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BENEFICIARIES' PRESCRIPTION UTILIZATION AND EXPENDITURES

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The impact of Medicare Part D on Medicare-Medicaid Dual-eligible Beneficiaries' Prescription Utilization and Expenditures

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**ABSTRACT**

Features of Part D gave rise to broad concern that the drug benefit would negatively impact prescription utilization among the six million dual eligible beneficiaries, either during the transition from state Medicaid to Part D coverage, or in the long-run. At the same time, Part D contained other features, such as its auto-enrollment and premium subsidization policies, which were designed to safeguard utilization for this vulnerable group. Using national retail pharmacy claims, we examine the experience of dual eligibles during the first 18 months of Part D. We find no evidence that Part D adversely affected pharmaceutical utilization or out-of-pocket expenditures in the transition period, or in the 18 months subsequent to Part D implementation.

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## **INTRODUCTION**

The Part D drug benefit represents the single largest change to Medicare in its 40 year history. Due to the size of the program—the program enrolls over 25 million seniors and is expected to cost over \$700B in its first 10 years of implementation—considerable attention has been paid to studying the effect of the part D benefit on aggregate drug utilization among seniors, seniors' out-of-pocket expenditures, total federal expenditures and revenues of drug manufacturers (1).

There are, however, important reasons to examine the effect of the Part D drug benefit on specific subpopulations, especially the more six million beneficiaries who were dually eligible for Medicare and Medicaid (dual eligibles). With Part D implementation, dual eligible beneficiaries faced new rules governing their access to pharmaceuticals and were no longer subject to the same protections found under Medicaid law (2). Further, while dual eligibles pay no premium and face no deductible under Part D, they may face slightly higher co-payments for covered drugs, or full out-of-pocket cost of drugs not included in their Part D plan formulary. Potential adverse effects of instances of higher cost sharing are compounded by the relatively low income and asset levels among dual beneficiaries, and by random auto-enrollment of the vast majority of duals beneficiaries into Part D plans whose formularies may not include drugs demanded by specific individuals (3).

In addition, dual eligible beneficiaries have a higher incidence of disabling and chronic illness and lower incomes and education than the average Medicare population (4), making these beneficiaries more vulnerable to coverage lapses due to the administrative complexity associated with transitioning from Medicaid to Part D.

Early data on dual eligibles' access to prescription drugs provided cause for concern. For example, in a telephone survey of employed dual-eligibles in Kansas conducted in early 2006, 20% of participants reported difficulties obtaining medications, 13% were required to switch medications, and 8% stopped taking at least 1 medication (5). In another study of a nationally random sample survey of psychiatrists regarding their experiences with prescription drug access among dual eligibles, more than one half (53%) of physician respondents had at least one patient with a medication access problem and more than one fifth (23%) of physicians reported having discontinued or temporarily stopped a patients' medication because of prescription drug coverage or management issues (6). Some of these problems may have been due to system level difficulties (such as identifying the low-income status of patients) in transition where the dual eligibles were incorrectly charged, improperly asked to pay deductibles, or not listed in plans they thought they were enrolled in.

These new rules and other challenges to implementing Part D were widely anticipated and there was considerable apprehension

regarding the potential for disrupted access to prescription drugs for the dual eligibles (7). In response, varying state contingency plans were developed to help transition dual eligibles into PDPs. For example, during early 2006, 37 states implemented temporary coverage programs to provide low-income Medicare beneficiaries access to drugs through Medicaid (6). Additionally, the Centers for Medicare and Medicaid Services (CMS), required all Part D plans to have "transition plans," for example, to offer a one-time supply of drugs not included in the formulary but which were previously consumed by new enrollees (8). These programs may have played an important role in mitigating any short-run difficulties faced by dual-eligibles during their transition between Medicaid and Part D coverage.

To date, no empirical analyses have been performed to look at the effect of Part D on the burden faced by dual eligibles in terms of drug usage, out-of-pocket costs and total drug expenditures (9). We attempt to fill this gap by using pharmacy claims from a national pharmacy chain accounting for approximately 15% of the outpatient prescription drug market in the United States.

Therefore, this study offers an opportunity to study the impact of Part D on this vulnerable population based on a broad national sample of Medicare beneficiaries.

