The Effect of Medicare Part D on Pharmaceutical Prices and Utilization

October 2007

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PRELIMINARY AND INCOMPLETE –

COMMENTS WELCOME

We thank Abigail Alpert, Tamara Hayford, and Patrick Healy for outstanding research assistance and Steve Berry for helpful comments. We are grateful to Merck and Co. for providing us IMS data, and to IMS for giving permission for us to use their data. This project was supported by National Science Foundation Research Grant 0518858 "The Effect of Government Procurement of Pharmaceuticals." The opinions contained herein are those of the authors and not necessarily of any funding agency. Contact information for authors: duggan@econ.bsos.umd.edu, fiona.scottmorton@yale.edu. All errors are our own.

Keywords: Procurement, Medicare, Part D, pharmaceuticals
JEL category: I11, I18, L11, L51

I. Introduction

The federal government's Medicare program currently provides health insurance to more than 43 million elderly and disabled U.S. residents. This program primarily covers the cost of hospital inpatient and outpatient care as well as physician services, home health care, and some long-term care. Beneficiaries share in the cost of this care through deductibles, copays, and a monthly premium, and approximately 85 percent of beneficiaries are in the fee-for-service (as opposed to managed care) version of Medicare.[1] For providing care to these recipients, health care providers are paid a fixed amount for each service that depends on the patient's diagnosis and his/her treatment. Thousands of fee-for-service prices must therefore be set by the Centers for Medicare and Medicaid Services (CMS) and these are updated periodically.

For the first forty years of its existence after its creation in 1965, this program provided virtually no coverage for beneficiaries' prescription drug costs outside of treatments administered in a doctor's office or hospital.[2] Partly because of this, the majority of beneficiaries' prescription drug expenditures were paid for out-of-pocket. But as prescription drug expenditures increased much more rapidly than other health care spending in recent years, the political pressure increased for Medicare to correct this deficiency in the program. This culminated in the enactment of the Medicare Modernization Act in December of 2003. The most important provision of this legislation was the creation of Medicare Part D, which would begin providing coverage for prescription drug costs in January of 2006 for those beneficiaries who chose to enroll.

Rather than setting prices for each covered drug and reimbursing pharmacies directly, CMS contracted with private insurers to provide prescription drug coverage. Each Medicare recipient could then choose between the plans offered in her geographic area based on the drugs covered, the monthly premium, and other plan parameters. Almost 75 percent of basic plan expenses were to be subsidized by the federal government. Many features of this coverage were regulated by CMS, including a requirement that plans cover at least two treatments in each therapeutic category and offer the standard financial scheme or an actuarially-equivalent level of benefits. However, participating Part D plans were free to negotiate their own prices with pharmaceutical manufacturers. One of the central criticisms of this legislation was that it would

[1] The remaining beneficiaries are enrolled in Medicare HMOs, which bear risk by accepting capitated payments.
[2] The program did provide coverage for certain cancer treatments and for some other physician-administered drugs.

lead to higher prices than if the federal government used its negotiating power on behalf of program participants to bargain for lower prices.

In this paper, we investigate the effect of Medicare Part D on the price and utilization of pharmaceutical treatments. Theoretically, the program could either increase or reduce prices, which we formalize below in a theoretical model. On the one hand, once enrolled in Part D, enrollees who had previous been uninsured would have a lower elasticity of demand than previously, leading to an increase in manufacturers' profit-maximizing prices. On the other hand, Part D plans could exclude certain treatments from their formulary (a list of covered drugs) or steer their enrollees away from certain treatments in response to the prices of those treatments. This could give these plans a strong lever with which to negotiate price reductions from pharmaceutical manufacturers. And even if transaction prices were not affected, the insurance provided by Part D would lower beneficiaries' out of pocket prices, presumably leading to an overall increase in utilization.

To estimate empirically the effect of Medicare Part D, we merge together data from two sources. The first source is produced by IMS and contains aggregate data on total annual sales, standardized quantity, and the quantity per daily dose for each product from 2001 to 2006. This data allows us to calculate the average price per daily dose as well as the total number of daily doses for each drug in each year, our two outcome variables of interest. The second source comes from the Medical Expenditure Panel Survey (MEPS), which is produced by the U.S. Agency for Healthcare Quality and Research, and contains data on a nationally representative sample of prescriptions filled in each year. This latter data set allows us to estimate the share of all consumers of a drug who were enrolled in Medicare just prior to the enactment of Part D.[3]

Our estimation strategy exploits variation across drugs in the Medicare market share to estimate the effect of Part D on pharmaceutical prices and utilization. Our key identifying assumption is that the drug-specific Medicare market share is orthogonal to other unobserved factors that affect the change in average prices or total utilization. With this assumption, we model the effect of Part D on the change in average prices or utilization as a linear function of the pre-policy Medicare market share.

[3] Because the individual-level MEPS data are not yet available for 2006, we cannot use this same data to estimate policy-induced price or utilization changes.

Our first set of results strongly suggests that Medicare Part D led to a substantial *decline* in average pharmaceutical prices. More specifically, our findings suggest that each 10 percentage point increase in the pre-policy Medicare market share is associated with a 1.4 percent decline in a drug's average price. If one assumes that all Medicare recipients enroll in Part D, this suggests a reduction of 14 percent. The actual increase for Part D enrollees, however, is presumably almost twice as large given that slightly more than half of Medicare recipients either kept their existing prescription drug insurance coverage or elected to remain uninsured. Combined with the mechanical effect of Part D on out-of-pocket prices, our findings suggest that the average cost of prescription drugs for an uninsured Medicare recipient with average prescription drug spending fell substantially.[4] In light of this, it is not surprising that our results also suggest a substantial increase in utilization among Medicare-intensive drugs.

We next probe further on this result by investigating whether the price and utilization effects vary with the pre-policy insurance coverage of Medicare recipients. Our examination of MEPS data suggests that almost half of Medicare recipients' prescription drug expenses were already covered by either public or private insurance. To the extent that many of these individuals retained this coverage rather than shifting to Part D, one would expect a larger effect for drugs sold differentially to Medicare recipients who did not have insurance prior to Part D. Consistent with this, our estimates reveal a much larger effect on both price and utilization for drugs with a high fraction of Medicare recipients who did not already have insurance, with no corresponding effect for those having a high fraction of already insured Medicare recipients.

One plausible mechanism for an effect of Part D on pharmaceutical prices is that plans could exclude certain drugs from their formulary or give preferential treatment to certain drugs on their formulary. Thus a pharmaceutical firm would have an incentive to sell at a lower price in the hope that the plan would "move market share" for its product. However, for a small subset of "protected" therapeutic classes (such as HIV antiretrovirals), plans would not be able to do this because legislation required them to cover all drugs. Consistent with this, our analyses provide suggestive evidence that Part D did not reduce prices by as much for these classes.

In our final empirical section we investigate whether the effect of Medicare Part D varied within therapeutic classes (as defined by IMS). All else equal, a plan would have a financial

[4] Lichtenberg (2007) uses data from one pharmacy chain to estimate the effect of Part D on the number of prescriptions and on out-of-pocket spending. His results suggest large reductions in out-of-pocket costs, though he does not distinguish between mechanical effects of the plan co-pays and a change in gross pharmaceutical prices.

incentive to steer enrollees to the less expensive treatments within a therapeutic category or perhaps even to exclude the more expensive treatments from its formulary. A potentially offsetting factor would be the effect on enrollment, as Medicare recipients might avoid a plan that only covered the inexpensive treatments. But if the first effect more than offset the second, then one might expect to see differential declines in price for the more expensive treatments, as firms whose products were relatively expensive responded to the credible threat of losing market share. Consistent with this, our findings suggest no decline in price for the least expensive treatments within a category versus substantial reductions for the more expensive ones.

Taken together, our results suggest that Part D reduced Medicare recipients' prescription drug costs by even more than a simple examination of plan co-pays, deductibles, and monthly premiums would suggest. This may partially explain why spending by the federal government in the first year of the program was substantially lower than the initial estimates suggested.[5] Determining whether these price and utilization effects will persist in future years, and whether Part D affected health outcomes or spending on other categories of medical care, represents an important area for future research.

The outline of the paper is as follows. In section two we provide background on the Medicare program and on key features of Part D. In section three we develop a model that considers the effect of Part D on pharmaceutical firms' profit-maximizing prices. Section four describes our data and the construction of our sample of 548 drugs. In the next two sections we specify our empirical framework, summarize our main results, and describe how our estimates vary with enrollee or product characteristics. The final section concludes.

II. Background on the Medicare Program and Part D

A. Medicare Parts A, B, and C

The Social Security Amendments of 1965 established a health insurance program for elderly individuals in the U.S. known as Medicare. Since that time, the Medicare program has consisted of two main components, Hospital Insurance and Supplementary Medical Insurance, which are also known as Part A and Part B, respectively. Virtually all individuals above the age of 65 are automatically entitled to Part A benefits, which currently provide coverage for inpatient

[5] Costs were projected at $780 billion for the first ten years of Part D, though spending in 2006 was X percent lower than initially estimated.

hospital care, some home health care services, and up to 100 days of care in a skilled nursing facility. Those enrolled in Part A have the option to enroll in Part B, which primarily provides coverage for physician services, outpatient hospital care, and laboratory services. In contrast to Part A, enrollment in Part B requires the payment of a monthly premium.

