



Original Research

# Effects of Medicare Part D on drug affordability and use: Are seniors with prior high out-of-pocket drug spending affected more?

David A. Mott, Ph.D.<sup>a,\*</sup>, Joshua M. Thorpe, Ph.D.<sup>a</sup>,  
Carolyn T. Thorpe, Ph.D.<sup>b</sup>, David H. Kreling, Ph.D.<sup>a</sup>,  
Abhijit S. Gadkari, Ph.D.<sup>a</sup>

<sup>a</sup>*Sonderegger Research Center, Division of Social and Administrative Sciences, University of Wisconsin School of Pharmacy, Madison, WI, 53705 USA*

<sup>b</sup>*Department of Population Health Sciences, Health Innovation Program University of Wisconsin—Madison, E5/724 CSC, 600 Highland Ave. Madison, WI, 53792 USA*

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## Abstract

**Background:** Medicare Part D was expected to have differential impacts on patient drug expenditures and use based on beneficiaries' levels of pre-Part D patient drug spending, but it is unknown whether these projections have borne out.

**Objectives:** We sought to evaluate whether and how the policy effect of Medicare Part D on drug expenditures and use was modified by levels of pre-Part D drug spending.

**Methods:** A quasi-experimental, pretest-posttest, nonequivalent control group design was used. Data were obtained from a regional supermarket chain for all prescriptions dispensed between January 1, 2005, and December 31, 2007 (n = 1,230,612) to patients aged 60 years and older as of January 1, 2005 (n = 51,305) to construct 12-month pre-Part D and post-Part D periods. Annual medication use was measured as the total number of pill days acquired. Annual drug expenditures were measured as total expenditures, patient out-of-pocket expenditures, and the proportion of total expenditures paid out of pocket by the patient.

**Results:** Part D resulted in significant reductions in out-of-pocket spending (17.6%) and significant increases in drug use (4.0%) for individuals in the highest pre-Part D drug-spending group relative to controls. The reduction in out-of-pocket spending for the highest pre-part D spending group was significantly greater compared with the moderate and lowest pre-Part D spending groups.

**Conclusions:** Our findings suggest that, as expected, Part D facilitated access to medications for patients who previously experienced the greatest costs without adversely increasing use and costs among those with the lowest prior cost.

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**Keywords:** Medicare Part D; Use; Out-of-pocket spending; Access

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\* Corresponding author. 777 Highland Avenue, Madison, WI, 53705, USA. Tel.: +608 265 9268; fax: +608 262 5262.  
E-mail address: [damott@pharmacy.wisc.edu](mailto:damott@pharmacy.wisc.edu) (D.A. Mott).

## Introduction

In the early part of this century, high need for medications coupled with limited access to prescription drug insurance and rising medication costs presented considerable challenges for older adults in the United States.<sup>1</sup> Estimates from 2002 showed that nearly half of all Medicare beneficiaries lacked drug coverage for at least a part of the year<sup>2</sup> and that beneficiaries' average annual out-of-pocket drug spending had risen from \$644 to \$996 from 2000 to 2003.<sup>1</sup> Under the Medicare Prescription Drug Improvement and Modernization Act of 2003, the Part D prescription drug benefit became available to all Medicare beneficiaries starting January 1, 2006. The overall goal of this largest expansion in the Medicare program since its inception was to improve coverage for prescription drugs among the Medicare population and, in doing so, ease their financial burden associated with obtaining prescription drugs and increase access to medications.<sup>3</sup>

There is evidence that implementing the Part D benefit has reached some level of success in attaining these goals. In the first 2 years after implementing Medicare Part D, the proportion of Medicare-eligible individuals with "creditable" drug coverage (ie, coverage at least as generous as the standard Part D benefit) increased to approximately 90%.<sup>4,5</sup> Recent reports also have shown that, overall, implementing Part D yielded modest but significant increases in medication use and decreases in Medicare beneficiaries' out-of-pocket drug spending.<sup>5–11</sup>

These early studies show promising results but provide little insight regarding the impact of Medicare Part D for individuals with varying levels of prior financial burden for drugs. One report before implementation projected that although the distribution of pre-Part D out-of-pocket drug spending among Medicare-eligible individuals was widely dispersed, Medicare Part D was expected to lower the overall out-of-pocket drug costs primarily by decreasing the number of beneficiaries with the highest out-of-pocket costs.<sup>3</sup> However, it is unknown whether these projections have borne out, that is, whether Part D decreased out-of-pocket drug spending among individuals with high pre-enrollment out-of-pocket drug spending and, thus, improved access to medications among a subgroup of beneficiaries who needed it most.

