

The Impact of Medicare Part D on Beneficiaries with Type 2 Diabetes/ Drug Utilization and Out-of-Pocket Costs

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Executive Summary

Diabetes, a chronic condition characterized by the inability to maintain proper blood sugar levels, affects a growing number of Medicare beneficiaries and significantly impacts the Medicare program. In 2005, 21 percent of seniors, or 10.3 million people over age 60, were living with a diagnosis of diabetes.¹ One out of every four Medicare dollars was spent to treat the disease in 2000.^{2,3} The expansion of the Medicare program in 2006 to include outpatient prescription drug coverage (“Part D”) gave all Medicare beneficiaries with type 2 diabetes, the most common form of the disease, the opportunity to receive Medicare coverage for medications to help control their blood sugar levels and reduce the potential for costly medical complications. The intent of this sweeping change to Medicare was to create affordable access to drug coverage for all seniors, thus improving their ability to purchase necessary prescription drugs and better manage their health.

This study is the first to use a large, national claims dataset to examine the effect of Part D enrollment on drug utilization and out-of-pocket costs for enrollees with type 2 diabetes. We use Avalere Health’s DataFrame® database of Part D plan benefit and formulary designs to characterize access to diabetes-related drugs in Part D and Wolters Kluwer’s Source Lx, a nationally representative claims data repository, to analyze drug utilization and out-of-pocket costs from January 1, 2004, through September 30, 2007. We begin by describing access to drugs under the benefit. We then estimate the impact of Part D on beneficiaries’ drug utilization and out-of-pocket costs for drug therapy. Finally, we examine the cost experience of beneficiaries not dually eligible for Medicare and Medicaid relative to the thresholds specified in law for the coverage gap in the standard Part D benefit and the catastrophic level.

We find that most drugs recommended in clinical guidelines to treat type 2 diabetes and the two most common co-occurring conditions—hypertension and dyslipidemia—are covered by Part D plans with copayments between \$0 and \$30. In 2007, Part D plan formularies included an average of 85 to 88 percent of the drugs available to treat type 2 diabetes, hypertension, and dyslipidemia. These levels are in line with coverage levels for other drugs that treat chronic diseases including those in the “protected” classes. The majority of hypertension and dyslipidemia drugs were placed on tier 1, the level associated with the lowest cost sharing, with enrollee copayments between \$0 and \$10, while the majority of diabetes drugs were placed on tier 2 with copayments between \$20 and \$30. Most Part D plans have four cost-sharing tiers.

The claims data suggests that Medicare Part D has improved access to medications. Part D plan enrollees with type 2 diabetes show an increase in utilization and a decrease in per prescription out-of-pocket costs of drugs used to treat diabetes and the two related conditions. Prescription Drug Plan (PDP) and Medicare Advantage Prescription Drug (MA-PD) plan enrollees experience increases of 11.2 and 6.2 percent, respectively, in the average number of diabetes-related prescriptions per enrollee. Out-of-pocket diabetes drug costs per prescription are 35 percent lower for PDP enrollees and 25 percent lower for MA-PD plan enrollees, as compared to fellow Medicare beneficiaries who do not enroll in a Part D plan. (Note that many Medicare beneficiaries not enrolled in Part D plans do have other forms of insurance coverage for prescription drugs. Some lack drug coverage altogether.)

This initial investigation of claims data indicates the majority of enrollees with type 2 diabetes who reached the coverage gap threshold in 2006 did so by August. By the end of 2006, 43 percent of non-Medicaid beneficiaries enrolled in PDPs and 33 percent of those in MA-PD plans

reached the gap threshold. We did not, however, observe a drop in the number of prescriptions filled after that point. Sicker beneficiaries—those whose type 2 diabetes is accompanied by both hypertension and dyslipidemia—are more likely to reach the threshold than those whose diabetes is not accompanied by those common co-occurring conditions. Further study is needed to confirm these results and to investigate the effects of the Part D coverage gap on the medication usage behavior of this population.

Future research needs we have identified in the course of this study include (a) examining the effect of major market changes, such as Food and Drug Administration-mandated label changes in 2007 for Thiazolidinediones, on beneficiary access and utilization patterns in Part D, and (b) analyzing the impact of Part D on direct health outcome measures such as A1C, blood pressure, and lipid levels.

Background

In 2005, 21 percent of seniors, or 10.3 million people over age 60, were living with a diagnosis of diabetes. Prior to the rollout of the Medicare outpatient prescription drug benefit (“Part D”) in 2006, one out of every four Medicare dollars was spent to treat the disease.^{4,5} Because the ranks of those diagnosed are growing, policymakers, providers, and researchers are working to improve access to medical treatment for diabetes—a leading cause of morbidity and mortality in the United States.⁶ Their shared goal is to improve patient compliance and health outcomes.

Nearly all Medicare beneficiaries with type 2 diabetes (96 percent) have at least one other chronic condition, and almost half (46 percent) have five or more chronic conditions.⁷ Most of these comorbidities relate to cardiovascular disease, with hypertension (66 percent) and dyslipidemia or abnormal cholesterol levels (36 percent) being the two most common. Treatment guidelines recommend aggressive drug therapy; a typical person with type 2 diabetes takes 4.1 diabetes-related medications.⁸ In 2001, the average type 2 diabetes patient spent approximately \$2,700 out of pocket on drugs.⁹

There is no known cure for diabetes, but careful control of blood sugar levels can reduce the rate of complications and has the potential to lower the costs of care.^{10,11} Multiple studies have shown that type 2 diabetes can be managed effectively with drug therapies targeting glycemic control in combination with proper exercise, diet, and routine medical tests.¹² The recommended first-line treatment for someone newly diagnosed typically involves lifestyle changes. If drug therapy is required, the patient is often prescribed the oral drug metformin.¹³ Blood glucose levels are monitored by measuring a patient’s A1C. Current guidelines recommend A1C to be less than 7 percent, with treatment tailored to individual patient needs.¹⁴ A second line of pharmaceutical agents may be prescribed, including insulin along with other, newer classes of antidiabetic drugs. These second-line therapies are typically added to a drug regimen until the appropriate level of glycemic control is achieved.

