

## The Effect of Medicare Part D on Pharmaceutical Prices and Utilization

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Prescription drug expenditures represent the most rapidly growing component of health care spending, increasing from 5 percent of health care spending in 1980 to more than 10 percent by 2005 (Centers for Medicare and Medicaid Services (CMS) 2007a). Further, almost 60 percent of all prescriptions in the United States are filled for beneficiaries of Medicare, Medicaid, and other government programs. Rapid innovation in new pharmaceuticals has contributed substantially to quality of life and longevity in the US (Frank Lichtenberg 1996). These facts, combined, indicate that government procurement schemes are critical both in determining government expenditure on pharmaceuticals and in stimulating innovation of new treatments.

In this paper, we show that the institutions and mechanisms used by the government to purchase prescription drugs can strongly affect market outcomes. By institutions, we have in mind large buyer groups, structured incentives for patients to consume certain products, and the development and use of formularies. A formulary is a mechanism that allows a buyer to identify a therapeutically similar treatment as a viable substitute for a patented treatment, and to create price competition due to the ability to substitute away from the more expensive product. When bargaining with the seller of a patented product, the ability to shift demand to a substitute drug is a powerful negotiating tool.

Our paper provides evidence for what we consider a surprising outcome: in the case of the new prescription drug program for Medicare enrollees, moving consumers from cash-paying status to membership in an insured group *lowers* optimal prices for branded prescription drugs below what they otherwise would be. This is surprising because the standard effect of insurance is to create inelastic demand and therefore elicit higher prices from a seller with market power (Duggan and Scott Morton 2006). However, the insurers that we study bundle insurance with a formulary and other mechanisms to create elastic demand. An individual consumer typically does not know which drugs are acceptable therapeutic substitutes; the consumer's physician typically has poor knowledge of prices, especially negotiated prices; and any one consumer is too small a share of demand to negotiate with a pharmaceutical company. A prescription drug plan can potentially surmount all three hurdles.

Our evidence leads us to conclude that the formulary and other mechanisms perform the special role of allowing buyers to move market share among drugs with patent protection, thereby raising cross-price elasticities and lowering purchase prices (or reducing price increases) for branded drugs. This result contrasts with the common intuition that an uninsured consumer,

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paying at the margin for her own purchases, is the best tool with which to create competition in the market and impose pricing discipline on sellers. Certainly, this reasoning is at least part of the rationale behind many current policies in health care such as tax-free health care savings accounts (R. Glenn Hubbard, John F. Cogan, and Daniel P. Kessler 2005). Our evidence suggests that this picture is incomplete; for maximum effect, the consumer also needs to be part of a group that can substitute one provider for another.

Our setting is the recent significant increase in government intervention in the pharmaceutical industry represented by Medicare Part D. For the first 40 years of its existence after its creation in 1965, the Medicare program provided virtually no coverage for beneficiaries' prescription drug costs outside of treatments such as cancer drugs administered in a doctor's office or hospital. But as prescription drug expenditures increased much more rapidly than other health care spending in recent years, the political pressure built for Medicare to cover prescription drugs. In December 2003, the Medicare Prescription Drug Improvement and Modernization Act created Medicare Part D, which would begin providing coverage for prescription drug costs in January of 2006 for those Medicare recipients who chose to enroll.

Part D is the largest expansion of Medicare since the program's inception and has been projected to cost \$780 billion over its first ten years (2006–2015).<sup>1</sup> This feature alone made the program controversial at the outset. Not only is Part D a very large entitlement program, it significantly expands the role of the government as a buyer of prescription pharmaceuticals. Governments outside the United States use their power as large buyers to pay relatively low prices for new, patent-protected medications. In contrast, Part D is set up so that the government does not directly purchase drugs, but rather subsidizes participating private prescription drug plans, which then negotiate with pharmaceutical companies over drug prices.

Part D can also be contrasted to Parts A and B of Medicare, in which the CMS sets prices for each covered service and reimburses providers directly per service.<sup>2</sup> In Part D, CMS pays the participating plan a lump sum per enrollee and has no control over the prices paid to pharmaceutical manufacturers by the plan or the prices charged to enrollees by the plan. Instead, the legislation creates competition among plans for the business of enrollees, which is intended to drive drug prices and premiums to competitive levels. Each Medicare recipient can choose between the plans offered in her area based on the drugs covered, the prices of those drugs, the monthly premium, and other plan parameters.

In the empirical work below, we investigate the effect of Medicare Part D on the price and utilization of branded pharmaceutical treatments. Theoretically, the program could either increase or decrease prices paid to pharmaceutical companies. On the one hand, once enrolled in Part D, enrollees who had previously been uninsured would have a lower elasticity of demand than before, leading to an increase in the manufacturers' profit-maximizing prices for drugs with market power.<sup>3</sup> On the other hand, Part D plans could exclude certain treatments from their formulary or steer their enrollees away from certain treatments in response to the prices of those treatments, which a cash-paying individual could not typically do on her own. This could give these plans a strong lever with which to negotiate price reductions from pharmaceutical manufacturers. We are also interested in the effect of the program on utilization.<sup>4</sup> In addition to any ex-manufacturer price effect, the insurance provided by Part D would lower beneficiaries' out-of-pocket prices, and therefore affect utilization (Teresa Gibson, Ronald Ozminowski, and Ron Goetzel 2005).

<sup>1</sup> See the "Medicare Trustees Report," <http://www.cms.hhs.gov/reportstrustfunds/downloads/tr2006.pdf>.

<sup>2</sup> Hospital inpatient reimbursement in Part A depends both on the patient's diagnosis and on the treatment.

<sup>3</sup> See Nina Pavcnik (2002) for evidence on the effect of cost sharing on firms' profit-maximizing prices.

<sup>4</sup> Recent research by Wesley Yin et al. (2008) and Lichtenberg and Shawn Sun (2007) suggests that Part D did increase utilization, although the authors of both studies utilize data from just one pharmacy chain to estimate this.

Our estimation strategy exploits variation across branded drugs in their pre-Part D Medicare market shares to estimate the effects of Part D on pharmaceutical prices and utilization. Our first set of results strongly suggests that Medicare Part D led to a substantial relative decline in average branded pharmaceutical prices. In other words, though branded prescription drug prices trend upward from 2003 to 2006, brands with high sales to consumers eligible for Medicare Part D experienced significantly lower average price increases than other brands.

Additionally, our estimates reveal that the effect is driven by the consumption of drugs by Medicare recipients *without insurance before Part D*. It appears to be the movement of Medicare recipients from cash-paying uninsured status to insured under a plan that causes the relative decline in per unit prices. The most plausible mechanism driving this result is not the insurance per se, but the activities of the insurer.

However, for therapeutic classes with just one or two brands, plans would not be able to move market share to therapeutic substitutes because legislation required them to cover all drugs in small classes. Consistent with this prediction, our analyses show that prices do not decline in relative terms for brands with zero or only one substitute in a class.

Combining our results with the mechanical effect of Part D on out-of-pocket prices, we expect that the average cost of prescription drugs for an uninsured Medicare recipient with average prescription drug spending fell substantially. In light of this, it is not surprising that our results suggest a substantial increase in utilization among Medicare-intensive drugs, although our estimated coefficients for utilization are not precisely estimated.