Additionally, all Medicare beneficiaries were offered the opportunity—and encouraged by

means of financial incentives—to enroll in the Part D benefit, including individuals with low out-of-pocket spending burdens.<sup>12</sup> These patients may have had low out-of-pocket costs because of low need for medication, or conversely, because they were unable to afford needed prescription medications (ie, unmet need). Part D relies on the inclusion of individuals with low need for medication (and their contribution of premium payments) to offset costs to the program incurred by those with high medication needs who will use more. Part D solvency, at least in part, therefore, relies on the assumption that providing a prescription benefit to all beneficiaries does not have the unintended consequence of increasing use among those with low medication needs. Understanding the extent to which Part D affected the use among beneficiaries with prior low medication-spending burdens would provide some insight into the ability of Medicare Part D to remain solvent.

We sought to assess whether Part D had the intended effects of helping individuals with heavy financial burden without increasing use among individuals with low financial burden by examining the Medicare Part D policy effect for subpopulations of Part D-eligible older adults based on their levels of out-of-pocket drug spending before the policy taking effect. Specifically, we sought to (1) evaluate whether the policy effect of Medicare Part D on drug use and cost differed by levels of pre-Part D out-of-pocket drug spending and (2) characterize the Part D policy effect within each level of pre-Part D out-of-pocket spending. For both aims, we examined how the outcomes changed from pre-Part D period to post-Part D period for Medicare-eligible individuals compared with a control group of noneligible individuals.

## Methods

### *Approach to study the Medicare Part D policy effect*

We adopted a broad, population-level approach to examine the Medicare Part D policy effect. According to our approach, we were interested in examining whether the initial availability of Medicare Part D in January 2006 changed relevant drug-expenditure and drug-use outcomes relative to the year immediately preceding that of the availability of Medicare Part D for a defined population of seniors eligible for Medicare Part D and a defined control population of persons presumably not eligible for Medicare Part D. To statistically test the Medicare

Part D policy effect, we used a difference-in-difference (DD) approach. This is a powerful approach to estimate policy effects, because it accounts for differences in outcomes among study groups (a group exposed to the policy and a group not exposed [control]) and changes in outcomes within groups across time (a period before the policy was in effect and a period after the policy was in effect). Additionally, the DD approach controls for all differences across the study groups that are invariant across time.<sup>13</sup> This feature of the DD approach makes it possible to control for individual-level characteristics that may confound the Medicare Part D policy effect, even without measuring them. Such factors include stable clinical factors, disease severity, and preferences to use medical care, which remain the same across the short study period. The DD approach was used in a previous study of the policy effect of Medicare Part D.<sup>6</sup>

#### *Data source*

Data were obtained from a regional supermarket chain with 22 pharmacies located in the southeastern United States for all prescriptions dispensed between January 1, 2005, and December 31, 2007 ( $n = 1,230,612$ ) to all patients aged 60 years and older as of January 1, 2005 ( $n = 51,305$ ). Each record in the database contained information about the patient (a unique, nonidentifiable ID number, date of birth, sex, and zip code of residence) and the prescription (drug name and strength, National Drug Code, fill date, number of days' supply, quantity dispensed, total payment/price, patient payment, and insurer payment). The study was approved by the university's Institutional Review Board.

#### *Design and sample*

We used a quasi-experimental, pretest-posttest, nonequivalent control group design. The preintervention period was defined as the 12 months before the beginning of Part D (January 1, 2005, through December 31, 2005). The postintervention period was the 12 months after Part D began (January 1, 2006, through December 31, 2006). The treatment group included individuals who were eligible, according to age, for Part D coverage on January 1, 2006 (ages: 65+ years). The control group was constructed to include individuals who were ineligible for Medicare coverage during the entire study period and was comprised of individuals aged 60–62 years on January 1, 2006. Although it is possible that a small number of individuals in this comparison

group were eligible for Medicare coverage because of disability, they were assumed to be ineligible.<sup>14</sup> To be included in the analysis, patients were required to have at least 1 fill in the preintervention period (2005) as well as in 2006 and 2007. Requiring a fill in 2007 helped ensure that all patients in our sample remained users of the supermarket pharmacy in 2006.