## **METHODS**

### **Data**

We selected a 5% random sample of unique pharmacy customers who filled at least one prescription both in the 2005 and the 2006 calendar years at any retail or mail order member of a national pharmacy chain. For each of these subjects, we obtained claims data for every prescription filled between January 1, 2005 and April 31, 2007. We formed two groups - a 'treatment' group comprising of dual-eligibles who were between 65- 78 year old on January 1, 2005; and a 'control' group comprising near-elderly patients with Medicaid coverage between 60-63 year as of January 1, 2005(17). Importantly, these near-elderly control subjects were not eligible for Medicare. For identification of Medicaid subjects, we looked for the use at least one prescription that was reimbursed by Medicaid during the entire pre-Part D period of January 1, 2005 to December 31, 2005. Subjects identified as covered by Medicaid and ages 65-78 as of January 1, 2005, constituted our sample of dual eligibles. Due to the infrequent churning of the dual eligibles in and out of Medicaid (10), we relied on a single Medicaid prescription to identify dual-eligibles (11). Subjects in the control group were identified by their having filled at least one prescription reimbursed by Medicaid during both the pre- and post-Part D periods. In order to ensure that we do not include non-elderly dual eligible patients in the control group, we excluded patients in this age

range if any of their prescriptions were reimbursed by Medicare during the entire study period (12).

For each prescription claim, we obtained data including subjects' demographic characteristics (age, sex, language preference, zip code of residence), insurance characteristics (prescription drug plan, method of payment), pharmacy characteristics (zip code location), prescription characteristics (National Drug Code [NDC], 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 subjects' zip code of residence (i.e. the residence recorded at subjects' first pharmacy claim in 2005) to link the pharmacy claims data to data from the 2000 Census, including information on the total population, median household income, income per capita, fraction urban, fraction African American, unemployment rate, and poverty rate within the zip code of residence.

### **Statistical analyses**

We began with a simple exploration of how our data matched up to national estimates on total number of prescriptions used, total out-of-pocket payments and total prescription expenditures (13). We then studied the effect of Medicare Part D on four pharmaceutical outcomes using regression discontinuity designs: (1) total number of prescriptions per month, (2) pill-day - a

prescription utilization measure similar to medication possession ratio that counts the number of days with a pill summed across all prescriptions, (3) monthly out-of-pocket costs, and (4) total prescription expenditures (14). We excluded subjects age 80 and over, since the proportion of subjects in nursing homes is higher among subjects in this group and since changes in the Medicare Modernization Act regarding nursing and long-term care subjects do not extend to the majority of the Medicare population (15).

To estimate the impact of Part D, we estimate the break in trend at the start of 2006 for each of the outcome variables among the dually eligible sample. To interpret this trend break as the impact of Part D, we control for secular trends in the outcome variable unrelated to Part D. The most straightforward way to do this is to estimate a difference-in-differences multivariate regression: we estimate the break in trend among our Medicare dual eligible subject sample (while controlling for characteristics of each subject); we then adjust this impact by the break in trend estimated among the near-elderly control sample. The *adjusted* trend break provides an estimate of the impact of Part D on dual eligible beneficiaries, having net out secular trends in the outcome variable. Estimating trend breaks is done using multivariate Generalized Estimating Equations (GEE), which is commonly preferred over linear least squares when estimating highly skewed medical expenditure and utilization outcomes (cite?) (18).

In our fully specified model, we estimate the impact of Part D during both the enrollment period and "stable" period after the May 31, 2006, enrollment deadline; and allow for both the intercept (break in trend) and the slope of outcome variable trend lines to differ. Details about the specifications of these models are given in the Appendix.

Note that for the near-elderly to be a good control for dual eligible subjects, secular trends in their prescription drug expenditures and utilization must be similar. We test whether trends in outcomes among the 60-63 year old sample was similar to our dual eligible sample group during the *pre*-Part D period (January 2005 to December 2005). To do so, test whether the slope of the trend lines during the *pre*-Part D period differ significantly. We expect there to be a difference in mean level of each outcome variable between the two groups; however, the difference in the outcome variables need to be constant over the *pre*-Part D period in order for the near-elderly to suffice as a good control.

Next, we examine medication adherence and discontinuation as some of the heterogeneity in medication switches maybe masked in the total utilization measures that we studied above. Using multinomial regressions we estimated the probability of continuing, discontinuing or initiating a medication with a specific NDC-code between the *pre*-Part D period and the stable Part D period (19). We studied the differential rate of

continuation between dual-eligibles and the control group. We compared this profile in continuation probabilities between dual eligibles and control group.

Finally, we use the same difference-in-difference strategy discussed earlier to examine changes in the overall percentage of generic prescription use between pre Part-D and stable post-Part D period and contrasted them between the dual-eligibles and control group patients with at least one prescription in the stable post period.

Standard errors for all parameters were obtained via 1000 bootstrap replicates clustered by subjects, and a variety of model fit criteria was used to check the goodness of fit for our models (20).

## **RESULTS**

Table 1 describes basic characteristics of our dual eligible (n = 10,837) and control cohorts (n = 3,199). Dual eligibles were older and fewer preferred English as their primary language, but were otherwise comparable to the control group of patients.

Despite being younger, our control group had greater average annual drug utilization and expenditures, which may reflect both the severity of health conditions for elderly Medicaid patients about to enter Medicare as well as the most death of the most

severely ill patient before reaching older ages (mortality effects). Unadjusted changes between pre and post Part D periods were not significant for any of the drug utilization measures for either the control or the dual-eligible group.

