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The effect of changes in drug benefit design among individuals with diabetes in large employer-sponsored insurance plans

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THE EFFECT OF CHANGES IN DRUG BENEFIT DESIGN AMONG INDIVIDUALS WITH DIABETES IN LARGE EMPLOYER-SPONSORED INSURANCE PLANS

by

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DISSERTATION

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Advisor **Date**

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DEDICATION

To the loving memory of my beloved mother, Neng Yiv Lee Yang, who sacrificed everything for my siblings and me.

To my father, Nao Bee Yang, who instilled in me the value of education.

To my lifelong partner, Thuan Cao, who never let me fall.

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TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

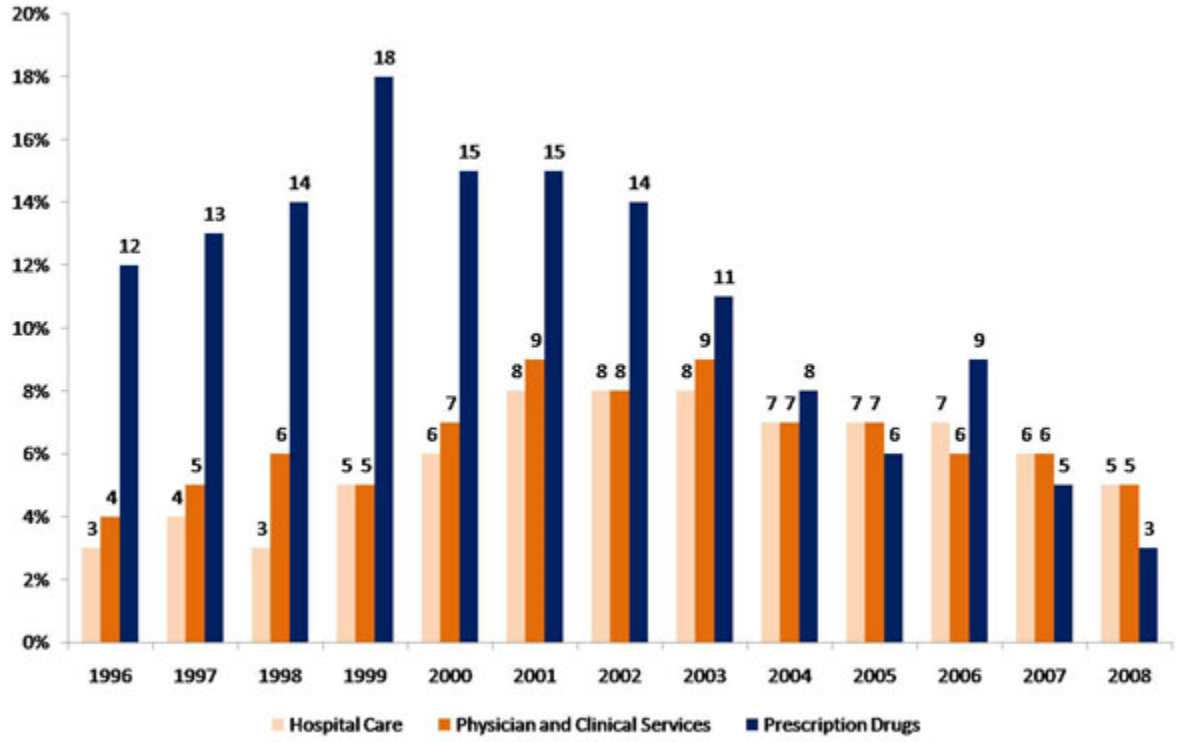
CHAPTER 1

THE EFFECT OF CHANGES IN HEALTH BENEFIT DESIGN AMONG INDIVIDUALS WITH DIABETES IN LARGE EMPLOYER-SPONSORED INSURANCE PLANS

1.1 Introduction

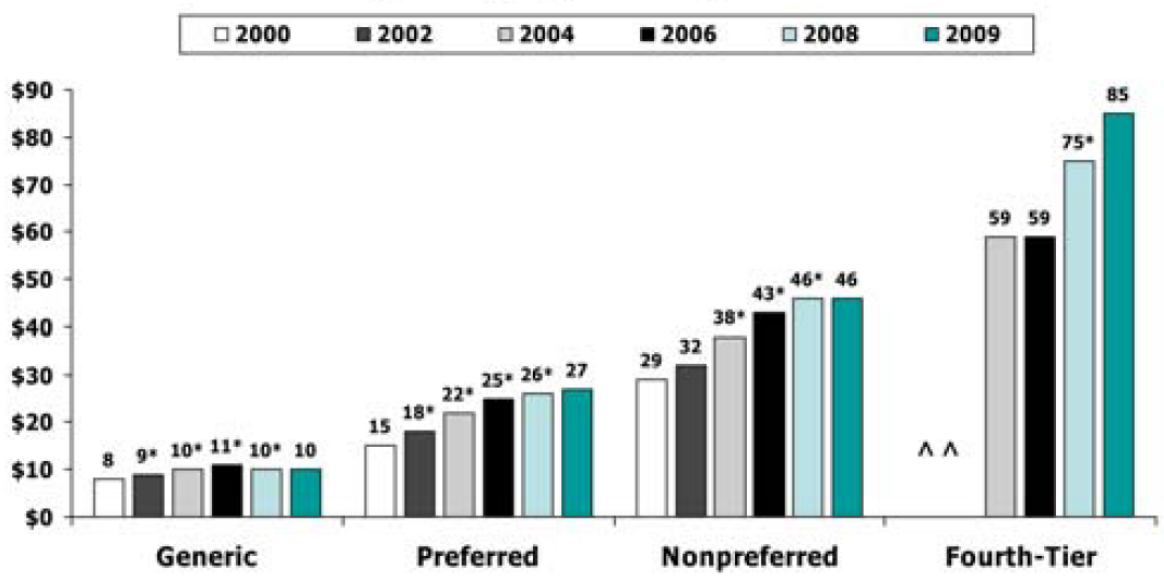
Prescription drugs expenditures, accounting for only 10% of total healthcare spending in 2008 (compared to 31% for hospitals and 21% for physician services), are one of the fastest growing components of U.S. health care budget (Kaiser Family Foundation 2010). Centers for Medicare & Medicaid Services (CMS) project that growth in prescription drug spending is expected to accelerate through 2019, reaching 7.7 percent due to increases in drug prices, which are expected to account for about half of this growth. The U.S. spends more than $246 billion on prescription drugs alone in 2009, six times the $40.3 billion spent in 1990, because of higher use of antiviral drugs, as well as faster price growth for brand-name prescription drugs (CMS, National Health Expenditure Projections 2009-2019; Kaiser Family Foundation 2010). According to statistics from the Kaiser Family Foundation, from 1998 to 2008, prescription drugs contributed 13% of the total growth in national health expenditures, compared to 30% for hospital care and 21% for physician and clinical services (Figure 1.1, Kaiser Family Foundation 2010). In addition, from 2000 to 2009 average copay for generic drugs and preferred drugs increased by 25% and 80%, respectively, for workers with employer-sponsored health plans (Figure 1.2, Kaiser Family Foundation 2010).

Figure 1.1: Average Annual Percentage Change in Selected National Health Expenditures, 1996-2008



Source: Kaiser Family Foundation calculations using National Health Expenditure historical data from Centers for Medicare & Medicaid Services, http://www.cms.hhs.gov/NationalHealthExpendData/ http://www.kaiseredu.org/Issue-Modules/Prescription-Drug-Costs/Background-Brief.aspx

Figure 1.2: Among Covered Workers with Three, Four, or More Tiers of Prescription Drug Cost Sharing, Average Copayments, 2000-2009



*Estimate is statistically different from estimate for the previous year shown at p<.05.

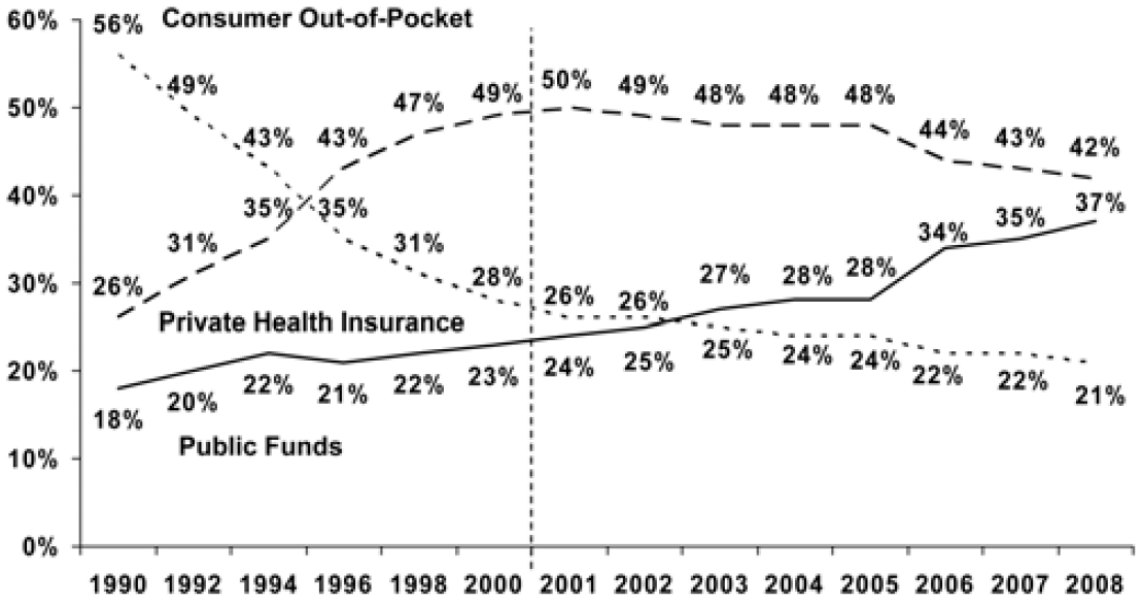
^Fourth-Tier drug copay information was not obtained prior to 2004; fourth-tier drugs have new types of cost-sharing arrangements that typically build additional layers of higher copayments or coninsurance for specifically identified types of drugs such as lifestyle drugs or biologics.

Source: Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2000-2009, Exhibit 9.4, http://ehbs.kff.org/?page=charts&id=2&sn=24&ch=1139.

With spending for prescription drugs rising so rapidly, employers and insurers are seeking different cost-cutting strategies to stem this tide. These include cost-shifting, cost-sharing or multi-tiered formularies, where consumer cost-sharing increases for products on higher tiers compared with lower tiers, use of value-based formularies, and working with local pharmacies. In 2009, over three-quarters (78%) of workers with employer-sponsored coverage were in plans with 3 or 4 tiers of cost sharing for prescription drugs, almost three times the proportion in 2000 (27%) (Kaiser Family Foundation 2010). The implementations of such cost-control mechanisms have helped slow the growth in outpatient prescription drug spending. Since

2000, the double-digit rates of increase in prescription drug spending have declined each year except for 2006, which was the year Medicare Part D was implemented. By 2008, the annual rate of increase in prescription drug spending was 3%, compared to 5% for hospital care and 5% for physician services (Figure 1.3, Kaiser Family Foundation 2010).

