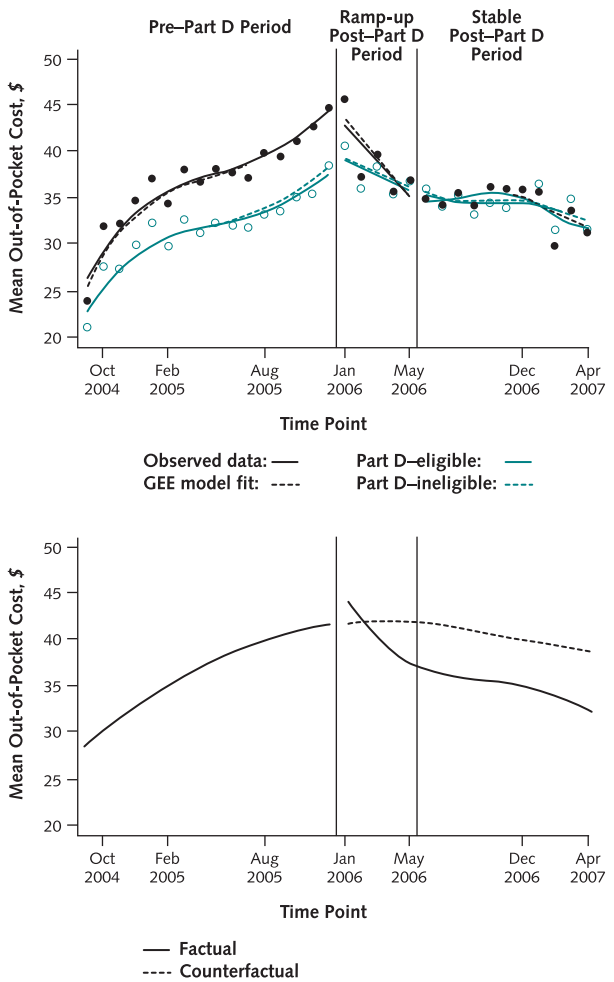
We used Stata software, version 9.2 (Stata, College Station, Texas), for all analyses. Estimates with P values less than 0.05 were considered statistically significant.

Table 1. **Sample Characteristics***

Characteristic	Part D–Eligible Persons (n = 117 648)			Part D–Ineligible Persons (n = 59 663)		
	All	Pre–Part D	Post–Part D	All	Pre–Part D	Post–Part D
Age, *y*	72.1 (3.7)	–	–	61.8 (1.1)	–	–
Women, %	57.5 (49.4)	–	–	55.7 (49.7)	–	–
English-language preference, %	96.7 (17.8)	–	–	98.1 (13.7)	–	–
ZIP code characteristics†						
Total population, *1000 n*	29.8 (16.9)	–	–	29.2 (16.8)	–	–
Median household income, *$1000*	45.9 (16.6)	–	–	47.5 (17.1)	–	–
Income per capita, *$1000*	23.3 (9.8)	–	–	23.5 (9.7)	–	–
Urban residence, %	89.2 (22.8)	–	–	87.2 (24.9)	–	–
African American, %	12.0 (19.7)	–	–	11.7 (19.2)	–	–
Employment rate, %	94.4 (3.4)	–	–	94.7 (3.4)	–	–
Poverty rate, %	11.0 (8.0)	–	–	10.5 (7.8)	–	–
Total monthly prescription drug utilization, *pill-days*	–	83.9 (77.1)	93.6 (81.1)	–	77.1 (74.4)	81.0 (76.4)
Total monthly out-of-pocket prescription expenditures, *$*	–	57.3 (85.8)	53.5 (71.6)	–	50.2 (63.8)	53.7 (69.6)
Total monthly prescriptions, *n*	–	2.7 (2.0)	2.9 (2.1)	–	2.6 (2.0)	2.7 (2.1)

* Cells report sample means (SDs). The total sample of 177 311 persons was observed in 2005 and 2006.
† Based on the 2000 U.S. Census.

Figure 1. **Trends in out-of-pocket prescription expenditures.**



Top. Trends in average monthly out-of-pocket costs. **Bottom.** Trend in factual out-of-pocket costs versus counterfactual costs associated with no implementation of Part D. GEE = generalized estimating equation.

Role of the Funding Source

Drs. Yin, Basu, and Alexander had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Dr. Zhang was supported in part by a grant from Merck & Co. Dr. Meltzer is supported by the Centers for Disease Control and Prevention Chicago Center of Excellence in Health Promotion Economics and the Merck Foundation through the University of Chicago Program for Pharmaceutical Policy Research. Dr. Alexander is supported by career development awards from the Agency for Healthcare Research and Quality and the Robert Wood Johnson Physician Faculty Scholars Program. The funding sources had no role in the design and conduct of the study, analysis or interpretation of the data, or preparation or final approval of the manuscript before publication.

RESULTS

Sample Characteristics

Table 1 shows the characteristics of our 5% sample of unique pharmacy customers. This sample included 117 648 persons age 66 to 79 years (Part D–eligible group) and 59 663 persons age 60 to 63 years (Part D–ineligible group), which represent 5.1 million and 1.8 million pharmacy customers, respectively. The 2 groups were similar in all demographic and socioeconomic characteristics other than age, although some differences were statistically significant because of the large sample sizes. The average annual drug utilization and expenditures were lower in the Part D–ineligible group, which reflects the average 10-year age difference between the 2 groups.

Table 1 also shows the unadjusted changes in drug utilization and out-of-pocket expenditures between the sample before and after implementation of Medicare Part D. In the part D–ineligible group, statistically significant unadjusted changes in drug utilization and expenditures were observed that were considered to be independent of the Part D drug benefit.