Within two years of the passage of the 1965 Social Security Amendments, there were 19.5 million elderly individuals enrolled in Part A and 17.9 million in Part B.[6] The eligibility criteria for the program were expanded in 1973 when recipients of Social Security Disability Insurance (SSDI) benefits were allowed to enroll in the program following a two-year waiting period from the onset of their disability.[7] By 2005 the number enrolled in Medicare Part A and Part B had increased to 42.5 million and 39.7 million, respectively, with approximately 84 percent of them age 65 or older and the rest receiving Medicare through their SSDI enrollment.

The design of Part A and Part B has remained similar throughout Medicare's existence in that both reimburse providers on a fee-for-service basis. They also both introduce substantial cost-sharing so that recipients share in the cost of their medical care. For example, Part A requires the payment of a deductible for each hospital admission while Part B incorporates both an annual deductible and a twenty percent co-pay for covered services.

Beginning in 1982, Medicare recipients could alternatively choose to receive their health care coverage through a Medicare HMO or similar managed care plan. In contrast to Parts A and B, these managed care providers are paid a fixed risk-adjusted amount per recipient per month that is independent of care delivered and thus bear financial risk for the costs of their enrollees' medical care. Plans are required to cover a certain level of services though they have the option to provide additional benefits as well. The Balanced Budget Act of 1997 changed the name of this part of the program to Medicare Part C, but its current name is Medicare Advantage.

B. Medicare Part D

While Medicare has provided coverage for the costs of hospital care, physician services, and many other types of medical care since its inception in 1966, until recently the program provided very little coverage for prescription drugs. Only those pharmaceutical treatments

[6] See Finkelstein (2007) for a careful examination of the effect of Medicare's introduction on health care spending and treatment patterns and Finkelstein and McKnight (2007) for its effect on health outcomes.

[7] Recipients of Railroad Retirement benefits and those with end stage renal disease were also made eligible, though they accounted for a much smaller number of Medicare recipients

administered in a physician's office or other institutional setting were covered by the program. This omission took on added significance during the 1990s and early 2000s when prescription drug expenditures were growing two times more rapidly than all other health care spending (Duggan, 2005). According to data from the Medical Expenditure Panel Survey, by 2003 per-person expenditures among Medicare recipients for prescription drugs were equal to $1789, with more than half of this paid out-of-pocket and just 7.8 percent paid for by the Medicare program.

Perhaps partly as a result of this growth in pharmaceutical spending, the U.S. Congress passed, and on December 8, 2003 President Bush signed into law, the Medicare Prescription Drug Improvement and Modernization Act. While there were several components to this legislation, the most important feature was the creation of Medicare Part D, which beginning in January of 2006 would provide insurance coverage for prescription drug costs to Medicare recipients who voluntarily enrolled in the program. 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 (Duggan, Healy, and Scott Morton, 2008). The first type, known as a prescription drug plan (PDP), provides coverage only for prescription drug costs while Medicare Advantage plans (MA-PD) insure all Medicare-covered services (e.g. hospital care and physician services) including prescription drugs. To contract with the Centers for Medicare and Medicaid Services (CMS) to provide either type of plan, a firm must provide coverage throughout at least one of the 34 geographic regions defined by CMS.

Plans are allowed to develop a formulary that excludes certain drugs from coverage, though they are required to have at least two drugs on the formulary for each therapeutic category. 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 $2000 in spending, no coverage for the next $2850 (with this often referred to as the "donut hole"), and a 5 percent co-pay once out-of-pocket expenditures reach $3600. These figures change annually and are displayed graphically in Figure 1.

Plans are financed through a combination of enrollee monthly premiums and subsidies from the federal government. Before the start of the year, each PDP and MA-PD must submit an estimate to CMS of the plan's average monthly revenue requirement for providing the basic benefit during the upcoming year. This plan bid would include not only prescription drug expenditures by the plan but also administrative costs and plan profits. These bids are then used to calculate a national average bid, which is multiplied by a certain percentage (34 percent in 2007) to calculate the base monthly premium paid by enrollees. If a plan's bid differs from the national average bid by a certain amount, its monthly premium will differ from the base premium by the same amount. Thus if a plan increases its bid (costs) by one dollar, its government subsidy does not change but its monthly premium increases by one dollar.[8] Similarly for plans with low bids (costs), enrollees pay lower premiums. For further details on how both the benefits and cost-side of Part D operate, see Duggan, Healy, and Scott Morton, 2008.

To enroll in Part D, a Medicare recipient can choose among those prescription drug plans (PDPs) and Medicare Advantage plans (MA-PDs) offered in her region of the country. When making this choice, a Medicare recipient would presumably consider the plan's monthly premium, the drugs included on the plan's formulary, and service.[9] To encourage current Medicare recipients to enroll in Part D early in 2006, monthly premiums increased by 1 percent for each month that a person delayed beyond May of that year. Thus even an individual with zero expected prescription drug costs during the coming year might enroll in the program so as to keep her future premiums low. For individuals newly eligible for Medicare after January of 2006, the grace period before premiums began to increase is equal to X (**check**) months.

Medicare recipients with incomes below a certain level or who are dually enrolled in the Medicaid program are eligible for subsidies for their PDP monthly premiums. Medicaid recipients are required to enroll in a Part D plan and receive the largest possible premium subsidy. This subsidy is equal to the lesser of the premium for their plan and the regional average premium, so the subsidy will not cover the entire cost of a plan if its price is above average. Medicaid recipients also have no deductible or coverage gap and their copayments are heavily subsidized. Other Medicare recipients with incomes below the poverty line receive

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[8] A portion of each plan's subsidy is based on enrollee characteristics and thus to the extent that premium changes influence the composition of beneficiaries it can influence plan subsidies. Also if a plan's costs diverge by more than 2.5 percent from their bid the government shares in the profit or the loss. See Merliss (2007) for more details on the bidding process.

[9] See Lucarelli and Simon (2007) for an examination of the determinants of plans' monthly premiums.

similarly large subsidies, with these subsidies phased out linearly for those with incomes between 100 and 135 percent of the federal poverty line.

By January of 2007, there were 17.3 million PDP enrollees and 6.7 million MA-PD enrollees. Approximately 36 percent of PDP enrollees were automatically enrolled in a PDP because they were also on Medicaid (6.3 million) and an additional 2.2 million were eligible for low-income subsidies because they had incomes at or below 135 percent of the poverty line. This information is summarized in Appendix Table 1.

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. To qualify for the subsidy, a firm's coverage had to be at least as generous as the standard benefit described above. The subsidy was equal to 28 percent of the cost incurred by the employer (up to a maximum of $5350 per Medicare recipient). In January of 2007 there were 6.9 million Medicare recipients whose coverage was subsidized in this way. An additional 8.2 million Medicare recipients had prescription drug coverage from some other source, such as an existing employer, the VA, or the Federal Employees Health Benefits program.

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 equilibrium prices and quantities in the pharmaceutical sector. The next section presents an illustrative model to consider the sign and potential magnitude of these effects.

III. Theoretical Model

Here we provide some intuition and a formal illustration of the pricing changes that pharmaceutical manufacturers will find optimal upon commencement of Part D. As a first approximation of the environment, we will assume that the market for Part D plans is perfectly competitive. Plans set prices and service levels to attract consumers and also bargain with manufacturers to buy drugs. In every region in the US there are at least 27 plans competing for local Part D enrollees. While the market is more concentrated than this number would suggest (approximately 40% of enrollees belong to the largest 3 plans), nevertheless we will abstract from the issue of whether plans have market power in the current paper. Such concerns are an important topic for future research.

Given that plans are effectively not setting the market price for a drug, it is the drug's manufacturer who is choosing prices before and after the Part D program. Our data source is a healthcare data collection firm called IMS. IMS captures a drug's revenue using wholesaler invoices. Importantly, our measure of revenue does not take into account special rebates that may be contracted upon by the manufacturer and the ultimate payor (typically with some sort of pharmacy benefit manager as an intermediary). We will return to this issue below, but note here that the reason we use IMS data is that we know of no data source that does measure these rebates.

In the data we observe an average price across all sales except long term care and hospitals; loosely speaking, all retail sales including mail order. (A detailed discussion of the data is postponed to the subsequent section.) This is comprised of sales to Medicare Part D enrollees, Medicaid enrollees, private insurance customers, cash-paying customers, and all other consumers. Each of these types of buyer could purchase her drugs at the same pharmacy, but the customer's price and the pharmacy's reimbursement would be determined by the set of contracts in place for that buyer's insurance scheme. Let us take each buyer in turn and consider their demand elasticities before and after Part D was implemented.

Assume all Medicare enrollees have no coverage prior to Part D and must pay cash for their prescription drugs. Further assume that all of them enroll when the plan begins. Consider a linear differentiated products demand curve for product i (possibly) facing therapeutic substitutes j as in Deneckere and Davidson (1985) or Shubik (1980):

$$q_i = V_i - \alpha_g p_i - \gamma_g (p_i - \frac{1}{N}\sum_{j=1}^{N} p_j) \qquad (1)$$

Here, consumers within a group are identical with valuation V for a product i. p_i is the price of drug i, N is the total number of products in the therapeutic area market, and q_i is the quantity demanded of drug i. $\gamma_g \geq 0$ is the substitutability parameter for a customer group g. α_g is the parameter measuring the elasticity of demand of the customer group, *g*. These latter two parameters will change when the members of the group move from cash payment to Part D enrollment. First, when this group paid cash for prescription drugs, its members were not able to create effective price competition between molecules by threatening to switch to a therapeutic substitute. This is because a single physician and consumer, even if they are aware of prices, cannot offer to move their demand in response to a discount under the current system of posted prices at drugstores. However, PBMs, such as those that are part of Part D, do exactly this to determine which of several substitutes *j* they will purchase. The result of the change in institutional structure is an increase in the substitutability parameter γ_g from something close to zero in the cash regime to a positive level under Part D.