Caregivers generally rely on authoritative treatment guidelines to manage the care of patients with diabetes. Because guidelines emphasize the persistent monitoring and titration of drug therapy until glycemic goals are achieved, and considering the costs of needed medications, insurance coverage for prescription drugs is essential for this population. A study of Medicare beneficiaries with chronic conditions, including diabetes, found that those lacking prescription drug coverage acquired fewer medications in the essential therapeutic classes and experienced lower refill adherence.¹⁵ Prescription non-adherence is associated with a decline in self-reported health status and a higher rate of emergency department visits and non-elective surgeries.^{16, 17}

Before Part D, one-quarter of seniors reported having no drug coverage.¹⁸ In 2002, approximately one-half of Medicare beneficiaries were enrolled in employer-sponsored plans or Medicare health maintenance organizations (HMOs), which often included drug coverage with cost-sharing requirements.¹⁹ Approximately 17 percent of Medicare beneficiaries received drug coverage through Medicaid. Another 9 percent purchased Medicare supplemental (“Medigap”) plans that included drug coverage.

By 2007, the second year of Part D operations, 55 percent (24.1 million) of the Medicare population had enrolled in Part D plans, with nearly three-quarters of enrollment concentrated in standalone Prescription Drug Plans (PDPs) and the remainder in Medicare Advantage Prescription Drug (MA-PD) plans.²⁰ Approximately 38 percent of older adults had other drug coverage through,

for example, employers, TRICARE (military coverage), or the Veterans Health Administration. Most employers that offered retiree drug benefits before Part D was created continued providing drug benefits to retirees after Part D was implemented, covering nearly 12 million retirees on Medicare in 2006.²¹ By 2007, less than 10 percent of seniors were without prescription drug coverage.²²

Similar to traditional health plans, Medicare Part D allows for deductibles, cost sharing, and the application of formulary management techniques. Unlike traditional health plans, most Part D plans have a gap in coverage in which enrollees are responsible for the total costs of their drugs. For 2006, this gap began at \$2,250 in total drug costs—enrollee out-of-pocket costs plus plans' drug costs. Beneficiaries whose total out-of-pocket drug costs exceeded \$3,600 reached the catastrophic level in which beneficiary cost sharing is limited to 5 percent.

A small number of studies have analyzed the impact of Part D on various Medicare subgroups. Most found that beneficiaries enrolled in a Part D plan would have reduced out-of-pocket drug costs and increased utilization.^{23, 24, 25, 26} One study, looking only at beneficiaries diagnosed with diabetes, found that a large portion of patients would be affected by the coverage gap under the standard Part D benefit design and would see significant out-of-pocket spending.²⁷

This study focuses on beneficiaries with type 2 diabetes and calculates the effect of enrollment in PDPs and MA-PD plans on drug utilization and out-of-pocket costs. We begin by describing access to drugs under the benefit. We then estimate the impact of Part D on beneficiaries' drug utilization and out-of-pocket costs for drug therapy. Finally, we examine the cost experience of beneficiaries not dually eligible for Medicare and Medicaid relative to the thresholds specified in law for the coverage gap in the standard Part D benefit and the catastrophic level.

The Analytic Approach

Using Avalere Health's proprietary DataFrame[®] database, we calculate average coverage on Part D plan formularies in 2007 for drugs used to treat diabetes and those used to treat diabetes and its most common co-occurring disorders: hypertension and dyslipidemia ("diabetes-related drugs"). We further examine the utilization management tools Part D plans apply to drugs, as well as cost-sharing—both tier placement and cost-sharing amounts—to produce a clear picture of enrollee access under Part D. A description of DataFrame and the methodology used to create the drug list is in Appendix A; the full drug list is in Appendix B.

We use Wolters Kluwer's Source Lx, a nationally representative claims data repository, to calculate the impact of Medicare Part D on patients' out-of-pocket drug costs and utilization. The dataset includes integrated medical and clinical records for patients with type 2 diabetes age 65 or older from July 1, 2004, to September 30, 2007.

The dataset is subdivided to compare drug utilization patterns and out-of-pocket costs for beneficiaries with type 2 diabetes who enrolled in a PDP or MA-PD plan to those who did not enroll in the Medicare drug benefit. An analytic model is applied to calculate the relative impact of Part D enrollment on these beneficiaries. This dataset includes 162,259 PDP enrollees, 11,563 MA-PD plan enrollees, and 153,265 non-enrollees. The average age of PDP enrollees is 74; MA-PD plan enrollees average 76 years of age; non-enrollees average 73. Males comprise 40 percent of PDP enrollees, 44 percent of MA-PD plan enrollees, and 50 percent of non-enrollees.

We also use longitudinal data to compare Part D enrollees' drug utilization and out-of-pocket costs to their own experience before enrolling. A second analytic model is applied to assess the degree to which Part D enrollment affected the experience of these beneficiaries. Within this dataset, there are 408,001 PDP enrollees and 34,103 MA-PD plan enrollees. The average age of the PDP and MA-PD plan enrollees is 74 before and after enrollment. Thirty-eight percent of the PDP enrollees are male, compared to 43 percent of MA-PD plan enrollees.

A detailed description of the datasets and econometric regression models is in Appendix A.

Study Results

Access to Medications

Though coverage varies plan-by-plan, in general, diabetes, hypertension, and dyslipidemia drugs are covered comprehensively under Part D. Plan formularies include an average of 85 to 88 percent of the drugs used to treat type 2 diabetes, hypertension, and dyslipidemia. This level of coverage is similar to that for other classes of drugs used to treat chronic conditions, including the six so-called "protected" classes where Part D plans are required by the Medicare agency to cover "all or substantially all" drugs. For example, Part D formularies include an average of 75 percent of antipsychotics and 88 percent of antidepressants.²⁸

More than 80 percent of diabetes-related drugs are placed on cost-sharing tiers 1 and 2 (see Table 1). PDPs and MA-PD plans commonly assign copayments of \$0 to \$10 to tier 1 drugs, \$20 to \$30 to tier 2 drugs, and \$50 to \$60 to tier 3 drugs, though spreads between tiers may vary and many plans apply percentage coinsurance on tier 3 rather than fixed-dollar copayments. Most hypertension and dyslipidemia drugs are found on tier 1, driven by the large number of generic drugs available in these classes. A majority of diabetes drugs are found on tier 2. If there is a significant difference in copayments between tier 1 and tier 2, the placement of diabetes drugs on tier 2 may pose a financial disincentive for their use.²⁹

Part D plans generally apply prior authorization (PA) and step therapy (ST) requirements to only a small proportion of covered drugs used to treat type 2 diabetes, hypertension, and dyslipidemia—close to the 2007 national average of 9 percent for PA and 1 percent for ST.¹ Quantity limits (QL) are the most common form of utilization management in these classes, with rates exceeding the national average of 8 percent.³⁰ Their use varies among the three classes of drugs; QLs are applied to 9 percent of hypertension drugs, 12 percent of diabetes drugs, and 27 percent of dyslipidemia drugs. However, for these classes of drugs, the QLs imposed are typically in line with common dosing recommendations.

i Prior authorization: the physician must obtain approval from the plan before prescribing. Step therapy: drugs may be prescribed only after other drugs are found to be ineffective. Quantity limits: the plan caps a drug's supply for a given period of time.