Figure 1.3: Distribution of Total National Prescription Drug Expenditures by Type of Payer, 1990-2008



Notes: Consumer Out-of-Pocket includes direct spending by consumers for health care goods and services not covered by a health plan and cost-sharing amounts (coinsurance, copayments, deductibles) required by public and private health plans. It does not include consumer premium payments and cost sharing paid by supplementary Medicare policies, which are included in the Private Health Insurance category. May not total 100% due to rounding.

Source: Kaiser Family Foundation calculations using National Health Expenditure historical data from Centers for Medicare & Medicaid Services, http://www.cms.hhs.gov/NationalHealthExpendData/.

Previous studies have shown that both insurance status and the level of insurance benefits affect the use of prescription drugs. The RAND Health Insurance Experiment was one of the first studies to suggest that consumers are price-sensitive for these and other health goods (Lohr, Brook et al. 1986). Subsequent studies have shown that the uninsured people have a smaller probability of essential medication[1] use than the insured. Moreover, among the insured, higher cost-sharing levels reduced less essential medication use more than more essential medication (necessary to maintain or improve health) use (Lohr, Brook et al. 1986; Goldman, Joyce et al. 2004). Contrary to much conventional wisdom, some of the most prevalent chronically ill populations—patients with hypertension, diabetes, or high cholesterol, to name a few—are fairly price-sensitive to medications for their conditions. However, the mechanisms by which patients reduce their utilization are not well understood.

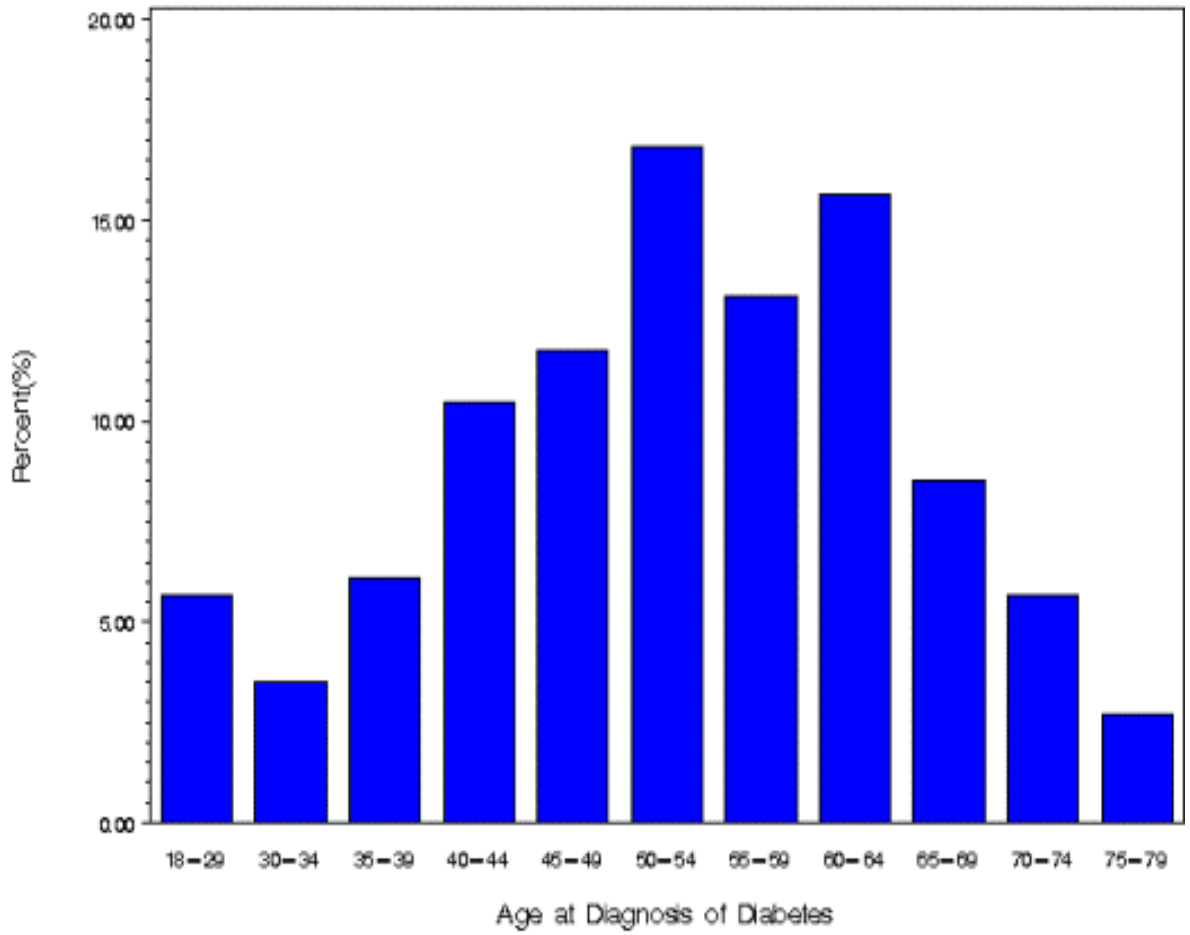
[1] Essential medication was defined as "necessary to maintain or improve health status" (Lohr, 1986; Goldman, 2004).

1.2 Research Objective

Prescription drugs have become an indispensable means to treat and manage chronic illnesses. Thus, the issues of affordability and trade-offs between medications and other health care services are important for chronically ill patients, particularly for patients with diabetes who typically have more than one comorbidity that require drug therapy, and their insurance plans. These issues call for a fuller understanding of the dynamic structure of demand for prescription drugs and other health care services (inpatient and outpatient) via an analysis of cost-shifting approach (e.g. higher copays or coinsurance amount). Many employers and insurers are increasingly using this approach to influence patient utilization of medications and drug spending, thus shifting medication costs from the insurers to the patients. Previous research has shown that switching from a flat to a two-tier copayment benefit plan reduced mean drug spending in an employer-sponsored population by 6-19 percent, but with no significant increases in out-of-pocket costs (Joyce, Escarce et al. 2002). Other studies that focused on three-tier drug plans show that increases in patients' out-of-pocket costs lower health plan drug spending (Motheral and Fairman 2001).

In this dissertation, I analyze the effect of prescription drug cost-shifting via changes in drug benefit design on healthcare expenditure among individuals with diabetes. I take into account the comorbid effect of diabetes for the age population ranging from 18 to 62, given that over three-fourth of individual with diabetes age 18 through 79 are diagnosed before age 64 and more than half are diagnosed between 40 and 59 (Figure 1.4, Centers for Disease Control and Prevention (CDC) 2008).

Figure 1.4 Distribution of Age at Diagnosis of Diabetes Among Adult Incident Cases Aged 18–79 Years, United States, 2008



Source: Centers for Disease Control and Prevention (CDC), National Center for Health Statistics, Division of Health Interview Statistics, data from the National Health Interview Survey.

1.3 Why Diabetes?

The health and economic effects of diabetes are enormous. Diabetes is one of the most common chronic conditions for which prescription medications exist. From 1997 to 2007, the proportion of people with diabetes who reported using oral anti-diabetic medications more than doubled, from 5.9 million to 14.6 million (AHRQ 2010). Given the aging of the population, changes in ethnic makeup, and the dramatic increase in obesity and sedentary lifestyles in the United States, the prevalence of diabetes is increasing at an alarming rate. According to the Centers for Disease Control and Prevention (2011), approximately 25.8 million Americans (all ages) have this chronic condition, including 18.8 million people diagnosed with diabetes while 7.0 million people who have diabetes but are unaware that they have the disease, or 8.3 percent of the U.S. population estimated to have this condition (CDC 2011).

In 2010, an estimated 10.9 million persons, or 26.9%, aged 65 years and older in the United States were reported to have diabetes. While approximately 215,000 people aged 20 or younger, or 0.26% of all people in this age group, were diagnosed with diabetes (type 1 or type 2) and about 1.9 million people aged 20 years or older were newly diagnosed with diabetes (CDC 2011). Given that about 35% of U.S. adults aged 20 years or older had prediabetes from 2005-2008, based on fasting glucose or hemoglobin A1c levels, in terms of 2010 U.S. population, this percentage yields an estimated 79 million American adults aged 20 years or older with prediabetes, a condition marked by elevated blood sugar that is not yet in the diabetic range (CDC).

According to data from the American Diabetes Association (ADA), in the United States diabetes is associated with high rates of hospitalization and a high incidence of heart disease, angina, myocardial infarction, end-stage-renal disease (renal failure), and non-traumatic (limbs

amputation), blindness among working-aged adults (American Diabetes Association, 2011). Furthermore, diabetes is the seventh leading cause of death in the United States based on U.S. death certificates in 2007 (CDC 2011). As expected, these disabling conditions contribute to a severe decrease in a person's quality of life. For instance, the risk for death among people with diabetes is about twice that of people of similar age but without diabetes and it is likely to be underreported as a cause of death. Studies show that only 35-40% of decedents with diabetes had it listed anywhere on the death certificate, and only 10-15% had it listed as the underlying cause of death (CDC 2011). It is projected that between 2009 and 2034, the number of people with diagnosed and undiagnosed diabetes will increase from 23.7 million to 44.1 million (Huang, Basu et al. 2009)

Not surprisingly, diabetes is becoming one of the major public health problems because a great proportion of the healthcare expenditure has been spent on the treatment of its associated morbidity and mortality. Case in point, people with diabetes are 21.8 times as likely to be admitted for skin ulcers/gangrene, 15 times as likely for peripheral vascular disease, 10 times as likely for congestive heart failure, and almost 10 times as likely for atherosclerosis; cerebrovascular accidents and heart disease are 6–10 times more common in diabetic patients (Gambert and Pinkstaff 2006). In addition, diabetes occurs in all populations and age groups but is increasing in prevalence in the elderly and in blacks, Hispanics, Native Americans, and Asians (ADA 2011; CDC 2011). Due to the combined burdens and complications of diabetes, individuals at age 60 that are diagnosed with diabetes have a reduction in life expectancy and quality-of-life years of 7.3 and 11.1 years, respectively, for men, and 9.5 and 13.8 years, respectively, for women (Gambert and Pinkstaff 2006). Last but not least, Diabetes' direct medical costs and the indirect costs of lost productivity and premature mortality are substantial

costs both to society and its citizens. According to the CDC (2011), diabetes costs a total of $174 billion, with $116 billion in direct medical costs and $58 billion in indirect costs (disability, work loss, premature mortality). Overall, the average medical expenses among people with diagnosed diabetes are more than 2 times higher than for people without diabetes (after adjusting for population age and sex differences).

1.4 Organization of Dissertation

This paper is organized as follows. In Section 2, I provide a brief overview of the chronic disease diabetes and a literature review on the effects of prescription drug cost-shifting on healthcare expenditure among individuals with diabetes. In Section 3, I discuss my data and measures. In Section 4, I discuss the economic framework. I will present the result with discussion in Section 5 and summary and major findings will be discussed in Section 6. Concluding remarks are offered in Section 7.