Optimal prices for firms (with marginal costs equal to c) are

$$p_i = \frac{V + c(\gamma \frac{(N-1)}{N} + \alpha)}{2\alpha + \gamma(\frac{N-1}{N})} \qquad (2)$$

As γ_g rises, it can be shown that the optimal price for drug i falls, provided V is larger than c. In the pharmaceutical industry marginal costs are typically quite small relative to valuations for the drug. A second effect that the cash/PartD group experiences is a change in the impact of price on demand. This group is now subsidized at approximately 75% of the cost of the drug benefit. α_g falls as the level of price that causes the consumer to drop out of the market (buy zero units) declines. The optimal price increases with a decline in α_g.[10] Thus we have two effects working in opposite directions and it will be an empirical question which dominates.

The private pay consumers and the remaining cash-paying consumers do not experience either of these structural changes upon the implementation of Part D. If the average price that we measure in the data were comprised of only two groups, privately insured and cash/PartD, we would see a change at the implementation of Part D that looked something like the following:

$$\begin{aligned} \Delta \overline{p_i} &= s_i^{private} \Delta p_i^{private} + s_i^{cash/PartD} \Delta p_i^{cash/partD} \\ \Delta \overline{p_i} &= s_i^{cash/PartD} \Delta p_i^{cash/partD} \end{aligned} \qquad (3)$$

The first term is zero because there is no change in the optimal price for private patients due to Part D. The change in the average price of drug *i* will depend on the fraction of that drug

[10] In this case, the condition V>c+1 provides the result.

purchased by cash-paying but Part D eligible consumers(s) as well as the change in price those consumers pay. In our data we will have a measure of the former, and estimate the latter. Note that the prices we use in the estimation are not the posted prices at the drugstore but the revenues of each drug divided by units sold – a better measure of average realized price per unit.

According to the Part D rules, there are six "protected" therapeutic classes in which PDPs must be less aggressive with their formularies than in other therapeutic areas. All products in the HIV, anti-cancer, anticonvulsant, immunosuppressant, antipsychotic, and antidepressant categories must be included in all Part D formularies. While a PDP cannot exclude any drug in these categories, it can create financial incentives or hurdles such as prior authorization to affect a patient's choice of drug. We do not know whether the restrictions applied to these classes have any real impact on the behavior of PDPs. If they do, their effect will be to reduce the substitutability among drugs (lower γ_g) and reduce the PDPs ability to extract discounts from manufacturers. This will dampen the price-lowering feature of the Part D program. We modify our specification to allow for different effects for drugs in protected classes.

$$\Delta \overline{p_i} = s_i \Delta p_i^{cash/partD} + s_i \Delta p_i^{cash/partD} * \mathrm{I}_{protected} \qquad (4)$$

Naturally, we expect quantity consumed by cash/PartD group to increase. We will test for an expansion of demand for "daily doses" in the empirical section of the paper.

We use this specification to test the differential response of another group in addition to the protected classes: drugs without therapeutic competition. Recall that our basic model outlines two effects, one a reduction in elasticity of demand due to an increase in insurance status, and the other an increase in cross-price elasticity of demand due to bargaining by the PDP. If a drug does not have effective competition from therapeutic substitutes, the PDP cannot engage in this bargaining. This might occur if a drug is first-in-class or has significantly better clinical performance than others that treat the same condition. In such situations we would not expect an increase in γ_g at the implementation of Part D. We exploit this form of heterogeneity when estimating equation (4) for our cash/PartD group by estimating a differential effect for drugs without therapeutic substitutes.

Duals

Any Medicaid consumer who was also eligible for Medicare was automatically switched to Part D when it began. These consumers moved from a system where demand from state programs was very inelastic (and a function of average price in the private market) into the Part D system where the PBM can create a substantial cross-price elasticity of demand. However, many of the drugs that the duals consume are in the six "protected classes," and, since most duals are heavily subsidized, the PBM cannot create financial incentives to affect their drug choices. Still, there was typically even less substitutability in Medicaid, so we expect declines in γ_g due to Part D, but we expect them to be somewhat smaller for duals than our cash group. Second, Medicaid sales for many drugs consumed disproportionately by duals will be much smaller after Part D takes effect and patients move from one program to the other. Any reduction in the inelastic segment of demand will lower the externality felt by the manufacturer when setting the private price (Mark Duggan and Fiona Scott Morton, 2005). Therefore, we expect the optimal private price for drugs with high dual share to decline. The introduction of Part D provides no theoretical rationale for private prices of drugs that sell only small quantities to Medicaid to change. We therefore model the price change of the large dual share drugs as an interaction between dual share (s^{dual}) and the change in the private price. For these reasons, we expect two optimal prices for drugs sold disproportionately to Medicaid to fall: the price for duals and private prices.

$$\begin{aligned}\Delta \overline{p_i} &= s_i^{dual}(\Delta p_i^{dual} + \Delta p_i^{private}) + s_i^{dual}(\Delta p_i^{dual} + \Delta p_i^{private}) * \mathrm{I}_{protected} \\ &+ s_i^{cash/PartD}\Delta p_i^{cash/partD} + s_i^{cash/PartD}\Delta p_i^{cash/partD} * \mathrm{I}_{protected}\end{aligned} \quad (5)$$

Duals' drugs are fully subsidized both under Medicaid and Part D and so members of this group experience no change in own-price elasticity of demand. The change in the average price will be a weighted average of the change in cash/Part D prices, where we have no prediction on sign, and the change in prices to duals and the private price where we expect a negative price change. Both of these effects could differ for drugs in the protected classes.

IV. 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 together 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) in the U.S. for all pharmaceutical products in each year from 2001 to 2006. The data also contains 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. According to our IMS data, total sales increased from $162.6 billion to $223.9 billion from 2001 to 2006.[11]

Each pharmaceutical product is assigned to one of fourteen therapeutic categories.[12] The top three categories accounted for 51.3 percent of U.S. sales in 2006 and include drugs used to treat central nervous system disorders, cardiovascular conditions, and conditions of the alimentary tract. The data are further divided into 260 subclasses, with cholesterol reducers, antiulcerants, and antidepressants accounting for the most sales in 2006. In some cases a product is assigned to more than one category or subclass, presumably because it is used to treat more than one condition. When this occurs there is more than one observation for the product in the data, and we therefore must aggregate across these to calculate total sales for the product.

A related issue that we confront in the IMS data is that there are often multiple products for the same drug. For example, in 2006 there are four different versions of the drug Prevacid that have strictly positive sales. In this case and related ones we aggregate sales for all versions of the same drug in each year. When doing this, we do not include any sales for generic competitors as the focus of the current study is on branded drugs that currently have, or previously had, patent protection.

B. Medical Expenditure Panel Survey

Our second main source of data is the Medical Expenditure Panel Survey, a publicly available data set that is constructed annually by the Agency for Healthcare Research and Quality. In carrying out this survey, AHRQ collects data on demographic characteristics,

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[11] Expenditure figures cited here and elsewhere in the paper are adjusted to 2006 dollars using the Bureau of Labor Statistics' Consumer Price Index for all Urban Consumers (CPI-U).

[12] In some cases a product is assigned to more than one category, presumably because it can be used to treat more than one condition. For these products, the data allows us to determine sales by category for the product. More specifically, if a product has $200 in sales in category A and $100 in sales in category B, the data would include two separate observations. By aggregating all observations for each product can we determine total product sales.

insurance coverage, health care utilization, and many other variables for a nationally representative sample of the civilian non-institutionalized population residing in the U.S. The survey is divided into several files with, for example, one focusing on hospital inpatient care and another on emergency room visits.

The file that is particularly relevant for the current study is the Prescribed Medicines file which provides information on household-reported prescriptions that were filled during the year. For each reported prescription this file lists the drug name, the total amount paid, the amount paid out-of-pocket and separately 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. According to this survey data, the top four drugs ranked in terms of 2003 sales are Lipitor, Zocor, Prevacid, and Nexium, which exactly corresponds with the top four in 2003 from our IMS data described above.

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 along with information about her health insurance coverage in each month during the year. The 2003 CDF includes information for 34,215 individuals. Comparing this to the number of individuals in the Prescribed Medicines file, there are no prescriptions reported for approximately 40 percent of the individuals in the sample.

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 not surprisingly given the eligibility criteria described above is much greater among those aged 65 and up (98.8 percent) than among the non-elderly (2.2 percent). Figure 2 summarizes the relationship between age and Medicare enrollment for individuals aged 40 or older. As the figure shows, the fraction on Medicare increases relatively smoothly with age among the non-elderly because of the increasing rates of SSDI enrollment. This fraction then increases sharply from 15 percent at the age of 64 to 96 percent at age 65.

Medicare recipients have substantially greater utilization of prescription drugs than their counterparts not in the program. According to the MEPS, the average number of prescriptions in 2003 among Medicare recipients was 28.0 versus just 6.5 for those not in the program. Because of this, the fraction of prescriptions accounted for by beneficiaries of this program (40.3 percent) is almost three times greater than their share of the population (14.4 percent).