TABLE 1: Part D Access to Drugs Used to Treat Diabetes and Two Most Common Comorbidities

Condition	Plan Coverage	Tier Placement				Utilization Management		
		Tier 1	Tier 2	Tier 3	Tier 4+	PA	ST	QL
Type 2 Diabetes	86%	33%	58%	8%	1%	4%	3%	12%
Hypertension	85%	68%	14%	17%	2%	1%	4%	9%
Dyslipidemia	88%	62%	25%	12%	1%	< 1%	1%	27%

Access to medications and patient utilization are influenced by other factors, beyond formulary coverage and tier placement, that are not in the scope of this paper. Major market events, including the release of a new drug or a decision by the Food and Drug Administration (FDA) to initiate a product withdrawal will affect access to and utilization of drugs in certain classes. The publication of medical research on the relative merits and safety of medications, or labeling changes by the FDA, will also affect patient access by influencing physician prescribing patterns. For example, the recent ACCORD (Action to Control Cardiovascular Risk in Diabetes) study found that attempts to reduce the blood sugar of diabetes patients to below current recommendations may be dangerous.³¹ An area for future research is examining the effect of these market events on patient access and utilization patterns.

Enrollee Out-of-Pocket Drug Costs

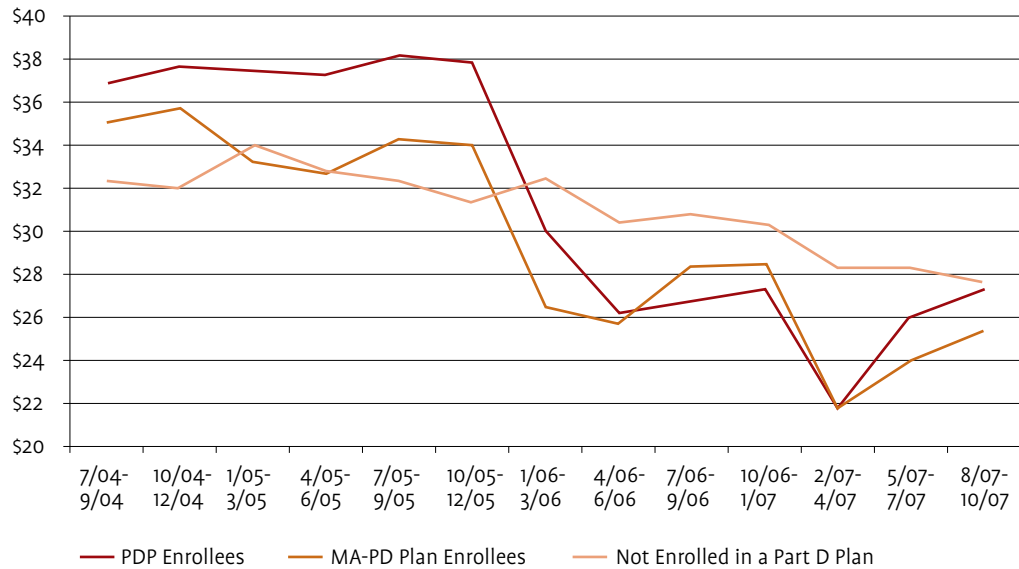
We estimated the impact of Part D enrollment on out-of-pocket drug costs. We found that Medicare beneficiaries enrolled in Part D plans face lower out-of-pocket costs *per prescription* for diabetes drugs than for those who do not enroll in Part D plans: 35 percent lower for PDP enrollees and 25 percent lower for MA-PD plan enrollees.ⁱⁱ Our results further indicate that Part D increases *total* out-of-pocket drug spending for diabetes drugs by 28 percent for PDP enrollees and 9 percent for MA-PD plan enrollees as compared to those not enrolled. Taken together—lower out-of-pocket costs per prescription and higher out-of-pocket costs in total—the finding implies that utilization of diabetes drugs rises after Part D enrollment. Higher utilization may be a sign of improved patient adherence to prescribed medication regimens. This finding suggests that seniors with type 2 diabetes have had better access to medications since the advent of Part D.

When compared to their experience before Part D enrollment, per prescription out-of-pocket costs of diabetes drugs are 36 percent lower for PDP enrollees and 20 percent lower for MA-PD plan enrollees. This finding seems to support the intent of the Part D benefit and points to the effectiveness of the government subsidies. (For more information on our econometric regression models, see Appendix C.)

We also found significant reductions in per prescription out-of-pocket costs paid by Part D enrollees when we included drugs for hypertension and dyslipidemia in our analysis (see Figure 1). Those who chose to enroll in PDPs and MA-PD plans had generally higher out-of-pocket costs before the benefit than those who did not enroll. However, after January 1, 2006, enrollees' out-of-pocket costs drop markedly and, throughout the study horizon, remain below those of non-enrollees.

ii Part D plan enrollees may pay premiums to enroll in their plans. These premium amounts are not factored into the calculations of out-of-pocket costs; only consumption-related cost sharing is counted.

FIGURE 1: Average per Prescription Out-of-Pocket Costs for Diabetes, Hypertension, and Dyslipidemia Drugs (Monthly Out-of-Pocket Costs, Averaged Quarterly)



Prescription Drug Utilization

While Part D decreases average per prescription costs for diabetes-related drugs (diabetes, hypertension, and dyslipidemia) for enrollees with type 2 diabetes, it also appears to lead to increased utilization (see Table 2). Prior to enrolling in Part D, PDP and MA-PD plan enrollees with type 2 diabetes purchased, on average, 3.08 and 3.01 diabetes-related drugs per month, respectively. After Part D, these numbers rose to 3.42 and 3.20—an 11.2 percent increase for PDP enrollees and 6.2 percent for MA-PD plan enrollees. Older adults who did not enroll in Part D also purchased more drugs, but by far less than PDP and MA-PD plan enrollees.