Our findings come with an important caveat: we analyze only the first year of Part D. This is a complex program in which both regulators and firms are learning over time and coping with moral hazard, adverse selection, technological change, and political pressure. It is plausible, for example, that pharmaceutical manufacturers have not yet fully adjusted to the policy change, and thus more work is clearly warranted to estimate the medium- and-long term effect of the program.

The outline of the paper is as follows. In the next section, we provide background on the Medicare program and on key features of Part D and discuss the effect of Part D on pharmaceutical firms' profit-maximizing prices. Section II describes our data and the construction of our sample of drugs. In the following two sections we specify our empirical framework, summarize our main results, and describe how our estimates vary across therapeutic categories. The final section concludes.

## I. Background on, and Incentive Effects of, Medicare Part D

### A. Institutional Background

While there are several components to the Medicare Prescription Drug Improvement and Modernization Act (MMA), the most important is the creation of Medicare Part D, which provides insurance coverage for prescription drug costs to Medicare recipients who voluntarily enrolled in the program beginning in January of 2006. This legislation also created the Medicare Discount Drug Card Program, which took effect in early 2004 and was designed to help Medicare recipients receive discounts on their prescriptions during the two-year window prior to the commencement of Part D.

In contrast to Parts A and B of the program, Part D benefits are provided through one of two types of private insurance plans.<sup>5</sup> The first type, known as a Prescription Drug Plan (PDP), provides coverage only for prescription drug costs, while Medicare Advantage Plans (MA-PD)

<sup>5</sup> For a detailed discussion, please see Duggan, Patrick Healy, and Scott Morton (2008).

insure all Medicare-covered services, including hospital care, physician services, and prescription drugs.<sup>6</sup>

A plan “sponsor” contracts with CMS to offer a plan in one (or more) of the 34 defined regions of the United States. Plans are allowed to have a formulary that excludes certain drugs from coverage, though they are required to have at least two drugs on the formulary for each therapeutic class.<sup>7</sup> Furthermore, a plan cannot exclude treatments from any of six protected classes (e.g., HIV antiretrovirals, cancer drugs) from the formulary. The actuarial value of the benefits offered by a plan must be at least as generous as those specified in the 2003 MMA legislation. In the 2006 calendar year this included a deductible of \$250, a 25 percent co-pay for the next \$2,000 in spending, no coverage for the next \$2,850 (this is often referred to as the “doughnut hole”), and a 5 percent co-pay once out-of-pocket expenditures reach \$3,600. These figures change annually. Plans are financed through a combination of enrollee monthly premiums and subsidies from the federal government.

To enroll in Part D, a Medicare recipient can choose among those plans offered in her region of the country. When making this choice, the recipient would consider the plan’s monthly premium, the drugs included on the formulary, the prices of those drugs, and service quality.<sup>8</sup> Dual eligibles, who are Medicare recipients also enrolled in the means-tested Medicaid program, were required to enroll in a Part D plan, although their premiums, co-pays, and deductibles were heavily subsidized by the government. In January of 2007, approximately 36 percent of the 17.3 million PDP enrollees were automatically enrolled in a PDP because they were also on Medicaid (6.3 million) and an additional 13 percent of enrollees (2.2 million) were eligible for low-income subsidies that reduce out-of-pocket costs.

### *B. Part D’s Impact on Manufacturers’ Incentives*

Given the significance of the changes in insurance coverage described above, and the particular structure of drug procurement for this program, it seems plausible that Medicare Part D had an impact on prices and quantities in the pharmaceutical sector. To simplify the theoretical discussion, we assume that the market for Part D plans is perfectly competitive. In every region in the United States there are at least 27 plans competing for local Part D enrollees. While the market is more concentrated than this number would suggest,<sup>9</sup> in this paper we will nevertheless abstract from the issue of whether plans have market power.

If plans are effectively not setting the market price for a patented brand, it is the brand’s manufacturer that is choosing prices before and after the Part D program. To fix ideas, suppose that all Medicare enrollees have no coverage prior to Part D and must pay cash for their prescription drugs, but then enroll in Part D when it begins. Notice that when this group paid cash for prescription drugs, its members were not able to create effective price competition between drugs by threatening to switch to a therapeutic substitute. Once in Part D, however, these consumers were represented by a PDP. The result of the change in institutional structure is an increase in the cross-price elasticity of substitution for this group. For a number of common models of demand, as consumers’ elasticity of substitution rises, the optimal price for the drug falls.<sup>10</sup> A second

<sup>6</sup> To reduce the likelihood that Part D would crowd out existing prescription drug coverage to retired workers by their former firms, CMS subsidized those firms that continued to provide this insurance.

<sup>7</sup> See Haiden Huskamp et al. (2003) for evidence on the effect of formularies on consumers’ utilization of pharmaceutical treatments. The findings suggest that formularies can substantially alter treatment patterns.

<sup>8</sup> See Kosali Simon and Claudio Lucarelli (2006) for an examination of the determinants of plans’ monthly premiums.

<sup>9</sup> The top three plans (UHC-Pacificare, Humana Inc., and Wellpoint, Inc.) accounted for 50 percent of Part D enrollment in 2006 (Kaiser Family Foundation 2007).

<sup>10</sup> For a specific model, please see Duggan and Scott Morton (2008).

effect comes from the fact that the group is now subsidized at 75 percent of the cost of the drug in the main coverage region and at 95 percent in the catastrophic region.<sup>11</sup> Sensitivity to price falls and this causes the optimal price to increase. In this setting, we see there are two effects working in opposite directions, and thus it is ultimately an empirical question that dominates.

Consumers with private insurance or those who continue to be uninsured do not experience these changes upon the implementation of Part D.<sup>12</sup> If the average price that we measure in the data comprised sales to consumers who move from uninsured to Part D and consumers who experience no change in demand, we would see a change in the average price of brands that depends on the fraction of that drug purchased by cash-paying but Part D-eligible consumers, as well as the change in price those consumers pay. The empirical strategy of the paper is to use data on average price and the fraction of a drug's sales to Part D-eligible consumers to back out the price changes caused by Part D.

There is one possible spillover between Part D and the private market that might cause private price changes caused by Part D to be nonzero. When dual eligibles move from Medicaid to Medicare, they shift from purchasing through a fairly inelastic purchaser (the state) to a more elastic purchaser (the PDP).<sup>13</sup> Because the inelastic Medicaid demand pays whatever market price is chosen by the manufacturer, a reduction in Medicaid demand might lower the optimal price for the brand in the private market (see Duggan and Scott Morton 2006). If a drug's dual share is zero, this effect will not be present. We investigate this issue in our empirical analyses below.

According to Part D regulations, there are six "protected" therapeutic classes in which each PDP must be less aggressive with their formularies than in other classes.<sup>14</sup> While a PDP cannot exclude any drug in a protected category, it can create financial incentives or administrative hurdles to affect a patient's choice of drug. We do not know whether the restrictions applied to these classes have a measurable impact on the behavior of PDP because in the first year of the program it was not clear how much CMS would oversee formularies. If restrictions are binding, their effect will be to reduce Part D's effect on the substitutability among drugs in these classes and therefore reduce the PDP's ability to extract manufacturer discounts.