Appendix Table 1 (available at www.annals.org) compares our sample and the nationally representative BRFSS sample of Medicare beneficiaries. Persons in our sample were more likely than those in the broader sample to live in an urban area (89% vs. 68%, respectively). However, our sample (both Part D–eligible and Part D–ineligible persons) was otherwise statistically similar to the BRFSS respondents from the same counties in which our sample resided.

Changes in Expenditures and Utilization after Accounting for Secular Trends

Figure 1 shows the trends in average monthly out-of-pocket expenditures for the Part D–eligible and Part D–ineligible groups. Expenditures for the Part D–eligible group in the pre–Part D period were higher than those for the ineligible group by about $5 on average, but no statistically significant difference was observed in trends between the groups during the pre–Part D era. Immediately after implementation of Part D, the expenditures appear to trend downward in both groups, but the downward trend in the eligible group was greater than that in the ineligible group in each period. The Part D–eligible group seemed to have a faster decrease in expenditures during the ramp-up period and throughout the stable post–Part D period. **Figure 1** also compares the trend in observed (factual) expenditures with the trend in counterfactual expenditures for eligible seniors if Part D had not been implemented, as estimated from the GEE analysis.

Figure 2 shows similar trends in average monthly drug utilization. During the pre–part D era, trends for the Part D–eligible group increased slightly faster than those for the Part D–ineligible group; this difference was statistically significant but not meaningful because it was less than 5% of that in the ineligible group. Similarly, although the num-

ber of pill-days decreased at a statistically significant rate during the ramp-up period in both the eligible and ineligible groups, the difference between the groups was small and not otherwise significant (**Appendix Table 2**, available at www.annals.org). During the stable post–Part D period, utilization for both eligible and ineligible groups again decreased slightly. However, **Figure 2** suggests that Part D benefits led to a slight increase in average utilization among all Part D–eligible seniors, with the difference between eligible and ineligible seniors growing steadily throughout the ramp-up and stable post–Part D periods.

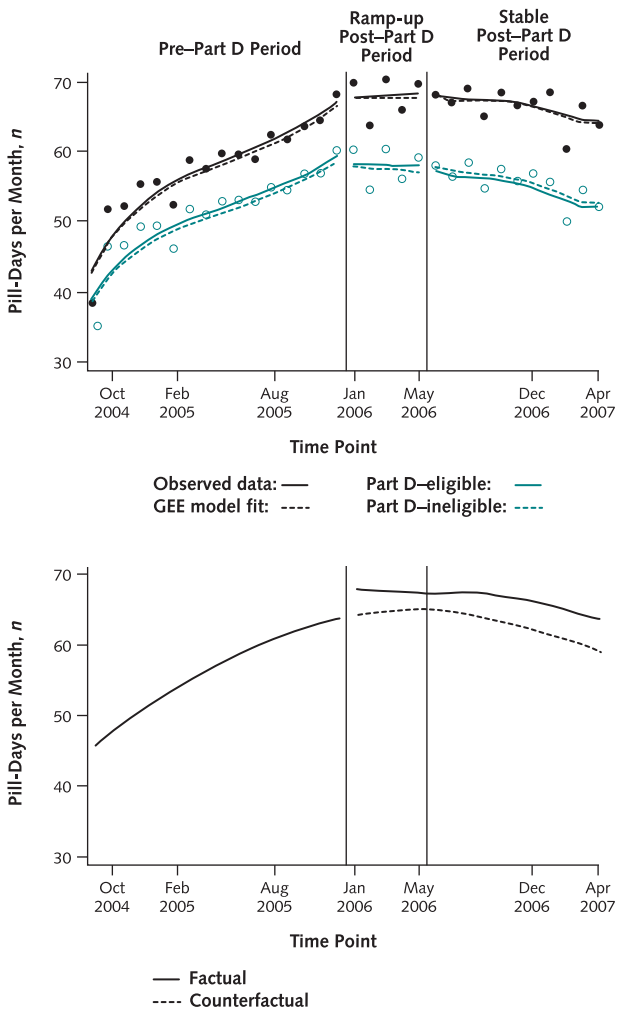
Table 2, which reports results from the GEE analysis, shows more formally the effect of Part D on expenditures and utilization. Column 1 shows the factual multivariate-adjusted average change in outcomes after Part D was enacted. Column 2 shows the predicted counterfactual change in outcomes if Part D had not been enacted. Column 3 shows the difference between columns 1 and 2, which represents change in outcomes attributed to Part D. During the ramp-up period, we estimate that Part D decreased average monthly expenditures by $3.80 (8.8%; $P < 0.001$) and increased utilization by 0.8 pill-day (1.1%; $P < 0.001$).

The estimated effects during the ramp-up period in **Table 2** may vary over time because enrollment was rapidly increasing during this period. Therefore, results during the stable period better represent the steady-state effect of Part D. During this period, Part D led to a decrease in expenditures of $5.20 per month (13.1%; $P = 0.003$) and an increase in utilization by 3.7 pill-days (5.9%; $P < 0.001$). **Appendix Table 2** (available at www.annals.org) reports coefficients in the full GEE model.