TABLE 2: Average Number of Diabetes, Hypertension, and Dyslipidemia Drugs Purchased each Month per Medicare Beneficiary with Type 2 Diabetes

	Before Part D	After Part D	Percent Change
PDP Enrollees	3.08	3.42	11.2%
MA-PD Plan Enrollees	3.01	3.20	6.2%
Not Enrolled in Part D	2.88	2.96	2.8%

The Coverage Gap

In this part of the study, we examine the drug spending of enrollees relative to the thresholds specified in law for the coverage gap and catastrophic level in the Part D benefit.ⁱⁱⁱ By “drug spending,” we mean combined outlays made by the Part D plan and the beneficiary. The parameters of this study do not enable a full analysis of the effects of the coverage gap. More research is needed to identify the characteristics of those affected by the gap and changes in utilization patterns, compliance, and outcomes that may result.

ⁱⁱⁱ Excludes beneficiaries dually eligible for Medicare and Medicaid

In the first year of Part D’s implementation, 43 percent of PDP enrollees having type 2 diabetes and 33 percent of MA-PD plan enrollees having type 2 diabetes incurred total drug costs (beneficiary out-of-pocket plus plan benefit payments) exceeding the coverage gap threshold, and less than 1 percent had total drug costs that surpassed the catastrophic coverage threshold. Sicker beneficiaries—those whose type 2 diabetes is accompanied by hypertension and dyslipidemia—are more likely to reach the gap threshold than those whose diabetes is not accompanied by those common co-occurring conditions.

Table 3 shows the breakdown of enrollees reaching the gap threshold and catastrophic threshold by diabetes-related diagnosis. Note, however, that because some Part D plans offer at least partial coverage in the gap, our analysis should not be construed as quantifying the number of enrollees who face added cost burden in the coverage gap.

TABLE 3: Percent of Part D Enrollees with Type 2 Diabetes Whose Total Drug Costs Pass the Coverage Gap Threshold and Whose Out-of-Pocket Costs Pass the Catastrophic Coverage Threshold in 2006 (Excluding Medicaid Dual Eligibles)

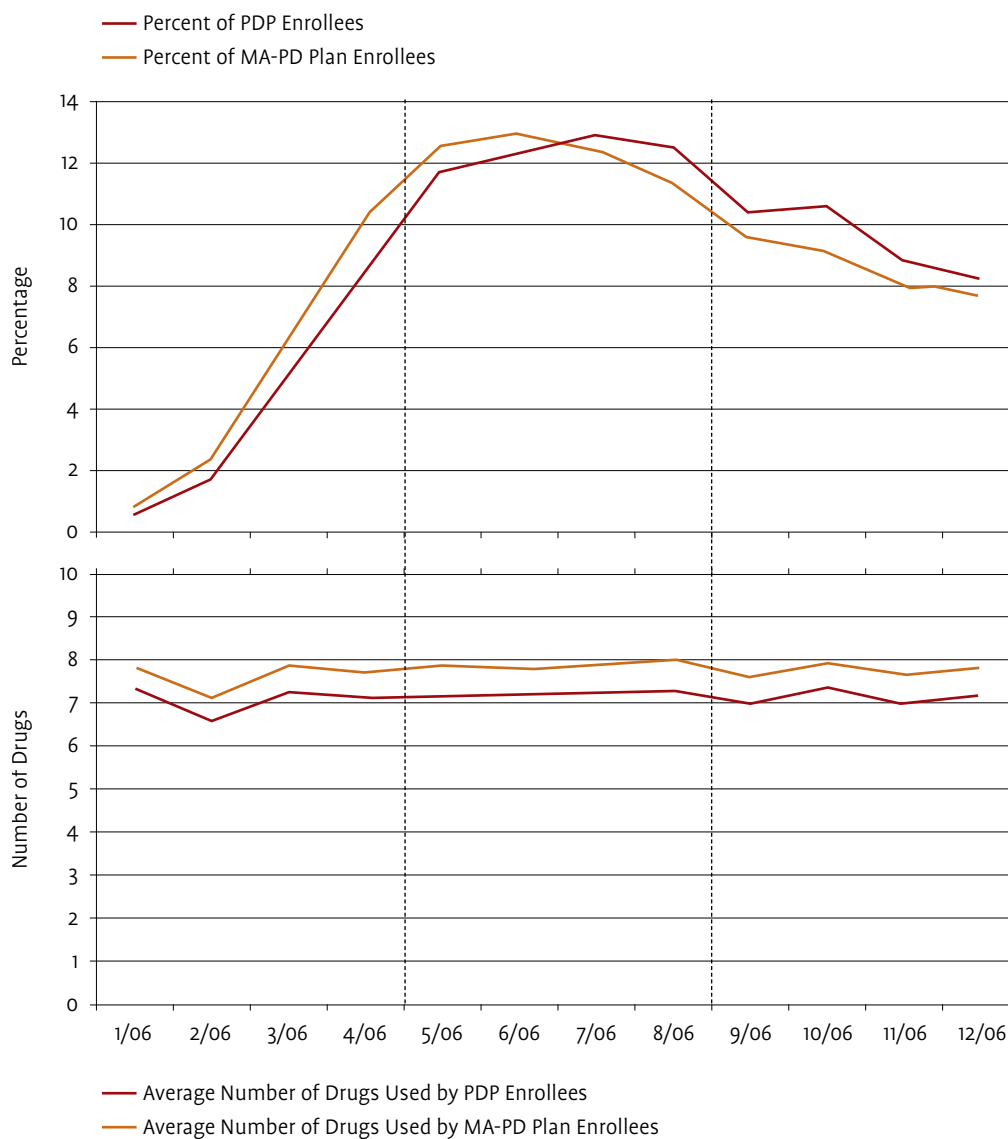
Enrollees	Coverage Gap		Catastrophic Coverage	
	PDP Enrollees	MA-PD Plan Enrollees	PDP Enrollees	MA-PD Plan Enrollees
Type 2 Diabetes Only	7.9%	5.9%	0.2%	0.1%
Type 2 Diabetes with Either Hypertension or Dyslipidemia	12.9%	9.3%	0.3%	0.2%
Type 2 Diabetes with Both Hypertension and Dyslipidemia	22.5%	18.4%	0.5%	0.3%
Total Enrollees ^{iv}	43.3%	33.6%	0.9%	0.5%

With more than one-third of Part D enrollees having type 2 diabetes reaching the coverage gap threshold in 2006, it is surprising that drug utilization does not appear to be greatly affected (see Figure 2). Of Part D enrollees with type 2 diabetes whose spending reaches the gap threshold, nearly half did so between May and August, though average utilization of diabetes-related drugs remained relatively constant throughout the year.

There are two possible explanations: either enrollees with type 2 diabetes were predominantly enrolled in plans that offered coverage in the gap; or, these beneficiaries found ways to pay for their medications while in the gap in order to maintain their drug treatment, such as by using lower-cost drugs or by drawing on personal financial resources, or both. Nevertheless, more research is needed to verify this result and to better understand its drivers, as well as to assess the effect of the coverage gap on enrollee behavior and health outcomes.