Similarly, CMS required that all PDPs include at least two drugs in each therapeutic class and at least one in each Formulary Key Drug Type (FKDT), which is a finer category than class. A class/FKDT with only one or two brands in it will create a challenge for any PDP bargaining for low prices. The CMS regulations limit the PDPs' ability to substitute away from drugs in the class, and presumably the manufacturers of these drugs are aware of their market power. We expect that drugs in these two situations (protected or "small" categories) will have small or negligible changes in cross-price elasticities. We modify our specification to allow for different effects for drugs in this less competitive environment.

Taken together, we predict an ambiguous effect of Medicare Part D on average pharmaceutical prices, with the sign depending on whether the policy-induced reduction in the elasticity of demand more than offsets any plan-induced increase in substitutability across treatments. This latter effect should be less important for brands in one of the six protected therapeutic categories and for those brands that are one of just one or two treatments in a class/FKDT. Furthermore,

<sup>11</sup> The subsidy depends on an enrollee's total prescription drug expenditures. As expenditures rise, an enrollee moves from 100 percent (deductible), to 25 percent, to 100 percent (doughnut hole), to 5 percent (catastrophic region) cost sharing.

<sup>12</sup> Spillovers in negotiation from an insurer's private plans to their Part D plans are prohibited by the legislation.

<sup>13</sup> It is worth noting that many states were negotiating for supplemental rebates based on state-level Medicaid formularies by 2005, so they are not completely unresponsive to price.

<sup>14</sup> All products in the HIV, anticancer, anticonvulsant, immunosuppressant, antipsychotic, and antidepressant categories must be included in all Part D formularies.

to the extent that Part D reduces Medicare recipients' out-of-pocket costs, it should lead to an increase in overall utilization that is increasing in the drug's Medicare market share. We investigate these issues in the empirical analyses below.

## II. Data and Constructing the Analysis Sample

### A. IMS Health

To estimate the impact of Medicare Part D on our outcome variables of interest, we begin by merging data from two sources. The first was obtained from IMS Health and contains data on total sales (excluding those to hospitals and long-term care) for all pharmaceutical products in the United States in each year from 2001 to 2006. The data also contain the number of standardized units of the product that were sold and the average number of units per daily dose in each year. This allows us to calculate the average price per day and the number of daily doses in each year for each product.<sup>15</sup> In calculating both prices and quantities, we aggregate sales for all versions of the same drug in each year.

### B. Medical Expenditure Panel Survey

Our second main source of data is the Medical Expenditure Panel Survey (MEPS), a publicly available dataset constructed annually by the Agency for Healthcare Research and Quality (AHRQ). In carrying out this survey, AHRQ collects data from a nationally representative sample of the civilian noninstitutionalized population residing in the United States and asks questions about prescriptions filled during the year, as well as demographic characteristics and insurance coverage. We use this dataset to calculate a brand's Medicare Market Share (MMS), which is the proportion of its consumers enrolled in Medicare.

For each reported prescription, the Prescribed Medicines file lists the drug name, the total amount paid, the amount paid out of pocket and the amount paid by each of ten possible sources of insurance, a person-level identifier, and a person-level weight. In the 2003 MEPS data (the same year in which the Medicare Modernization Act was signed into law), there are 304,324 prescriptions reported by 20,475 individuals. To increase our precision in measuring drug-specific Medicare market shares and related explanatory variables of interest, we utilize both the 2002 and 2003 versions of the MEPS Prescribed Medicines file.<sup>16</sup>

Using the person-level identifier, this data on the utilization of prescription drugs can then be linked to the MEPS Full Year Consolidated Data File (CDF), which includes the person's age and information about her health insurance coverage. One question summarized in the CDF portion of the survey asks whether the respondent was ever enrolled in Medicare during the 2003 calendar year. The weighted fraction answering yes to this question is 14.4 percent, which is much greater among those age 65 and older (98.8 percent) than among the nonelderly (2.2 percent). Because Medicare recipients have substantially greater utilization of prescription drugs than their counterparts not in the program, their fraction of prescriptions (40.3 percent) is almost three times greater than their share of the population.

The Prescribed Medicines file also has information on the source of payment for each prescription. The first column of Table 1 summarizes this information for all prescriptions, while

<sup>15</sup> Note that the prices we use in our estimation are not the posted prices at the drugstore, but the revenues of each drug divided by units sold from invoice data.

<sup>16</sup> This approximately doubles the number of prescriptions for the typical drug in our sample. The Medicare shares in 2002 and 2003 are very strongly correlated, with a correlation of 0.92.

TABLE 1—SOURCE OF PAYMENT FOR PRESCRIPTIONS IN THE 2003 MEPS

	All	Medicare	All other
Average total paid per prescription (US\$)	69.5	69.9	69.2
Percent paid out of pocket	44.9	50.9	40.5
Percent paid by private insurance	34.5	19.8	45.2
Percent paid by Medicaid	12.4	13.9	11.3
Percent paid by VA	3.3	5.8	1.5
Percent paid by Medicare	3.3	7.8	0.0
Percent paid by TRICARE	1.1	1.2	1.0
Percent paid by other insurance	0.5	0.5	0.5
Total number of prescriptions	298,293	129,990	168,303

columns 2 and 3 differentiate between those with and without Medicare coverage, respectively. In 2003 Medicare recipients paid approximately 51 percent of the cost out of pocket, while those not on Medicare paid substantially less, at 41 percent. The table also reveals that Medicare recipients received much less coverage from private insurers in that year (20 versus 45 percent) but this was partially made up for by greater coverage from public insurance including Medicaid, the Department of Veterans Affairs, and Medicare.<sup>17</sup>

The variation across drugs in the fraction of individuals taking the drug who were eligible for Part D prior to its enactment (and subsequently may have enrolled in it) is critical to the identification strategy of the paper. According to the 2003 MEPS, this variation is substantial. For example, Zoloft, an antidepressant drug that is ranked fifth in terms of sales in the IMS data, has a Medicare market share of 27.1 percent. The corresponding value for Plavix, which is used primarily by those at risk of heart attack or stroke and was ranked sixteenth in terms of sales in that same year, is 72.9 percent.

### C. Constructing the Analysis Sample

The MMA was signed into law on December 8, 2003. Medicare Part D did not begin operation, however, until more than two years later, in January 2006. During that interim period, the federal government created the Medicare Discount Drug Card Program. One stated goal of this program was to aid Medicare recipients in receiving lower prices for their prescriptions. Thus, MMA may have influenced both pharmaceutical prices and utilization before Part D took effect in 2006. In addition, if the optimal price for a drug was going to change significantly upon the initiation of Part D, a manufacturer may have wanted to adjust the drug's price gradually over time so as to avoid the publicity associated with a sharp price change. We therefore use 2003 as our base year when estimating the effect of the program.