Changes in Expenditures and Utilization, by Enrollment Status and Timing of Enrollment

Clear nonrandom selection into Part D plan enrollment occurred. **Figures 3** and **4** show that on average, early enrollers had higher out-of-pocket expenditures ($47, $40, and $30 for seniors who enrolled in the ramp-up period,

Figure 2. **Trends in prescription drug utilization.**



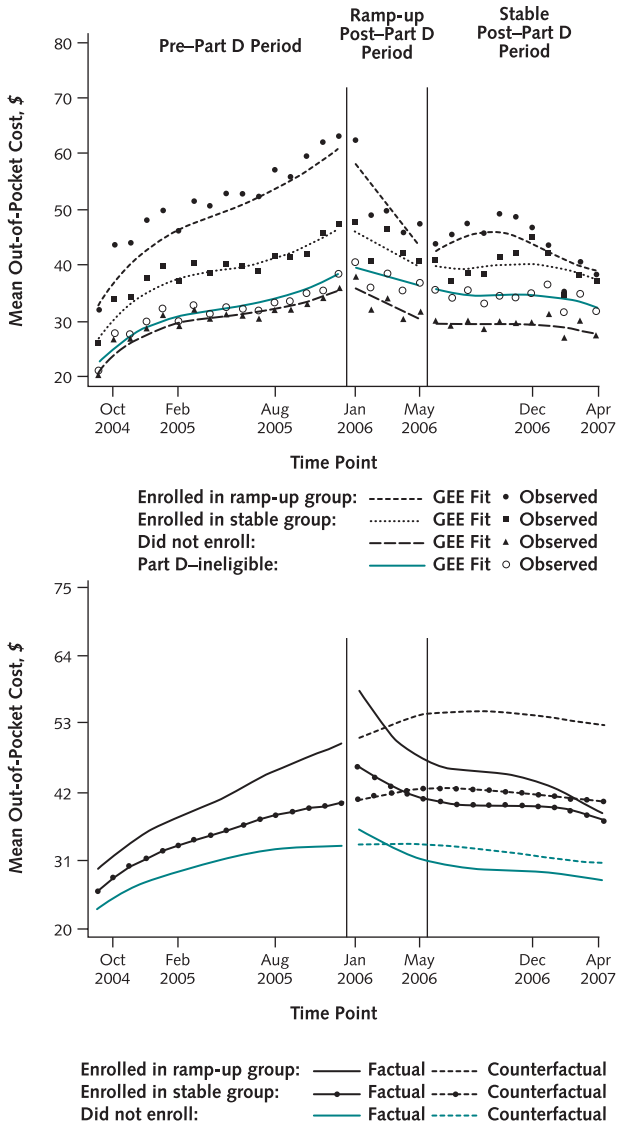
Top. Monthly pill-days of drug utilization. **Bottom.** Trend in factual utilization versus counterfactual utilization associated with no implementation of Part D. GEE = generalized estimating equation.

Table 2. **Effect of Medicare Part D on Out-of-Pocket Prescription Expenditures and Utilization**

Study Period and Outcome*	Average Adjusted Monthly Effects for Part D–Eligible Seniors†		Difference due to Part D†		
	Factual Effect	Counterfactual Effect‡	Absolute Change	Relative Change, %	*P* Value
Ramp-up post–Part D period					
Out-of-pocket cost, $	39.3 (38.9 to 39.7)	43.1 (42.0 to 44.2)	−3.8 (−4.7 to −2.9)	−8.8 (−6.6 to −11.0)	<0.001
Pill-days	68.2 (67.8 to 68.3)	67.4 (66.8 to 68.0)	0.8 (0.3 to 1.3)	1.1 (0.5 to 1.7)	<0.001
Stable post–Part D period					
Out-of-pocket costs, $	34.4 (34.0 to 34.8)	39.6 (38.2 to 41.3)	−5.2 (−3.8 to −6.6)	−13.1 (−16.6 to −9.6)	0.003
Pill-days	66.7 (66.3 to 67.1)	63.0 (62.3 to 63.7)	3.7 (3.2 to 4.2)	5.9 (5.1 to 6.7)	<0.001

* The ramp-up period is January 2006 through May 2006, before the deadline for enrollment in Medicare Part D. The stable period is June 2006 through April 2007, after the deadline for Part D enrollment.
† All individual effects were statistically significant.
‡ Counterfactual changes in outcomes (changes that would have resulted if Part D had not been implemented) were estimated by using the generalized estimating equation model described in the **Appendix Figure** (available at www.annals.org).

Figure 3. **Trends in out-of-pocket expenditures, by Part D enrollment.**



Top. Trends in average monthly out-of-pocket costs. **Bottom.** Trends in factual out-of-pocket costs versus counterfactual costs associated with no implementation of Part D. GEE = generalized estimating equation.

those in the stable period, and those who did not enroll, respectively) and used more drugs (86, 54, and 53 pill-days, respectively) than late enrollers or nonenrollees.

Table 3 shows the estimated effect of Part D on average monthly out-of-pocket expenditures and pill-days, by enrollment status. For seniors who enrolled in a Part D plan in the stable post–Part D period (after the enrollment deadline), we estimate that the Part D benefit increased average monthly utilization by 14.19 pill-days (19.2%; $P < 0.001$) and decreased average monthly out-of-pocket expenditures by $8.78 (17.2%; $P = 0.043$). Nonenrollees experienced a relatively small but statistically significant decrease in utilization of 2.22 pill-days (4%; $P < 0.001$) and a decrease in out-of-pocket expenditures of $2.72 (8.5%; $P < 0.001$).