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 columns 2 and 3 differentiate between those with and without Medicare coverage, respectively. As the first row of the table demonstrates, the total amount paid for the average prescription is approximately $69.48 during this year, with the average slightly higher for Medicare prescriptions ($69.90). 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 Medicaid, the VA, and Medicare. Recall that Medicare did cover the cost for certain prescription drugs such as cancer treatments in this year.

The model developed in Section 3 suggests that an important source of variation across drugs in the impact of Medicare Part D is the fraction of individuals taking the drug who were eligible for Part D prior to its enactment and subsequently may have enrolled in it. According to the 2003 MEPS, this variation is substantial. For example Zoloft, an anti-depressant drug that is ranked 5th 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 16th in terms of sales in that same year, is 72.9 percent.[13]

C. Constructing the Analysis Sample

The Medicare Modernization Act was signed into law on December 8, 2003. This Act had a number of provisions that were intended to reduce the cost of prescription drugs for Medicare recipients. The most important of these was the creation of Medicare Part D, but this change to the program did not take effect for more than two years in January of 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

[13] These shares are equal to the weighted fraction of a drug's prescriptions that are for individuals enrolled in Medicare at some point in 2003. One could alternatively calculate this as the weighted fraction of a drug's spending, which for Zoloft and Plavix would be .278 and .736, respectively. The correlation between these two shares for the 769 drugs out of the top 1000 that appear in the 2003 MEPS is 0.975.

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 1000 drugs in the IMS data according to their 2003 sales, which account for 97.2 percent of the $196.0 billion in total sales in that same year. In constructing this sample, we took care to combine all versions of the same drug. Thus in the example above, sales and utilization for all four versions of Prevacid would be aggregated into one drug. We then drop the 113 products that are available over the counter in 2006, as 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. Thus a drug such as Tylenol, which ranked 86 in terms of 2003 sales in our initial sample of 1000 drugs, is not included in our analysis sample.

We next drop the 194 remaining drugs that are generic, given that there will typically be many manufacturers for each of these drugs and these firms would have significantly less pricing power. We will not ignore generic drugs in our analysis however, as we will control for the presence of generic competition for the brand drugs remaining in our sample. The exclusion of generic and over-the-counter products leaves us with a sample of 693 drugs that currently or previously enjoyed patent protection, with these drugs accounting for $170 billion of the $196 billion (86.7 percent) in 2003 spending in our IMS data.

We then merge this IMS data on sales and utilization in each year from 2001 to 2006 to the MEPS data on Medicare market shares. 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.[14] Of the 693 products remaining in our sample, 125 do not appear in either the 2002 or the 2003 MEPS.[15] One important reason for this is that the MEPS does not include prescriptions that are administered in a physician's office or in some other institutional setting. Thus the drug Remicade, which is ranked 39th in total IMS

[14] 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 weighted correlation of 0.92.
[15] There are 544 products that appear in the 2003 MEPS and an additional 22 appear only in the 2002 MEPS.

sales and is used to treat autoimmune disorders by IV infusion in a physician's office, has zero observations in either the 2002 or the 2003 MEPS.

An additional reason that some products are missing is that the MEPS captures approximately 1 out of every 10,000 prescriptions in a typical year and thus some products with small patient populations will inevitably not be included. Consistent with this, the average number of daily doses is 16.2 times greater for the 568 drugs that are in the 2002 or 2003 MEPS than for the 125 that are not.[16] The 568 drugs that remain in our sample accounted for $155.0 billion of the $196.0 billion (79.1 percent) in total 2003 IMS spending.

There is a close correspondence between IMS spending in 2003 and the estimate of total spending from the 2003 MEPS. The correlation between these two is equal to 0.928, with this increasing to 0.981 when drugs are weighted by the number of prescriptions in the MEPS. However, there are some cases in which drugs have very different rankings in the IMS and MEPS data. To shed light on this issue, Table 2 lists drugs that are ranked in the top 20 in terms of 2003 spending in either IMS or the MEPS, with drugs sorted in terms of their highest rank. The most notable disparity in this table is for the drug Epogen, which is ranked 6th in the IMS data but just 435th in the MEPS, where it has only 19 prescriptions. Like Procrit, Epogen is administered by injection for the treatment of anemia brought on by kidney disease, so it not common in MEPS. In our empirical analyses below, we weight our specifications by the number of prescriptions in the MEPS to account for variation across drugs in the precision with which the Medicare market share and other explanatory variables are estimated.

A limitation to our focus on the top selling brand drugs in 2003 is that we will miss three potentially important sets of drugs. First, any drug introduced in 2004 or later will not be included in our analyses below. Second, any drug that had sales in 2003 but was not in the top 1000 sellers in that year will also not be included. Third, we do not include generic drugs in our analysis. Thus to the extent that Part D plans influenced the utilization of new products, generic drugs, or relatively low selling drugs, we will not capture this effect in the analyses that follow.

D. Identifying protected classes and therapeutic substitutes

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[16] Similarly the 125 omitted drugs are much more expensive on average, with the average cost per daily dose in 2003 more than 47 times greater than for their counterparts that are in the MEPS.

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. IMS has a category named "cancer and immunomodulators" which covers the protected classes of anti-cancer drugs and immunosuppressants. IMS also contains categories labeled "antidepressants," "antipsychotics," "anti-epileptics," and "HIV antivirals." We use anti-epileptics to proxy for the Part D class called anticonvulsants, but otherwise the matches are exact in terminology.

Measuring the extent of therapeutic substitutes is much more difficult. Even the lowest level of IMS categorization has many drugs in it, not all of which are appropriate clinical substitutes for each other. To be completed.

V. 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 this data to estimate specifications of the following type:

$$\Delta Y_{j,2006} = \alpha + \beta MMS_{j,2003} + \gamma \Delta Y_{j,2003} + \mu Yrs_{j,2003} + \varepsilon_{j,2003} \qquad (6)$$

with j indexing drugs and $\Delta Y_{j,2006}$ equal to the change in outcome variable Y 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 of 2003 but the plans did not start enrolling beneficiaries until January of 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 enrolled at some point in the program during the same year.[17] This specification, which uses one observation per drug, exploits the variation across drugs in their tendency to be used by Medicare recipients.

To interpret our estimate for β as the causal effect 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. We are also interested in the partial equilibrium effects of Medicare Part D on prices and utilization of Medicare recipients. 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.[18] By taking first differences of average prices or total utilization, we are differencing out any unobserved time invariant differences across drugs. To account for the possibility that drug prices, utilization, or sales may be trending differentially for Medicare-intensive drugs prior to the policy change, we also include the pre-existing trend (from 2002 to 2003) for the outcome variable of interest in each specification. And finally, given that total utilization and average prices for the same drug typically vary over the lifecycle of the drug, we also control for the number of years that the drug has been on the market.

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. This can be seen in Table 3, in which we display various summary statistics for average prices and for the change in average prices in our analysis sample. 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 (Duggan and Scott Morton, 2006) we take the log of the average price, which as shown in this same table is much more symmetrically distributed and has a skewness of approximately zero. 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

[17] In calculating this Medicare market share, we use the person weights in the MEPS. There is variation both across and within therapeutic subcategories in this MMS measure. Specifically the correlation of a drug's Medicare market share with the average weighted Medicare market share of other drugs in its therapeutic subcategory is .697.
[18] As is done in Amy Finkelstein (2007) when she looks at the effect of the start of Medicare.

rate of pharmaceutical prices is significantly greater for Medicare-intensive drugs following the enactment of Part D after controlling for the pre-existing trend in the price.

Table 4 summarizes the results from several specifications similar to equation (6) above. In this equation, we exclude 20 of the 568 drugs described above because they either have no sales (and thus no average price) in 2002, no sales in 2006, or are missing the year of FDA approval.[19] 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 the Medicare market share will vary across drugs.[20] The estimate of -0.128 for β in the first column, in which no other explanatory variables except a constant are included, suggests that the introduction of Medicare Part D lowered pharmaceutical prices by approximately 13 percent for beneficiaries of the program. This estimate is significant at the five percent level. The magnitude of this estimate increases slightly in the next specification to -0.136, in which we add the pre-existing trend in the log price change and the number of years that the drug has been on the market.

One potential concern with our estimate for the Medicare market share is that it weights all prescriptions equally. If, for example, the number of days covered in the typical prescription for a Medicare recipient is different than for those not on the program, this estimate may be misleading. We therefore introduce an alternative measure of the Medicare market share in the third specification that represents the fraction of total spending accounted for by Medicare recipients. The estimate of -0.128 for β 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 is essentially for β is unchanged. The specification summarized in the fifth column explores the sensitivity of our estimates to the exclusion of outliers (those in the top or bottom one percent of the price change distribution). In this case our estimate for β increases slightly to -0.142 and is significant at the one percent level.

As mentioned in the preceding section, the MEPS Prescribed Medicines files do not include information for drugs administered in a physician's office or clinic. 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 sixth specification we exclude these 21 drugs and obtain very similar estimates. In the final specification we replace our drug-specific estimate for the

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[19] The number of drugs excluded for having no sales in 2002, no sales in 2006, or a missing year of FDA approval are 15, 3, and 2, respectively.

[20] More specifically, we use Stata analytic weights.