### **Trends in expenditures and utilization**

Figure 1a shows the trends in average monthly out-of-pocket expenditures for dual eligibles and the control group of near-elderly subjects ages 60-63. Expenditures for the two groups tracked each other closely in the pre-Part D period, suggesting that the near-elderly suffices as a comparison group. Trends in expenditures continue to track each other closely in the post Part D period (21). Immediately following the implementation of Part D, expenditures for both groups continue to decrease during the transition period and then leveled off.

Figure 1b compares the trend in actual observed expenditures to the trend in predicted expenditures assuming Part D was never implemented (this is a "counterfactual" trend calculated using parameter estimates from the GEE regression analysis) (16). There were no significant changes in trends in the dual-eligibles' out-of-pocket expenditures due to Part-D. Similar results were found for total monthly expenditures (Figures 1(c) and 1(d)); pill-days (Figures 2(a) and 2(b)); and total number of prescriptions (Figures 2(c) and 2(d)). The formal results are summarized in

Table 2. Although slightly higher levels of changes were found for each of the outcomes in the transition period than the stable period, these changes were neither meaningfully large in magnitude or nor statistically different from zero.

### **Probability of starting, stopping, or continuing medication**

Next, we studied the probability of continuing, discontinuing or initiating a new medication between pre Part D and the stable phase of post Part-D. We find that among all medications for which at least one prescription was filled in either of the two periods, dual eligibles filled a prescription for 17.5% of the medications in both the pre and post periods (continuation), filled a prescription in the pre period but not in the post period for 42.5% of the medications (discontinuation), and filled a prescription in the post period but not in the pre periods for 40% of the medication (initiation) (Table 3). These proportions were almost identical for the control group patients implying that Part D did not meaningfully impact patterns of prescription usage among dual eligibles.

Focusing on only those medications that were used in the pre-Part D period, we found that the probability of filling a prescription for the same medication following Part D increased with the number of prescriptions filled in the pre period among both beneficiaries and control subjects. This supports the fact that patients who use a medication in a chronic manner are more likely

to continue to use it over time. However, as before, we did not find any difference in the probability of continuation between dual eligibles and the control group at any level of pre-period usage (Figure 3).

Finally we studied the proportion of generic prescriptions used between the pre- and the post-Part D period. We find that compared to the pre-period, dual eligibles were 4.8% more likely to use generic prescriptions in the post-period (Table 3). However, we see a similar change in the control group and suggested that this change was not due to Part D.

## **DISCUSSION**

In this analysis of a diverse sample of dual eligibles accounting for a substantial portion of the overall U.S. market of prescription drugs, we found that Part D did not adversely impact either prescription utilization or expenditures among beneficiaries dually eligible for Medicare and Medicaid. In addition, our results suggest that other aspects of dual eligibles' prescription utilization, such as the initiation of new therapies and the rates of generic drug utilization, also were not adversely impacted by Part D.

Despite designing Part D benefits for dual eligibles to protect this vulnerable population against the lack of continuity of necessary drugs, several concerns regarding its implementation and its promise of seamless access to drugs were raised at the

time of transition. Our findings of no adverse impact of Part D on dual eligibles both in the short-run and the in the long-run post part-D implementation are important to mitigate these concerns and also to highlight the joint role of federal and state policy-makers who devoted substantial efforts to ensuring that the transition to Part D would not lead to unintended consequences among this group. Perhaps, the most important of these efforts were the rapid steps taken by several state governments in allocating additional funds to cover drugs for dual eligibles during the first three months of Part D implementation, during which pharmacies, patients and providers figured out the nuances of the disintegrated system of PDPs and the varying formularies that accompanied them.

One interesting implication of our study results is that since the total reimbursed amount for prescriptions and also the total number of prescriptions and pill-days were not found to be affected by Part-D, it may indirectly imply that prices may not have been affected due to this transition. This is in line with the Congressional Budget Office's anticipation of the price effects of Part D (23).

Although our data are not nationally representative and may not characterize the experience of all dual eligibles, the data offer an important opportunity to examine the impact of this marked change in prescription coverage for millions of Americans.

Furthermore, in prior analyses, our subjects were found to be similar to a nationally representative sample, and estimates of the overall impact of Part D on prescription utilization were highly consistent with those predicted by economic theory (23). However, the experiences for the dual eligible patients that we find in our study may also be attributed to resources allocated by this pharmacy chain which may not be representative of the national experiences of all dual eligibles.