#### *Outcomes*

##### *Use*

Each person's annual medication use was measured as the total number of pill days and was calculated by summing the number of days' supply of all prescriptions filled by a person in a year. Therefore, pill days represent the total number of days' supply of medication, across all medications, that a patient acquired in a year. For example, a person who took 2 medications and acquired exactly enough pills to use these medications as prescribed everyday for a year would have a pill day value of 730 (2 medications  $\times$  365 days' supply per medication = 730 pill days).

##### *Expenditures*

We calculated 3 variables to summarize annual medication expenditures. Total annual medication spending was calculated by summing the total payment from all sources (patient and insurer) across all prescriptions filled in each year for each person. Total patient out-of-pocket drug spending was calculated by summing the patient payment amount across all prescriptions filled in each year. We determined the annual average percent of total payment paid out of pocket by each patient, by calculating the ratio of patient out-of-pocket payment to total payment for each prescription fill and determining the mean of these ratios.

##### *Covariates*

##### *Pre-Part D out-of-pocket drug spending*

To examine whether effects of Part D varied based on individuals' levels of out-of-pocket drug spending before Part D began, we constructed a categorical variable to classify patients based on their total amount of out-of-pocket drug spending in 2005. Cut points were established to partition individuals in the treatment and control groups into approximately equal-sized groups (thirds) representing "lowest" (up to \$66), "moderate" (\$66.01–469.61), and "highest" (more than \$469.61) out-of-pocket drug spending in 2005. There were no theoretical or policy-based reasons to guide our cut-point decision.

### Patient characteristics

Patient age at the beginning of our study period (January 1, 2005) and his or her sex were abstracted from prescription-fill records for each patient, for use as control variables in our analyses.

### Data analysis

To explore the generalizability of findings from the study sample, we used data from the 2005 Behavioral Risk Factor Surveillance System (BRFSS) to compare the characteristics of residents from our sample's geographic area (ie, the 4 counties covered by the supermarket chain containing 95% of our sample) with the characteristics of all other community-dwelling older adults in the United States. The BRFSS is an annual state-based telephone interview survey coordinated by the Centers for Disease Control and Prevention. Variables included in the analysis were age (years), sex, race/ethnicity (non-Hispanic white, non-Hispanic black, Hispanic, and other race/ethnicity), formal education (years), health insurance (yes, no), income (<\$20,000 per year vs \$20,000+ per year), perceived medical cost barriers in past year (yes, no), perceived health status (fair/poor vs good/very good/excellent), number of days during the past 30 days when physical health was reported as not good and number of days during the past 30 days when mental health was reported as not good. Bivariable analyses were performed to examine whether the characteristics of older adults residing in our sample's geographic area were similar to those residing in the rest of the United States. All analyses incorporated sampling weights and adjusted standard errors for the complex sampling design of BRFSS.

In terms of the expenditure and utilization variables in 2005 and 2006, we examined means and standard deviations for individuals eligible for Part D and the control group individuals, along with mean age (as of January 1, 2005) and sex distribution in each pre-Part D out-of-pocket drug-spending category. Differences in means within each spending category between study groups within each study year were tested using *t*-tests. The association of the sex and the study group within each year was determined using Chi-square tests.

To examine whether the effect of Part D differed based on pre-Part D out-of-pocket drug spending, we used a difference-in-difference-in-difference (DDD) modeling approach that controlled for

observed changes over time in medication use and expenditures in the control group. We estimated the following linear regression model:

$$Y_{ijk} = B_0 + B_1\text{post} + B_2\text{Part D eligible} + B_3\text{HighSpend} + B_4\text{LowSpend} + B_5\text{post} \times \text{Part D eligible} + B_6\text{post} \times \text{HighSpend} + B_7\text{post} \times \text{LowSpend} + B_8\text{Part D eligible} \times \text{HighSpend} + B_9\text{Part D eligible} \times \text{LowSpend} + B_{10}\text{post} \times \text{Part D eligible} \times \text{HighSpend} + B_{11}\text{post} \times \text{Part D eligible} \times \text{LowSpend} + B_{12}\text{age} + B_{13}\text{sex} + e_{i,j,k}$$

The coefficients  $B_{10}$  and  $B_{11}$  were the coefficients of interest from this model. These coefficients show whether the policy effect of Part D is different between the high and moderate levels of pre-Part D spending and the moderate and low levels of pre-Part D spending, respectively. To determine whether the policy effect of Part D was different between the high and low levels of pre-Part D spending, a similar model was estimated with the low level of pre-Part D spending as the excluded group.