Table 3 also shows the estimated effect of Part D by timing of enrollment. Among seniors who enrolled during the ramp-up period, Part D is estimated to have decreased expenditures by $7.90 (13.4%; $P < 0.001$) during the ramp-up period and by $11.10 (20.4%; $P < 0.001$) during the stable period. As expected, seniors who enrolled during the stable period experienced a small and statistically insignificant decrease in average monthly expenditures during the ramp-up period and a slightly larger and significant decrease of $2.40 (5.6%; $P = 0.026$) during the stable period. Overall, the effect of Medicare Part D on pill-days was similar to that on out-of-pocket costs, but in the opposite direction. Among early enrollees, Part D led to an increase of 5.5 pill-days per month (5.9%; $P < 0.001$) during the ramp-up period and 13.7 pill-days during the stable period (16.1%; $P < 0.001$). Utilization among seniors who enrolled during the stable period was largely unaffected by Part D during the ramp-up period. However, during the stable period, this group experienced a large increase in average monthly utilization of 16.7 pill-days (32.6%; $P < 0.001$).

Discussion

The Medicare Modernization Act Part D Prescription Benefit was implemented to improve beneficiary access to affordable prescription medicines (1). In this analysis of more than 6 million unique Part D enrollees and nonenrollees who were customers of a large national pharmacy chain, we found modest increases in prescription utilization and decreases in out-of-pocket expenditures for persons age 66 to 79 years in 2006 compared with 2005. These estimates of the overall effect of Part D—an approximate 13.1% decrease in expenditures and an approximate 5.9% increase in prescription utilization—are remarkably similar to predictions of these estimates based on economic theory (10, 17).

Our analyses were limited to seniors who filled at least 1 prescription during 2005 or 2006 and may not be nationally representative of all Medicare beneficiaries. However, our report is one of the first analyses of the effect of Part D, and it reflects the experiences of millions of U.S. seniors, who account for approximately 15% the market share in the United States. In addition, our participants were similar to the general Medicare population in terms of most key observable characteristics.

Our approach has several strengths. First, we differentiated between the ramp-up period, when enrollment in Part D plans was increasing, and the period after which persons could enroll without penalty, when enrollment was largely stable. Whereas the effect over the ramp-up period captures the selection effect of early enrollees and the effect of increasing enrollment, analysis from the later stable pe-

riod better represents the steady-state effect of Part D on utilization and expenditures. Second, we both combined and compared outcomes among Part D enrollees and nonenrollees. The combined analyses, which measure changes in drug utilization and expenditures for all Part D–eligible persons from 2005 to 2006, avoid the confounding that is associated with simply comparing eligible Part D enrollees with eligible nonenrollees.

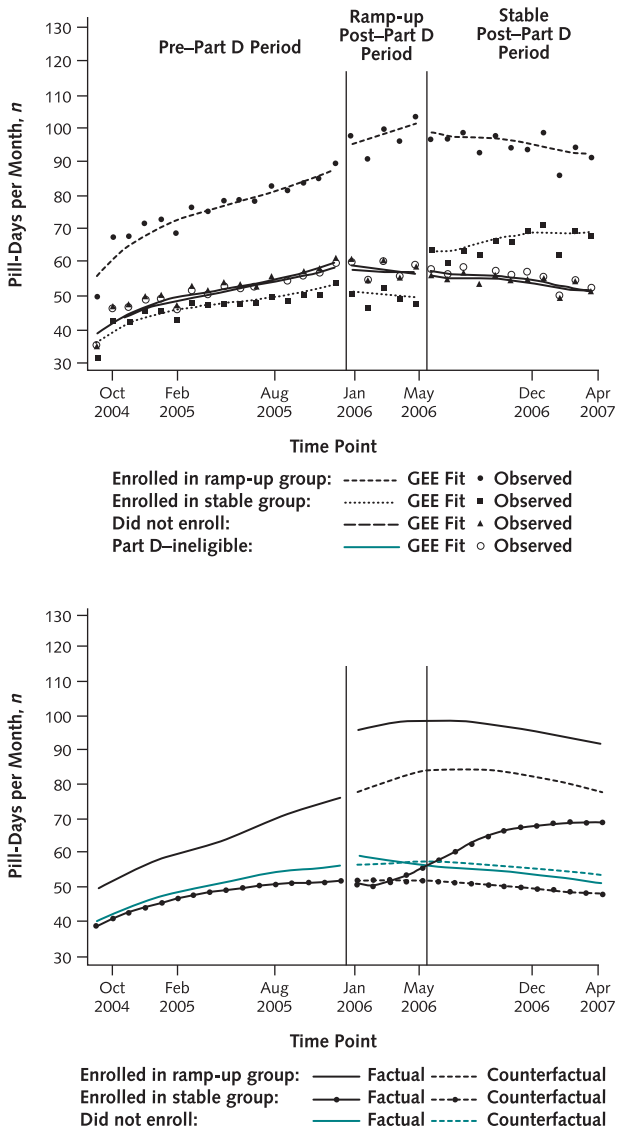
The effects of Part D were modest on average but were substantially greater among persons who enrolled. In addition, persons who enrolled earliest had the highest expenditures and utilization before Part D was implemented; given their demand for drugs, these persons may have been the most likely to gain from enrollment in more generous Part D plans. Indeed, early enrollees experienced the largest decreases in expenditures and increases in utilization.

Our finding that late enrollees experienced small decreases in expenditures but large increases in utilization may be due to unmet demand among these persons before Part D. The generosity of Part D plans may have led to lower unit expenditures for drugs and allowed greater utilization while offsetting total decreases in out-of-pocket expenditures. Alternatively, this finding may be interpreted as moral hazard in drug consumption—that is, increases in drug consumption due to greater prescription coverage rather than to seniors' unmet health care needs. Whether the effect on utilization represents overuse from a social perspective depends on whether the marginal increase in total (out-of-pocket plus third-party) cost of the drugs was justified by their increase in clinical benefits. Although this is not knowable without clinical data on this specific group, the delay in enrollment among late enrollees suggests that moral hazard may largely explain observed changes in utilization among these persons.