CHAPTER 2

BACKGROUND

2.1 Diabetes Mellitus

Diabetes mellitus is a metabolic disorder in which the body is unable to produce or use insulin, a hormone it needs to convert food into energy (ADA 2011; CDC 2011). There are three types of diabetics. Approximately 5 to 10 percent of all people with diabetes have "type 1" diabetes, a condition that typically begins in childhood or adolescence and requires lifelong insulin treatment. The vast majority of people with diabetes, that is, 90 to 95 percent, have "type 2" diabetes, a condition that typically develops in adults over 30 who have a family history of diabetes, are overweight, or are physically inactive. Type 2 diabetes can be controlled through a combination of proper diet, weight loss, and exercise, although oral medications or insulin are often necessary. A third type diabetes known as "gestational" develops during pregnancy and can have harmful effects on both the mother and child because of elevated glucose levels. It is estimated that up to 4 percent of all women develop gestational diabetes during pregnancy and return to normal following the pregnancy. However, these women have approximately 45 percent of increased risk of recurrence with the next pregnancy and approximately 63 percent increased risk of developing type 2 diabetes in later life (CDC 2011).

Since more people with diabetes die from complications of the disease rather than the disease itself, diabetes death rates alone understate the extent to which diabetes contributes to mortality. Similarly, people with diabetes are often hospitalized for the complications of diabetes rather than for the disease itself, so estimates understate the extent of total hospitalizations for diabetes.

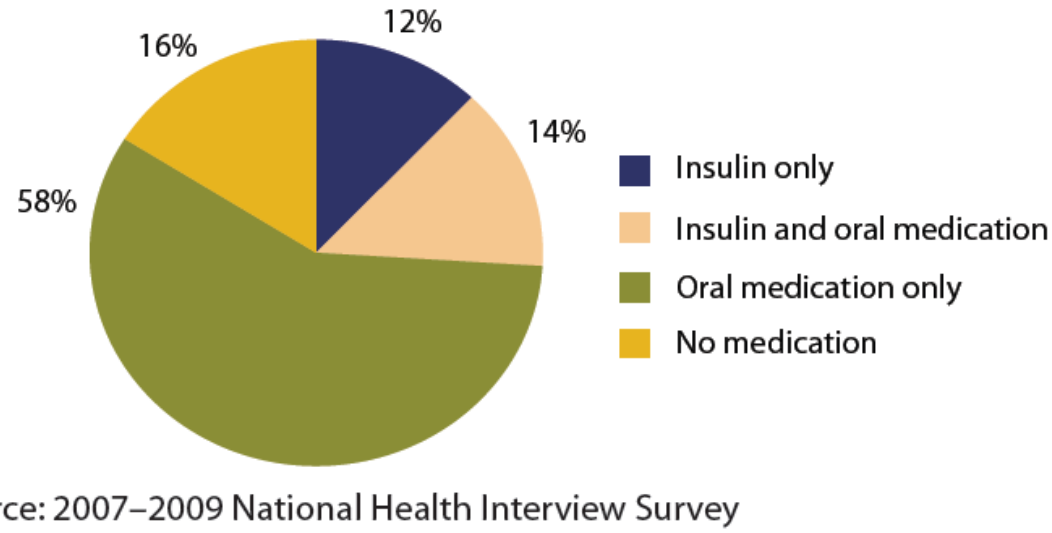
2.2 Medications for Diabetes

There are three basic types of diabetes medication:

- Oral diabetes medication
- Insulin
- Other injectable diabetes medicine (besides insulin)

People diagnosed with type 1 diabetes usually undergo insulin treatment because the body cannot produce it while people with type 2 diabetes, whose bodies still produce some insulin, usually begin with oral medication to control blood sugar. Some people with type 2 who initially began treatment with oral medication may eventually need to take insulin because the oral medications they have been taking for years are no longer effective in controlling their blood sugar (American College of Physicians 2007). Also, sometimes people with type 2 diabetes may need to take two or three different pills, or a combination drug — one tablet that contains two types of medications combined. In many cases, combination therapy is more effective than just using one type of drug (Chart 2.1; Sarpong and Miller 2010). Of course, these drug therapies are no substitute for lifestyle modification (diet, exercise, substance abuse, just to name a few) once an individual has been diagnosed with diabetes.

Chart 2.1 Percentage of Adults with Diagnosed Diabetes Receiving Treatment with Insulin or Oral Medication, United States, 2007-2009



Source: 2007–2009 National Health Interview Survey

Among adults with diagnosed diabetes (type 1 or type 2), 12% take insulin only, 14% take both insulin and oral medication, 58% take oral medication only, and 16% do not take either insulin or oral medication.

Source: Centers for Disease Control and Prevention. National diabetes fact sheet: national estimates and general information on diabetes and prediabetes in the United States, 2011.

2.2.1 Types of Insulin

There are different types of insulin available for treatments that vary in how quickly and how long they can control blood sugar (National Diabetes Information Clearinghouse 2008). Unlike oral medication, insulin is taken by injection or other ways such as syringes, injection pens, and insulin pumps, into the bloodstream. They are classified on the following basis:

- how soon it starts working (onset)
- when it works the hardest (peak time)
- how long it lasts in the body (duration)

There are five classes of insulin available for injections:

Rapid-acting--starts working within one to 20 minutes and its peak time are about one hour later and last for three to five hours.

- Insulin lispro (Humalog®)
- Insulin aspart (NovoLog®)

Short-acting--this insulin has peak effect of four hours and works for about six hours.

- Humulin® R
- Novolin® R

Intermediate-acting--this insulin starts to show its effect about 90 minutes after injection, peak at 4 to 12 hours and lasts for 16 to 24hours.

- Humulin N
- Novolin N

Long-acting--this insulin can last up to 24 hours.

- Insulin glargine (Lantus®)

Premixed--a combination of either a rapid onset-fast acting or a short acting insulin and

intermediate acting insulin in one vial, which makes it easier to inject two different types of insulin at the same time.

- Insulin lispro protamine/insulin lispro (Humalog® Mix50/50, Humalog® Mix75/25)
- Insulin aspart protamine/insulin aspart (NovoLog® Mix 50/50, NovoLog® Mix 70/30)
- NPH insulin/regular insulin (Humulin® 70/30, Novolin® 70/30).

2.2.2 Other Injectable Medications

Besides insulin, there are other injectable drugs used in the treatment of diabetes (American Diabetes Association 2011):

- **Pramlintide**--(brand name Symlin) is a synthetic form of the hormone amylin, which is produced along with insulin by the beta cells in the pancreas. Users inject it with meals and it has been approved for people with type 1 diabetes who are not achieving their goal A1C levels and for people with type 2 diabetes who are using insulin and are not achieving their A1C goals.
- **Exenatide**--(brand name Byetta), the first in a new class of drugs for the treatment of type 2 diabetes called incretin mimetics, works to lower blood glucose levels primarily by increasing insulin secretion. Like pramlintide, exenatide is injected with meals. Exenatide has been approved for use by people with type 2 diabetes who have not achieved their target A1C levels using metformin, a sulfonylurea, or a combination of metformin and a sulfonylurea.

2.2.3 Oral Medication

Currently there are five classes of oral diabetes medications, all of which help lower blood sugar levels, by making the pancreas produce more insulin, helping decrease insulin requirements by the body or reducing gluconeogenesis (i.e. formation of glucose from noncarbohydrate sources, such as amino acids) by the liver. These different classes of diabetes medications can be used in combination or with insulin to achieve control of the blood sugar (see Table 2.1, Appendix B; AHRQ 2007).

- **Sulfonylureas** stimulate the pancreas to make more insulin.
- **Biguanides** shut off the liver's excess glucose production
- **Alpha-Glucosidase Inhibitors** slow absorption of carbohydrates in the intestine
- **Thiazolidinediones** increase the body's sensitivity to insulin
- **Meglitinides** stimulate the pancreas to make more insulin

These five pharmacological methods of controlling blood sugar can substantially delay or prevent costly medical complications arising from diabetes (Cohen, Neslusan et al. 2003).

2.3 Literature Review

A literature review of research on pharmacy benefit cost cutting strategies implemented by employers and insurers reveals that, in 2000, 80% of health plans with prescription drug benefits offered 3-tier formularies compared with 36% of plans 2 years earlier (Kaiser Family Foundation 2003). Also, more than half of all people with prescription drug insurance were in three-tier plans by 2002 (Thomas, Wallack et al. 2002). In these multi-tiered formularies plans, drugs are arranged into copayment tiers to create financial incentives for patients to use generic medicines over brand-name products or select a brand-name drug designated as "preferred" over "nonpreferred."

In 2008, findings from a survey of more than 150 employers by Buck Consultants revealed that 99% of the respondents offer a pharmacy benefit. Out of these respondents, 44% required employees to share 21% to 30% of the medication cost while another 45% required employees to share 11% to 20% of the drug cost; the remaining 11% required cost sharing greater than 30%. Furthermore, 72% of employers implemented a 3-tier cost-sharing structure in which tier 1 includes the lowest-cost generic medications, tier 2 includes preferred brands, and tier 3 includes nonpreferred medications. Given that tier 1 has the lowest out-of-pocket cost for medications, members have a strong incentive to use tier 1 as opposed to other tiers with higher out-of-pocket costs for medications. In other related studies, when plan members have higher copays or coinsurance amounts, their medication adherence rates decrease, contributing to increased medical costs and absenteeism (Davis, Collins et al. 2005).

Shifting costs or increasing cost sharing to patients, rather than seeking innovative ways to reduce drug spending and thereby share a lower overall cost, could lead to patients forgoing valuable treatments as a result of greater cost-share if other measures are not taken to ensure that

patients adhere to their drug therapy. There are two possible explanations for the popularity of such cost-cutting strategies, e.g. the multi-tier formularies benefit. First, many drugs that were excluded under the single-tier formularies are often included in drug benefits with more tiers (Penna 2000). Second, research has shown that adding copayment tiers lowers drug spending, particularly the portion paid by health insurance plans (Motheral and Fairman 2001).

In most of the studies that focused on the impact of tiered formularies, the findings revealed that adding tiers to copayments for prescription drugs in the private insurance market was associated with a reduction in total spending (decreases of 5%-20%) by the drug plan and greater spending by patients (Huskamp, Deverka et al. 2003; Gibson, McLaughlin et al. 2005; Huskamp, Deverka et al. 2005) . In these studies, there are 3 notable common findings: adding tiers to copayment structures was associated with increased switching within drug classes (switching toward "preferred" drugs on formulary occurring among 5% to 49.4% of patients) (Motheral and Fairman 2001; Fairman, Motheral et al. 2003; Huskamp, Deverka et al. 2003; Nair, Wolfe et al. 2003; Gibson, McLaughlin et al. 2005; Huskamp, Deverka et al. 2005), decreased overall utilization of affected medicines (Fairman, Motheral et al. 2003; Huskamp, Deverka et al. 2003; Gibson, McLaughlin et al. 2005; Huskamp, Deverka et al. 2005; Landsman, Yu et al. 2005), and either no change (Huskamp, Deverka et al. 2005) or an increase in the rate of discontinuation of prescribed drug treatments (Motheral and Fairman 2001; Fairman, Motheral et al. 2003; Huskamp, Deverka et al. 2003; Nair, Wolfe et al. 2003; Huskamp, Deverka et al. 2005; Landsman, Yu et al. 2005). A study by Nair and colleagues found that changes in spending by the plan and by patients were consistent with the findings of other studies but there was no statistically significant associations between adding tiers to formularies and changes in total spending (Nair, Wolfe et al. 2003).