One limitation of our study is that we assume that the absence of a prescription claim for an individual subject represents zero utilization for that subject, rather than missing data. However, individuals may obtain their prescriptions from more than one pharmacy chain, and thus it is possible that subjects observed here obtained only part of their medicines from this chain alone. Although loyalty to one pharmacy chain would not threaten our conclusions (due to our use of 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 sub-sample of subjects for whom we have complete prescription benefits manager (PBM) data suggested that similar large proportions of subjects of each age group (>90%) filled all of their prescriptions within the pharmacy chain in both 2005 and 2006, and we applied inclusion criteria requiring subjects to have at least one prescription claim during both 2005 and 2006.

## **Conclusions**

Part D represents a policy change of enormous proportions. Any undertaking as complex as this is bound to face challenges, and particularly during the transition period during the first few months of the benefit there was considerable concern about the impact of the transition on dual eligibles. Many of these challenges were anticipated, and efforts by numerous stakeholders were made to address those that weren't anticipated. Our report suggests that dual eligible patients' prescription utilization and expenditures have neither increased nor decreased due to Part D.

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8. See Smith et al., 2006 for a comprehensive snapshot of the actions taken by all 50 states during this transition; V. Smith, K. Gifford, S. Kramer and L. Elam. *The transition of dual eligibles to Medicare part d prescription drug coverage: State actions during implementation*. Results from a 50-state snapshot
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11. In fact, using the Panel 9 of the Medical Expenditure Survey data we estimated that in this age-group, 85% remained continuously eligible for Medicaid between 2004 and 2005.
12. Again using the Panel 9 of the Medical Expenditure Survey data we estimated that in the 60-63 years age-group, 88% remained continuously eligible for Medicaid between 2004 and 2005.
13. Even though our data are not nationally representative, we wanted to ensure that we do not have an atypical group of dual-eligibles or the control group. Therefore, we compared descriptive statistics on the utilization measures for our data with MEPS subjects aged 60-63 and 65-78 years old in 2005 and who were continuously Medicaid eligible or dual-eligible respectively during 2004 and 2005.
14. Each subject in our sample contributed 28 observations corresponding to 28 months of data. We divided the 28 months into three periods. The first period, January 2005 to December 2005, represented the "pre-Part D" period. The second period, January 2006 to May 2006, represented months during which various state-level and federal-level temporary measures installed to facilitate transition are believed to have influenced utilization and is referred to as the "transition post-Part D" period. The third period, June 2006 to April 2007, represented months following this initial transition period and is called the "stable post Part D period".
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16. To estimate counterfactual trends, we used the contemporaneous time-profile of the corresponding outcomes in a control group of Medicaid-eligible subjects aged 60-63 years. We first confirmed that the trends in outcomes in the 60-63 year old cohort provided an adequate control for the subjects in our elderly dual-eligible group during the pre Part-D era (September 2004 to December 2005). To do so, we examined both the statistical significance and the substantive relevance of the coefficients in our

regression model that represented the differential trends between the dual-eligible and the control group during the pre Part-D era. We then used the predicted control trends in the post Part-D era to represent the outcomes in the dual-eligible group had there been no Part-D policy in place.

17. The precise age cut-off for the control group was 62 years and 8 months as of January 1, 2005 so that they do not become eligible for Medicare at the end of our analysis period. Also we exclude 64 and 65 year olds as of January 1, 2006 since they had partial year Medicare eligibility and would transition into the dual-eligible status in the middle of our time-frame of analysis.
18. These trends were estimated and predictions were generated using generalized estimating equations (GEE). We adjusted for subject demographics (gender, English-speaking status, Medicaid coverage, and age), zip-code level characteristics (total population, median household income, per-capita income, urbanicity, proportion black, unemployment rate and poverty), fixed effects for calendar months (January - December), periods (pre Part D, transition post Part D, and stable post Part D), and the treatment group. Moreover, we explored a variety of splines for representing differential time trends between periods, ultimately using 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 transition post Part D period due to the short time interval in this period. We added up to three-way interactions between the period and treatment group fixed effects and the splines over time. We assessed overall model fit using a variety of goodness of test criteria. We used a gamma distribution for modeling out-of-pocket expenditures and negative binomial distributions for modeling pill-days and number of prescriptions. All estimators employed log-link models. Additionally, we explored the correlation structure between monthly observations within subjects and finally employed a first-order auto-regressive correlation structure for out-of-pocket costs and number of prescriptions and an unstructured correlation matrix for pill-days.
19. The average probabilities per person for continuing, discontinuing or initiating a medication were compared between the dual eligible group and the control group. In an adjoining analysis, we restricted our analysis to only those NDC codes that were filled in the pre-Part D period. Using logistic regression, we estimated the probabilities of continuation as a function of the number of prescription filled in the pre Part D period. Higher number of prescriptions filled in the pre-period indicates a chronic use of that medication that patients should be more likely to continue in the next period.
20. Model fit criteria to check the goodness of fit for our models included the Pearson correlation test between residuals and predicted values, Hosmer Lemeshow test examining systematic biases in predictions across deciles of the corresponding linear

predictors, and Pregibon Link Test examining residual non-linearity in outcomes with respect to covariates. Although all of these test were statistically significant for both the outcomes, none showed any substantive bias in predictions. For example the Pearson correlations coefficient for out-of-pocket costs and pill-days were -0.009 and 0.004 respectively and yet they were statistically significant (p-values < 0.001 for both). The overall model fits are illustrated in Figures 1 (a), (c) and 2 (a), (c) and appear to track the trends in observed outcome well. All analyses were performed with Stata version 9.2 (Stata Corp., College Station, TX).