We focus initially on the top 1,000 drugs in the IMS data according to their 2003 sales, which account for 97 percent of the \$196 billion in total sales in that same year. We then drop over-the-counter (OTC) drugs and generics,<sup>18</sup> although we later control for the presence of generic competition for the branded drugs in our sample. This exclusion leaves us with a sample of 693 drugs

<sup>17</sup> Recall that Medicare did cover the cost for certain prescription drugs, such as cancer treatments, in this time period.

<sup>18</sup> Of the top 1,000 products, 113 were available over the counter in 2006; these drugs would not be covered by Medicare Part D plans and would also rarely appear in the MEPS Prescribed Medicines file that we use to construct Medicare market shares. We next drop the 194 remaining drugs that are generic, given that there will typically be many manufacturers for each of these drugs and firms would have significantly less pricing power.

that currently or previously enjoyed patent protection, with these treatments accounting for 87 percent of the \$196 billion in 2003 spending in our IMS data. We then merge these IMS data on sales and utilization in each year from 2001 to 2006 to the MEPS data on Medicare market shares, with 125 of these 693 treatments dropped from our sample because they do not appear in the MEPS.<sup>19</sup> This leaves us with a sample of 568 drugs that account for 79 percent of total 2003 IMS spending.

One limitation to our focus on the top-selling brand drugs in 2003 is that any drug introduced in 2004 or later or that was not in the top 1,000 sellers in 2003 will not be included in our analyses. Additionally, generic drugs or drugs sold over the counter are not included in our sample. Thus, to the extent that Part D plans influenced the price or utilization of these other products, our main analyses of the top-selling brand drugs will not capture these effects.

#### D. Identifying Protected Classes and Therapeutic Substitutes

Our model predicts a different response to the program from both drugs in the protected classes and drugs without substantial therapeutic competition. To identify the former we rely on IMS drug classifications. To determine which drugs were the only treatments, or one out of just two in the therapeutic class, we consulted a list of top-selling drugs and link it to the US pharmacopoeia and CMS therapeutic classes and FKDT.<sup>20</sup> Recall, PDP are required to “cover” at least two drugs per class and at least one in each FKDT.

### III. Empirical Framework and Main Results

The IMS data described above provide us with total sales by product in each year from 2001 to 2006. We can also estimate the number of daily doses for each product by dividing the total quantity (in standardized units) in each year by the corresponding average number of standardized units per daily dose in each year. This allows us to form an estimate of the average price per day for each product. We use these data to estimate specifications of the following type:

$$(1) \quad \Delta P_{j,2003-6} = \alpha_1 + \beta_1 MMS_{j,2003} + \mu_1 Yrs_{j,2003} + \delta_1 AnyGeneric_{j,2006} + \varepsilon_{1j,2003},$$

$$(2) \quad \Delta Q_{j,2003-6} = \alpha_2 + \beta_2 MMS_{j,2003} + \mu_2 Yrs_{j,2003} + \delta_2 AnyGeneric_{j,2006} + \varepsilon_{2j,2003},$$

with  $j$  indexing drugs and  $\Delta P_{j,2003-6}$  ( $\Delta Q_{j,2003-6}$ ) equal to the change in price (quantity) for drug  $j$  from 2003 to 2006. As described above, we focus on this three-year change because the legislation that created Part D was enacted in December 2003, but plans did not start enrolling beneficiaries until January 2006.

The explanatory variable of particular interest in this specification is  $MMS_{j,2003}$ , which represents our estimate of the Medicare market share for drug  $j$  using the MEPS Prescribed Medicines files from 2002 and 2003. This is defined to be equal to the fraction of prescriptions filled in 2002 and 2003 for individuals who were ever enrolled in the program during the same year.<sup>21</sup> This specification, which uses one observation per drug, exploits the variation across drugs in their tendency to be used by Medicare recipients. Given that total utilization and average prices

<sup>19</sup> There are two plausible reasons for this. First, MEPS does not include prescriptions that are administered in a physician’s office or other institutional setting. Second, MEPS captures approximately 1 out of every 10,000 prescriptions in a typical year and thus some products with small patient populations may not be included.

<sup>20</sup> One version of this can be found at <http://www.usp.org/pdf/EN/mmg/drugListTableV3.0.pdf>.

<sup>21</sup> In calculating this Medicare market share, we use the person weights in the MEPS.

for the same drug may vary over the life cycle of the drug and can be affected by the presence of generic competition, we also control for the number of years that the drug has been on the market ( $Yrs_{j,2003}$ ) and for whether the drug faces generic competition ( $AnyGeneric_{j,2006}$ ).<sup>22</sup>

It is worth noting that average prices tend to move fairly steadily in our data, and tend to trend up. In contrast, average quantities fluctuate much more due to the entry of therapeutic substitutes, new generations of medicines, clinical news, and other factors we do not observe. Additionally, average quantities in our sample decline from 2003 to 2006, primarily because we restrict attention to drugs that were the top sellers in 2003.

To interpret our estimates for  $\beta_1$  and  $\beta_2$  as the causal effects of Medicare Part D on the outcome variable of interest, we are assuming that there are no omitted factors that are correlated with the Medicare market share, and that also influence the change in the outcome variable of interest.<sup>23</sup> Over the short period of this study, that assumption seems reasonable to us. By taking first differences of average prices or total utilization, we remove any unobserved time-invariant differences across drugs.

### A. The Impact on Average Prices

An examination of the distribution of average price and the change in average prices for the drugs in our analysis sample reveals that they are highly skewed to the right. For example, the change in the average price from 2003 to 2006 for the drugs in our sample has a skewness of more than 12. Thus, following recent research on pharmaceutical prices (Duggan and Scott Morton 2006), we take the log of the average price, which is much more symmetrically distributed and has a skewness of approximately zero.<sup>24</sup> This has intuitive appeal as well, as prices are likely to change proportionally rather than by a fixed dollar amount in response to common factors that affect prices in this sector. With this transformation, we are essentially exploring whether the growth rate of pharmaceutical prices is significantly different on average for Medicare-intensive drugs following the enactment of Part D.

Table 2 summarizes the results from several specifications similar to equation (1) above. In this equation, we exclude 20 of the 568 drugs described above because they either have no sales in 2006 or are missing the year of FDA approval. We weight the observations in each specification by the number of prescriptions in the MEPS to account for the fact that the precision of our estimate for  $MMS_j$  will vary across drugs. The estimate of  $-0.128$  for  $\beta_1$  in the first column, in which no other explanatory variables except a constant are included, suggests that the introduction of Part D reduced the growth rate of pharmaceutical prices by an average of approximately 12 percentage points, with this estimate significant at the 5 percent level. However, because the coefficient on the constant term  $\alpha_1$  is equal to 0.134, this finding suggests that average prices for Medicare Part D recipients remained essentially unchanged, while those for other consumers increased by an average of 13 percent. Our estimates indicate that a drug moving from zero to 100 percent MMS would have price growth drop from 13 percent to 1 percent.

<sup>22</sup> As demonstrated in a previous version of this paper (Duggan and Scott Morton 2008), our results for both price and quantity changes are similar if we control for the preexisting trend for the outcome variable of interest.