Joyce and colleagues examined the impact of multi-tiered formularies, mandatory generic substitution rules, and copayment levels on expenditures for generic and brand name drugs and patient's out-of-pocket payments on the working-age with employer-provided drug coverage (Joyce, Escarce et al. 2002). This study found that many of the new insurance mechanisms for prescription drugs were effective at controlling expenditures. For example, Joyce et al. found that doubling copayment levels in one-, two-, and three-tier plans (i.e., moving from $5 to $10 or $5/$10 to $10/$20 or $5/$10/$15 to $10/$20/$30) reduced drug expenditures by 22 to 35%, which translates to elasticities of –0.22 to –0.33. Also, adding tiers reduced drug expenditures. Moving from a one- to two-tier plan (i.e., $5 to $5/$10 or $10 to $10/$20) reduced expenditures by 6 to19%. Adding a third tier had less dramatic effects on average drug spending than adding a second tier, and adding mandatory generic substitution (MGS) rules to two-tier plans yielded expenditure reductions of about 8 percent. Interestingly, patient's out-of-pocket costs were not affected by benefit design. Increases in patient cost-sharing were balanced by reductions in utilization of drugs with higher cost-sharing levels and substitution between cheaper, generic drugs and expensive brand name drugs. Although patient out-of-pocket spending did not change when cost-sharing increased, the share of total costs borne by patient rose significantly.

In a study of the U.S. working-age insured, Goldman et al. concluded that increased cost-sharing in drug benefits are associated with reduction in use of almost all therapeutic classes of prescription drugs (Goldman 2004). This study focused on the impact of benefit design on drug expenditures and total days supplied of medications for selected chronic conditions. Price elasticities of demand were estimated for both disease-specific medications and other drugs for the full sample and for users with chronic conditions. As a proxy for price, an out-of-pocket index for each plan was generated, effectively collapsing the benefits generosity of each plan

into a single variable. Patients being treated for long-term chronic conditions, such as hypertension, lipid disorders, depression, gastric acid disorders, and diabetes, were found to have demand for disease-specific drugs that was fairly price-responsive but less responsive than demand for drugs from outside drug classes. In other words, increased cost-sharing in drug benefits reduced the use of "nonessential" drugs more than "essential" drugs. For patients being treated for conditions, such as allergic rhinitis and osteoarthritis, that produce intermittent symptoms that can be treated with medications, demand for disease-specific drugs was very price-responsive, even more so than for drugs from outside classes.

Moreover, patients without evidence of medical treatment for specific conditions were more price-sensitive to disease-specific drugs than those with ongoing treatment. Elasticities for all drugs among the full sample ranged from –0.25 to –0.45, elasticities for disease-specific drugs among those with ongoing treatment ranged from –0.07 to –0.30, and elasticities for drugs from an outside drug class for chronically ill patients ranged from –0.14 to –0.30. In general, existing research implies that price elasticity for prescription drugs is fairly inelastic (less than one), but that estimates do vary. Landsman et al (2005) found similar price responses across 9 therapeutic classes. Several other studies found modest but inconsistent effects of higher copayments on use of essential and nonessential drug classes (Motheral and Henderson 1999; Motheral and Fairman 2001; Fairman, Motheral et al. 2003).

In another related study, Roe and colleagues (2002) compared more and less aggressive three –tier plans and found that those with lower copayments at each level had no overall savings, while more aggressive plans with higher copayments at each level had cost trends that increased more slowly. Furthermore, other studies have found that shifting individuals from a 2-tier to a 3-tier drug benefit copayment structure resulted in changes in medication utilization and

more aggressive cost-sharing requirements combined with other management strategies were associated with a shift to less costly medications (generic and mail order), and lower total prescription drug spending (Thomas, Wallack et al. 2002; Nair, Wolfe et al. 2003)

Studies on prescription drugs utilization have centered on the theme of own price elasticity. The RAND Health Insurance Experiment (HIE) found that elasticities for prescription drugs were not different from outpatient services, which ranged from –0.17 for coinsurance rates from 0% to 25% to –0.31 for coinsurance rates from 25% to 95% (Manning, Newhouse et al. 1987). Having found that HIE enrollees with generous insurance filled significantly more prescriptions than did those with less generous coverage, they concluded that "drugs, like medical care expenditures in general, respond to cost-sharing faced by consumers" (Leibowitz, Manning et al. 1985). However, this conclusion has been widely debated on grounds that the HIE results cannot distinguish between the own-price effect of insurance on the covered service in question (prescription drugs) and the cross-price effect of coverage for services that complement drug therapy (physician visits). In 1989, Leibowitz published a second paper reporting no significant relationship between insurance plan generosity and utilization rates for over-the-counter medicine.

The results about whether or not the increases in drug prices are associated with significant adverse health status are ambiguous. Some studies found that rising drug prices are associated with increased adverse health effects (Johnson, Goodman et al. 1997; Tamblyn, Laprise et al. 2001; Heisler, Langa et al. 2004). While other studies found no significant changes in health status following increased cost-sharing for prescription drugs (Pilote, Beck et al. 2002; Schneeweiss, Walker et al. 2002).

Similar results to Goldman (2004) were found in a study where survey respondents were asked about various cost-related reductions in use (Piette, Heisler et al. 2004). The findings of this study indicated that patients reported less cost-related reductions for disease-specific drugs than they did for overall drugs. Additionally, drugs for conditions with intermittent symptoms, such as arthritis or pain conditions, were reduced more frequently than those for life-threatening chronic conditions such as hypertension or heart disease.

The price-sensitivity of elderly individuals is likely to differ from that of the working-age population. Theoretically, the proportion of income spent on a product is one of several determinants of price-sensitivity. Hwang et al. (2001) found that out-of-pocket spending increased with age and income and varied by insurance status. Specifically, persons in the oldest age category (age eighty or older) spent more than five times out of pocket than did persons in the youngest age category (birth to nineteen years) and twice as much as persons in the middle age category (ages forty-five to sixty-five). Given that outlays for prescription drugs account for a smaller fraction of income for the working-age insured than for the elderly or uninsured, it is possible that this income factor drives the elderly to be more price-sensitive. Conversely, elderly individuals may have a greater underlying preference for drug therapy because they view prescription drugs as necessary and believe that fewer substitutes exist for drug therapy, e.g., diet and lifestyle modifications may have less impact late in life, and thus, they may become less price-sensitive. Of course then the net effect of these factors on price-sensitivity is theoretically ambiguous.

2.4 Significance of This Study

Although previous research provides good insights in evaluating the effects of the drug benefit changes from some particular perspectives, a number of limitations motivated my current research study. The first major issue concerns with the data used for estimation. Some studies used small samples so their estimation results could be affected by serious sample selection bias. The second issue pertains to the fact that most previous studies used cross-sectional data. Once again, the question of selection bias arises because it is difficult to control for the individual heterogeneity in estimating the demand for medical care by using cross-sectional data.

The third major limitation of those prior studies is about the scope of their studies. Most studies focused only on the direct effects of the rising drug prices on pharmaceutical costs and use in general or for general chronic conditions, not specifically on diabetes as I intend to focus in this study. Depending on the substitutability of prescription drugs and other types of care, the increases in drug prices could potentially have spillover effects on other medical care sectors such as inpatient and outpatient services. In addition, their effects on demands for medical care might distribute over a long term through the changing of underlying health status. Most previous studies estimated static models of demand for medical care (Joyce, 2002; Huskamp, 2003; Goldman, 2004) and the dynamic price effects on medical demand are largely left unexplored. Furthermore, there is limited literature on the marginal effect of comorbidities on the demand for medical care.[2] Pladevall et al. (2004) found that patients with diabetes and comorbid conditions, poor adherence to antidiabetic, lipid-lowing, and antihypertensive medications drug regimens resulted in poor clinical health outcomes. Given these motivations, in this study, I seek to explore the dynamic cost-sharing effects on healthcare

[2] I used the following criteria to search for existing literature for comorbid effect of diabetes on the demand for medical care online: diabetes, comorbidity, marginal effect, prescription drug demand elasticity.

expenditures among the individuals with diabetes, one of the most common chronic condition for which prescription medications exist, taking into account the comorbid effect of diabetes.

CHAPTER 3

METHODS

3.1 Data

I used the 2000 and 2001 Thomson Healthcare[3] MarketScan Research Database. MarketScan, a health care information company within the Thomson Corporation, had contracts with over 45 large employers for the submission of the health insurance data for their employees. It is the largest multi-source private sector healthcare database in the U.S., containing paid claims of more than 7 million privately insured individuals, and over $13 billion in annual healthcare expenditures. To keep the identity of the employers and health plans confidential, neither employers nor health plans are identified by name in the database. This database contains longitudinal data for each person, including person and family identifiers, enrollment history, uses of inpatient care, outpatient care and prescription drugs, health expenditure, and detailed health insurance coverage information from 2000 to 2001.

There are five different files in the MarketScan database from 2000 to 2001. In order to conduct a sample selection for diabetic patients, I linked information from these five different files:

(1) the *enrollment* file, which contains patients' demographics and detailed information on their health plan enrollment history;

(2) the *employer benefit plan design* file, which contains summary benefit descriptions for major medical and prescription drug benefits for many health plans;

(3) the *outpatient pharmaceutical claims* file, which contains a claim for each prescription filled by each person with information on days of prescription drug supplied,

[3] Thomson Healthcare was formerly known as MEDSTAT, located in Ann Arbor, Michigan.

national drug codes, therapeutic classes, and expenditure information including total payments, out-of-pocket payments made by patients, and net payments made by the employer;

(4) the *outpatient service claims* file, which contains individual outpatient claims aggregated to the level of each outpatient visit with information on diagnosis, treatment procedures, and payment; and

(5) the *hospital inpatient claims* file, which contains individual hospital claims aggregated to the level of the hospital stay and provides information on diagnosis, treatment, and length of stay, as well as basic payment information.

3.2 Study Design

This retrospective cohort study utilized a quasi-experimental, pre-post with comparison group design, to analyze the effect of cost-shifting on healthcare expenditure among enrollees diagnosed with diabetes enrolled in employer-sponsored insurance plans. The principal measure of interest is a change in the health benefit plan. Medical and pharmacy claims were used to evaluate outcomes for enrollees with a change in drug benefit plan or undergoing cost shifting in their pharmacy benefit coverage (the intervention group) compared with enrollees without a change in drug benefit plan (the comparison group).

3.2.1 Diabetes Sample: Identification of Enrollees with Diabetes

To identify enrollees with diabetes in the database, I used a combination of diagnosis codes and drug-specific pharmacy claims. Enrollees with diabetes were identified as those who, between 2000 and 2001, had two or more medical claims with a diabetes diagnosis code according to the ICD-9 codes 250.xx or one or more prescription drug claims for an antidiabetic agent based on the national drug code (NDC).

To be included in the study sample, enrollees in both the intervention and comparison groups had to be continuously enrolled for the entire 24-months study period (12 months before the plan change and 12 months after the plan change) and be greater than or equal to 18 years of age and less than or equal to 62 years of age at the beginning of the study period. Using information from the enrollment files, I defined an anchor date from October 1, 2000 to March 31, 2001. However, after analyzing the health benefit plan change date trend, three individuals in the intervention group changed their plans on November 14, 2000 and January 2, 2001 and January 3, 2001 while the rest of the enrollees changed their plan on January 1, 2001. Therefore, I redefined the anchor date to January 1, 2001 for the *intervention* group[4] (dropping the November 14, 2000 plan change) and chose a proxy anchor date of January 1, 2001 for the *comparison* group which has 1 plan throughout the 24-months study period.