Medicare market share with the therapeutic category average Medicare market share. This may be a more accurate measure of the fraction of *potential* customers for a drug who are enrolled in the program. Using this estimate we obtain very similar estimates to those using the drug-specific measure.

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 concentrated among those shifting into Part D plans as opposed to those remaining with their previous coverage, these estimates may understate the average impact on net prices for Part D enrollees. We explore this issue in more detail in Section Six.

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

The results presented in the preceding section suggest that the enactment of Part D reduced gross pharmaceutical prices for Medicare recipients by an average of 12 percent. The program reduced the net price of pharmaceutical treatments even further through an additional channel - the subsidies summarized in Figure Ono. For example, the typical plan during the 2006 calendar year covered 75 percent of the first $2000 in prescription drug costs once a person had reached their annual out-of-pocket deductible of $250. Additionally, Medicare recipients enrolled in Part D pay just five percent of their costs once their out-of-pocket spending reaches $3600, with the government covering 80 percent and the plan the remaining 15 percent.

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. The magnitude of this increase would depend on several factors, including the elasticity of demand for the affected treatments as well as the distribution of net price changes for these same treatments. To the extent that the utilization of prescription drugs is very responsive to price, one would expect a substantial effect on utilization (Gibson et al, 2005).

To investigate the effect of Medicare Part D on the total utilization of prescription drugs, in this section we estimate specifications that are analogous to those in the preceding section and are estimated on the same sample of 548 drugs. 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 -0.63 and 1.08, respectively.

The results from these specifications are summarized in Table Five. The estimate of 0.516 for β 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 .108. Even though the estimate is not statistically significant, the point estimate suggests an increase of more than 67 percent in utilization among Medicare recipients. In the next specification, we include the pre-existing trend from 2002 to 2003 in utilization and the number of years that the drug had been on the market as of 2003. The estimates for the coefficients on both of these variables are statistically significant, suggesting that drugs that were experiencing sales increases from 2002 to 2003 continued to see increases during the next three years and that older drugs experienced significantly lower increases in sales. The inclusion of these variables leads to an increase to 0.616 in our estimate for β, which is statistically significant at the 5 percent level and suggests an increase in the utilization of prescription drugs of approximately 85 percent. The estimates for β in the next several columns are similar in magnitude, ranging from a low of .541 to a high of .876, and in all cases the estimates are statistically significant.

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 548 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 pharmaceutical prices suggests almost an 80 percent reduction in the out-of-pocket cost *on the margin*. This is similar in magnitude to the implied utilization increase of 85 percent from specification (2), suggesting an elasticity of approximately one.

This estimate is somewhat greater than the corresponding one from most previous studies summarized in Gibson et al (2005). But for many reasons the elasticities calculated here are not strictly comparable because they are estimated for a different population, consider different drugs, and have a non-linear relationship between out-of-pocket spending and total prescription drug costs. Additionally given the large standard errors for β in every specification in Table 5, the 95 percent confident interval for our estimates using aggregate data includes the estimates from most previous research.[21]

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[21] This remains true when one considers that many Medicare recipients already had prescription drug coverage, and thus our elasticity estimate is even larger.

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

A. Differentiating between Insured and Uninsured Medicare Recipients

Just prior to the enactment of the Medicare Modernization Act, a substantial fraction of Medicare recipients already had insurance coverage for prescription drug costs. As shown in Table 1 and described above, payments by private and public health insurers accounted for 20 and 29 percent, respectively, of 2003 prescription drug expenditures for this group. However, as this same table shows, the majority of Medicare recipients' prescription drug expenses were paid for out-of-pocket.

We begin this section by investigating whether the price effects estimated above also vary with the baseline insurance coverage of Medicare recipients. For at least three reasons, it is plausible that these effects would differ by a significant amount. First, 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 the shift may have reduced pharmaceutical prices. Second, many individuals with some other kind of insurance may have retained this rather than switch into a Part D plan. For these individuals, one would expect relatively little change in a manufacturer's optimal price. And third, the shift from being uninsured to a Part D plan may have affected prices by reducing the sensitivity to prices or (indirectly) increasing the sensitivity to price differences.

The specifications summarized in Table 6 shed light on this issue. In column (1), we report the results from our baseline specification summarized in the preceding section, in which our estimate for the coefficient on the overall Medicare market share is -0.136. 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:

$$\Delta Y_{j,2006} = \alpha + \beta_1 MMS\_Self_{j,2003} + \beta_2 MMS\_Ins_{j,2003} + \gamma \Delta Y_{j,2003} + \mu Yrs_{j,2003} + \varepsilon_{j,2003} \qquad (7)$$

The average values for these two variables in our sample of 548 drugs are 0.249 and 0.152, respectively, and the latter share variable includes both private and public insurance.

The estimates for β_1 and β_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 -.209 for β_1 implies that the average (gross) price of prescription drugs consumed by uninsured Medicare recipients fell by almost 20 percent from 2003 to 2006, and this estimate is significant at the one percent level. The magnitude of the corresponding estimate for β_2 is an order of magnitude smaller, has the opposite sign, and is statistically insignificant. This suggests that the price declines observed for Medicare-intensive drugs were driven by declines for drugs consumed disproportionately by individuals without health insurance.

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 profit-maximizing Part D plans to obtain lower prices than state Medicaid programs did. The estimate of -.261 for the coefficient on the dual eligible share is consistent with this hypothesis, though this estimate is not statistically significant.[22] It is worth noting, however, that its magnitude is actually larger than the corresponding estimate of -.231 for β_1, which remains statistically significant at the one percent level.

In the next three columns of this table, we summarize the results from an analogous set of specifications for the utilization (in terms of number of daily doses) of the 548 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 .766 for β_1 in specification (5) is more than twice as large as the corresponding estimate for β_2 and is statistically significant at the ten percent level.

The results in the final three columns investigate the effect of Medicare Part D on total U.S. revenues. Given that the policy intervention reduced pharmaceutical prices while increasing the quantity of these treatments that was consumed, it is theoretically ambiguous whether the revenues of pharmaceutical manufacturers increased or declined as a result of this legislation. The statistically significant estimate of .504 for β_1 in column (7) suggests that the utilization effect more than offset the effect of declining prices, so that sales accelerated for Medicare-intensive drugs. Because the marginal cost of most pharmaceuticals is quite low, it is

[22] Because the shift from Medicaid to Part D would have reduced Medicaid market shares, there could be a spillover effect to Medicaid recipients not enrolled in Medicare. Because we have only aggregate data for the post Part D period, we cannot yet investigate this possibility.

plausible that manufacturer profits could have risen also. The estimates are quite similar for the uninsured and insured Medicare recipients, though both are statistically insignificant.

Taken together, the results presented in this section suggest that Medicare Part D reduced the price and increased the utilization of drugs sold differentially to Medicare recipients who lacked insurance coverage for prescription drug costs prior to the enactment of Part D. We find little evidence to suggest that there was a corresponding effect on either price or utilization for 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.[23] If there were only two treatments within a category, then the plan was required to cover just one of them. This requirement was introduced to reduce plans' ability to "cream skim" the least costly patients by excluding all treatments for certain conditions. This ability to exclude certain treatments from the formulary provided plans with potentially important leverage when negotiating prices with pharmaceutical manufacturers.

The requirements for a plan providing Part D coverage 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, step therapy, or fail first provisions. All else equal, however, a plan's leverage in negotiating low prices would be less than if they could exclude the treatment altogether.

To investigate whether the price effects of Medicare Part D were different for these classes, in this section we summarize the results from specifications of the following type:

$$\Delta Y_{j,2006} = \alpha + \beta MMS_{j,2003} + \lambda Protected_j + \sigma MMS_{j,2003} * Protected_j + \gamma \Delta Y_{j,2003} + \varepsilon_{j,2003} \quad (8)$$

[23] Certain therapeutic categories were excluded from Part D coverage, such as weight loss drugs.

In this equation, $Protected_j$ is set equal to one if drug j is in one of the protected categories and is otherwise set equal to zero. This variable is then interacted with the Medicare market share defined above to explore whether the average price effects estimated above differ for drugs in this category. To the extent that Part D plans were less successful at negotiating price reductions in these protected categories, one would expect a positive estimate for σ.

The results summarized in Table 7 shed light on this prediction. In the first column we include all 548 drugs in the sample, with 72 of these treatments falling into one of the six protected classes. The estimate of .062 for σ is approximately half as large as the main effect estimate β, suggesting that Medicare-intensive drugs in protected classes experienced smaller price declines than their counterparts not in protected classes. However, this estimate is not statistically significant. We cluster our standard errors by therapeutic subcategory given that the protected class indicator varies at this level.

In the next column, we exclude cancer treatments from the estimation sample, which reduces the number of drugs in the protected categories from 72 to 51. We do this because, as described above, these drugs are typically administered in physicians' offices or in other institutional settings and these prescriptions would not be captured in the MEPS. With this change, our estimate for σ increases to .113, though it remains statistically insignificant. Dividing this by the estimate of -.134 for β, our point estimate suggests that the price effect of Medicare Part D is 84 percent smaller for drugs in protected classes.

An examination of the results displayed in the next two columns yields a similar picture. When drugs in the protected categories are excluded from the regression the estimate for β is essentially unchanged. However when we include only the 51 drugs in the four protected categories (anti-depressants, anti-psychotics, anti-retrovirals, and anti-epilpetics) in the fourth specification, the estimate for β changes sign to .045, though it remains statistically insignificant.