<sup>23</sup> In this paper we will not consider insurance-induced changes in practice patterns of physicians, the introduction of new drugs, and similar general equilibrium effects, as is done in Daron Acemoglu et al. (2006), Amy Finkelstein (2007), and Amy Finkelstein and Robin McKnight (2008), in which the authors look at the effect of the introduction of Medicare. See also David Cutler (1995) and Leemore Dafny (2005) for related research on the effect of other important changes to the Medicare program, or David Card, Carlos Dobkin, and Nicole Maestas (2008) and Ahmed Khwaja (2008) for research on the effect of Medicare coverage.

<sup>24</sup> We inflation-adjust 2003 prices to 2006 dollars using the consumer price index for urban consumers (CPI-U).

TABLE 2—THE IMPACT OF MEDICARE PART D ON THE CHANGE IN AVERAGE PHARMACEUTICAL PRICES FROM 2003–2006

	$\mu$ ( $\sigma$ )	Dependent variable: $\Delta \log(\text{price per day}_{i,2003-6})$					
		(1)	(2)	(3)	(4)	(5)	(6)
Medicare market share <sub>2002-03</sub>	0.348 (0.264)	-0.128** (0.057)	-0.127** (0.057)	-0.138** (0.056)	-0.136** (0.056)	-0.133** (0.056)	-0.143*** (0.054)
Years on the market <sub>2003</sub>	10.95 (7.36)		0.000 (0.002)	0.001 (0.002)	0.001 (0.002)	0.001 (0.002)	0.002 (0.002)
Any generic competition	0.381 (0.486)		0.005 (0.023)	0.010 (0.023)	0.010 (0.023)	0.011 (0.023)	-0.008 (0.022)
Constant	— —	0.134 (0.026)	0.128 (0.028)	0.127 (0.028)	0.126 (0.028)	0.125 (0.028)	0.127 (0.032)
Observations	548	548	548	538	517	517	200
$R^2$	—	0.016	0.016	0.024	0.024	0.024	0.049
Outliers excluded?	No	No	No	Yes	Yes	Yes	Yes
Cancer drugs excluded?	No	No	No	No	Yes	Yes	Yes
RX or spending MMS?	RX	RX	RX	RX	RX	Spending	RX
Top 200 only	No	No	No	No	No	No	Yes

*Notes:* Each column summarizes the results from specifications of the change in the log price per daily dose on the explanatory variables listed in the first column. The unit of observation is the drug, and the sample is constructed as described in Section IIC. Specifications 1 through 4 and specification 6 use the share of a drug's prescriptions purchased by Medicare-enrolled individuals, while specification 5 uses the share of spending for that drug. Specifications 3 through 6 drop those observations with values of the dependent variable in the top 1 percent or the bottom 1 percent of the distribution. Specifications 4 through 6 exclude 21 cancer and immunosuppressant drugs. Specification 6 limits to just the top 200 drugs. Heteroskedasticity-robust standard errors are included in parentheses. The mean and standard deviation of the dependent variable are equal to 0.087 and 0.349, respectively.

\*\*\*Significant at the 1 percent level.

\*\*Significant at the 5 percent level.

\*Significant at the 10 percent level.

The magnitude of our estimate for  $\beta_1$  is almost identical, at  $-0.127$  in the next specification, in which we add the control variables described above. This estimate increases slightly to  $-0.138$  and remains significant at the 5 percent level in the third specification, in which we exclude outliers that are in the top 1 percent or bottom 1 percent of the log price change (from 2003 to 2006) distribution.

The MEPS Prescribed Medicines files do not include information for drugs administered in a physician's office or clinic. The most common are injectable chemotherapy treatments. One might therefore be concerned that estimates for the Medicare market share for the cancer drugs that are in the sample are inaccurate. In the fourth specification we exclude these 21 treatments and obtain a very similar estimate for  $\beta_1$ .

One potential concern with our estimate for the Medicare market share is that it weights all prescriptions equally. We therefore introduce an alternative measure of the Medicare market share in the fifth specification which represents the fraction of total spending on the drug accounted for by Medicare recipients. The statistically significant estimate of  $-0.133$  for  $\beta_1$  using this measure is virtually identical to the previous estimates. In the next specification we consider only the top 200 drugs, as we did in our previous work for the Medicaid program, and find that our estimate for  $\beta_1$  increases to  $-0.143$  and is significant at the 1 percent level.

Taken together, our results indicate that average prices increased by significantly less from 2003 to 2006 for drugs sold differentially to Medicare recipients. When interpreting these estimates, it is important to consider that many Medicare recipients already had insurance for

prescription drug costs prior to the enactment of Medicare Part D. To the extent that the price effects were driven only by those enrolling in Part D plans, the estimates for  $\beta_1$  will understate Part D's average impact on pharmaceutical prices. We explore this issue in more detail below.

### B. *The Impact of Part D on the Utilization of Prescription Drugs*

Medicare Part D reduced the out-of-pocket price of pharmaceutical treatments beyond the effects discussed above through an additional channel—the mechanical effect of the insurance coverage. For example, the typical plan in 2006 covered 75 percent of the first \$2,000 in prescription drug costs once a person had reached their annual deductible of \$250. Additionally, Medicare recipients enrolled in Part D pay just 5 percent of their costs once their out-of-pocket spending reaches \$3,600. Because Part D reduced both the gross price of prescription drugs and the share of that price paid by Medicare recipients, one would expect average utilization of these treatments to have increased.

To investigate the effect of Part D on the total utilization of prescription drugs, in this section we estimate quality specifications that are analogous to those in the preceding section for prices. In this case, the dependent variable is equal to the change in the log of the number of daily doses from 2003 to 2006, with the mean and standard deviation of this variable in the sample equal to  $-0.62$  and  $1.12$ , respectively.<sup>25</sup>

The results from these specifications are summarized in Table 3. The estimate of  $0.516$  for  $\beta_2$  in the first specification, in which only the Medicare market share and a constant are included, is positive but statistically insignificant, with a  $p$ -value of  $0.108$ . In the next specification, we include the number of years that the drug had been on the market as of 2003 and a control for the presence of generic competition. The estimates for the coefficients on the first of these variables is statistically insignificant, while the estimate for  $\delta_2$ , the coefficient on  $AnyGen_{j,2006}$ , is significantly negative with a  $t$ -statistic of  $-5.5$ . This is consistent with previous evidence that use of branded drugs declines substantially once they face generic competition. The estimates of  $\beta_2$  in the next five columns, which summarize specifications analogous to those for price changes, are similar in magnitude, although in all cases the estimates are statistically insignificant.

The large estimates for  $\delta_2$  in specifications two through six of Table 3 suggest that utilization changes among drugs that face generic competition are substantially different from those that do not. To increase the comparability of the drugs included in our sample, in specification 7 we focus on just the 318 drugs in our sample that did not face generic competition by 2006. While smaller in magnitude than the previous estimates, the estimate of  $0.265$  for  $\beta_2$  in this specification is significant at the 10 percent level.