This process provides 12 months expenditure in the pre-period and post-period or a total of 24 months time. Furthermore, to find enrollees with continuous enrollment with pharmacy benefit coverage, I examined the health plan files for evidence of prescription coverage and excluded any persons without drug benefits or with insufficient detail in the database during the entire two pre-post periods. Figure 3.1 (*a* and *b*) shows a sketch of sample selection timeline.

[4] I dropped patient with November 14, 2000 changed date but kept the other two patients because all their expenditures for 2001 occurred after the changes to their drug benefit designs.

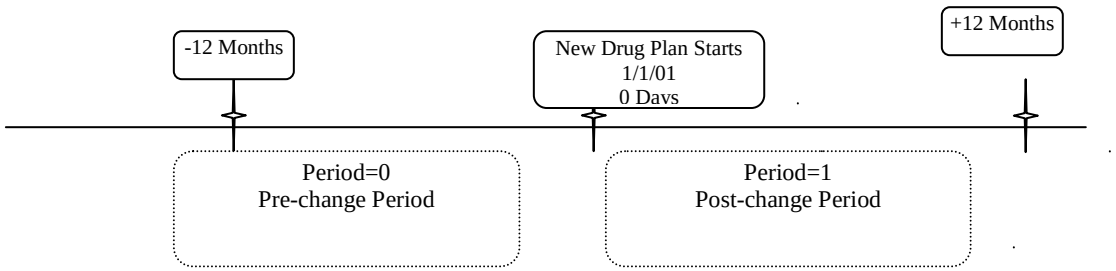


Figure 3.1 (a) Timeline for intervention group

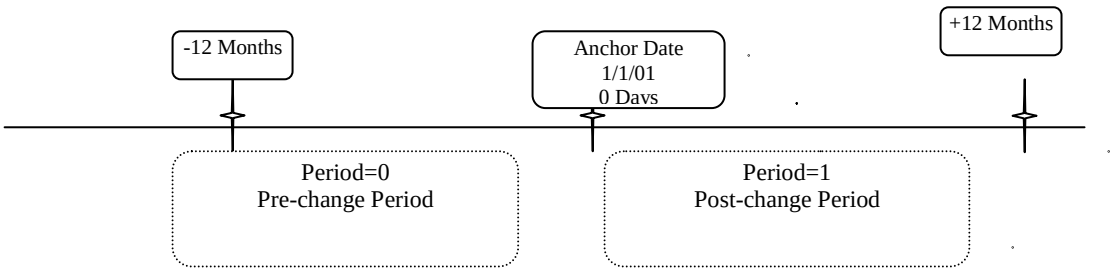


Figure 3.1 (b) Timeline for comparison group

Next, using national drug code (NDC) to identify antidiabetic agents, I examined the outpatient pharmaceutical claims record to find persons with at least 2 pharmacy claims[5] for antidiabetic medication in each of two periods: the pre-change (January 1, 2000, to December 31, 2000) and the post-change (January 2, 2001, to December 31, 2001). For the intervention group, the enrollees whose employers switched to new health benefit plan coverage must have two health benefit plans within the 24 months and the health benefit plan coverage changed on January 1, 2001, and remained in the same coverage structure through the rest of 2001. The comparison group included enrollees whose employer remained under the same health benefit plan coverage structure from January 1, 2000 to December 31, 2001. All enrollees meeting the

[5] I imposed at least 2 pharmacy claims to ensure that the person selected did indeed have diabetes, not just a miscode or a one time prescription fill for some other health conditions.

aforementioned criteria were included in the analyses of total healthcare expenditure (beneficiary's copay and deductibles and remainder of the charge paid by the insurer), total out-of-pocket expenditure (patient's copay and deductible for pharmaceutical, inpatient and outpatient services) and individual out-of-pocket (pharmaceutical, outpatient and inpatient services). A sample of 3,257 enrollees with diabetes was identified using this algorithm; 2,447 and 810 for the intervention and comparison groups, respectively. Table 3.1 displays the sample selection details and Table 3.2 shows the drug benefit design in the pre-change and post-change periods.

Table 3.1: Sample Determination

Criterion	Individual
ICD-9CM diagnosis code (250.0x)	
Aged 18-62	
Key Variable Present (drug benefit plan)	
Two Time Periods (pre-post)	
Final Sample Size (person-years)	3257

Note: Sample size is the number of individuals after selecting for each criterion. The final sample is 3,257 individuals over two time periods.

In the final sample, there were 5 plan types (see Table 3.3): comprehensive, HMO, Non-capitated point of service (POS), preferred provider organization (PPO), capitated or partial capitated POS; and a total of 28 plans. In the comparison group there were 8 plans and all of them were comprehensive plan type with no "patient incentive to use certain providers" and no "primary care physician assigned." While in the intervention group there were 23 plans and they included all 5 plan type as mentioned above.

3.2 Drug Benefit Plan Characteristics for Intervention Group: Pre-change vs Post-change

Pre-change Benefit Plan	Frequency of plan	Generic Copay-card	Generic Copay-mail	Preferred Brand Copay-card	Preferred Brand Copay-mail	Non-preferred Brand Copay-card	Non-preferred Brand Copay-mail
Plan Group1	1	5	10	10	20	25	45
Plan Group2	4	5	10	10	20	20	45
Plan Group3	1	2	2	2	2		
Plan Group4	1	5	5	5	5		
Plan Group5	3	24	24	24	24		
Plan Group6	2	8	8	16	16	25	25
Total No. of Plans	12						

Post-change Benefit Plan	Frequency of plan	Generic Copay-card	Generic Copay-mail	Preferred Brand Copay-card	Preferred Brand Copay-mail	Non-preferred Brand Copay-card	Non-preferred Brand Copay-mail
Plan Group1	4			15	30	35	70
Plan Group2	1			10	20	20	45
Plan Group3	1	2	2	2	2		
Plan Group4	2	5	5	5	5		
Plan Group5	3	24	24	24	24		
Plan Group6	2			16	16	25	25
Total No. of Plans	13						

3.3 Plan Type Characteristics

Plan Type	Patient incentive to use certain providers?	Primary Care Physician (PCP) assigned?	Referrals from PCP to specialists required?	Out of network services covered?	Partially or fully capitated?
1 COMP	no	no	n/a	n/a	no
2 HMO	yes	yes	yes	no	yes
3 Non-cap POS	yes	yes	yes	yes	no
4 PPO	yes	no	n/a	yes	no
5 Cap or Part Cap POS	yes	yes	yes	yes	yes

3.2.2 Methodological Approach

I seek to answer two questions:

(1) Do changes in drug benefit design have a significant effect on patient out-of-pocket (copays and deductible) drug expenditure among individuals with diabetes in large employer-sponsored insurance plans?

Hypothesis I:

H_0: The out-of-pocket expenditure for drug is the *same* in the intervention group with a *change* in drug benefit design and the comparison group without a change in drug benefits coverage.

H_1: The out-of-pocket expenditure for drug is *different* in the intervention group with a *change* in drug benefit design and the comparison group without a change in drug benefits coverage.

(2) If this relationship holds, what is the impact of changes in drug benefit design on the *total healthcare expenditure* (sum of both employer and enrollee's cost for all three services),

individual service expenditure for each of the three services, *total out-of-pocket* (the sum of patient's copays and deductible for pharmaceutical, outpatient and inpatient services) and *individual out-of-pocket* for pharmaceutical, outpatient and inpatient services?

Hypothesis II:

H_0: The expenditures (total healthcare expenditure, total out-of-pocket and individual out-of-pocket for inpatient and outpatient services) are the s*ame* in the intervention group with a *change* in drug benefit design and the comparison group without a change in drug benefits design.

H_1: The expenditures (total healthcare expenditure, total out-of-pocket and individual out-of-pocket) are *different* in the intervention group with a *change* in drug benefit design and the comparison group without a change in drug benefits design.

In this investigation, a strong assumption is made regarding the key variable of interest, changes in drug benefit design:

Assumption (Causality):
An increase in employees' share of expenditure and a decrease in total healthcare expenditure (employees plus employers' share of expenditure) must be due to a change in inputs or input mix which is broadly defined as changes in drug benefit design implemented by the employers as a way for employers to shift cost to employees.

I expect that this assumption can be justified in the dynamic employer-sponsored health benefit setting via appropriate statistical analysis. The design of this research is to use a longitudinal data with a focus on patient population facing a similar array of drug choices, that is, people diagnosed with diabetes and using antidiabetic agents. I am limiting my unit of analysis to individuals with diabetes to reduce sources of heterogeneity. The data covers the time period 2000–2001. The response variables are total healthcare expenditures, total out-of-pocket expenditures, and individual expenditure per service per enrollee, and individual out-of-pocket

expenditure per service per enrollee for the diabetes population, obtained from the pharmaceutical, outpatient and inpatient services files. To measure the effect of changes in benefit plan coverage on each of the response variables, generalized estimating equations were used, whereby the relationship between the response and covariates is modeled separately from the correlation between repeated measurements on the same individual (Diggle 2002).

3.3 Measures

3.3.1 Response Measures: Direct Cost of Diabetes

From the insurers' perspective of the analysis, direct costs were reimbursements from the insurer to health care providers for inpatient, outpatient, physician, and prescription drug services, as well as for other services (e.g., physical therapy, nursing home services). Costs were reported based on claims for services provided in 2000 and 2001. Patients' out-of-pocket (e.g., copays and deductibles) are included for the patients' perspective of the analysis. All expenditures for each year were adjusted using the Consumer Price Index (CPI) and all estimates in this dissertation are reported in 2001 dollars.

The main response variables are *total healthcare expenditure*, *total out-of-pocket expenditure*, *individual service expenditure* for each of the three services, and *individual out-of-pocket expenditure* for each of the three services. Out-of-pocket expenditure on prescription drugs, outpatient services, and inpatient services are calculated as the yearly spending per diabetic enrollee, while total out-of-pocket expenditure is the sum of the out-of-pocket expenditure on prescription drugs, outpatient services, and inpatient services. Individual service expenditure is the sum of spending by the insurer in the database and the required out-of-pocket spending by the patient for each of the service (drugs, outpatient services, and inpatient services). Total healthcare expenditure is the sum of spending by the insurer in the database and the

required out-of-pocket spending by the patient for prescription drugs, outpatient services, and inpatient services.

3.3.2 Explanatory Variables

The primary explanatory variable of interest involves changes in benefit plan design for prescription drugs. In the presence of health insurance, the price faced by a diabetic patient for health services is determined by the diabetic patient's health plan benefit design.

3.3.3 Covariates

Other explanatory variables associated with healthcare expenditure were included in the models. Patient-level sociodemographic characteristics included sex, age, urban residence, and median income in the patient's area of residence (by ZIP code) from the US Census files. Both income and residence (i.e. urban or rural) were obtained using employee county zip code provided in the dataset to link to Federal Information Processing Standard (FIPS) (USDA, Economic Research Service 2004). I also included region to control for geographic characteristic. In addition, a comorbidity score, using Elixhauser comorbidity measures, was calculated to be included in the analysis to explore its effect on the outcomes.