Our analyses complement another empirical study of the effect of Part D among seniors that estimated an 18% decrease in out-of-pocket expenditures and a 13% increase in utilization (11). However, that study had several limitations that may account for the considerably larger effect of Part D than we estimate. First, the authors drew a random sample of pharmacy claims (rather than selecting every claim for a random sample of claimants, as was done in our study), thereby oversampling people with high utilization—that is, those who experienced greater-than-average effects of the drug benefit. Second, the investigators did not account for changes in the composition of the pharmacy claims data sample over time. We drew from a stable population to avoid confounding selection effects. Third, the earlier study accounted for trends unrelated to Part D by using all nonelderly persons as a control group. Prevailing trends in utilization and expenditures among those control participants may have differed from those of seniors, leading to biased estimates. In contrast, we restricted our control group to persons who were most similar in age to persons who were eligible for the Part D benefit; we then explicitly tested whether preexisting trends for persons in both groups were statistically similar. Finally, the earlier analysis used log-transformed ordinary least-squares regressions that may produce biased estimates of the effect of the raw scale if heteroscedasticity is present in the log scale (18, 19), a problem that we avoided by using a GEE log-link model.

Although we identified modest increases in prescription utilization and decreases in out-of-pocket expenditures, whether such changes are cost-effective is not clear. This depends in part on the degree to which expansion of prescription drug coverage may lead to lower medical ex-

Figure 4. **Trends in prescription drug utilization, by Part D enrollment.**



Top. Monthly pill-days of drug utilization. **Bottom.** Trends in factual out-of-pocket costs versus counterfactual costs associated with no implementation of Part D. GEE = generalized estimating equation.

Table 3. **Effect of Medicare Part D on Out-of-Pocket Prescription Expenditures and Utilization, by Part D Enrollment***

Study Period and Outcome†	Average Adjusted Monthly Effect for Part D–Eligible Seniors‡		Difference due to Part D‡		
	Factual Effect	Counterfactual Effect§	Absolute Change	Relative Change, %	*P* Value
Ramp-up post–Part D period					
Out-of-pocket cost, $					
Nonenrolled persons	33.1 (32.6 to 33.6)	35.2 (34.7 to 35.8)	−2.2 (−2.6 to −1.7)	−6.1 (−7.5 to −4.7)	<0.001
All enrolled persons	48.7 (47.7 to 49.7)	55.0 (53.3 to 56.6)	−6.3 (to 12.7 to 0.1)	−11.4 (−23.0 to 0.2)	0.053
Enrolled during ramp-up period	50.8 (49.9 to 51.8)	58.7 (56.7 to 60.7)	−7.9 (−9.4 to −6.4)	−13.4 (−15.9 to −10.9)	<0.001
Enrolled during stable period	42.9 (40.1 to 45.6)	44.7 (42.0 to 47.4)	−1.8 (−3.6 to 0.0)	−4.1 (−8.2 to 0.0)	0.048
Pill-days					
Nonenrolled persons	57.8 (57.2 to 58.3)	58.8 (58.0 to 59.6)	−1.1 (−1.6 to −0.5)	−2.1 (−3.1 to −1.1)	<0.001
All enrolled persons	85.8 (85.1 to 86.5)	82.0 (80.9 to 83.1)	3.8 (−2.2 to 9.9)	4.7 (−2.7 to 12.1)	0.21
Enrolled during ramp-up period	98.5 (97.6 to 99.4)	93.1 (91.6 to 94.5)	5.5 (4.5 to 6.4)	5.9 (4.9 to 6.9)	<0.001
Enrolled during stable period	50.5 (49.4 to 51.5)	51.2 (49.8 to 52.5)	−0.7 (−1.5 to 0.2)	−1.3 (−2.9 to 0.3)	0.114
Stable post–Part D period					
Out-of-pocket cost, $					
Nonenrolled persons	29.1 (28.6 to 29.6)	31.9 (30.8 to 32.9)	−2.7 (−3.5 to −1.9)	−8.5 (−11.0 to −6.0)	<0.001
All enrolled persons	42.4 (41.6 to 43.1)	51.2 (49.6 to 52.6)	−8.8 (−17.3 to −0.3)	−17.2 (−33.9 to −0.5)	0.043
Enrolled during ramp-up period	43.4 (42.5 to 44.3)	54.5 (52.6 to 56.4)	−11.1 (−14.0 to −9.8)	−20.4 (−24.3 to −16.5)	<0.001
Enrolled during stable period	39.5 (38.2 to 40.7)	41.8 (39.6 to 44.0)	−2.4 (−4.4 to −0.3)	−5.6 (−10.5 to −0.7)	0.026
Pill-days					
Nonenrolled persons	53.9 (53.4 to 54.5)	56.2 (55.5 to 56.8)	−2.2 (−2.6 to −1.8)	−4.0 (−4.8 to −3.2)	<0.001
All enrolled persons	88.1 (87.5 to 88.7)	73.9 (72.9 to 74.9)	14.2 (10.8 to 17.6)	19.2 (14.5 to 23.9)	<0.001
Enrolled during ramp-up period	95.7 (94.9 to 96.5)	82.4 (81.1 to 83.7)	13.7 (12.8 to 14.6)	16.1 (15.1 to 17.1)	<0.001
Enrolled during stable period	66.9 (65.9 to 67.9)	50.2 (49.0 to 51.4)	16.7 (15.7 to 17.7)	32.6 (30.6 to 34.6)	<0.001

* Estimates are based on 117 648 unique pharmacy customers (73 356 did not enroll in Medicare Part D, 32 587 enrolled during the ramp-up period, and 11 705 enrolled during the stable period).
† The ramp-up period is January 2006 through May 2006, before the deadline for enrollment in Medicare Part D. The stable period is June 2006 through April 2007, after the deadline for Part D enrollment.
‡ All individual effects were statistically significant.
§ Counterfactual effects (those that would have resulted if Part D had not been implemented) were estimated by using the generalized estimating equation model described in the **Appendix Figure** (available at www.annals.org).

penditures, or offsets, for inpatient and outpatient care among beneficiaries (20).