To gauge the plausibility of these results, it is instructive to obtain a back-of-the-envelope estimate of the implied elasticity of prescription drug purchases for the 318 drugs in our sample. For a Medicare recipient with average prescription drug spending, the effective co-pay would be 25 percent. Adding to this a 12 percent average reduction in gross prices suggests almost an 80 percent reduction in the out-of-pocket cost *on the margin* for purchases in the coverage area. Combining this with the estimated effect on utilization in column (7), our results suggest an elasticity of approximately  $-0.38$ , which falls within the range of drug elasticity estimates from other contexts cited in a recent review article (Gibson et al., 2005).

<sup>25</sup> Utilization is on average declining because we are focusing on top-selling drugs in 2003. Many of these treatments will have seen declines in spending in the subsequent three years.

TABLE 3—THE IMPACT OF MEDICARE PART D ON THE CHANGE IN RX UTILIZATION FROM 2003 TO 2006

	Dependent variable: $\Delta \log(\text{daily doses}_{j,2003-06})$							
	$\mu$ ( $\sigma$ )	(1)	(2)	(3)	(4)	(5)	(6)	(7)
Medicare market share <sub>2002-03</sub>	0.348 (0.264)	0.516 (0.320)	0.434 (0.320)	0.381 (0.313)	0.389 (0.316)	0.321 (0.313)	0.517 (0.470)	0.265* (0.137)
Years on the market	10.95 (7.36)		-0.004 (0.010)	-0.001 (0.011)	-0.001 (0.011)	-0.001 (0.011)	0.007 (0.017)	-0.023*** (0.007)
Any generic competition?	0.381 (0.486)		-1.072*** (0.191)	-1.084*** (0.191)	-1.087*** (0.192)	-1.088*** (0.193)	-1.199*** (0.243)	
Constant	—	-0.826 (0.161)	-0.251 (0.169)	-0.228 (0.164)	-0.235 (0.164)	-0.208 (0.166)	-0.292 (0.246)	0.001 (0.112)
Observations	548	548	548	538	517	517	200	318
R <sup>2</sup>	—	0.009	0.262	0.293	0.294	0.293	0.318	0.108
Outliers excluded?	No	No	No	Yes	Yes	Yes	Yes	Yes
Cancer drugs excluded?	No	No	No	No	Yes	Yes	Yes	Yes
RX or spending MMS?	RX	RX	RX	RX	RX	Spending	RX	RX
Top 200 only	No	No	No	No	No	No	Yes	No
Exclude if face gen comp?	No	No	No	No	No	No	No	Yes

Notes: Each column summarizes the results from specifications of the change in the log number of daily doses on the explanatory variables listed in the first column. The unit of observation is the drug, and the sample is constructed as described in Section IIC. Specifications 1 through 4 and specifications 6 and 7 use the share of a drug's prescriptions purchased by Medicare-enrolled individuals, while specification 5 uses the share of spending for that drug. Specifications 3 through 7 drop those observations with values of the dependent variable in the top 1 percent or the bottom 1 percent of the distribution. Specifications 4 through 7 exclude 20 cancer and immunosuppressant drugs. Specification 6 limits to just the top 200 drugs and specification 7 considers only those sample drugs that do not face generic competition. Heteroskedasticity-robust standard errors are included in parentheses. The mean and standard deviation of the dependent variable are equal to -0.56 and 1.13, respectively.

\*\*\*Significant at the 1 percent level.

\*\*Significant at the 5 percent level.

\*Significant at the 10 percent level.

#### IV. Heterogeneity in Part D's Impact on Pharmaceutical Prices and Utilization

##### A. Differentiating between Insured and Uninsured Medicare Recipients

We begin this section by investigating whether the price effects estimated above also vary with the baseline insurance coverage of Medicare recipients. The shift from being uninsured into a Part D plan may have affected prices by placing individuals paying with cash into a large group that could bargain over prices, increasing their effective sensitivity to price differences. Second, the dual eligibles enrolled in both Medicare and Medicaid were required to switch from Medicaid drug coverage to a Medicare Part D plan. As recent research has demonstrated (Duggan and Scott Morton 2006), the procurement rules used by Medicaid distort prices upward, suggesting that a shift out of Medicaid may have reduced prices.

The specifications summarized in Table 4 shed light on this issue. In column 1, we report the results from our baseline specification that excluded the 21 cancer and 10 outlier treatments and was summarized in the preceding section. Column 2 presents the results from an analogous specification in which we differentiate between the Medicare self-pay and Medicare insured market shares as follows:

TABLE 4—THE IMPACT OF MEDICARE MARKET SHARE: DIFFERENTIATING BETWEEN THOSE WITH AND WITHOUT RX INSURANCE

	$\mu$ ( $\sigma$ )	$\Delta \log(\text{price per day}_{j,2003-06})$			$\Delta \log(\text{daily doses}_{j,2003-06})$			$\Delta \log(\text{total revenues}_{j,2003-06})$	
		(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
Medicare market share <sub>2002-03</sub>	0.345 (0.262)	-0.136** (0.056)			0.389 (0.316)			0.273 (0.314)	
Medicare self-pay share <sub>2002-03</sub>	0.213 (0.191)		-0.225*** (0.070)	-0.243*** (0.077)		0.461 (0.424)	0.379 (0.449)		0.247 (0.438)
Medicare insured share <sub>2002-03</sub>	0.132 (0.134)		0.059 (0.156)			0.232 (0.881)			0.330 (0.860)
Dual eligible share <sub>2002-03</sub>	0.043 (0.076)			-0.182 (0.274)			-0.914 (1.674)		
Other medicare insured share <sub>2002-03</sub>	0.089 (0.107)			0.190 (0.305)			0.850 (1.216)		
Years on the market	10.9 (7.3)	0.001 (0.002)	0.001 (0.002)	0.001 (0.002)	-0.001 (0.011)	-0.001 (0.011)	-0.001 (0.011)	-0.002 (0.011)	-0.002 (0.011)
Any generic competition	0.385 (0.487)	0.010 (0.023)	0.011 (0.023)	0.010 (0.023)	-1.087*** (0.192)	-1.088*** (0.193)	-1.096*** (0.194)	-1.071*** (0.187)	-1.071*** (0.187)
Constant	—	0.126 (0.028)	0.115 (0.030)	0.118 (0.028)	-0.235 (0.164)	-0.226 (0.180)	-0.211 (0.179)	-0.107 (0.164)	-0.111 (0.178)
Observations	517	517	517	517	517	517	517	517	517
R <sup>2</sup>	—	0.024	0.027	0.033	0.294	0.294	0.297	0.293	0.293

Notes: Specifications 1 through 3, 4 through 6, and 7 through 8 summarize the results from specifications of the change in the log price per daily dose, the log number of daily doses, and the log of product revenues, respectively, that use the explanatory variables listed in the first column. The unit of observation is the drug, and the sample is constructed as described in Section IIC. All eight specifications use the share of a drug's prescriptions purchased by Medicare-enrolled individuals as the measure of Medicare market share, drop those observations with values of the dependent variable in the top 1 percent or the bottom 1 percent of the distribution, and exclude the 20 cancer and immunosuppressant drugs. Heteroskedasticity-robust standard errors are included in parentheses.