The next four columns report the results for an analogous set of specifications for the utilization measure defined above. In the fifth specification, the estimate for σ is large in magnitude at -1.988 though it is statistically insignificant. This suggests that Medicare-intensive drugs in protected classes experienced *decreases* in utilization following the enactment of Part D. The estimate becomes even larger in specification (6) though it shrinks in specification (8).

Whether this finding reflects a reduction in the overall utilization of treatments in Medicare-intensive protected categories rather than a shift from Medicare-intensive drugs to other treatments in the same category is not clear. Of the four protected categories that we include, anti-psychotics have the highest average Medicare market share at 0.42 (versus 0.39, 0.31, and 0.25 for anti-epileptics, HIV anti-retrovirals, and anti-depressants, respectively). This category is also the one of the four protected categories with the largest increase (18 percent in the number of daily doses) in average utilization among the drugs included in our sample. This suggests that the negative estimate for the Medicare market share in specifications 5, 6, and 8 may at least partially reflect a shift rather than a decline in utilization in protected categories. We consider this issue of within-category substitution in the next section.

C. Expensive versus Inexpensive Treatments

Firms that provided Part D coverage were required to cover at least two drugs in each therapeutic category. Because plans shared in the cost of their enrollees' prescription drugs, they would, all else equal, prefer to cover (or steer enrollees toward) the less expensive treatments within a therapeutic category. On the other hand, to the extent that more expensive treatments were on average more effective, a plan might want to cover these treatments so that more Medicare recipients would select their plan. Which of these two effects would dominate is theoretically ambiguous.

In this section, we investigate whether the effect of Medicare Part D on pharmaceutical prices and utilization varied with a drug's price relative to its therapeutic competitors. We rank the 548 drugs in our sample within their IMS therapeutic subcategories by their price per daily dose. We then define a variable *PriceRank* that is increasing in the drug's price rank as follows. If there are two drugs in the category then the lower priced one has a value of 0 while the higher priced one has a value of 1. If there are three drugs within a therapeutic category then the lowest and highest priced drugs would have *PriceRank* values of 0 and 1, respectively, while the drug with the median price would have a *PriceRank* of 0.5.[24] Using this variable, which is constrained to lie between 0 and 1, we estimate specifications of the following type:

$$\Delta Y_{j,2006} = \alpha + \beta MMS_{j,2003} + \delta PriceRank_{j,2003} + \omega MMS_{j,2003} * PriceRank_{j,2003} + \gamma \Delta Y_{j,2003} + \varepsilon_{j,2003} \quad (9)$$

[24] Similarly if there were five drugs in the category then the values would be 0, 0.25, 0.5, 0.75, and 1.0.

In this regression, we interact the *PriceRank* variable with the Medicare market share to examine whether the price and utilization effects estimated above vary within a therapeutic category. If, for example, price declines were larger for the relatively expensive drugs within a therapeutic category, we would expect a negative estimate for β5. More specifically, the effect for the lowest priced drugs would be β while the effect for the highest priced drugs would be β + ω.

Columns (1) through (4) of Table 8 summarize the results from specifications with the log price change from 2003 to 2006 as our dependent variable. Here we cluster the standard errors by therapeutic subcategory given the interdependence between the values of *PriceRank* within this category. We also exclude drugs that are the only one out of our 548 sample drugs in the category. In the first specification we include only the Medicare market share, the pre-existing trend in prices, and the price rank as our explanatory variables. The estimate for δ on *PriceRank* in this specification is just -.017 and statistically insignificant, suggesting that there was little differential increase in price for expensive drugs relative to less expensive drugs within the same subcategory. Our estimate of -.131 for β, the coefficient on Medicare market share, is statistically significant.

In the second specification we include as an explanatory variable the interaction of this *PriceRank* measure with the Medicare market share. This variable essentially tests whether average prices of drugs consumed by Medicare recipients dropped differentially for the more expensive drugs within a therapeutic category. The estimate of -.301 for ω is statistically significant at the 10 percent level. The inclusion of this variable reduces the magnitude of our estimate for β, which switches sign to a statistically insignificant .020. Comparing this with our estimate for β in specification 1, this result suggests that the price declines were largest for the most expensive drugs. For example, the implied effect of -.279 (β + ω) for a category's most expensive drug is more than twice as large as the average effect. This is consistent with the hypothesis that Part D plans steered their enrollees toward lower cost drugs within a therapeutic category, and that manufacturers of more expensive drugs responded by lowering their prices.

In our first variation, we drop cancer drugs (specification 3) and the results are very similar. We have estimated a companion set of specifications in which we include the Medicare uninsured share and its interaction with *PriceRank* and obtain qualitatively similar results. For example, our estimate of w in this case is larger in magnitude at -.336 though it is not statistically significant with a p-value of .126.

Utilization results in Table 8 – to be completed.

D. Therapeutic Substitutes - to be completed.

Our theoretical model predicts that drugs which have poor or nonexistent therapeutic substitutes and substantial sales to uninsured Medicare recipients will experience relatively greater price increases. The reason for this, again, is that the PDP is good at lowering prices through creating therapeutic price competition, but may not be able to do so if a drug has poor substitutes. All else equal, the effect of the lower elasticity of demand of Part D enrollees would dominate and provide the manufacturer with an incentive to raise price.

VII. Conclusions – to be completed

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Kaiser Commission

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Figure 1: Out-of-Pocket Spending in 2006 for Medicare Part D Recipients