To better characterize the effect of Medicare Part D availability on changes in use and expenditures from 2005 to 2006 within each level of pre-Part D out-of-pocket drug spending, we estimated separate DD regression models for each of the 4 outcomes described earlier using subsamples of the study population based on levels of pre-Part D spending. We estimated the following linear regression model for each level of pre-Part D spending:

$$Y_{ij} = B_0 + B_1\text{post} + B_2\text{PartD eligible} + B_3\text{post} \times \text{Part D eligible} + B_4\text{age} + B_5\text{sex} + e_{ij}$$

The coefficient  $B_3$  represents the policy effect of interest. We used the regression results to estimate adjusted means for each outcome to compare the pre-post differences between treatment and control groups within each pre-Part D spending category.

Because utilization and expenditure data are often non-normal and right skewed, various data transformations (eg, logarithmic) are often used to mitigate any resultant biases to variance estimates.<sup>15</sup> Although a logarithmic transformation has attractive statistical properties, there are also conceptual considerations about whether the relationships being examined are additive or multiplicative. For older adults who already tend to have high medication use and expenditures, we believe

Table 1

Summary of outcome variables and patient characteristics at baseline (2005) for individuals eligible for Part D and those of the control group by level of pre-Part D out-of-pocket drug spending

Outcome variables and patient characteristics	Overall	Lowest level of pre-Part D spending	Moderate level of pre-Part D spending	Highest level of pre-Part D spending
Part D eligible, n	11,133	3,681	3,778	3,674
Total drug spending	\$1208 (\$6276)	\$123 (\$495)	\$1018 (\$1452)	\$2490 <sup>a</sup> (\$1987)
Patient out-of-pocket drug spending	\$530 <sup>a</sup> (\$852)	\$13 <sup>a</sup> (\$17.9)	\$218 (\$118)	\$1369 <sup>a</sup> (\$1054)
% Patient paid out of pocket	46 (37)	22 <sup>a</sup> (34)	50 <sup>a</sup> (33)	66 <sup>a</sup> (30)
Pill days	680 <sup>a</sup> (817)	80 (322)	555 <sup>a</sup> (577)	1410 (817)
Age	74.5 <sup>a</sup> (6.5)	74.1 <sup>a</sup> (6.1)	74.3 <sup>a</sup> (6.5)	75.2 <sup>a</sup> (6.8)
% Female	62.3 <sup>b</sup>	58.8	61.8	66.2 <sup>b</sup>
Control, n	1652	415	763	474
Total drug spending	\$1142 (\$1559)	\$112 (\$333)	\$691 (\$746)	\$2769 <sup>a</sup> (\$1893)
Patient out-of-pocket drug spending	\$409 <sup>a</sup> (\$560)	\$29 <sup>a</sup> (\$17)	\$220 (\$116)	\$1045 <sup>a</sup> (\$693)
% Patient paid out of pocket	49 (28)	58 <sup>a</sup> (34)	48 <sup>a</sup> (26)	45 <sup>a</sup> (21)
Pill days	620 <sup>a</sup> (707)	81 (222)	451 <sup>a</sup> (400)	1366 (765)
Age	61.0 <sup>a</sup> (0.58)	61.0 <sup>a</sup> (0.58)	61.0 <sup>a</sup> (0.58)	61.0 <sup>a</sup> (0.59)
% Female	59.5 <sup>b</sup>	60.0	58.7	60.3 <sup>b</sup>

Numbers in parentheses are standard deviations. Spending categories (lowest, moderate, and highest) were created by determining cut points representing thirds of the distribution of the pre-Part D patient out-of-pocket drug-spending variable for seniors eligible for Part D.

<sup>a</sup>  $P < .05$ ; difference in mean between seniors eligible for Part D and the control group individuals overall and within pre-Part D spending level, *t*-test.

<sup>b</sup>  $P < .05$ ; test of association between seniors eligible for Part D and the control group individuals overall and within pre-Part D spending level, Chi-squared test.

it unlikely for any policy to have a multiplicative impact on medication use and expenditures. We deemed an additive model to be a more realistic representation of the possible Part D impact in older adults' use and, therefore, made no transformation to outcome variables in the study. Additionally, log transformations are comparisons of geometric means between treatment and control, when the relevant comparison for answering population-level policy questions is the arithmetic (nontransformed) mean.<sup>16</sup> To account for possible violations of distributional assumptions, we estimated model standard errors using a bootstrapping approach. Generalized least-square regression was used to estimate all models, which adjusts standard errors for clustering within individuals. All analyses were conducted using STATA version 10.0 (STATA Corp, College Station, TX).