Our analyses have several limitations. First, although we observed similar pre–Part D trends in the Part D–eligible and Part D–ineligible groups, our estimates of counterfactual trends assuming Part D was not enacted may be biased if some confounder affects these trends differentially during the post–Part D period. For example, among persons 60 to 63 years of age, anticipation of generous Medicare coverage might have differentially decreased utilization during the post–Part D period. Nonetheless, anticipation effects are unlikely to be a significant factor given the interval before persons 60 to 63 years of age become eligible for Part D benefits. Second, our approach assumes that the absence of a prescription claim for an individual represents no utilization for that person, rather than missing data. However, the people we studied may have obtained only some of their medicines from the pharmacy chain that we examined. Although loyalty to 1 chain would not threaten our conclusions (because we used a similarly defined control group), any correlation between loyalty and Part D enrollment would influence findings drawn from this serial cross-sectional analysis. However, our analysis of a subsample of persons for whom we have complete data on prescription benefits suggested that similar large proportions of persons in each age group (>90%) filled all of their prescriptions within the pharmacy chain in both 2005 and 2006, and we applied inclusion criteria requiring study participants to have had at least 1 prescription claim during both 2005 and 2006. Although alternative statistical approaches, such as generalized linear mixed models, might be used to address this issue, we believe that a larger proportion of zeros in this data set are true representations of no prescription use; considering all these zeros to be missing at random may generate even larger biases. Finally, our analyses do not distinguish between expenditures and utilization that occurred before and after reaching the "doughnut hole," in which Part D beneficiaries incur higher out-of-pocket expenses. Because our analysis was limited to a single national pharmacy chain and because only an estimated 3 to 7 million people entered the doughnut hole in 2006 (21), our ability to estimate effects in this subgroup of patients was limited.

In conclusion, we estimate that the Medicare Part D benefit led to modest increases in drug utilization and modest decreases in out-of-pocket expenditures among a random sample of pharmacy customers who were eligible for the benefit. The findings complement projections and early reports suggesting similar effects and highlight the

need for further work to examine whether these patterns have any effect on health outcomes.

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References

1. **Doherty RB.** Assessing the new medicare prescription drug law. Ann Intern Med. 2004;141:391-5. [PMID: 15353431]
2. **Kaiser Family Foundation.** Medicare Prescription Drug Coverage among Medicare Beneficiaries. Publication 7453. Washington, DC: Kaiser Family Foundation; 2006.
3. **Bach PB, McClellan MB.** The first months of the prescription-drug benefit—a CMS update. N Engl J Med. 2006;354:2312-4. [PMID: 16738266]
4. **Centers for Medicare & Medicaid Services.** Medicare drug plans strong and growing: beneficiaries compared plans and continued to sign up for prescription drug coverage [Press release]. 30 January 2007. Accessed at www.cms.hhs.gov/apps/media/press_releases.asp on 2 February 2007.
5. Chartpack: Seniors' Early Experiences with the Medicare Prescription Drug Benefit—April 2006. Kaiser Family Foundation Health Poll Report Survey. 6–11 April 2006. Washington, DC: Kaiser Family Foundation; 2006.
6. **Cline RR, Mott DA.** Exploring the demand for a voluntary Medicare prescription drug benefit. AAPS PharmSci. 2003;5:E19. [PMID: 12866945]
7. **Heiss F, McFadden D, Winter J.** Who failed to enroll in Medicare Part D, and why? Early results. Health Aff (Millwood). 2006;25:w344-54. [PMID: 16882686]
8. **Kaiser Family Foundation.** The Medicare Rx Law: Estimates of Medicare Beneficiaries Out-of-Pocket Drug Spending in 2006. Modelling the impact of the MMA. Publication 7201. Washington, DC: Kaiser Family Foundation; 2006.
9. **Centers for Medicare & Medicaid Services.** Medicare Part D spending projections down again, Part A and Part B increases highlight need for further reforms [Press release]. 11 July 2006. Accessed at www.cms.hhs.gov/apps/media/press/release.asp?Counter=1895 on 31 August 2006.
10. **Pauly MV.** Medicare drug coverage and moral hazard. Health Aff (Millwood). 2004;23:113-22. [PMID: 15002634]
11. **Lichtenberg FR, Sun SX.** The impact of Medicare Part D on prescription drug use by the elderly. Health Aff (Millwood). 2007;26:1735-44. [PMID: 17978393]
12. **Krieger N.** Overcoming the absence of socioeconomic data in medical records: validation and application of a census-based methodology. Am J Public Health. 1992;82:703-10. [PMID: 1566949]
13. **Geronimus AT, Bound J.** Use of census-based aggregate variables to proxy for socioeconomic group: evidence from national samples. Am J Epidemiol. 1998;148:475-86. [PMID: 9737560]
14. **Stuart B, Simoni-Wastila L, Baysac F, Shaffer T, Shea D.** Coverage and use of prescription drugs in nursing homes: implications for the medicare modernization act. Med Care. 2006;44:243-9. [PMID: 16501395]
15. **Rubin D.** Estimating causal effects of treatment in randomized and nonrandomized studies. J Educ Psychol. 1974;66:688-701.
16. **Holland P.** Statistics and causal inference. J Am Stat Assoc. 1986;81:945-61.
17. **Khan N, Kaestner R, Lin SJ.** Prescription drug insurance and its effects on utilization and health in the elderly. NBER Working Paper 12848. Cambridge, MA: National Bureau of Economic Research; January 2007.
18. **Manning WG, Basu A, Mullahy J.** Generalized modeling approaches to risk adjustment of skewed outcomes data. J Health Econ. 2005;24:465-88. [PMID: 15811539]
19. **Manning WG.** The logged dependent variable, heteroscedasticity, and the retransformation problem. J Health Econ. 1998;17:283-95. [PMID: 10180919]
20. **Gaynor M, Li J, Vogt WB.** Is drug coverage a free lunch? Cross-price elasticities and the design of prescription drug benefits. NBER Working Paper 12758. Cambridge, MA: National Bureau of Economic Research; December 2006.
21. **Berkowitz SA, Gerstenblith G, Anderson GF.** Medicare prescription drug coverage gap: navigating the "doughnut hole" with patients. JAMA. 2007;297:868-70. [PMID: 17327528]