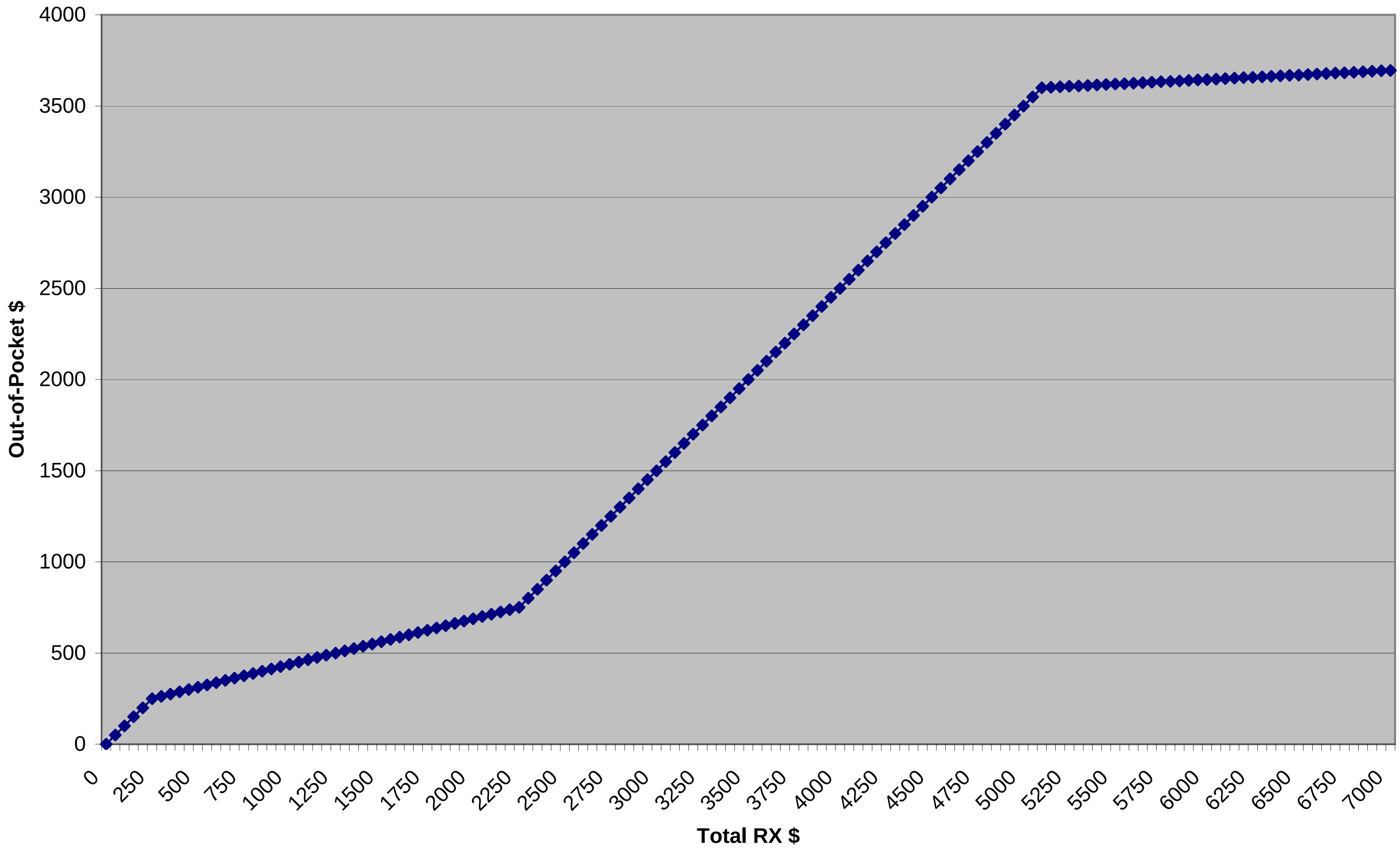

Figure 2: Medicare Enrollment by Age: 2003 Medical Expenditure Panel Survey

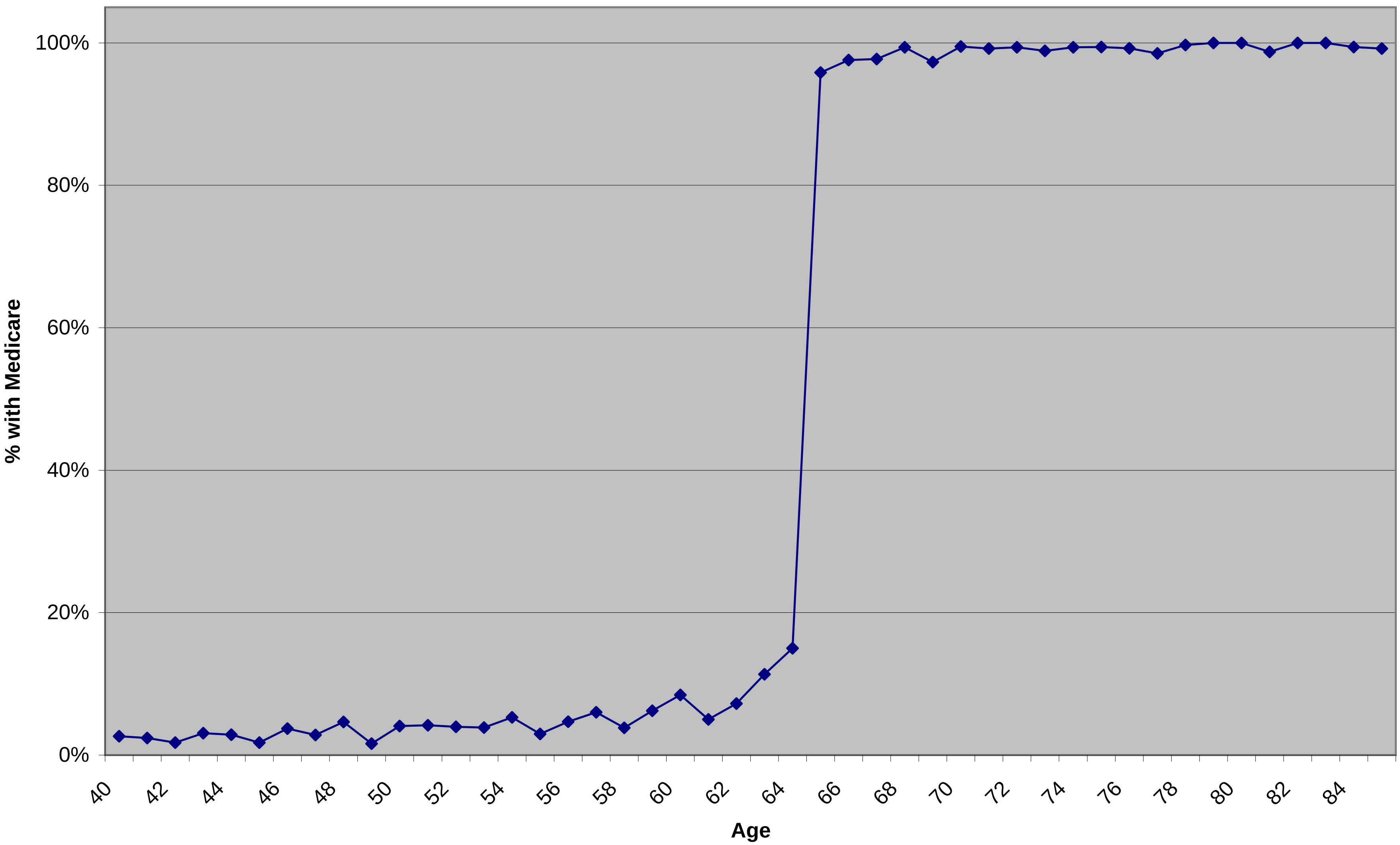

Table 1: Source of Payment for Prescriptions in the 2003 MEPS

	All	Medicare	All Other
Average Total Paid per Prescription	$69.48	$69.90	$69.17
% Paid Out-of-Pocket	44.9%	50.9%	40.5%
% Paid by Private Insurance	34.5%	19.8%	45.2%
% Paid by Medicaid	12.4%	13.9%	11.3%
% Paid by VA	3.3%	5.8%	1.5%
% Paid by Medicare	3.3%	7.8%	0.0%
% Paid by TRICARE	1.1%	1.2%	1.0%
% Paid by Other Insurance	0.5%	0.5%	0.5%
Total Number of Prescriptions	298,293	129,990	168,303

Table 2: Rankings of Top 20 Drugs in IMS and/or the MEPS by 2003 Sales

	IMS Rank	MEPS Rank	MEPS Scripts	Medicare Share
Lipitor	1	1	7534	0.455
Zocor	2	2	4208	0.574
Prevacid	3	3	2651	0.417
Nexium	4	4	2093	0.316
Zoloft	5	10	2596	0.271
Celebrex	7	5	2590	0.499
Epogen	6	435	19	0.537
Norvasc	14	6	3926	0.592
Advair	12	7	1788	0.293
Zyprexa	8	35	623	0.463
Paxil	13	8	2435	0.292
Neurontin	9	14	1624	0.515
Allegra	17	9	2654	0.19
Procrit	10	48	74	0.652
Effexor	11	16	1610	0.275
Pravachol	15	11	1772	0.538
Plavix	16	12	1664	0.729
Actos	25	13	1311	0.402
Aciphex	35	15	1227	0.435
Singulair	22	17	2080	0.185
Wellbutrin	18	23	1359	0.116
Ortho	29	18	2254	0.006
Oxycontin	19	81	336	0.376
Protonix	23	19	1341	0.446
Fosamax	20	24	1730	0.662
Vioxx	21	20	1686	0.385

Table 3: Distribution of Price and Price Change: Log and Level

	Price per Day 2006		*Δ Price per Day 2003-06*	
	PPD_{06}	$Log(PPD_{06})$	Δ PPD_{06}	Δ $Log(PPD_{06})$
5th Percentile	0.375	-0.982	-0.018	-0.069
10th Percentile	0.716	-0.334	0.002	0.001
25th Percentile	1.327	0.283	0.172	0.104
50th Percentile	2.611	0.96	0.356	0.172
75th Percentile	3.665	1.299	0.674	0.248
90th Percentile	7.72	2.044	1.277	0.348
95th Percentile	12.671	2.539	2.388	0.442
Mean	4.251	0.809	0.747	0.174
Std Dev	9.573	1.049	3.478	0.199
Skewness	10.548	-0.013	12.098	-0.543

First panel summarizes the distribution of the level and log of the price per day in 2006 for the 548 drugs in the sample. Second panel summarizes the change in the per day from 2003 to 2006 and the log change in the price per day from 2003 to 2006. Drugs are weighted by the number of observations in the MEPS.

Table 4: The Impact of Medicare Part D on the Change in Average Pharmaceutical Prices from 2003-06

Dependent Variable: Δ Log(Price Per Day$_{j,2006}$)

	(1)	(2)	(3)	(4)	(5)	(6)	(7)
Medicare Market Share $_{j,2003}$	-.128**	-.136**	-.128**	-.126**	-.142***	-.135**	-.143*
	(.057)	(.056)	(.056)	(.058)	(.054)	(.056)	(.075)
Δ Log(Price Per Day$_{j,2003}$)		-0.277	-0.274	-0.073	-0.144	-0.278	-0.277
		(.271)	(.272)	(.229)	(.298)	(.272)	(.274)
Years on the Market$_{j,2003}$		-0.0003	-0.0002	0.0009	0.0005	-0.0003	-0.0004
		(.0019)	(.0019)	(.0023)	(.0018)	(.0019)	(.0018)
Constant	0.225	0.249	0.246	0.224	0.235	0.248	0.252
	(.026)	(.034)	(.034)	(.034)	(.035)	(.034)	(.035)
# of Observations	548	548	548	200	538	527	527
R-squared	0.016	0.040	0.040	0.033	0.030	0.040	0.040
RX or Spending MMS?	RX	RX	Spending	RX	RX	RX	RX
Top 200 Only:	No	No	No	Yes	No	No	No
Outliers Excluded?	No	No	No	No	Yes	No	No
Cancer Drugs Excluded?	No	No	No	No	No	Yes	Yes
Therapeutic Category MMS?	No	No	No	No	No	No	Yes

Each column summarizes the results from specifications of the change in the log price per day 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 4C. Specifications 1, 2, and 4 through 7 use the share of a drug's prescriptions purchased by Medicare enrolled individuals while specification 3 uses the share of spending for that drug. Specification 4 in each table limits to just the top 200 drugs. Specification 5 drops those observations with values of the dependent variable in the top 1 percent or the bottom 1 percent of the distribution. Specifications 6 and 7 exclude 21 cancer and immunosuppressant drugs while specification 7 also uses the average Medicare market share in the therapeutic category. Heteroskedasticity-robust standard errors are included in parentheses. *, **, and *** indicate significance at the 10th, 5th, and 1st percentile, respectively. The mean and standard deviation of the dependent variable are equal to .174 and .199, respectively.