3.4 Identification of Conditions Comorbid with Diabetes

To gain a better understanding of the effect of comorbidities on diabetes related cost, I identified comorbidities as recognized in the literature to drive medical costs, morbidity, and mortality in diabetes in both the intervention and comparison groups (CDC 2009; ADA, 2007; ADA, 2011; Simpson, Corabian et al. 2003; O'Brien, Shomphe et al. 1998; Hodgson and Cohen 1999; Ramsey, Newton et al. 1999). These conditions included cardiovascular disease, hypertension, infections related to diabetes (e.g., septicemia, bacteremia), other metabolic diseases (e.g., hyperosmolarity), nephropathy, neuropathy, and retinopathy. I used the Elixhauser method which uses ICD-9-CM codes and has been shown to predict mortality and hospitalization outcomes (see Table 3.4, Appendix) (Elixhauser, Steiner et al. 1998; Southern, Quan et al. 2004). In contrast to the Charlson Score, the original Elixhauser method involves retaining individual binary indicators for each disease category (rather than creating a summary score by adding indicators for all diseases). As an alternative to the original Elixhauser method, I summed all of the indicators to create a total Elixhauser score (Dominick, Dudley et al. 2005)[6]

I performed a search over the analysis period of year 2000 and 2001 for ICD-9 codes related to each comorbidities as indicated, whereby an Elixhauser Comorbidity score was calculated by summing the indicators of the comorbidity diagnosis from the inpatient and outpatient services claims data for each patient. Scores on the Elixhauser comorbidity measures, a numeric scale reflecting the risk of death or serious disability in the next year based on the presence of a diagnosis for 1 of 30 conditions (e.g., heart disease, cancer, depression) were included for the intervention group and comparison group in all the regression models (Elixhauser, Steiner et al. 1998).

[6] Since my analysis is on diabetes, in summing the Elixhauser score, I subtracted 2 comorbidities (diabetes with chronic complications and diabetes without chronic complications) from the measures to get a total of 28 out of 30 comorbidities (see Table 3.2, Appendix).

3.5 Sample Characteristics

Table 3.5 shows patient characteristics in terms of key variables (refer to Appendix, Table 3.6, for more details of the sample population). The summary of sample characteristics is produced for the overall study population who satisfy the inclusion criteria. The classification is made on the basis of changes in drug benefit coverage status. Change in drug benefit coverage category is the intervention group, whereas no change in drug benefit coverage category is the comparison group. The first two rows report the mean and standard deviation of pre- and post-period total expenditures for the intervention and comparison groups. Presumably, the pre-period mean expenditure should not be significantly different for intervention and control groups as indicated by the t-test.

Table 3.5: Sample Characteristics by Changes in Drug Benefit Design

	Comparison Group		**Intervention Group**		**t statisitc**
	N=810		**N=2,447**		
Variables	**Mean**	**Std Dev**	**Mean**	**Std Dev**	
Pre Total Expenditure	4220.47	4011.81	4456.34	6345.07	-1.24
Post Total Expenditure	6573.15	11039.91	4827.03	6451.19	4.27***
Age in years	46.54	10.79	48.69	9.99	-5.05***
Elixhauser comorbidity score	0.22	0.92	2.78	6.40	-19.11***
Income by zip code	29223.99	7950.03	30872.22	7507.97	-5.18***
Residence (urban) (No. (%))	786 (97.04)		2412 (98.57)		-2.39*

For the comparison group, anchor date is set to January 1, 2001 as the intervention group.
* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

CHAPTER 4

Conceptual Framework

4.1 Theoretical Framework

According to economic theory, a rational patient's consumption of an optimal amount of the drug, given preferences and income constraints, depends on his or her assessment of the full price of a prescription drug and the drug's benefits and adverse effects. Specifically, the theory assumes that rational patients will weigh the costs and benefits of drugs versus other methods of producing health and will consume combinations of these that maximize their health, subject to their income constraints. From this utility maximization framework, economists can derive a demand curve for a specific good that is a function of its price, the price of all other goods, and the consumer's income. For normal goods, the derived relationship between price and quantity is negative, a result often referred to as "downward sloping" demand.

From a health economics perspective, in principle, there are two different views on the demand for healthcare. One suggestion is that the individual demands healthcare as an input into her production of health--sometimes referred to as the Grossman model (Grossman 1972). The Grossman model suggests that the demand for health care is a derived demand in the process of investment in health capital, thus, it views healthcare as an input along with other health inputs such as nutrition and personal exercise. Since good health is a desired outcome according to the model, individuals may purchase inputs that improve their health, such as prescription drugs or other medical services, because health is a depreciating stock in which individuals must invest over time. As a result, the demand for prescription drugs is a derived demand from the demand for good health. It follows that, given a patient's utility function or "preferences set," all other things equal, the demand for prescription drugs is a function of a drug's price, the price of other

inputs, including other drugs, and a patient's income. Since the price of prescription drugs is itself a function of one's insurance status and level of pharmacy benefits, this theory implies that insurance status and pharmacy benefits' level of generosity (i.e. cost-shifting or greater cost-sharing level) will affect a consumer's choice.

An alternative view to the Grossman model sees the demand for health care within a principal-agent framework (Zweifel and Manning 2000). Thus, the individual decides if and when to seek health care while the provider of the services decides how much care to use once the first decision has been taken. Depending on the particular view of the demand for health care that one adopts, the methods for analyzing the effect on the demand for healthcare will vary. That is, the effect of health benefits on the demand for prescription drug spending by assuming the change in the benefit is imposed by the employers to shift cost to the employees as opposed to treating the change in benefit plans due to employees' self-selection of health benefit plans.

The role of insurance in health financing has twofold. The first one to raise revenues for health care services, while the second is to pool these resources so that health risks can be effectively shared among the members of the insurance scheme (Folland, Goodman et al. 2007). Risk sharing is both an equitable and an effective way of financing health care due to the uncertainty of individual risk of ill health in the population. This is especially important to public policies that are attempting to overcome health insurance to improve access to care and to reduce individual spending at the time of use, which is essential for those with limited ability to pay for their care. Given the different ways of analyzing the effect of health insurance on utilization and expenditures, whereby the findings depend on the researcher's view of demand on health care, the extent to which the relationship between the price of health care and consumption occurs in any given context is an empirical issue, given other factors such as

indirect costs (i.e. transportation). Although there are other problems associated with health insurance, including moral hazard and adverse selection, this is not the subject of analysis in this paper.

4.2 Hypotheses

Based on these theoretical underpinnings, this section presents hypotheses about the effect of employer shifting cost via changing drug benefit plan coverage to the employees in a population diagnosed with diabetes. Previous research has shown that patients with prescription drug benefits have incentives to consume more drugs than they would normally consume because patients are paying only a fraction of the full drug price (Pauly 1968; Pauly 2004).

What is the effect of the price of prescription drug on the demand for pharmaceutical services?

According to the law of demand, there is an inverse relationship between the quantity demanded of a commodity and its price. Given the existing literature on the price elasticity of prescription drug and the assumption that this prescription drug therapy is considered as "essential medication" for treating diabetic, the price elasticity is relatively inelastic or less than 1. With two years of data, I expect that when an employer shifts cost to an employee by raising the price of the drug, the employee's out-of-pocket drug expenditure will increase, but the total drug expenditure which included both the patient and the employer's share indicated by the benefit plan's payment will decrease.

What is the effect of the price of prescription drug on the demand for inpatient services?

I predict that shifting cost to the employees via a relatively higher co-payment required for pharmaceutical services will increase the consumption of inpatient services, thus, the out-of pocket for inpatient services will increase but the total inpatient services expenditure, including patient's out-of-pocket plus employer's share indicated by the benefit plan's payment, will

decrease. A chronically ill patient will continue to demand inpatient service to some degree depending on the severity of his or her condition and comorbid conditions.

What is the effect of the price of prescription drug on the demand for outpatient services?

I assume that for a patient to obtain prescription for a prescription drug this patient must visit his or her physician only when the prescription drug needs to be filled, not on a regular basis where he or she has to receive treatment as an outpatient to help manage his or her diabetes. I anticipated that the relationship between prescription drug price and outpatient service is complementary but weak or negative and slightly below zero. Thus, the higher copayment level for prescription drug will decrease patient's out-of-pocket spending for outpatient services and the total outpatient services expenditure that included both patient and employer's spending.

4.3 Empirical Strategy

This section includes a discussion on some theoretical background on the empirical analysis of health care expenditure. In general, health economists are interested in modeling a response variable Y as a function of a vector $X = (X_1, X_2, \ldots, X_p)^T$ of covariates in a regression model for the mean function $\mu(x) \equiv E(Y|X = x)$ to estimate the effect of one or more of the covariates X_j on Y. This marginal effect is measured by a general functional of $\mu(x)$: the partial derivative of $\mu(x)$ with respect to covariate x_j in vector $x = (x_1, x_2, \ldots, x_p)^T$. Denoted by $D_j(\mu; x) \equiv \partial\mu(x)/\partial x_j$, this parameter is the rate of change in $\mu(X)$ with respect to X_j evaluated at $X = x$. When X_j is an indicator variable (i.e. pre-change=0 and post-change=1), $D_j(\mu; x_{-j})$ is defined as the difference in $\mu(x)$ at the two levels of X_j, i.e. $D_j(\mu; x_{-j}) \equiv \mu(x_j = 1, x_{-j}) - \mu(x_j = 0, x_{-j})$, where x_{-j} is the vector x without x_j (Basu and Rathouz 2005).

As noted by Greene, this parameter is called the *marginal effect* of the covariate and is given by $\xi_j \equiv EX\{D_j(\mu; X)\}$ (Greene, 2000, p. 824). Thus, it is the population average rate of

change in $\mu(X)$ with respect to X_j, controlling for other factors X_{-j}. When X_j is a binary indicator variable, the parameter of interest is the *incremental effect* given by

$\pi_j \equiv EX_{-j} \{D_j(\mu; X_{-j})\}$, where the expected value is over X_{-j}, marginally with respect to X_j. The parameter π_j is the population average contrast in the mean of Y for $X_j = 1$ (i.e. post-change period) and $X_j = 0$ (i.e. pre-change period). Once more, the expectation is taken over X, but as X_j is fixed at 0 or 1 in $D_j(\mu; X_{-j})$, π_j only involves the marginal distribution of X_{-j}. The interpretation of both ξ_j and π_j are as effects of X_j on the mean of, adjusting for all other covariates in the model, where this adjustment is to the population distribution of X. In the case of linearity, where $\mu(x)$ is linear in x_j, either ξ_j or π_j is simply equal to β_j.

Many response variables in health economics are characterized by non-negative values, heteroscedasticity, heavy skewness in the right tail, and kurtotic distributions. Thus, it is inappropriate to apply ordinary least square (OLS) on the raw scale of Y, the response variable. Traditionally, to overcome such problems, econometricians have relied on logarithmic or other transformations of Y. This is then followed by regression of the transformed Y on X using OLS (Box and Cox 1964). However, such practice can potentially create biased estimators of $\mu(x)$ unless the researcher spent considerable effort to discern the specific forms of heteroscedasticity. Moreover, the OLS based models with logged response variable are less precise than GLM for certain data generating processes (Manning and Mullahy 2001).