## Results

### Sample characteristics

Individuals in counties represented by our sample were less likely to have less than a high-school education (7% vs 15%,  $P < .05$ ), were less

likely to have a household income less than \$20,000 (14% vs 26%,  $P < .01$ ), had a higher proportion of African American residents (14% vs 7%,  $P < .01$ ), and were less likely to report a delay in seeing a doctor because of cost (2% vs 6%,  $P < .05$ ). There were no statistically significant differences with regard to age, sex, insurance coverage, or any of the measures of health status.

Table 1 shows baseline sample characteristics for the Part D-eligible and control groups overall and with regard to pre-Part D out-of-pocket spending level. The overall mean age of patients in our sample was 72.8 years (STD [standard deviation] = 7.6), and 62.0% were females. There were 11,133 and 1625 individuals identified in the Part D-eligible and the control groups, respectively. Individuals who were Part D eligible were significantly older (74.5 vs 61.0 years,  $t = -84.5$ ,  $P < .0001$ ) and were more likely to be females (62.3% vs 59.5%,  $\chi^2(1 \text{ df}) = 4.68$ ,  $P < .05$ ) than individuals in the control group.

Several significant differences between Part D eligibles and the control group individuals within each level of pre-Part D spending were also detected. Among individuals with moderate and highest levels of pre-Part D spending, generally,



Table 2  
Results for Part D policy effect across levels of pre-Part D out-of-pocket drug spending (DDD regression models)

Outcome variables	Highest vs. moderate	Highest vs. lowest	Moderate vs. lowest
Total spending	225.2 (–36.4 to 712.6)	152.7 <sup>a</sup> (20.0-300.4)	–72.5 (–568.6 to 141.5)
Patient out-of-pocket drug spending	–234.2 <sup>a</sup> (–286.3 to –180.1)	–227.8 <sup>a</sup> (–286.9 to –172.5)	6.4 (–15.7 to 28.2)
% Spending out of pocket	–6.2 <sup>a</sup> (–8.7 to –3.9)	–20.2 <sup>a</sup> (–24.2 to –16.5)	–13.9 <sup>a</sup> (–17.9 to –10.1)
Pill days	16.8 (–30.5 to 64.4)	68.3 <sup>a</sup> (17.6-114.8)	51.5 <sup>a</sup> (15.5-84.6)

The numbers are coefficients (95% bias corrected confidence interval). The coefficients represent the difference in the change in the level of a dependent variable in the post-period relative to the pre-period for Part D eligibles relative to the control group individuals between each level of pre-Part D out-of-pocket drug spending. The value of –234.2 in column 2 for patient out-of-pocket drug spending suggests that the policy effect of Part D resulted in a significantly greater reduction in out-of-pocket drug spending of \$234 after availability of Part D for eligible seniors with the highest level of pre-part D spending compared with eligible seniors with a moderate level of pre-Part D spending relative to the control group individuals.

<sup>a</sup>  $P < 0.05$ .

the differences reflect the fact that Part D eligibles used more medications, paid more out of pocket for medications, and paid a larger proportion of medication costs out of pocket relative to the control group.

#### *Difference in Part D policy effect between levels of pre-Part D out-of-pocket drug spending*

The results of the DDD models showed statistically significant differences in the overall policy effect of Part D for most of the outcomes across the 3 levels of pre-Part D out-of-pocket drug spending (Table 2). The change in all 4 outcomes for individuals in the highest pre-Part D out-of-pocket drug-spending group was significantly different relative to individuals in the lowest pre-Part D out-of-pocket drug-spending group. Part D resulted in significantly greater reductions in absolute (\$234.2) and relative (6.2 percentage points) out-of-pocket spending for individuals in the highest pre-Part D out-of-pocket drug-spending group relative to individuals in the

moderate pre-Part D out-of-pocket drug-spending group. In terms of differences between the moderate and lowest pre-Part D out-of-pocket drug-spending levels, Part D resulted in significantly greater increases in pill days of medication (51.5 pill days) and significantly greater reductions in the proportion of out-of-pocket drug spending (13.9 percentage points).