\*\*\*Significant at the 1 percent level.

\*\*Significant at the 5 percent level.

\*Significant at the 10 percent level.

$$(3) \quad \Delta Y_{j,2003-6} = \alpha + \beta_1 MMS\_Self_{j,2003} + \beta_2 MMS\_Ins_{j,2003} + \mu Yrs_{j,2003} \\ + \delta_1 AnyGeneric_{j,2006} + \varepsilon_{j,2003},$$

in which  $Y$  is the outcome variable, price, or quantity. The average values for the two Medicare explanatory variables in our sample of 517 drugs are 0.217 and 0.135, respectively, and the latter share variable includes both private and public insurance.

The estimates for  $\beta_1$  and  $\beta_2$  displayed in column 2 suggest that the price effects of Medicare Part D do vary with a particular drug's level of pre-Part D insurance coverage on the part of Medicare recipients. More specifically, the estimate of  $-0.225$  for  $\beta_1$  implies that the average (gross) price of prescription drugs consumed by uninsured Medicare recipients fell by more than 20 percent from 2003 to 2006 relative to other drugs, and this estimate is significant at the 1 percent level. The magnitude of the corresponding estimate for  $\beta_2$  has the opposite sign and is statistically insignificant. This suggests that the relative price declines observed for Medicare-intensive drugs were driven by declines for drugs consumed disproportionately by beneficiaries previously without prescription drug coverage. Additionally, because the estimate of 0.115 for the constant  $\alpha_1$  is smaller in magnitude than our estimate of  $-0.225$  for  $\beta_1$ , our results suggest that Medicare recipients' average prices declined by approximately 10 percent in real terms while those for other consumers increased by 12 percent.

In the next specification summarized in column 3, we differentiate between Medicare recipients also enrolled in Medicaid and those with an alternative source of insurance. Given the price distortions created by Medicaid's procurement rules, one might expect the movement of duals into Part D to cause a reduction in private market prices. If so, we will see price reduction associated with a drug's dual share, rather than its MMS. The estimate of  $-0.182$  for the coefficient on the dual eligible share is consistent with this hypothesis, although it is not statistically significant. Furthermore, the estimate of  $-0.243$  for  $\beta_1$  remains of similar magnitude and is statistically significant at the 1 percent level. We thus conclude that the movement of duals is not responsible for the effect we measure.

In the next three columns of this table, we summarize the results from an analogous set of specifications for the utilization (in terms of the log of the number of daily doses) of the 517 drugs in our sample. To the extent that the enactment of Part D reduced the net cost of prescription drugs by more for uninsured Medicare recipients than for their counterparts who already had insurance, one would expect a larger increase in utilization for drugs consumed by this group. Consistent with this, the estimate of  $0.461$  for  $\beta_1$  in specification 5 is almost twice as large as the corresponding estimate for  $\beta_2$ , though given the large standard errors the difference is not statistically significant.

The results in the final columns investigate the effect of Part D on total US revenues. Given that Part D reduced pharmaceutical prices below what they otherwise would have been while increasing the quantity consumed, it is theoretically ambiguous whether the revenues of pharmaceutical products increased or declined as a result of this legislation. The estimate of  $0.273$  for  $\beta_1$  in column 7 suggests an increase in revenues for Medicare-intensive drugs, though it is not statistically significant.

Taken together, the results presented in this section suggest that Medicare Part D led to smaller price increases than would otherwise have occurred for Medicare recipients who lacked insurance coverage for prescription drug costs, which is the group most likely to have enrolled in Part D plans. We find little evidence to suggest that there was a corresponding effect on the price of drugs sold differentially to Medicare recipients who already had prescription drug coverage.

### B. *Protected Therapeutic Categories*

While private firms providing Part D benefits had considerable latitude in designing their formularies, they were required to cover at least two treatments in each eligible therapeutic category. This requirement was introduced to reduce plans' ability to "cream skim" the least costly patients by excluding treatments for certain conditions. However, the ability to exclude certain treatments from the formulary provides plans with potentially important leverage when negotiating prices with pharmaceutical manufacturers.

The Part D requirements were substantially more stringent for a small subset of the 146 therapeutic categories defined by CMS. Specifically, plans were required to cover "substantially all" drugs in the following six therapeutic categories: antiretrovirals, antidepressants, antipsychotics, anticonvulsants, immunosuppressants, and antineoplastics. Part D plans could still try to steer patients toward certain treatments within these categories through differential co-pays, prior authorization requirements, or step therapy. However, plans were restricted in their use of utilization tools in the protected classes.

Thus, all else equal, a plan's leverage in negotiating low prices for drugs in these six protected categories would be less than if it could exclude the drug altogether. The same would be true for categories with just one or two available treatments. Note that this group of drugs is therefore missing one of the two effects we discussed above: while the impact of insurance increasing

optimal prices is present, the offsetting effect of therapeutic competition among substitutes is likely to be very weak.

To investigate whether the price effects of Medicare Part D were different for protected classes or for classes with just one or two treatments, we estimate specifications of the following type:

$$(4) \quad \Delta Y_{j,2003-6} = \alpha + \beta MMS_{j,2003} + \lambda Prot_j + \sigma MMS_{j,2003} Prot_j + \mu Small \\ + \rho MMS_{j,2003} Small_j + \varepsilon_{j,2003}.$$

In this equation,  $Prot_j$  is set equal to one if drug  $j$  is in one of the protected categories, and is otherwise set equal to zero. Similarly,  $Small_j$  is set equal to one if drug  $j$  is in a therapeutic category with just one or two available treatments. Both variables are interacted with the Medicare market share to explore whether the average price effects differ for drugs in this category. To the extent that Part D plans were less successful at negotiating price reductions in these two categories, one would expect positive estimates for  $\sigma$  and  $\rho$ .

The results summarized in Table 5 shed light on this prediction. In the first three columns we include all 517 drugs in the sample, with 48 of these treatments falling into one of the six protected classes, and 22 of them belonging to a category with just one or two available treatments. In the first specification we add only the  $Prot_j$  indicator and its interaction with  $MMS_j$  to our baseline specification. Consistent with our prediction, our estimate for  $\sigma$  is positive and at 0.175 is larger in magnitude than the estimate of  $-0.141$  for  $\beta$ . However, this estimate for  $\sigma$  is not statistically significant. Standard errors are clustered by therapeutic subcategory given that the protected class indicator varies at this level.

In the specification summarized in the next column, we add the indicator for being in a “small” therapeutic category and its interaction with the Medicare market share to our baseline specification. Consistent with our theoretical predictions, the estimate for the coefficient on the interaction variable is positive and statistically significant at the 10 percent level. The magnitude of this estimate of 0.304 is more than twice as large as the main effect estimate of  $-0.142$ , suggesting that, if anything, Medicare-intensive treatments in the “small” categories experienced average price increases relative to other drugs.

These findings for price effects are similar when we include both indicators and their interactions with the Medicare market share in specification three, and becomes significant at the five percent level when we focus only on treatments without generic competition (column 4). Taken together, our results suggest that Medicare Part D did not lead to lower price increases for treatments in the “small” therapeutic categories.