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Appendix Figure. Full specification of the generalized estimating equation model.

We estimate:
Log(E{Y| X, M, Pre, RU, STB, Trt}) =

$$\beta_0 + \underbrace{\beta_1*M*Pre + \beta_2*M^2*Pre + \beta_3*M^3*Pre}_{\text{(Pre–Part D trends for Part D–ineligible group)}} + \beta_4*Trt + \underbrace{\beta_5*M*Pre*Trt + \beta_6*M^2*Pre*Trt + \beta_7*M^3*Pre*Trt}_{\text{(Pre–Part D changes in trends for Part D–eligible group)}} +$$

$$\underbrace{\beta_8*RU + \beta_9*M*RU}_{\text{(Ramp-up post–Part D trends for Part D–ineligible group)}} + \underbrace{\beta_{10}*RU*Trt + \beta_{11}*M*RU*Trt}_{\text{(Ramp-up post–Part D changes in trends for Part D–eligible group)}} +$$

$$\underbrace{\beta_{12}*STB + \beta_{13}*M*STB + \beta_{14}*M^2*STB + \beta_{15}*M^3*STB}_{\text{(Stable post–Part D trends for Part D–ineligible group)}} + \beta_{16}*STB*Trt + \underbrace{\beta_{17}*M*STB*Trt + \beta_{18}*M^2*STB*Trt + \beta_{19}*M^3*STB*Trt}_{\text{(Stable post–Part D changes in trends for Part D–eligible group)}} + \gamma^T*X$$

where
Y = outcomes that include monthly out-of-pocket costs, pill-days, and number of prescriptions
M = (months – 15) and months range from 1 to 32
Pre = indicator for time < January 2006
RU = indicator for time > January 2006 and ≤ May 2006
STB = indicator for time > May 2006
Trt = indicator for treatment group
X = additional covariates as reported in the Statistical Analysis section.

Step 1: Examine estimates of β_5, β_6, and β_7. They represent the changes in the cubic trend between the treatment and control group during the pre–Part D period. Perform joint test to see if statistically significant. Even if significant (which may be a manifestation of sample size), examine the values to infer whether the trends are substantively different between the treatment and control groups. If they are not different, then proceed to form the counterfactual trend by using the control trends in the post–Part D period.

Step 2: Predict factual (actual) and counterfactual (predicted) trends.

Predict factual trend for the ramp-up post–Part D period:

$$\hat{E}\{Y|X_{Trt}, M_{RU}\} = \exp(\hat{\beta}_0 + \hat{\beta}_4 + \hat{\beta}_8 + \hat{\beta}_9*M + \hat{\beta}_{10} + \hat{\beta}_{11}*M + \hat{\gamma}^T*X)$$

where only M in the ramp-up post–Part D period and Xs for the treatment group are used.

Predict counterfactual trend for the ramp-up post–Part D period:

$$\hat{E}\{Y|X_{Trt}, M_{RU}\} = \exp(\hat{\beta}_0 + \hat{\beta}_4 + \hat{\beta}_8 + \hat{\beta}_9*M + \hat{\gamma}^T*X)$$

where only M in the ramp-up post–Part D period and Xs for the treatment group are used.

The difference between these factual and counterfactual estimates averaged over the M in the ramp-up post–Part D period and Xs in the treatment group provides an estimate of the policy effect for the ramp-up post–Part D period.

Predict factual trend for the stable post–Part D period:

$$\hat{E}\{Y|X_{Trt}, M_{STB}\} = \exp(\hat{\beta}_0 + \hat{\beta}_4 + \hat{\beta}_{12} + \hat{\beta}_{13}*M + \hat{\beta}_{14}*M^2 + \hat{\beta}_{15}*M^3 + \hat{\beta}_{16} + \hat{\beta}_{17}*M + \hat{\beta}_{18}*M^2 + \hat{\beta}_{19}*M^3 + \hat{\gamma}^T*X)$$

where only M in the stable post–Part D period and Xs for the treatment group are used.

Predict counterfactual trend for the stable post–Part D period:

$$\hat{E}\{Y|X_{Trt}, M_{STB}\} = \exp(\hat{\beta}_0 + \hat{\beta}_4 + \hat{\beta}_{12} + \hat{\beta}_{13}*M + \hat{\beta}_{14}*M^2 + \hat{\beta}_{15}*M^3 + \hat{\gamma}^T*X)$$

where only M in the stable post–Part D period and Xs for the treatment group are used.