#### *Difference in Part D policy within levels of pre-Part D out-of-pocket drug spending*

There were statistically significant differences in the total policy effect of Part D within the 3 out-of-pocket drug-spending groups between 2005 and 2006 (Table 3). Among individuals with the highest pre-Part D out-of-pocket drug spending, out-of-pocket spending (both absolute and proportional) decreased significantly more for Part D eligibles relative to that of the control group, and pill days of medication increased significantly more for Part D eligibles relative to those of the control group. The mean adjusted proportion of

Table 3  
Overall policy effect of Part D on 5 outcomes by pre-Part D out-of-pocket drug-spending levels: 2005-2006

Outcome variables	Highest	Moderate	Lowest
Total spending	119.6 (–10.9 to 273.7)	–105.6 (–696.7 to 80.5)	–33.1 (–89.9 to 13.4)
Patient out-of-pocket drug spending	–241.0 <sup>a</sup> (–286.4 to –180.6)	–6.8 (–19.7 to 21.1)	–13.2 (–27.1 to –4.5)
% Spending out of pocket	–15.3 <sup>a</sup> (–17.1 to –13.3)	–9.1 <sup>a</sup> (–11.8 to –7.1)	4.9 <sup>a</sup> (1.4-8.6)
Pill days	56.1 <sup>a</sup> (2.5-127.6)	39.4 <sup>a</sup> (0.07-68.5)	–12.2 (–38.9 to 14.2)

The numbers are coefficients (95% Bias Corrected Confidence Interval). The models controlled for patient age, sex, a group dummy variable, and a study period dummy variable.

<sup>a</sup>  $P < .05$ .

out-of-pocket drug spending decreased by 16.8 percentage points for Part D eligibles (65.1% to 48.3%) compared with 1.6 percentage points for the control group (49.7% to 48.2%) (Fig. 1). Prescription use increased by 43 pill days for Part D eligibles (1398 to 1441) compared with a decrease of 13 pill days for the control group (1458 to 1445) (Fig. 2). Mean adjusted out-of-pocket drug spending decreased by 21.2% for Part D eligibles compared with 4.1% for the control group individuals (data available from the authors).

Among individuals with moderate pre-Part D out-of-pocket drug spending, the proportion of out-of-pocket drug spending decreased significantly more for Part D eligibles relative to that of the control group, and the number of pill days of medication increased significantly more for Part D eligibles relative to that of the control group between 2005 and 2006 (Table 3). The mean adjusted proportion of out-of-pocket drug spending decreased by 9 percentage points for Part D eligibles (50.6% to 41.6%), whereas individuals in the control group experienced no change (46.0% to 46.0%) (Fig. 1). Although both Part D eligibles and the control group individuals experienced an increase in mean adjusted pill days of medication, the increase for Part D eligibles (91 pill days: 535 to 626) was nearly twice the increase for the control group individuals (53 pill days: 549 to 602)

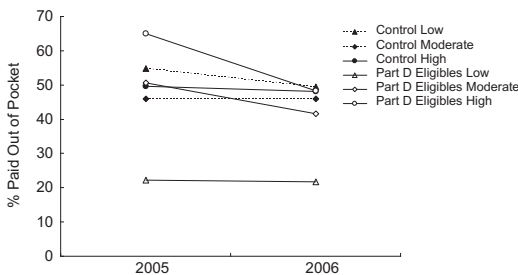


Fig. 1. Change in adjusted percentage of prescription drug costs paid out of pocket with regard to Medicare Part D eligibility in 2006 (Part D eligible vs control) and 2005 prescription spending levels (low, moderate, high). Note: Dashed lines indicate control group trends adjusted for age and sex; solid lines indicate Part D-eligible group trends adjusted for age and sex. For Part D eligibles in the low-, moderate-, and high-spending groups, the adjusted percentage of drug costs paid out of pocket decreased by 0.6, 9.0, and 16.8 percentage points, respectively. For control individuals in the low-, moderate-, and high-spending groups, the adjusted percentage of drug costs paid out of pocket decreased by 1.5, 0.0, and 5.5 percentage points, respectively.