4.3.1 Generalized Linear Model (GLM)

Due to such problems of retransformation, economists have focused on the use of generalized linear models (GLMs) with quasi-likelihood estimation (Wedderburn 1974). In the GLM approach, a link function relates $\mu(x)$ to a linear specification $x^T \beta$ of covariates. By using this approach, the retransformation problem is eliminated because $\mu(x)$ is transformed instead of Y. If the response function is exponential, the conditional mean of the marginal effect can be denoted as:

$$D_j(\mu_j, x) = \frac{\partial \mu(x)}{\partial x_j} = \beta_j e^{x_j \beta} \qquad (4\text{-}1)$$

Another advantage to using this method is that GLMs allow for heteroscedasticity through a variance structure relating Var$(Y|X = x)$ to the mean, with correct specification the estimators are efficient (Crowder 1987) and may correspond to an underlying distribution of the response measure.

4.3.2 Generalized Estimating Equations (GEE)

In health economics, many studies have used log link models with the gamma error distribution as their choice of model (Blough, Madden et al. 1999; Manning and Mullahy 2001; Basu, Manning et al. 2004). Even though this is the case, it is still a challenge for researchers to identify the appropriate link function and variance structure *a priori* (Blough, Madden et al. 1999; Manning and Mullahy 2001) because there is little guidance on the functional form of $\mu(x)$ or about distributional characteristics of Y given X. The generalized estimating equations (GEE), introduced by (Liang and Zeger 1986), is a method of analyzing correlated data that otherwise could be modeled as a generalized linear model. As an extension of the independence estimating equations (GLM), correlated data using GEE are modeled using the same link function, linear

predictor setup (systematic component), variance function, and additional covariance structure of the correlated components.

In this framework, the covariance structure does not need to be specified correctly to get reasonable regression coefficients and standard errors. The model for GEE forms like GLM except with no full specification of the joint distribution and thus no likelihood function: $g(\mu_i)=x_i^T\beta$. These data sets can arise from longitudinal studies, in which subjects are measured at different points in time, or from clustering, in which measurements are taken on subjects who share a common characteristic such as belonging to the same litter.

Let Y_{ij} , where j=1,…, n_i, and i=1,.., K, represent the j^{th} measurement on the i^{th} subject. These are n_i measurements on subject i and total measurements

$$\sum_{i=1}^{k} n_i$$

The estimating equation can be expressed in the following form:

$$\sum_{i=1}^{k} D'V^{-1}(Y-\mu)=0 \qquad (4\text{-}2)$$

where

$$Di=\frac{\partial \mu_i}{\partial \beta}$$

The solution to the GEE gives a consistent estimate of β that is asymptotically multivariate normal with covariance matrix

$$\sigma^2[D'V^{-1}D]^{-1}=\sigma\left\{\sum_{i=1}^{k}[D_i'V_i^{-1}D_i\right\}^{-1} \qquad (4\text{-}3)$$

4.3.3 Model Specification

In examining the effect of employers shifting cost via changing drug benefit plan design to the employees, I begin by presenting a general representation of my model. In this analysis, the correlated measures are pre- and post-period individual expenditure and GEE are a suitable technique for the data. The response variable (total healthcare expenditure, total out-of-pocket expenditure, individual out-of-pocket expenditure for pharmaceutical services, outpatient services and inpatient services), is expressed as a function of benefit plan change (treat), time effect (post), interaction term for plan change conditional on time effect (treat*post), comorbidities (comorb), gender, age, urban or rural (residence), and income using marginal log link regression models with the gamma error distribution in GEE as discussed above:

$$\log_e(\mu_i) = \alpha + \beta_1 \text{treat} + \beta_2 \text{post} + \beta_3 \text{treat*post} + \beta_4 \text{comorb} + \beta_5 \text{gender} + \beta_6 \text{age} + \beta_7 \text{residence} + \beta_8 \text{income} + \beta_9 \text{region} \quad (4\text{-}4)$$

As mentioned above, GEE involves specifying a marginal mean model relating the response to the covariates and a plausible correlation structure between responses at different time periods (or within each cluster, i.e. treat). The resulting parameter estimates are consistent irrespective of the underlying *true* correlation structure, but may be inefficient when the correlation structure is misspecified (Diggle 2002). Moreover, GEE parameter estimates are also sensitive to outliers (Qu, Lindsay et al. 2000; Diggle 2002).

4.3.4 Analytical Work

Finally, data analysis was carried out in order to estimate the associated expenditure or cost of the changes in drug benefit plan. The costs associated with each of the response variables were estimated vis-à-vis the comparison group as explained above. In order to calculate the cost associated with treat (intervention group), intervention group were pooled with comparison group. A dichotomous variable (treat=1|0) was created to indicate intervention group (treat=1) and comparison group (treat=0). The variable treat was the main variable of interest here. Regression using GEE estimation technique was used for the analysis.

CHAPTER 5

EMPIRICAL ANALYSIS AND FINDINGS

5.1 Expenditure by Changes in Drug Benefit Design Status

The expenditures were found using regression method adjusting for age, incomes, residence (urban vs rural) and Elixhauser comorbidity score. Using the estimates from regression models, expenditures were predicted for each observation. Then predicted expenditures are averaged by changes in drug benefit design or the intervention group status. Following common practice and existing literature, a value of $1 was added to all zeroes values encountered dependent variables to avoid undefined solutions for the log of zero (Powers et al. 2005; Diehr et al. 1999). All regression models are reported in log and marginal effect.

Referring back to Chapter 3, Table 3.5 shows the plan expenditure for the baseline year (2000) and the intervention year (2001) as well as the difference in expenditure for the intervention group that changed due to changes in drug benefit design relative to its comparison group. The mean baseline age is 48.69 and 46.54 for the intervention group and comparison group, respectively. A little more than half of the intervention group and comparison group were male, 57% and 59% respectively. The majority of enrollees in both groups reside in the urban areas. Geographically, the vast majority of the patients in the comparison group live in the north central while the intervention group is concentrated in the northeast, north central and south region.

5.1.1 Total Expenditure

Table 5.1 shows the estimated results from the full regression model for total healthcare expenditure and total out-of-pocket expenditure for all services (pharmaceutical, outpatient and inpatient services). These are estimates of expenses for the post period (2001) following changes in drug benefit design. The regression equation included all covariates selected in the data summary Table 5.6, Appendix. The estimation of coefficients and their implied values (the marginal effect) in dollar terms are also presented. For total healthcare expenditure, the estimates for changes in drug benefit design conditional on time effect (plan*year) and time effect are significant even below the 1% level, while for total out-of pocket expenditure the interaction term and time effect was not significant but the plan change is significant below 1% level. For total healthcare expenditure, in 2001 dollar terms, the plans with changes to health benefit design dependent on time (on average) spent about $1,532.32 less in 2001 than the plans without changes to health benefit design dependent on time. For total out-of-pocket expenditure, individuals with changes to health benefit design (on average) spent about $96.67 more in 2001 than individuals without changes to health benefit design. A possible explanation for this may be that changes in drug benefit design have shifted a larger burden of medical care to the patients, and thus they would have higher total out-of-pocket expenditure. However, the interaction term for plan change and time appears to be not significant because this is a one-year follow-up or short-term analysis that may not be able to detect the time effect on total out-of-pocket spending.

In the total healthcare expenditure model, gender, age and comorbidity score are significant below the 1% level. The comorbidity score indicates that the spending in the plan increases significantly for diabetic patients with comorbidities , i.e. by a margin of $177.75 on average. However, the place of residence does not appear to have a significant effect on plans'

spending. It may be that diabetes is indiscriminate in its effect and is a chronic illness that requires medical attention, thus, incurring spending irrespective of the individual's level of income or residence. In terms of geographic location, individuals living in the south have a significant effect on total healthcare expenditure and those living in the west have an impact on total out-of-pocket expenditure models below the 5% level, that is, enrollees living in the south spent on average $556.36 less than those living in northeast and those living in the west spent $74.81 more than those living in the northeast, respectively.

Looking at the result from the total out-of-pocket regression model, as employers shift cost to the employees, older enrollees aged 45 to 62 are likely to reduce their spending on average than the younger enrollees, 18 to 44 year olds (age category of 18 – 34 is the omitted category). Income appears to be a significant predictor for total out-of-pocket expenditure but not for total healthcare expenditure. Similarly to the result in the total healthcare expenditure model, the Elixhauser comorbidity score is a significant predictor of overall out-of-pocket spending.

5.1.2 Individual Services Expenditure

The results in Table 5.2 and 5.3 show changes in benefit plan design conditional on time to be a significant predictor for all three models (drug, inpatient, outpatient services). Specifically, relative to the comparison group's spending in drug, inpatient and outpatient services, the intervention group is more likely to decrease spending on average by $160.46, 4949.64 and $364.41, respectively. To a certain extent, geographical location appears to be a significant predictor for inpatient (i.e. south) but not for drug spending and outpatient services spending. Again, the comorbidity score is a significant predictor for increased spending in all three services below 1% level.

The parameter estimates from the total drug spending equation indicate that gender and age have significant impact on total drug spending increase. For example, female patients spent $374.47 more on average than male patients and older patients have higher drug spending on average than younger patients, i.e. 18-34. However, in the total outpatient spending regression model, only enrollees in the middle age group or older have a significant impact on spending. These age groups are likely to decrease spending on average as their employers increasingly shift cost to them. Some studies have suggested that shifting cost to the patients may lead to lower medication adherence which could further intensify the disease, thus, resulting in higher demand for inpatient services. However, the result from the total inpatient spending model shows no apparent implication of such relationship, which could be due to the fact that this is a short-term analysis (2000-2001) focusing on chronically ill patients with diabetes whose medications are considered as essential medications as discussed previously. In the regression model for total outpatient spending, whether a patient is a female from any income level living in the urban area or not appears to have no significant impact on total outpatient expenditure. While in the total inpatient spending model, whether a patient is a female from any age group and in any income level appears to have no significant impact on total inpatient expenditure.

5.1.3 Individual Services Out-of-Pocket Expenditure

In the models for out-of-pocket expenditure for each service, the main variable of interest, changes in drug benefit plan, has a significant effect on only drug and inpatient out-of-pocket spending, not out-of-pocket spending for outpatient services. However, the interaction term indicates a significant effect on drug and outpatient services out-of-pocket spending but not on inpatient services out-of-pocket spending. Table 5.4 and 5.5 display the parameter estimates for all three response variables. I assume that the changes in drug benefit design were imposed

by the employers to shift cost to the employees as part of their cost cutting strategy. Therefore, the estimate for the main variable of interest in the drug model show that patients undergoing changes in their drug benefit design are now faced with a higher cost so they are expected to have higher out-of-pocket drug spending on average by $79.36 relative to the comparison group. The effect of time on changes in plan shows that the out-of-pocket drug spending was associated with an increase but by a smaller amount ($15.64). The outpatient model indicates that changes in drug benefit plan conditional on time appear to be a significant predictor but the effect is relatively small.