21. In fact, the joint test of the three coefficients that represent the interactions of the cubic monthly splines with the dual-eligible group and the pre-part-D era (Appendix) was not significant (p-value= 0.11).
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Figure 1: Observed and predicted time trends in outcomes for dual eligibles and the control group. The corresponding factual and counterfactual trends post Part D for the dual eligibles are also presented.

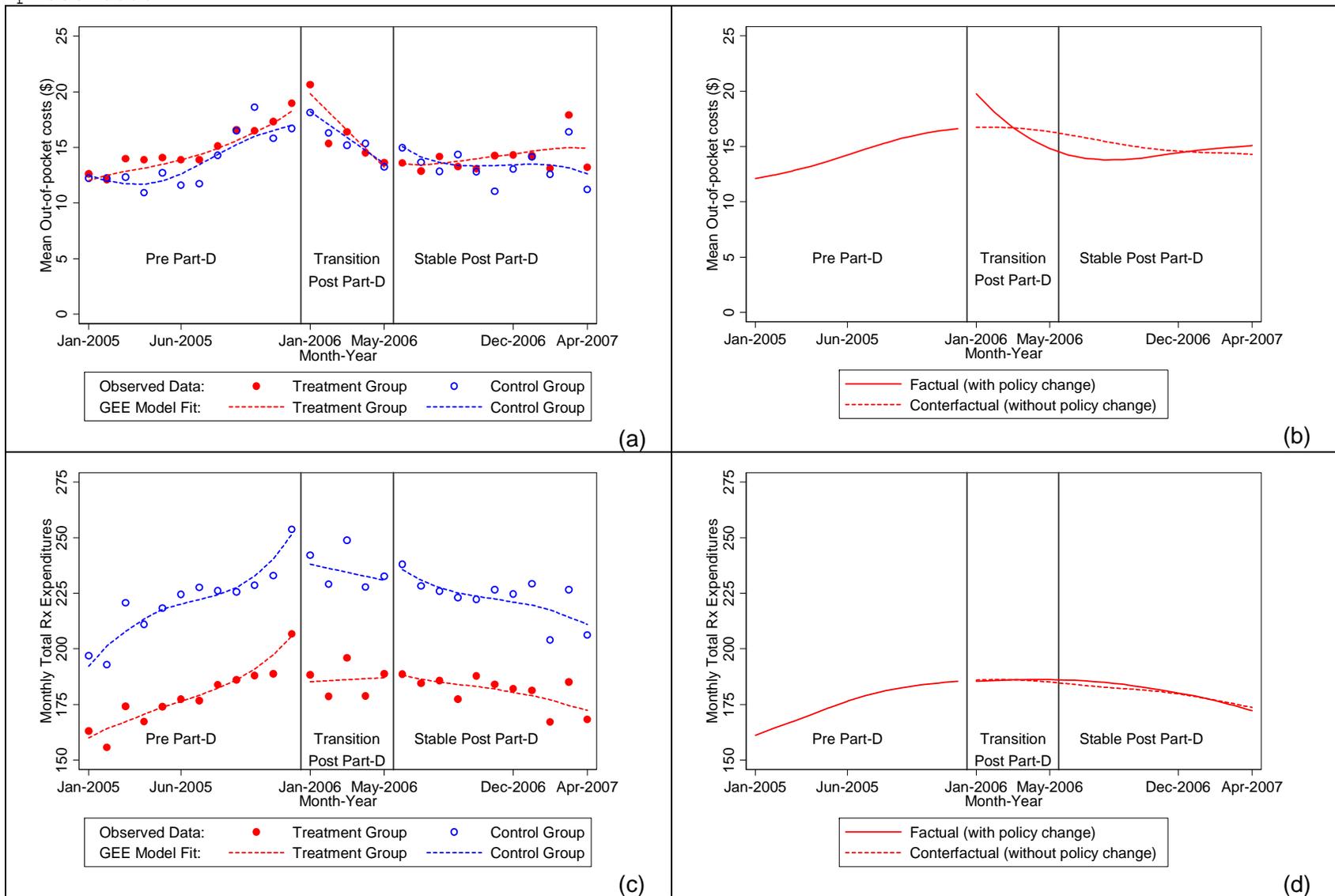
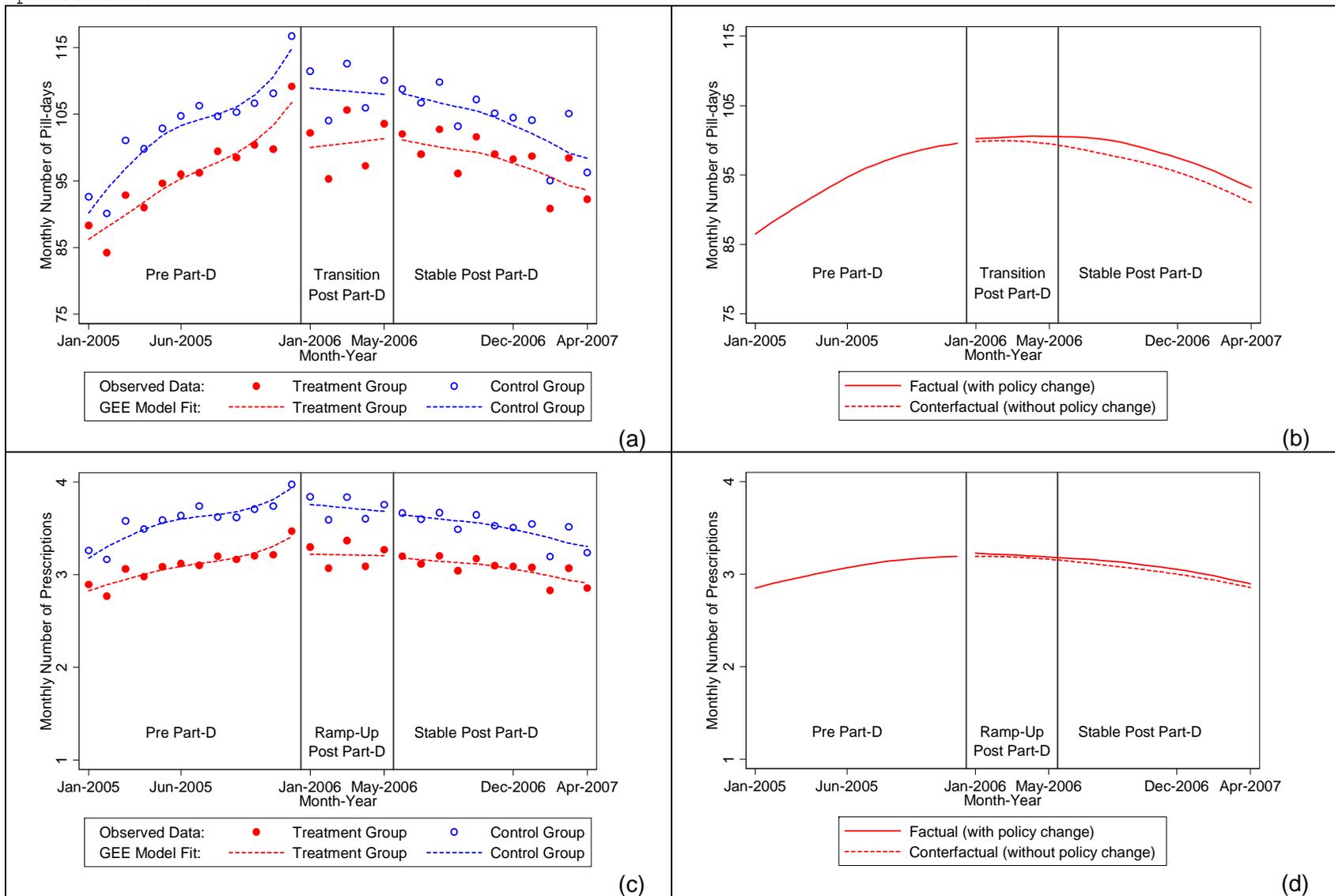