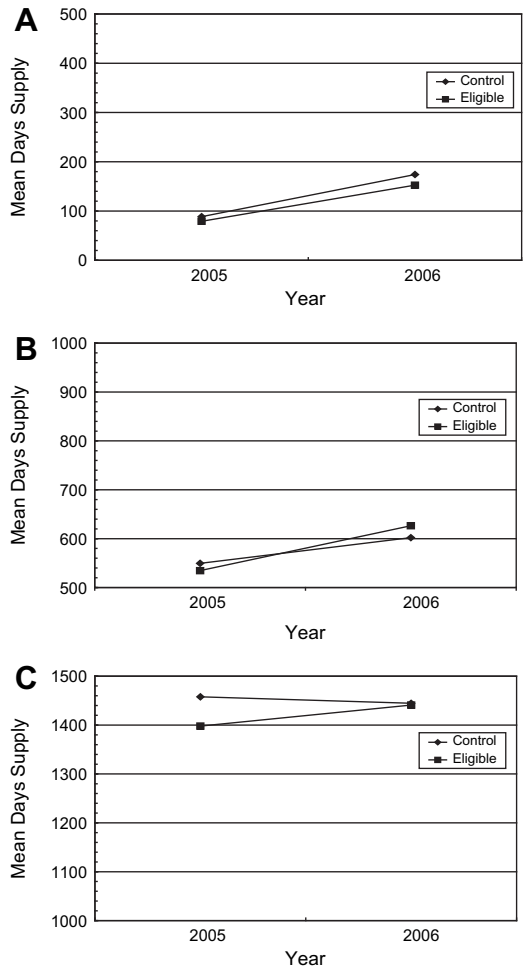


Fig. 2. Change in adjusted mean pill days with regard to Medicare Part D eligibility in 2006 (Part D eligible vs control) and 2005 prescription spending levels [(A) low, (B) moderate, and (C) high]. Note: Trends are adjusted for age and sex. For Part D eligibles in the low-, moderate-, and high-spending groups, adjusted mean pill days increased by 92.4%, 17.0%, and 3.1%, respectively. For control individuals in the low- and moderate-spending groups, adjusted mean pill days increased by 95.5%, and 9.6%, respectively. For control individuals in the high-spending group, adjusted mean pill days decreased by 0.9%.

(Fig. 2). Mean adjusted out-of-pocket drug spending increased by 19.8% for Part D eligibles compared with 22.2% for the control group (figure available from the authors).

Among individuals with the lowest pre-Part D out-of-pocket drug spending, the only statistically significant difference between Part D eligibles and

the control group individuals was the change in the proportion of out-of-pocket drug spending (Table 3). According to Fig. 1, the mean adjusted proportion of out-of-pocket drug spending for individuals eligible for Part D decreased by 0.6 percentage points (22.3% to 21.7%) compared with a decrease of 5.5 percentage points for the control group (55.0% to 49.5%).

## Discussion

There has been great interest in studying the Medicare Part D benefit,<sup>5–11,17–19</sup> but this study is novel in that it uses pre/post data to characterize effects in seniors eligible for Part D based on their prior level of drug-spending burden. A significant strength of this study is our use of a DD approach that eliminates substantial sources of bias because of differences between the study groups that remain stable across follow-up. As hypothesized, the overall policy effect of Medicare Part D between 2005 and 2006 was significantly different depending on the level of pre-Part D out-of-pocket drug spending experienced by a Part D-eligible senior. For eligible seniors with the highest level of pre-Part D drug spending, out-of-pocket drug spending declined by 17.6%—net of changes in the control group—and the proportion of drug costs paid out of pocket decreased by 15.3 percentage points—net of changes in the control group—after Part D was available. For eligible seniors with a moderate level of pre-Part D out-of-pocket drug spending, the proportion of drug costs paid out of pocket decreased by 9 percentage points—net of changes in the control group—after Part D was available. A previous study showed that seniors who were the first to enroll in Part D (and who had the highest levels of pre-Part D out-of-pocket drug spending and use) experienced an 8.8% decrease in out-of-pocket drug spending after Part D.<sup>7</sup> It appears that the availability of relatively generous Part D plans resulted in prescription drugs becoming significantly more affordable for eligible seniors most burdened by out-of-pocket drug spending before Part D availability.

Another stated goal for Medicare Part D, increasing seniors' access to prescription drugs, was improved significantly for eligible seniors with a high level of spending burden for prescription drugs. For eligible seniors with the highest and moderate levels of pre-Part D out-of-pocket drug spending, drug use (pill days) increased by 4.0%

and 7.1%—net of changes in the control group, respectively—after Part D availability. A previous study found a 1.1% increase in drug use (pill days) among seniors who initially enrolled in Part D.<sup>7</sup> The increase in use could be a reflection of seniors meeting a pent-up need for prescription drugs that were not affordable and accessible before Part D availability. Conversely, the increase could be a reflection of the use of unnecessary drugs because of the availability of generous drug coverage (ie, moral hazard). Future research is needed to provide an answer to the nature of the increased use. At a minimum, the availability of Part D appeared to change the use of prescription drugs for eligible seniors, most burdened by drug costs, to a level similar to that of the control group.