^{iv} Within our dataset, 70,243 PDP enrollees and 3,886 MA-PD plan enrollees cross the coverage gap threshold; 1,459 PDP enrollees and 57 MA-PD plan enrollees crossed the catastrophic threshold.

FIGURE 2: Percent of Part D Enrollees with Type 2 Diabetes Whose Total Drug Costs Pass the Coverage Gap Threshold in 2006 and Average Utilization of All Drugs (Excluding Medicaid Dual Eligibles)



Discussion

We determine that Part D plans cover most drugs recommended in guidelines to treat type 2 diabetes and its common co-occurring conditions: hypertension and dyslipidemia. Application of prior authorization and step therapy requirements is close to Part D national averages for all drug classes. Nevertheless, Part D plans' formularies and cost-sharing requirements may vary significantly and may change year to year. Therefore, each Medicare beneficiary having type 2 diabetes and enrolled in a Part D plan should reassess his or her coverage every year.

Our analysis shows that Part D enrollees with type 2 diabetes use more diabetes, hypertension, and lipid-lowering drugs than they did before Part D. The Part D benefit also decreases out-of-pocket costs per prescription. When comparing the experience of enrollees versus non-

enrollees, we find that enrollees use more drugs and pay less for each one than those without this coverage. Together these findings are consistent with other studies on the effects of Part D on different subgroups of Medicare beneficiaries.³² The results suggest that Part D to date has achieved its goal of increasing access to and affordability of drugs for Medicare beneficiaries.

Over the course of this study, we identify a number of areas that warrant further investigation. We observe that, in 2006, more than one-third of enrollees with type 2 diabetes had total drug costs that exceeded the coverage gap threshold of \$2,250; however, we do not observe a concomitant decrease in utilization. This result is puzzling and, given high stakeholder interest in the coverage gap policy, merits further research to verify these results and to better understand the effects of the coverage gap on enrollee behavior.

Though drug coverage for Medicare beneficiaries has grown under Part D, health complications and costs associated with diabetes continue to generate interest in improving the quality of diabetes care. Studies have shown that patients with diabetes do not receive recommended care that could improve health outcomes.^{33,34} While our study did not focus on well-established short-term and long-term measures of health outcomes for those with type 2 diabetes, this is an important area for further investigation. Diabetes quality measures for providers assess processes of care, including monitoring A1C and lipid levels, screening for eye and foot problems, and achieving glycemic control. However, the feasibility of analyzing the effect of Part D on these measures is hindered by the lack of availability of integrated data from Medicare Parts A, B, and D.

Finally, our research does not consider the effects of major market changes on beneficiary access and utilization patterns in Part D, such as FDA-mandated label changes in 2007 for Thiazolidinediones. Given the prevalence of type 2 diabetes in the Medicare population and the market-driven design of the benefit, further inquiry is warranted to understand how these changes affect Part D enrollees with type 2 diabetes.

Conclusion

The creation of Medicare Part D has improved drug coverage and lessened the financial burden for many beneficiaries with type 2 diabetes. Yet, health policy decision-makers should consider ways to further improve access. The extent to which broad access and increased utilization actually improve patient outcomes can best be determined through analysis of a publicly available national integrated medical and pharmacy claims dataset. Policymakers should move rapidly to make such a dataset available. Doing so will help purchasers, providers, researchers, and federal agencies better understand key aspects of the benefit to support better outcomes for Medicare beneficiaries with type 2 diabetes.

TECHNICAL APPENDICES

Appendix A: Data and Methodology

Access

The data used to measure access to medications for diabetes and its two most common comorbidities, hypertension, and dyslipidemia, was obtained from DataFrame®, Avalere Health's proprietary database. This database is derived, in part, from Centers for Medicare & Medicaid Services (CMS) files on Part D plan features and includes information for the nearly 4,000 Medicare prescription drug plans' formularies, cost-sharing requirements, and benefit structures. The analysis includes only plans that operated in the United States in 2007 and excludes plans operating in a U.S. territory (e.g., Puerto Rico, American Samoa, U.S. Virgin Islands).

To define the list of medications included in the analysis, we use guidelines published by the American Diabetes Association (ADA), the National Institutes of Health (NIH), the U.S. Department of Health and Human Services (HHS), and the National Heart, Lung, and Blood Institute,^{35, 36, 37} classifying them according to the American Hospital Formulary Service (AHFS) Pharmacological-Therapeutic Classification®. An independent pharmacist verified the complete list for accuracy.³⁸

We classify drugs at the name, strength, and form level.^v When a drug appears on multiple tiers within one plan, we assign the drug to the lowest tier. Similarly, if any form of the drug was not subject to utilization management (prior authorization, step therapy, or quantity limits) within a plan, we assign the least restrictive designation to the drug.

Out-of-Pocket Drug Costs, Drug Utilization, and the Coverage Gap

The datasets for the empirical models were obtained from the Wolters Kluwer's Source Lx data repository, which integrates healthcare claims data from physician practices, pharmacies, and hospitals for more than half of the U.S. population. The resource includes approximately 161 million longitudinal prescription patients and 159 million longitudinal patients with diagnosis and procedures, with 72 million patients linked to both diagnoses and prescriptions, more than 800,000 prescribers, and an overall sample representing 40,000 pharmacies, 1,000 hospitals, 800 clinics/outpatient facilities, and 80,000 physician practices. The Source Lx sample represents 31 percent of paid prescriptions, 20 percent of hospital claims, and 40 percent of physician services. All 50 U.S. states are represented in this sample. The dataset does not include information on medical service cost or Part B drug utilization.

The data used for this study includes medical and clinical records for all patients with type 2 diabetes age 65 or older from July 1, 2004, to September 30, 2007. The dataset also includes detailed information about patients' demographics, insurance status, site of service for medical treatments, physician information, and type of payment for each medical service. Medicaid dual-eligible beneficiaries are identified from the type of payment for medical services. The data identifies patients enrolled in a PDP or MA-PD plan.

Three samples were established for modeling purposes. The first sample includes 10,259,161 medical observations for 408,001 patients enrolled in a PDP. The second sample includes 778,422 medical observations for 34,103 patients enrolled in a MA-PD plan. The third sample includes patients whose medical records appear for the first time after Part D became effective. This third sample

^v If a drug is listed on a plan's formulary in any strength or form, we determined that a patient has access to this product and it is therefore considered a "covered" drug on that plan.

eliminates any bias in insurance status that may exist prior to the Part D benefit's implementation. The beneficiaries in this file could be enrolled in a PDP or an MA-PD plan or neither. Enrollees are excluded if they switched between a PDP and MA-PD plan or were enrolled in a Medicare Advantage plan before Part D implementation and remained in the MA-PD plan.