Figure 2: Observed and predicted time trends in outcomes for dual eligibles and the control group. The corresponding factual and counterfactual trends post Part D for the dual eligibles are also presented.



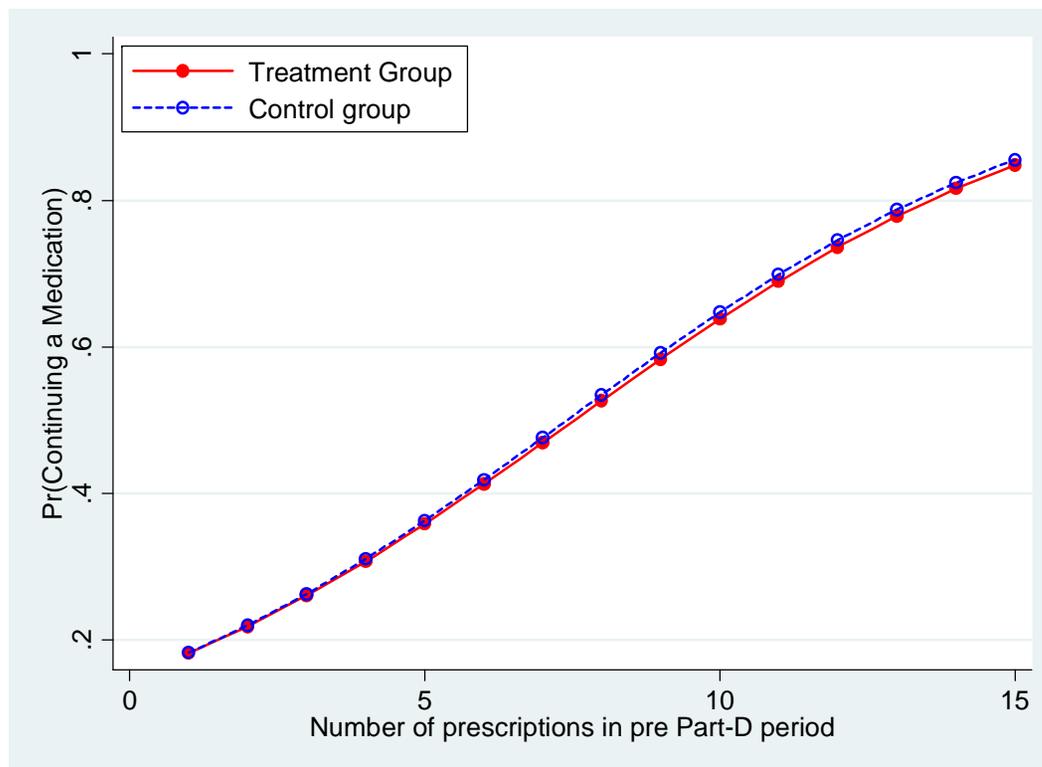


Figure 3: The average probability of continuing a medication (NDC-code-specific), filled in the pre-part D era, in the post part D stable period.

TABLE 1. DESCRIPTION OF SUBJECTS FILLING PRESCRIPTIONS WITHIN NATIONAL PHARMACY CHAIN.

	CONTROL Subjects on Medicaid 60- 63 years old (n=3,199)		TREATMENT Dual Eligibles 66-79 years old (n=10,837)	
Age, years (SD)	61.8 (1.1)		72.2 (3.7)	
Female sex, percent	67.3		69.4	
English language preference, percent (SD)	92.1		82.3	
Characteristics of zip-code based on 2000 Census				
Total population, thousands (SD)	29.6 (16.9)		32.1 (17.5)	
Median household income, thousands (SD)	19.2 (6.6) 7.9 (3.0)		20.8 (8.2) 8.5 (3.9)	
Income per capita, thousands (SD)	91.8		94.3	
Fraction urban population, percent	22.2		19.2	
Fraction African-American, percent	92.1		92.4	
Unemployment rate, percent	16.7		15.9	
	Pre-Part D	Post-Part D	Pre-Part D	Post-Part D
Total <i>monthly</i> prescription drug utilization, pill-days (SD)	103 (128)	106 (132)	96 (115)	99 (121)
Total <i>monthly</i> number of prescriptions (SD)	3.6 (4.4)	3.6 (4.4)	3.1 (3.6)	3.1 (3.7)
Total <i>monthly</i> out-of-pocket prescription expenditures, \$US (SD)	13.8 (65.8)	14.1 (66.1)	14.9 (65.4)	14.7 (65.1)
Total <i>monthly</i> prescription expenditures, \$US (SD)	222 (367)	227 (390)	178 (275)	183 (304)

The sample of 177,311 subjects includes 59,663 unique control group subjects (ages 60-63), and 117,648 treatment group subjects (ages 66-79), observed in both 2005 and 2006. Standard deviations (SD) are reported in parentheses.

Table 2: Impact of Part D on out-of-pocket prescription expenditures and prescription utilization. Impact reported as average monthly expenditures or utilization and reported separately for period prior to Part D enrollment deadline ("Transition period") and period following Part D enrollment deadline ("Stable period").

	Average adjusted monthly outcomes for beneficiaries ages 66-79		Differences due to Part D	
	Actual outcomes	Predicted outcomes without Part D	Absolute change	Percent change
<b>"Transition period"</b>				
OOP Rx Costs (\$)	16.5 (0.48) <sup>+</sup>	17.8 (1.33) <sup>+</sup>	-1.25 (1.19)	-7.0 (6.7)
Total Rx Costs (\$)	186.1 (2.7) <sup>+</sup>	180.7 (5.4) <sup>+</sup>	5.49 (4.9)	3.0 (2.7)
Pill-days	100.7 (0.91) <sup>+</sup>	99.1 (1.59) <sup>+</sup>	1.60 (1.24)	1.6 (1.2)
Total # of Rx	3.21 (0.03)	3.18 (0.05)	0.03 (0.04)	0.9 (1.25)
<b>"Stable period"</b>				
OOP Rx Costs (\$)	14.2 (0.49) <sup>+</sup>	14.7 (2.12) <sup>+</sup>	-0.50 (2.19)	-3.2 (14.9)
Total Rx Costs (\$)	181.2 (2.9) <sup>+</sup>	181.6 (7.2) <sup>+</sup>	-0.43 (7.2)	-0.2 (3.9)
Pill-days	98.0 (0.91) <sup>+</sup>	96.3 (2.02) <sup>+</sup>	1.61 (1.66)	1.7 (1.7)
Total # of Rx	3.07 (0.03) <sup>+</sup>	3.03 (0.06) <sup>+</sup>	0.04 (0.06)	1.3 (2.0)