The overall policy effect of Medicare Part D between 2005 and 2006 was greatest for Part D eligibles with the highest level of pre-Part D out-of-pocket drug spending. Drug use in this group also was the highest. One explanation for this result is that this group of Part D eligibles may have had relatively poor drug coverage in 2005. Our summary statistics lend support to this idea as the highest-spending Part D eligibles paid 65% of drug costs out of pocket compared with control group individuals who paid 45% of drug costs out of pocket. Poor drug coverage combined with the availability of more generous drug coverage may have induced this group of Part D eligibles to purchase Part D coverage and, subsequently, use more prescription drugs. Research has shown that the rate of uptake of Part D coverage and subsequent drug use was significant for Part D eligibles with no drug coverage in the pre-Part D period.<sup>8</sup> Future research could examine the overall Part D policy effect for Part D eligibles with and without drug coverage in the pre-Part D period by pre-Part D spending levels to further examine the effect of Part D.<sup>8,11</sup> Future research also could examine the source of the overall policy effect by examining changes in outcomes within individual therapeutic categories of drugs and examining changes in outcomes for brand name and generic drugs.<sup>8,10,11</sup>

Our results suggest that eligible seniors with the lowest level of pre-Part D drug spending experienced a significant increase in the proportion of out-of-pocket drug spending (4.9 percentage points—net of changes in the control group), mainly because of a decrease in control group out-of-pocket spending and no significantly different changes in drug use or absolute out-of-pocket spending. One implication of our results



is that enrolling seniors in Part D, who do not have significant prior out-of-pocket drug spending for drugs, is likely very important to offset the costs associated with publicly financing medications for older adults with the greatest needs for medications.

Given that the goal of adding prescription coverage to Medicare was to increase affordability of and access to prescription drugs for eligible seniors, these data suggest that Part D may have achieved these goals. Moreover, changes in total spending on prescription drugs among eligible seniors relative to controls did not differ, suggesting no dramatic changes in overall expenditures among elders (in spite of the slight increase in use). Although we focused on economic outcomes (ie, drug spending) and a broad measure of drug use (ie, pill days), future research should also examine how promoting affordability and access to prescription drugs impacted the *quality* of drug use among seniors and/or health outcomes.

This study has some important limitations to consider when evaluating its results. First, our results represent the patterns of medication use and expenditures from a cohort of older adults filling their prescriptions within a large pharmacy network in a single state, which limits the generalizability of our findings to older adults in other geographic locations and from differing socioeconomic backgrounds. Indeed, the results of our analysis of BRFSS data suggested that patients in our sample tended to reside in counties that were less socioeconomically disadvantaged than the rest of the United States, although they did not differ from the rest of the United States with regard to health insurance and health status, 2 of the strongest predictors of health care use.

Second, by restricting the sample to individuals with prescription fills in each consecutive year, our sample may be biased toward individuals with greater health care needs and/or those with greater access to care. How the availability of Medicare Part D influenced Part D eligibles who had no prescription fills in the pre-Part D period is unknown and is an important question for future research. Third, our data do not account for patients using pharmacies outside the supermarket chain to obtain prescription drugs. Unfortunately, there is no large body of research examining patient loyalty to community pharmacies and the degree (ie, number of fills) to which they use other pharmacies. We assumed that the rate of using pharmacies outside the supermarket

chain was the same across the study groups and the study periods. Because we have data from a supermarket chain with more than 20 pharmacies, it is possible that patients use other pharmacies within the same supermarket chain. If this is the case, then the data we have capture this phenomenon.

Fourth, this observational study used a quasi-experimental design (nonequivalent control group, pretest-posttest design) to infer the causal effect of Medicare Part D. Although this study design controls for a number of threats to validity, including baseline differences in health status and other patient characteristics, threats from differential maturation across treatment and control groups and regression to the mean cannot be ruled out.

Because eligible individuals could continue to enroll in Part D through May 2006 without penalty, potentially leading to a substantial proportion of patients with partial-year coverage in 2006, the results we found for the policy effect of Part D may be attenuated. To examine the potential bias, we estimated DD models using 2007 as the post-Part D period rather than 2006. The results of these models showed similar results in terms of the number of significant coefficients and the size and direction of coefficients.

## Conclusion

Our results suggest that Medicare Part D increased medication affordability and access for eligible seniors with high drug cost burden in the year before Part D availability, while not substantially increasing use among those with lower prior drug spending burdens. This differential impact suggests that Medicare Part D has been initially successful in achieving its intended effects.

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