The first two samples enable us to compare out-of-pocket drug costs before and after Part D implementation for the same set of beneficiaries. We analyze PDP enrollees and MA-PD plan enrollees separately. The third sample allows us to compare out-of-pocket drug costs for those enrolled in PDPs or MA-PD plans to patients with the same diagnosis but who have not enrolled.

The impact of Medicare Part D on patients' out-of-pocket drug costs was estimated using multiple linear regression specifications. The following model was applied:

$$\text{SPENDING}_{ijt} = \alpha + \beta X_{it} + \gamma \text{PARTD}_{it} + \sum_c \lambda_c \text{COND}_{ict} + \sum_p \sigma_p \text{PHYSICIAN}_{ipt} + \epsilon_{ijt}$$

where SPENDING_{ijt} is out-of-pocket drug spending j incurred by patient i at time t . The variable PARTD_{it} stands for either PDP or MA-PD plan enrollment depending on the sample specification. For example, if the dataset captures only the PDP population, then PARTD_{it} will serve as a proxy for the enrollment of patient i to a PDP plan in time t . It takes the value of one if individual i has enrolled in a PDP at time t and zero otherwise. COND includes a set of dummy variables for patient i for each of her diagnosis codes c . Following Manning et al.'s work, medical spending data is normalized by log-transformation.³⁹ The coefficient of interest in this equation is γ , which represents the average effect of Part D on out-of-pocket drug spending. The endogeneity of treatment was controlled by adjusting for patients' preferred physicians.

Appendix B: Drug List for Diabetes, Hypertension, and Dyslipidemia by Active Ingredient

Diabetes

AHFS Class	Active Ingredient
Alpha-Glucosidase Inhibitors	Acarbose
Alpha-Glucosidase Inhibitors	Miglitol
Amylinomimetics	Pramlintide Acetate
Biguanides	Metformin HCl
Incretin Mimetics	Exenatide
Insulins	Insulin Aspart
Insulins	Insulin Glargine
Insulins	Insulin Glulisine
Insulins	Insulin Lispro
Insulins	Insulin Detemir
Insulins	Insulin Regular
Insulins	Insulin Isophane
Insulins	Insulin Aspart Prot & Aspart
Insulins	Insulin Lispro Prot & Lispro
Insulins	Insulin Isophane & Regular
Insulins	Insulin Zinc
Insulins	Insulin Regular (Human)
Meglitinides	Nateglinide
Meglitinides	Repaglinide
Sulfonylureas	Chlorpropamide
Sulfonylureas	Glimepiride
Sulfonylureas	Glipizide
Sulfonylureas	Glyburide
Sulfonylureas	Glyburide Micronized
Sulfonylureas	Tolazamide
Sulfonylureas	Tolbutamide
Sulfonylureas	Glipizide-Metformin HCl
Sulfonylureas	Glyburide-Metformin
Thiazolidinediones	Pioglitazone HCl
Thiazolidinediones	Rosiglitazone Maleate
Thiazolidinediones	Rosiglitazone Maleate-Glimepiride
Thiazolidinediones	Pioglitazone-Metformin HCl
Thiazolidinediones	Rosiglitazone Maleate-Metformin HCl

Hypertension

AHFS Class	Active Ingredient
Alpha-adrenergic Blocking Agents	Doxazosin Mesylate
Alpha-adrenergic Blocking Agents	Prazosin HCl
Alpha-adrenergic Blocking Agents	Terazosin HCl
Alpha-adrenergic Blocking Agents	Prazosin & Polythiazide
Alpha-adrenergic Blocking Agents	Doxazosin Mesylate SR
Angiotensin II Receptor Antagonists	Candesartan Cilexetil
Angiotensin II Receptor Antagonists	Eprosartan Mesylate
Angiotensin II Receptor Antagonists	Irbesartan
Angiotensin II Receptor Antagonists	Losartan Potassium
Angiotensin II Receptor Antagonists	Olmesartan Medoxomil
Angiotensin II Receptor Antagonists	Telmisartan
Angiotensin II Receptor Antagonists	Valsartan
Angiotensin II Receptor Antagonists	Candesartan Cilexetil-Hydrochlorothiazide
Angiotensin II Receptor Antagonists	Eprosartan Mesylate-Hydrochlorothiazide
Angiotensin II Receptor Antagonists	Irbesartan-Hydrochlorothiazide
Angiotensin II Receptor Antagonists	Losartan Potassium & Hydrochlorothiazide
Angiotensin II Receptor Antagonists	Olmesartan Medoxomil
Angiotensin II Receptor Antagonists	Telmisartan
Angiotensin II Receptor Antagonists	Valsartan
Angiotensin II Receptor Antagonists	Candesartan Cilexetil-Hydrochlorothiazide
Angiotensin II Receptor Antagonists	Eprosartan Mesylate-Hydrochlorothiazide
Angiotensin II Receptor Antagonists	Irbesartan-Hydrochlorothiazide
Angiotensin II Receptor Antagonists	Losartan Potassium & Hydrochlorothiazide
Angiotensin II Receptor Antagonists	Olmesartan Medoxomil-Hydrochlorothiazide
Angiotensin II Receptor Antagonists	Telmisartan-Hydrochlorothiazide
Angiotensin II Receptor Antagonists	Valsartan-Hydrochlorothiazide
Angiotensin-Converting Enzyme Inhibitors	Benazepril HCl
Angiotensin-Converting Enzyme Inhibitors	Captopril
Angiotensin-Converting Enzyme Inhibitors	Enalapril Maleate
Angiotensin-Converting Enzyme Inhibitors	Fosinopril Sodium
Angiotensin-Converting Enzyme Inhibitors	Lisinopril
Angiotensin-Converting Enzyme Inhibitors	Moexipril
Angiotensin-Converting Enzyme Inhibitors	Perindopril Erbumine
Angiotensin-Converting Enzyme Inhibitors	Quinapril HCl
Angiotensin-Converting Enzyme Inhibitors	Ramipril
Angiotensin-Converting Enzyme Inhibitors	Trandolapril
Angiotensin-Converting Enzyme Inhibitors	Benazepril & Hydrochlorothiazide
Angiotensin-Converting Enzyme Inhibitors	Captopril & Hydrochlorothiazide
Angiotensin-Converting Enzyme Inhibitors	Enalapril Maleate & Hydrochlorothiazide
Angiotensin-Converting Enzyme Inhibitors	Fosinopril Sodium & Hydrochlorothiazide
Angiotensin-Converting Enzyme Inhibitors	Lisinopril & Hydrochlorothiazide
Angiotensin-Converting Enzyme Inhibitors	Moexipril-Hydrochlorothiazide
Angiotensin-Converting Enzyme Inhibitors	Quinapril-Hydrochlorothiazide
Beta-Adrenergic Blocking Agents	Carteolol HCl
Beta-Adrenergic Blocking Agents	Nadolol
Beta-Adrenergic Blocking Agents	Penbutolol Sulfate