Counterfactual average monthly outcomes calculated as from predicted values of the GEE models; overall effects reported in the third column are calculated as differences between actual and counterfactual outcomes; overall outcomes as a percentage of the predicted outcomes without Part D reported in the fourth column; + p<0.05; standard errors obtained via 500 bootstrapped replicates.

Table 3. Adjusted probabilities for discontinuing, continuing and initiating new medications in post Part D stable period compared to per Part D period in the dual eligibles and the control group.

	Dual-Eligibles	Control	Difference
Probability of			
Discontinuing	42.5	43.6	-1.1
Continuing	17.5	18.1	-0.6
Initiating	40.0	38.3	1.7
%-point change in generics Rx use*	4.8	4.6	0.2

+ p<0.05; standard errors obtained via 500 bootstrapped replicates.  
 \* Among patients with at least 1 Rx in the Stable Post-Part D period

## Appendix

Denoting Y to represent a specific outcome, we model

$$\text{Log}(E\{Y | X, M, \text{Pre}, \text{TR}, \text{STB}, \text{Trt}\}) =$$

$$\beta_0 + \underbrace{\beta_1 * M * \text{Pre} + \beta_2 * M^2 * \text{Pre} + \beta_3 * M^3 * \text{Pre}}_{\text{(Pre Part D Trends for Control)}} +$$

*(Pre Part D Trends for Control)*

$$\underbrace{\beta_4 * \text{Trt} + \beta_5 * M * \text{Pre} * \text{Trt} + \beta_6 * M^2 * \text{Pre} * \text{Trt} + \beta_7 * M^3 * \text{Pre} * \text{Trt}}_{\text{(Pre Part D Changes in Trends for Treatment)}} +$$

*(Pre Part D Changes in Trends for Treatment)*

$$\beta_8 * \text{TR} + \underbrace{\beta_9 * M * \text{TR}}_{\text{(Transition Period post Part D Trends for Control)}} +$$

*(Transition Period post Part D Trends for Control)*

$$\beta_{10} * \text{TR} * \text{Trt} + \underbrace{\beta_{11} * M * \text{RU} * \text{Trt}}_{\text{(Ramp-up post Part D Changes in Trends for Treatment)}} +$$

*(Ramp-up post Part D Changes in Trends for Treatment)*

$$\beta_{12} * \text{STB} + \underbrace{\beta_{13} * M * \text{STB} + \beta_{14} * M^2 * \text{STB} + \beta_{15} * M^3 * \text{STB}}_{\text{(Stable post Part D Trends for Control)}} +$$

*(Stable post Part D Trends for Control)*

$$\beta_{16} * \text{STB} * \text{Trt} + \beta_{17} * M * \text{STB} * \text{Trt} + \beta_{18} * M^2 * \text{STB} * \text{Trt} + \beta_{19} * M^3 * \text{STB} * \text{Trt} + \gamma^T * X$$

*(Stable post Part D Changes in Trends for Treatment)*

*(Stable post Part D Changes in Trends for Treatment)*

where,

M = (Months - 15) and Months range from 1 to 32,

Pre = Indicator for Time < Jan 06

TR = Indicator for Time > Jan 06 and ≤ May 06

STB = Indicator for Time > May 06

Trt = Indicator for Treatment Group

X = additional covariates that include...

Step 1: Examine estimates of  $\beta_4$ ,  $\beta_5$  and  $\beta_6$ . 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 we proceed to form counterfactual using the control trends in the post Part D period.

Step 2: Predict factual and counterfactual trends:

2.a. 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 X's for the treatment group are used.

2.b. 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 X's for the treatment group are used.

2.c. Difference between these factual and counterfactual estimates averaged over the M in the Ramp-up post Part D period and X's in the treatment group provides as estimate of the policy effect for the Ramp-up post Part D period.

2.d. 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 X's for the treatment group are used.

2.e. 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 X's for the treatment group are used.

2.f. Difference between these factual and counterfactual estimates averaged over the M in the Stable post Part D period and X's in the treatment group provides as estimate of the policy effect for the Stable post Part D period.