The next four columns report the results from an analogous set of specifications for the utilization measure defined above. In specifications five, six, and seven, the estimate for both  $\sigma$  and  $\rho$  are significantly negative, suggesting that Medicare-intensive drugs in protected classes and in classes with just one or two treatments experienced *decreases* in utilization following the enactment of Part D. The first of these two estimates becomes small in magnitude and statistically insignificant in specification eight, where we focus on just treatments that do not face generic competition. However, the significant negative estimate for  $\rho$  remains, suggesting that perhaps Part D plans shifted recipients away from treatments in these “small” categories. While the CMS formulary discourages such shifting, plans are permitted to develop differentiated formularies, provided they can justify their choices to CMS as both providing sufficient quality, and not attempting to cream-skim. The combination of results suggests that brands given market power by the CMS formulary raised their prices and saw some market share losses due to Part D formulary design. However, because our quantity results are generally imprecise, we do not put emphasis on this explanation.

TABLE 5—THE IMPACT OF MEDICARE MARKET SHARE: VARIATION ACROSS THERAPEUTIC CATEGORIES

	$\Delta \log(\text{price per day}_{j,2003-06})$				$\Delta \log(\text{Daily Doses}_{j,2003-06})$			
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
Medicare market share $_{j,2002-03}$	-0.141** (0.059)	-0.142** (0.057)	-0.147** (0.061)	-0.173** (0.080)	0.527* (0.299)	0.429 (0.315)	0.572* (0.310)	0.345** (0.147)
Protected	-0.042 (0.071)		-0.043 (0.055)	-0.029 (0.073)	1.027* (0.497)		1.048** (0.498)	0.102 (0.156)
Protected $\times$ $MMS_{j,2002-03}$	0.175 (0.192)		0.174 (0.200)	0.173 (0.151)	-3.610** (1.662)		-3.655** (1.669)	-0.030 (0.355)
Small category		-0.083 (0.058)	-0.083 (0.058)	-0.103* (0.058)		0.712*** (0.212)	0.740*** (0.212)	0.631*** (0.171)
Small category $\times$ $MMS_{j,2002-03}$		0.304* (0.155)	0.303* (0.154)	0.366** (0.163)		-1.252** (0.542)	-1.272** (0.577)	-1.151** (0.454)
Years on the market	0.001 (0.002)	0.001 (0.002)	0.001 (0.002)	0.003 (0.003)	-0.001 (0.008)	-0.001 (0.008)	-0.001 (0.008)	-0.023*** (0.007)
Any generic competition	0.010 (0.024)	0.012 (0.023)	0.011 (0.024)		-1.095*** (0.248)	-1.074*** (0.232)	-1.082*** (0.249)	
Constant	0.127 (0.029)	0.127 (0.031)	0.128 (0.032)	0.119 (0.042)	-0.278 (0.140)	-0.270 (0.146)	-0.317 (0.144)	-0.054 (0.117)
Observations	517	517	517	318	517	517	517	318
$R^2$	0.025	0.026	0.028	0.059	0.315	0.297	0.319	0.131
Exclude if face gen comp?	No	No	No	Yes	No	No	No	Yes

Notes: Specifications 1 through 4 and 5 through 8 summarize the results from specifications of the change in the log price per daily dose and in the log number of daily doses, respectively, that use the explanatory variables listed in the first column. The unit of observation is the drug, and the sample is constructed as described in Section IIC. All eight specifications use the share of a drug's prescriptions purchased by Medicare-enrolled individuals as the measure of Medicare market share. All eight specifications drop those observations with values of the dependent variable in the top 1 percent or the bottom 1 percent of the distribution and exclude the 20 cancer and immunosuppressant drugs. Specifications 4 and 8 drop those treatments that face generic competition in 2006 or earlier. Heteroskedasticity-robust standard errors are included in parentheses.

\*\*\*Significant at the 1 percent level.

\*\*Significant at the 5 percent level.

\*Significant at the 10 percent level.

## V. Discussion

The introduction of Medicare Part D is arguably the most significant change to the Medicare program since its inception more than 40 years ago. The procurement rules that are used by Part D differ substantially from those used by Medicare for other health care services, by the federal-state Medicaid program, or by the US Department of Veterans Affairs for prescription drugs. One of the central criticisms of Part D was that it would lead to significant increases in pharmaceutical prices, to some extent offsetting the benefit of the additional insurance coverage.

In this paper, we investigate this issue using price, quantity, and sales data for the top-selling branded pharmaceutical treatments in the United States for the period before the enactment of Medicare Part D and in the one year immediately following. We combine this with information on the insurance coverage of each brand's consumers, which allows us to compare price and utilization changes as a function of each treatment's baseline Medicare market share. Our findings strongly suggest that Part D plans have succeeded in negotiating lower price increases for Part D enrollees—approximately 20 percent lower than they otherwise would have been—with this effect augmenting the mechanical effect of the program in reducing out-of-pocket prices. Our findings also suggest, consistent with recent research (e.g., Lichtenberg and Sun 2007), that Part D has increased the utilization of pharmaceutical treatments.

In contrast to the usual intuition that the uninsured customer is the most price-sensitive, we find that the insured customer is more price-elastic. The most plausible explanation is that in Part D, insurance is bundled with group purchasing and the implementation of a formulary. The

PDP's ability to obtain lower prices indicates that a significant benefit of the program is the way it is organized, regardless of the subsidy level. Our evidence indicates that the PDP's ability to encourage the use of therapeutic substitutes by a large group outweighs the classic insurance-induced increases in pharmaceutical prices, and therefore leads to relative price declines for brands. It is perhaps partly because of the price effects estimated in this paper that Part D expenditures by the federal government have been substantially lower than the most widely cited estimates suggested (CMS 2007b). Furthermore, our results provide an example of the more general point that including the uninsured in a large group with the ability to select providers may greatly reduce costs even in the absence of a government subsidy.

When interpreting the results in this paper, a number of caveats should be mentioned. First and most important, given the available data, we can investigate the effect of Part D only in its first year. To the extent that plans become more or less successful at negotiating prices in future years, the results may of course change. Second, we are unable to measure any ex post rebates that PDPs may have been able to negotiate and that affect net prices to PDPs. Such rebates do not appear on the invoice, which is the source of IMS data, and might be causing prices to be even lower than those measured here. The other rebates that we do not measure are Medicaid rebates paid by manufacturers to the Medicaid program. Dual eligibles' pharmaceutical purchases under Medicaid automatically generated this rebate. Once dual eligibles move into Medicare Part D plans, their pharmaceutical purchases occur at different prices, which is what we document here, but they no longer trigger automatic rebates. Any study of the total cost of Part D to the government would want to consider both sets of rebates. Third, our results do not shed light on the effect of the program on the health of enrollees nor on their ability to smooth consumption in response to adverse health shocks. And, finally, we have not considered the effect of Part D on innovation, as this is a long-run outcome. However, to the extent that Part D reduces prices for drugs that have close substitutes rather than for drugs that do not have substitutes, we would conjecture that Part D increases the incentives for firms to invent novel treatments. All of these issues remain important areas for future research.

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