Hypertension (continued)

AHFS Class	Active Ingredient
Beta-Adrenergic Blocking Agents	Pindolol
Beta-Adrenergic Blocking Agents	Propranolol HCl
Beta-Adrenergic Blocking Agents	Propranolol HCl SR Beads Cap
Beta-Adrenergic Blocking Agents	Sotalol HCl
Beta-Adrenergic Blocking Agents	Sotalol HCl (AFIB/AFL)
Beta-Adrenergic Blocking Agents	Timolol Maleate
Beta-Adrenergic Blocking Agents	Acebutolol HCl
Beta-Adrenergic Blocking Agents	Atenolol
Beta-Adrenergic Blocking Agents	Betaxolol HCl
Beta-Adrenergic Blocking Agents	Bisoprolol Fumarate
Beta-Adrenergic Blocking Agents	Esmolol HCl
Beta-Adrenergic Blocking Agents	Metoprolol Succinate
Beta-Adrenergic Blocking Agents	Metoprolol Tartrate
Beta-Adrenergic Blocking Agents	Carvedilol
Beta-Adrenergic Blocking Agents	Labetalol HCl
Beta-Adrenergic Blocking Agents	Atenolol & Chlorthalidone
Beta-Adrenergic Blocking Agents	Bisoprolol & Hydrochlorothiazide
Beta-Adrenergic Blocking Agents	Metoprolol & Hydrochlorothiazide
Beta-Adrenergic Blocking Agents	Nadolol & Bendroflumethiazide
Beta-Adrenergic Blocking Agents	Propranolol & Hydrochlorothiazide
Beta-Adrenergic Blocking Agents	Timolol & Hydrochlorothiazide
Beta-Adrenergic Blocking Agents	Esmolol HCl-Sodium Chloride
Calcium-Channel Blocking Agents,Miscellaneous	Diltiazem HCl
Calcium-Channel Blocking Agents,Miscellaneous	Diltiazem HCl SR Beads Cap
Calcium-Channel Blocking Agents,Miscellaneous	Diltiazem HCl SR Coated Beads Cap
Calcium-Channel Blocking Agents,Miscellaneous	Verapamil HCl
Calcium-Channel Blocking Agents,Miscellaneous	Trandolapril-Verapamil HCl
Central Alpha-Agonist	Clonidine HCl
Central Alpha-Agonist	Guanabenz Acetate
Central Alpha-Agonist	Guanfacine HCl
Central Alpha-Agonist	Methyldopa
Central Alpha-Agonist	Methyldopate HCl
Central Alpha-Agonist	Clonidine & Chlorthalidone
Central Alpha-Agonist	Methyldopa & Chlorothiazide
Central Alpha-Agonist	Methyldopa & Hydrochlorothiazide
Dihydropyridines	Amlodipine Besylate
Dihydropyridines	Felodipine SR
Dihydropyridines	Isradipine
Dihydropyridines	Nicardipine HCl
Dihydropyridines	Nifedipine
Dihydropyridines	Nimodipine
Dihydropyridines	Nisoldipine SR
Dihydropyridines	Amlodipine Besylate-Benazepril
Dihydropyridines	Enalapril Maleate-Felodipine
Dihydropyridines	Amlodipine Besylate-Atorvastatin Calcium
Direct Vasodilators	Diazoxide
Direct Vasodilators	Hydralazine HCl
Direct Vasodilators	Minoxidil
Direct Vasodilators	Hydralazine & Hydrochlorothiazide

Hypertension (continued)

AHFS Class	Active Ingredient
Loop Diuretics	Bumetanide
Loop Diuretics	Ethacrynic Acid
Loop Diuretics	Ethacrynate Sodium
Loop Diuretics	Furosemide
Loop Diuretics	Torsemide
Mineralocorticoid (Aldosterone) Receptor Antagonists	Eplerenone
Mineralocorticoid (Aldosterone) Receptor Antagonists	Spirolactone
Mineralocorticoid (Aldosterone) Receptor Antagonists	Spirolactone & Hydrochlorothiazide
Potassium-sparing Diuretics	Amiloride HCl
Potassium-sparing Diuretics	Triamterene
Potassium-sparing Diuretics	Amiloride & Hydrochlorothiazide
Potassium-sparing Diuretics	Triamterene & Hydrochlorothiazide
Thiazide Diuretics	Chlorothiazide
Thiazide Diuretics	Chlorothiazide Sodium
Thiazide Diuretics	Hydrochlorothiazide
Thiazide Diuretics	Methyclothiazide
Thiazide Diuretics	Bendroflumethiazide

Dyslipidemia

AHFS Class	Active Ingredient
Antilipidemic Agents Misc	Niacor
Bile Acid Sequestrants	Cholestyramine
Bile Acid Sequestrants	Cholestyramine Light
Bile Acid Sequestrants	Colesevelam
Bile Acid Sequestrants	Colestipol HCl
Fibric Acid Derivatives	Fenofibrate
Fibric Acid Derivatives	Fenofibrate Micronized
Fibric Acid Derivatives	Gemfibrozil
HMG-CoA Reductase Inhibitors	Atorvastatin Calcium
HMG-CoA Reductase Inhibitors	Fluvastatin Sodium
HMG-CoA Reductase Inhibitors	Lovastatin
HMG-CoA Reductase Inhibitors	Rosuvastatin Calcium
HMG-CoA Reductase Inhibitors	Pravastatin Sodium
HMG-CoA Reductase Inhibitors	Simvastatin
HMG-CoA Reductase Inhibitors	Niacin-Lovastatin SR
HMG-CoA Reductase Inhibitors	Ezetimibe-Simvastatin

Appendix C: Results

TABLE A-1: Drug Utilization and Out-of-Pocket Costs for Beneficiaries with Type 2 Diabetes Before and After Part D Enrollment