The difference between these factual and counterfactual estimates averaged over the M in the stable post–Part D period and Xs in the treatment group provides an estimate of the policy effect for the stable post–Part D period.

Appendix Table 1. **Comparison of Participant Characteristics with Those of a Nationally Representative Sample Derived from the Behavioral Risk Factor Surveillance Survey***

Characteristic	Pharmacy Sample†		BRFSS Respondents			
			Nationally Representative Sample		Sample Derived from Same Counties as Pharmacy Sample	
	Age 60–63 y	Age 66–79 y	Age 60–63 y	Age 66–79 y	Age 60–63 y	Age 66–79 y
Age, *y*	61.8 (1.1)	72.1 (3.7)	61.44 (1.12)	72.3 (4.07)	61.4 (11.2)	72.5 (4.07)
Women, %	55.7 (49.7)	57.5 (49.4)	51.7	56.5	51.9	56.5
ZIP code–based characteristics						
Total population, *1000 n*	29.2 (16.8)	29.8 (16.9)	17.7 (10.0)	17.8 (10.3)	23.9 (10.6)	22.7 (10.5)
Median household income, *$1000*	47.5 (17.1)	45.9 (16.6)	46.9 (12.4)	46.6 (12.3)	48.01 (12.1)	47.4 (12.2)
Income per capita, *$1000*	23.5 (9.7)	23.3 (9.8)	23.0 (6.52)	22.9 (6.39)	23.6 (6.43)	23.4 (6.34)
Urban residence, %	87.2 (24.9)	89.2 (22.8)	67.5 (28.8)	68.1 (28.8)	79.3 (23.6)	78.3 (24.0)
African American, %	11.7 (19.2)	12.0 (19.7)	10.1 (11.5)	10.4 (11.7)	10.7 (11.7)	11.0 (11.9)
Employment rate, %	94.7 (3.4)	94.4 (3.4)	94.1 (2.5)	94.1 (2.41)	94.4 (2.28)	94.3 (2.26)
Poverty rate, %	10.5 (7.8)	11.0 (8.0)	11.6 (5.35)	11.6 (5.21)	11.1 (5.09)	11.3 (5.17)

* Unless otherwise indicated, data are sample means (SD). BRFSS = Behavioral Risk Factor Surveillance Survey.
† Based on 59 663 persons age 60 to 63 years and 117 648 persons age 66 to 79 years.

Appendix Table 2. Coefficients from Generalized Estimating Equation Models*

Covariate	Response		
	Mean Out-of Pocket Costs	Number of Prescriptions	Pill-Days
Pre–Part D period			
Part D–ineligible persons			
Intercept	1.853 ± 0.10†	0.062 ± 0.065	3.681 ± 0.094†
Month*Pre	0.133 ± 0.01†	0.136 ± 0.004†	0.125 ± 0.003†
Month^2*Pre	0.024 ± 0.0017†	0.025 ± 0.0007†	0.023 ± 0.0004†
Month^3*Pre	0.001 ± 0.00008†	0.001 ± 0.00003†	0.001 ± 0.00002†
Part D–eligible persons			
TRT	0.074 ± 0.014†	−0.021 ± 0.007‡	0.014 ± 0.007†
Month*Pre*TRT	−0.008 ± 0.007	0.0005 ± 0.003	0.006 ± 0.001†
Month^2*Pre*TRT	−0.001 ± 0.001	0.00003 ± 0.00052	0.001 ± 0.00021†
Month^3*Pre*TRT	−0.00003 ± 0.00005	0.00001 ± 0.00002	0.00006 ± 0.00001†
Ramp-up post–Part D period			
Part D–ineligible persons			
RampUp	0.094 ± 0.014†	0.048 ± 0.005†	0.1 ± 0.004†
Month*RampUp	−0.027 ± 0.005†	−0.018 ± 0.002†	−0.029 ± 0.001†
Part D–eligible persons			
RampUp*TRT	−0.008 ± 0.015	0.018 ± 0.006‡	0.022 ± 0.004†
Month*RampUp*TRT	−0.031 ± 0.004†	0.002 ± 0.002	0.003 ± 0.001‡
Stable post–Part D period			
Part D–ineligible persons			
STB	1.988 ± 0.209†	1.53 ± 0.082†	2 ± 0.049†
Month*STB	−0.643 ± 0.066†	−0.509 ± 0.026†	−0.651 ± 0.016†
Month^2*STB	0.06 ± 0.006†	0.048 ± 0.003†	0.062 ± 0.002†
Month^3*STB	−0.002 ± 0.0002†	−0.001 ± 0.0001†	−0.002 ± 0†
Part D–eligible persons			
STB*TRT	−1.038 ± 0.196†	−0.009 ± 0.079	0.109 ± 0.042†
Month*STB*TRT	0.254 ± 0.059†	0.01 ± 0.024	−0.023 ± 0.012
Month^2*STB*TRT	−0.022 ± 0.006†	−0.00085 ± 0.002	0.00239 ± 0.001§
Month^3*STB*TRT	0.0006 ± 0.0002‡	0.00003 ± 0.00007	−0.00007 ± 0.00003§
Model specification			
Link	Log	Log	Log
Distribution	Gamma	Negative binomial	Negative binomial
Correlation structure	AR(1)	AR(1)	Unstructured

* Data are the coefficient estimates from the log-link models (±SE).
† $P < 0.001$.
‡ $P < 0.010$.
§ $P < 0.050$.