Table 5: The Impact of Medicare Part D on the Change in RX Utilization from 2003-06

Dependent Variable: Δ Log(Daily Doses$_{j,2003\text{-}06}$)

	(1)	(2)	(3)	(4)	(5)	(6)	(7)
Medicare Market Share $_{2002\text{-}03}$	0.516	.616**	.541*	.806*	.562*	.622**	.876**
	(.320)	(.305)	(.307)	(.450)	(.302)	(.307)	(.438)
Δ Log(Daily Doses$_{j,2002\text{-}03}$)		.580***	.579***	.639**	.539***	.577***	.574***
		(.189)	(.190)	(.326)	(.179)	(.188)	(.202)
Years on the Market		-0.019*	-0.019*	-0.021	-.018*	-.018*	-.018*
		(.011)	(.011)	(.017)	(.011)	(.011)	(.011)
Constant	-0.826	-0.672	-0.641	-0.756	-0.641	-0.678	-0.786
	(.161)	(.223)	(.224)	(.316)	(.221)	(.224)	(.279)
# of Observations	548	548	548	200	538	527	527
R-squared	0.009	0.110	0.107	0.102	0.106	0.109	0.118
RX or Spending MMS Measure?	RX	RX	Spending	RX	RX	RX	RX
Top 200 Only:	No	No	No	Yes	No	No	No
Outliers Excluded?	No	No	No	No	Yes	No	No
Cancer Drugs Excluded?	No	No	No	No	No	Yes	Yes
Therapeutic Category MMS?	No	No	No	No	No	No	Yes

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 4C. Specifications 1, 2, and 4 through 7 use the share of a drug's prescriptions purchased by Medicare enrolled individuals while specification 3 uses the share of spending for that drug. Specification 4 in each table limits to just the top 200 drugs. Specification 5 drops those observations with values of the dependent variable in the top 1 percent or the bottom 1 percent of the distribution. Specifications 6 and 7 exclude 21 cancer and immunosuppressant drugs while specification 7 also uses the average Medicare market share in the therapeutic category. Heteroskedasticity-robust standard errors are included in parentheses. *, **, and *** indicate significance at the 10th, 5th, and 1st percentile, respectively. The mean and standard deviation of the dependent variable are

Table 6: The Impact of Medicare Market Share: Differentiating between Those with and withouth Health Insurance

	μ (σ)	Δ Log(Price Per Day$_{j,2003\text{-}06}$)			Δ Log(Daily Doses$_{j,2003\text{-}06}$)			Δ Log(Total Revenues $_{j,2003\text{-}06}$)		
		(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
Medicare Market Share $_{j,2002\text{-}03}$	0.401	-.136**			.616**			.504*		
	(.197)	(.056)			(.305)			(.307)		
Medicare Self-Pay Share $_{j,2002\text{-}03}$	0.249		-.209***	-.231***		.766*	.712*		0.514	0.426
	(.145)		(.074)	(.079)		(.417)	(.435)		(.419)	(.433)
Medicare Insured Share $_{j,2002\text{-}03}$	0.152		0.024			0.292			0.482	
	(.082)		(.149)			(.775)			(.754)	
Medicare Dual Share $_{j,2002\text{-}03}$	0.048			-0.261			-0.425			-0.687
	(.039)			(.256)			(1.685)			(1.653)
Medicare Other Ins Share $_{j,2002\text{-}03}$	0.104			0.187			0.695			1.142
	(.063)			(.270)			(1.075)			(1.016)
Δ Log(Price Per Day $_{j,2002\text{-}03}$)	0.063	-0.277	-0.265	-0.255						
	(.113)	(.271)	(.274)	(.267)						
Δ Log(Daily Doses $_{j,2002\text{-}03}$)	-0.003				.580***	.582***	.585***			
	(.500)				(.189)	(.189)	(.190)			
Δ Log(Total Revenues $_{j,2002\text{-}03}$)	0.060							.570***	.570***	.576***
	(.514)							(.172)	(.172)	(.173)
Years on the Market	10.4	-0.0003	0.000	0.000	-0.019*	-0.019*	-0.019*	-0.017	-0.017	-0.017
	(6.4)	(.0019)	(.0019)	(.0019)	(.011)	(.011)	(.011)	(.011)	(.011)	(.011)
Constant	-	0.249	0.238	0.24	-0.672	-0.653	-0.647	-0.507	-0.506	-0.496
	-	(.034)	(.036)	(.036)	(.223)	(.223)	(.224)	(.228)	(.229)	(.229)
# of Observations	548	548	548	548	548	548	548	548	548	548
R-squared	-	0.040	0.044	0.048	0.110	0.111	0.111	0.109	0.109	0.111

Table 7: The Impact of Medicare Market Share: Differentiating between Protected and All Other Categories

	Δ Log(Price Per Day$_{j,2003\text{-}06}$)				Δ Log(Daily Doses$_{j,2003\text{-}06}$)			
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
Medicare Market Share $_{j,2002\text{-}03}$	-0.135*	-0.134*	-.135**	0.045	.580*	.580*	.550**	-1.554
	(.073)	(.074)	(.060)	(.194)	(.297)	(.297)	(.276)	(2.363)
Protected	-0.002	-0.016			0.092	0.250		
	(.047)	(.054)			(.415)	(.447)		
Protected * MMS $_{j,2002\text{-}03}$	0.062	0.113			-1.988	-2.632		
	(.160)	(.191)			(1.441)	(1.645)		
Δ Log(Price Per Day $_{j,2002\text{-}03}$)	-0.278	-0.277	-0.292	0.229				
	(.276)	(.277)	(.278)	(.300)				
Δ Log(Daily Doses$_{j,2002\text{-}03}$)					0.592***	0.591***	.466***	1.920***
					(.208)	(.207)	(.166)	(.662)
Years on the Market	-0.0004	-0.0003	-0.0007	0.0019	-0.017	-0.017	-.027***	.106**
	(.0019)	(.0019)	(.0021)	(.0034)	(.011)	(.011)	(.010)	(.048)
Constant	0.2466	0.2463	0.2507	0.1504	-0.606	-0.609	-0.496	-1.957
	(.0351)	(.0351)	(.0363)	(.0805)	(.197)	(.197)	(.185)	(1.078)
# of Observations	548	527	476	51	548	527	476	51
R-squared	0.041	0.041	0.042	0.020	0.143	0.147	0.125	0.318

Table 8: The Impact of Medicare Market Share: Differentiating by Therapeutic Category Price Rank

	Δ Log(Price Per Day$_{j,2003\text{-}06}$)				Δ Log(Daily Doses$_{j,2003\text{-}06}$)			
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
Medicare Market Share $_{j,2002\text{-}03}$	-.131*	0.020	0.022	0.023	.640*	0.942	0.968	0.921*
	(.072)	(.139)	(.140)	(.145)	(.357)	(.620)	(.624)	(.495)
Price Rank	-0.017	0.110	0.110	0.113	0.322	0.572	0.588	0.521
	(.040)	(.087)	(.087)	(.087)	(.296)	(.528)	(.530)	(.470)
Price Rank * MMS $_{j,2002\text{-}03}$		-.301*	-.303*	-.304*		-0.595	-0.638	-0.637
		(.177)	(.178)	(.177)		(.832)	(.837)	(.774)
Protected				-0.014				0.219
				(.050)				(.474)
Protected * MMS $_{j,2002\text{-}03}$				0.105				-2.460
				(.176)				(1.695)
Δ Log(Price Per Day $_{j,2002\text{-}03}$)	−0.283	-0.292	-0.293	-0.293				
	(.273)	(.276)	(.277)	(.279)				
Δ Log(Daily Doses$_{j,2002\text{-}03}$)					.587***	.599***	.596***	.609***
					(.215)	(.222)	(.221)	(.224)
Years on the Market	-0.0001	0.0002	0.0002	0.0002	-0.0137	-0.0128	-0.0125	-0.0119
	(.0019)	(.0019)	(.0019)	(.0019)	(.0131)	(.0133)	(.0133)	(.0133)
Constant	0.254	0.187	0.186	0.182	-0.905	-1.043	-1.058	-0.944
	(.048)	(.062)	(.062)	(.065)	(.393)	(.496)	(.497)	(.390)
# of Observations	513	513	495	495	513	513	495	495
R-squared	0.042	0.054	0.054	0.055	0.115	0.117	0.116	0.150

Appendix Table 1: Total Medicare Beneficiaries with Drug Coverage

Description	June 11, 2006 (millions)	January 16, 2007 (millions)	Percent change
Drug Coverage from Medicare or Former Employer			
Stand-Alone Prescription Drug Plan (PDP)	10.37	10.98	5.9%
Medicare Advantage with Prescription Drugs (MA-PD)	6.04	6.65	10.1%
Medicare-Medicaid (Automatically Enrolled)	6.07	6.27	3.3%
Medicare Retiree Drug Subsidy (RDS)	6.90	6.94	0.6%
FEHB Retiree Coverage	1.60	1.47	-8.1%
TRICARE Retiree Coverage	1.86	1.86	0.0%
TOTAL	**32.84**	**34.17**	**4.0%**
Additional Sources of Creditable Drug Coverage			
Veterans Affairs (VA) Coverage	2.01	1.85	-8.0%
Indian Health Service Coverage	0.11	0.03	-73.6%
Active Workers with Medicare Secondary Payer	2.57	2.57	0.0%
Other Retiree Coverage, Not Enrolled in RDS	0.10	0.10	0.0%
State Pharmaceutical Assistance Programs	0.59	0.31	-47.5%
TOTAL	**5.38**	**4.86**	**-9.7%**