	PDP			MA-PD Plan		
	Before Part D	After Part D	% Change	Before Part D	After Part D	% Change
Number of Individuals	251,984	407,935	60.7%	22,540	33,082	46.8%
Percent of Individuals Age 65 to 69 ^{vi}	23.28	24.45	5.0%	22.42	23.46	4.6%
Percent of Individuals Age 70 to 74	24.56	24.66	0.4%	25.95	25.91	-0.2%
Percent of Individuals Age 75 to 79	22.31	21.86	-2.0%	22.80	22.79	0.0%
Percent of Individuals Age 80 and over	29.86	29.03	-2.8%	28.82	27.84	-3.4%
Percent of Male Individuals	37.62	38.55	2.5%	42.58	42.89	0.7%
Average Number of Diagnosis Codes per Individual ^{vii}	18.28	18.41	0.7%	16.86	17.22	2.1%
Monthly Average Number of Diabetes Drugs Purchased per Individual	1.56	1.62	3.8%	1.54	1.56	1.3%
Monthly Average Number of Hypertension Drugs Purchased per Individual	1.99	2.13	7.0%	1.96	2.04	4.1%
Monthly Average Number of Dyslipidemia Drugs Purchased per Individual	1.15	1.18	2.6%	1.14	1.16	1.8%
Percentage of Generic Diabetes Drugs	53.28	58.15	9.1%	58.28	62.39	8.8%
Monthly Average Out-of-Pocket Costs per Individual for Diabetes, Hyertension, and Dyslipidemia Drugs	\$ 37.51	\$ 26.45	-29.5%	\$ 34.16	\$ 25.71	-25.7%

vi To find percent of beneficiaries in each age bracket, we averaged 2004 and 2005 for pre-Part D and 2006 and 2007 for post-Part D.

vii Average number of diagnosis codes calculated using ICD-9 codes

TABLE A-2: Analysis of the Impact of Part D on Out-of-Pocket Drug Cost per Prescription Before and After Part D Enrollment

	Prescription Drug Plan (PDP) Cost per Prescription		Medicare Advantage Prescription Drug (MA-PD) Plan Cost per Prescription	
	Coefficient	Percent Change	Coefficient	Percent Change
Part D Enrollment	-0.445 ‡ (0.001)	-35.95%	-0.224 ‡ (0.003)	-20.08%
Generic	-0.934 ‡ (0.001)	-60.72%	-0.990 ‡ (0.003)	-62.85%
Male	0.271 ‡ (0.001)	31.16%	0.227 ‡ (0.003)	25.45%
Payment Types				
Medicaid	-1.001 ‡ (0.002)	-63.24%	-0.950 ‡ (0.011)	-61.31%
Commercial	0.221 ‡ (0.001)	24.73%	-0.110 ‡ (0.004)	-10.40%
Other	-0.115 ‡ (0.001)	-10.85%	-0.442 ‡ (0.004)	-35.72%
Other Control Variables				
Age	Yes		Yes	
State	Yes		Yes	
Physicians' Specialty	Yes		Yes	
Diagnosis Codes	Yes		Yes	
Medical Services	Yes		Yes	
Observations	10,259,161		778,422	
R-squared	0.247		0.254	

* Significant at 10%; † Significant at 5%; ‡ Significant at 1% and p<0.0001.

Absolute value of standard errors in parentheses.

Note: The estimated coefficients of constant term and dummy variables for Gender, Age, State, Physicians' Specialty, Patients' Diagnosis Codes, and Medical Services are suppressed.

TABLE A-3: Comparison of Prescription Drug Plan (PDP) and Medicare Advantage Prescription Drug (MA-PD) Plan Enrollees with Non-Enrollees

	PDP Enrollees	MA-PD Plan Enrollees	Neither PDP nor MA-PD Enrollees
Number of Individuals	162,259	11,563	153,265
Percent of Individuals Age 65 to 69 ^{viii}	26.21	24.65	31.08
Percent of Individuals Age 70 to 74	24.89	25.81	23.30
Percent of Individuals Age 75 to 79	21.24	22.68	20.04
Percent of Individuals Age 80 and over	27.66	26.86	25.58
Percent of Male Individuals	40.12	43.73	50.04
Average Number of Diagnosis Codes per Individual ^{ix}	18.59	17.86	18.31
Monthly Average Number of Diabetes Drugs Purchased per Individual	1.54	1.46	1.39
Monthly Average Number of Hypertension Drugs Purchased per Individual	2.10	1.98	1.87
Monthly Average Number of Dyslipidemia Drugs Purchased per Individual	1.18	1.16	1.12
Percentage of Generic Diabetes Prescriptions	59.84	64.98	59.04
Monthly Average Out-of-Pocket Costs per Individual for Diabetes, Hypertension, and Dyslipidemia Drugs	26.52	31.25	33.95

viii To find percent of beneficiaries in each age bracket, we averaged 2004 and 2005 for pre-Part D and 2006 and 2007 for post-Part D.

ix Average number of diagnosis codes calculated using ICD-9 codes

TABLE A-4: Analysis of the Impact of Part D on Out-of-Pocket Drug Costs for Enrollees and Non-Enrollees

	Cost per Prescription		Total Prescription Cost per Individual	
	Coefficient	Percent Change	Coefficient	Percent Change
PDP Plan	-0.428 ‡ (0.002)	-34.82%	0.250 ‡ (0.007)	28.40%
MA-PD Plan	-0.283 ‡ (0.005)	-24.65%	0.087 ‡ (0.019)	9.09%
Generic	-1.094 ‡ (0.001)	-66.51%		
Male	0.222 ‡ (0.002)	24.86%	0.179 ‡ (0.007)	19.60%
Payment Types				
Medicaid	-0.993 ‡ (0.005)	-62.95%	-1.457 ‡ (0.022)	-76.61%
Commercial	0.196 ‡ (0.002)	21.65%	0.299 ‡ (0.011)	34.85%
Other	-0.089 ‡ (0.002)	-8.52%	0.442 ‡ (0.011)	55.58%
Other Control Variables				
Age	Yes		Yes	
State	Yes		Yes	
Physicians' Specialty	Yes		Yes	
Diagnosis Codes	Yes		Yes	
Medical Services	Yes		Yes	
Observations	2,357,528		293,338	
R-squared	0.275		0.069	

* Significant at 10%; † Significant at 5%; ‡ Significant at 1% and $p < 0.0001$.


Absolute value of standard errors in parentheses.

Note: The estimated coefficients of constant term and dummy variables for Gender, Age, State, Physicians' Specialty and Patients' Diagnosis Codes, and Medical Services are suppressed.

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