Although comorbidity score continues to be a significant predictor for inpatient and outpatient out-of-pocket spending, not drug, its effect on spending is small. Except for outpatient, both drug and inpatient out-of-pocket spending models show that out-of-pocket spending increased but varied by geographic location. In the drug out-of-pocket spending, female diabetics and middle age diabetics are likely to decrease their drug out-of-pocket spending because they are faced with a higher price for prescription drugs, although the effect is relatively small. As noted in the literature review, given that outlays for prescription drugs account for a smaller fraction of income for the working-age insured than for the elderly or uninsured, it is possible that this income factor drives the elderly to be more price-sensitive. However, elderly individuals may have a greater underlying preference for drug therapy because they view prescription drugs as necessary and believe that fewer substitutes exist for drug therapy, e.g., diet and lifestyle modifications may have less impact late in life, and thus, they may become less price-sensitive. In the analysis of out-of-pocket spending for outpatient services, only gender and ages 45 and over have a significant effect, whereby female patient are

likely to increase out-of-pocket spending while older patients are likely to reduce out-of-pocket spending for outpatient services

5.2 Discussion and Conclusion

The main purpose of this empirical analysis is to gain insights into the health care spending behavior of a chronically ill population diagnosed with diabetes by analyzing changes in drug benefit design imposed by employers, all things considered. Without pinpointing a particular aspect and doing a complex analysis, the database is allowed to speak for itself. The observations made from the data are interesting and have notable findings. However, caution should be taken when interpreting the results because I imposed the assumption that changes in drug benefit plans are due to the action of the employers as part of their cost shifting strategy and no other assumptions are made regarding to the details of the pre-changed and post-changed drug benefit plans. No special statistical tests were conducted to make inferences about the differences because the changes were fairly substantial and obvious.

The analysis shows that changes in drug benefit design decreased spending compared with spending in a comparison group across a diverse variety of benefit types and benefit changes; conversely, decreasing copayment level increased the spending. For instance, total health care spending for diabetes care in the intervention group decreased on average by $1,532.32 relative to the comparison group during the study period from 2000 to 2001; at the same time, drug out-of-pocket spending has increased on average by $160.46 .

Previous studies on the relationship between incentive formularies or cost shifting or greater cost-sharing and overall drug spending have produced various results (Hillman, Pauly et al. 1999; Motheral and Fairman 2001; Joyce, Escarce et al. 2002; Fairman, Motheral et al. 2003; Gibson, McLaughlin et al. 2005; Gibson, Ozminkowski et al. 2005). A study by Joyce and

colleagues (2002) analyzed cross-sectional differences in prescription drug spending in a sample of 25 firms with a variety of different pharmaceutical benefit arrangements. They found that enrollees in 3-tiered plans had lower total prescription drug spending and that such plans shifted cost from the insurer to the enrollee which is similar to my findings. Unlike my study, they included specific details about the plan types and they estimate predicted spending in 2- or 3-tier plans with substantially higher copayments (eg,$10/$20 or $10/$20/$30) to be more than 30% less than spending in a 1-tier plan with a low copayment ($5). Moreover, they found that the absolute amount of out-of-pocket spending did not vary significantly according to benefit type, but that the share of total spending to the patient increased; and, Joyce et al inferred changes in spending, rather than followed changes in the population, based on cross-sectional analyses.

Another related study by Motheral and Fairman (2001) examined effects of switching from a 2-tier to a 3-tier benefit compared with a control population that did not switch benefits. This is similar to my study where I have an intervention group with changes in drug benefit designs and comparison group without changes in drug benefit design. They found a 7% decrease in overall expenditures. Similarly, Gibson and colleagues (2005), using data from the mid-990s, analyzed the effect of an increase in copayments at a single firm compared with a control firm and found that utilization decreased by approximately 10%, but seemed to moderate with time.

The result in my study is therefore consistent with findings from existing literature in showing a symmetric result of decreased spending associated with an increase in copayments, thus, lending more weight to my findings. As previously discussed, there are potential risks to the health of the patients with greater cost sharing. A considerable number of studies have suggested that incentive formularies are associated with increased discontinuation rates and

decreased consistency of use, which raises health concerns, especially in the chronically ill population whose medications are essential (Huskamp, Deverka et al. 2003; Landsman, Yu et al. 2005). However, the direction and overall magnitude of this effect are not clear. The prior literature on substitution effects is mixed and other studies observed no change in generic fill rates (Leibowitz, Manning et al. 1985; Motheral and Fairman 2001).

This study is subject to several limitations. First, I assumed that changes in drug benefit design are imposed by the employers as a way for them to shift cost to the employees, thus, reducing the overall spending in the benefit plan while increasing the employees' out-of-pocket spending for drug. I focused on individuals aged 18 to 62 enrolled in large-employer sponsored health insurance plans. Therefore, these results may not generalize to the elderly, the poor, or the uninsured individuals. Second, my study was limited to a single year of follow-up after the introduction of the new pharmacy benefit. Further analyses are needed to address the long-run effect and the dynamic relationship of health benefits and patients' health outcome in chronically ill population, particularly diabetes. Third, this analysis did not adjust for clustering within employer group. That was because I was most interested in differences between comparison groups, with no change in drug benefit designs, from the intervention group with changes in drug benefit designs.

CHAPTER 6

SUMMARY OF STUDY AND FINDINGS

Both direct and indirect costs of the treatment and management of diabetes are known to be sizable. According to a November, 2010 report released, by UnitedHealth Group Inc, one of the nation's largest health insurers, it says that it will have a lot more health costs to pay in coming years because of diabetes (UnitedHealth, The United States of Diabetes 2010). The study predicted that the majority of Americans could have diabetes or pre-diabetes by 2020, at a cost of $3.35 trillion to the health care system over the next 10 years. Also, it reported that within 10 years, the disease will account for about a tenth of total health care spending, at an annual cost of $500 billion, up from an estimated $194 billion this year. In the report, UnitedHealth notably calls for more medication and care compliance programs, citing the Diabetes Control Program it conducts with community pharmacists as an example.

Thus, economic issues are becoming more important to consider in today's health care environment. Studies at a detailed disease level such as this study could provide useful guidance to the optimal design of prescription drug insurance benefits because increasing cost sharing to the patients is not always a benign instrument, and at times, it may come at a price. Although the empirical findings are not consistent in the current literature, some studies indicated that higher levels of cost sharing are associated with treatment disruption for chronically ill patients who depend on a regular regimen of prescription drugs. Moreover, higher levels of cost sharing can have significant effects on the use of essential medications, the outcomes of care, and the process of care.

6.1 Study Design and Organization of the Analysis

This study uses a retrospective research design with observational historical data. In order to ensure precision and reduce the potential for heterogeneity, it uses only specific group of patients with a specific condition. The subjects are individuals enrolled in large employer-sponsored health insurance plans ages 18 to 62 who were diagnosed with diabetes from 2000 to 2001. Specifically, this study seeks to measure the association between changes in drug benefit design and health care spending in a population diagnosed with diabetes. The effect of changes in drug benefit design is found as a consequence of employers cost shifting strategy on health care expenditures.

The analysis of this study relies on the assumption that changes in spending are caused by changes in the drug benefit plan resulting from the action of employers as they seek different ways to cut cost. Although there are no details provided regarding the different drug benefit types, this study provides a general sense of how shifting cost to employees by raising the copayment levels could have a significant impact on the overall spending in the insurance plans and on the patients even in a chronically ill population in the short-term, i.e. one year. Also, this study has shed some light on drug benefit design as a predictor of drug spending and overall expenditure to the employers and insurers even in chronically ill patients who depend on a regular regimen of prescription drugs.

6.2 Major Findings

All estimated costs are in 2001 dollars and costs, measured by expenditure or spending in the plans and patients, are all related to diabetes care, management or treatment. Growth of expenditures by changes in drug benefit design was estimated for the intervention group relative to the comparison group who did not have changes to the plan. The average follow-up year incremental out-of-pocket spending for drug following the changes in drug benefit design for an individual in the intervention group was $15.64. The overall effect on total healthcare expenditure was a reduction of $1,532.32 on average in the intervention group relative to the comparison group.

The findings suggest that the decrease in total health care expenditure borne mostly by the employers and insurers is explained by changes in drug benefit plan design during the study period from 2000 to 2001. Thus, higher levels of cost sharing transfer a large financial burden to the patient. All things considered, if all changes in healthcare spending are broadly defined as changes in drug benefit design imposed by the employers, then such changes are effective in managing the demand side of healthcare cost even in a chronically ill population who depends on regular drug therapy. However, these findings raise concern that cost shifting could lead to adverse health consequences, especially for chronically ill population, although existing literatures are inconclusive regarding to this issue.

There are several limitations in this dissertation. The major limitation of this study is the study population. Since the sample was drawn from an insured working-age population, the findings are not necessarily generalizable to other populations such as the poor or the elderly or the uninsured. Another limitation is that it does not include detail information on types of drug benefit design, which could affect the size of the estimates. Last but not least, this dissertation

does not address the health effect of a cost shifting from employers to employees, although other studies have demonstrated adverse outcomes associated with a change in cost sharing (Tamblyn et al. 2001).

CHAPTER 7

CONCLUSION

This study is an attempt to measure the effect of changes in drug benefit design on health care spending in a population diagnosed with diabetes in the United States. This is an important area of research for both economics reasons and health outcomes for the nation, especially with the projected number of Americans expecting to have diabetes or pre-diabetes in the next decade. In this analysis, disease specific health care costs are calculated as the marginal price resulting from changes in drug benefit design. Within its own limitations, this study makes important contributions to this field of knowledge. The findings indicated that changes in drug benefits have shifted a larger financial burden of pharmacy costs onto patients. The conclusions from this study are drawn only from the information of a specific segment of the general population. Diabetes is a major condition affecting all ages, income levels, races/ethnic groups, males or females, and geographical locations. In other words, it is indiscriminate in its effect, thus, it has been given a high focus in care and management.

Over the years, insurer and employers have explored different aspect of insurance to induce people to behavior in a certain manner or consume certain amount or type of care. As shown by the findings from the RAND study, when people have to pay for more of their care out of their own pockets, they use fewer medical services and that type of services matters. For instance, demand for inpatient and outpatient care was the least elastic, whereas use of dental and mental health services was most responsive to changes in copayment. More studies are indicating that demand for prescription drugs is elastic as well. Beneficiaries have responded by reducing their use of drugs, but their responses varies substantially among the top-selling therapeutic classes.

These findings raise concern that copayment increases could lead to adverse health consequences because of the large price effects, at least for individuals with chronic conditions such as diabetes. A significant decrease in health care expenditure in diabetes care may or may not be worth it for the increased risk of patients foregoing drug therapy, hence, intensifying the conditions to the point of increased use of inpatient services, which could be more costly down the road for all parties involved. These results definitely make benefit design an important public health tool for improving the health of the population. However, to use this tool effectively, public and private plans must educate patients appropriately to become more sensitive to the cost of treatment without encouraging them to forego cost-effective care.

7.1 Direction for Future Research

Although cost sharing was originally intended to curb insurance-related overuse, a "one-size fits all" approach could exacerbate the health outcomes of many patients, particularly those who are chronically ill and depend on regular regimen of prescription drugs. Many employers and insurers are turning to prescription drug cost sharing as an effective means to control prescription drug costs among employer-based and publicly funded health plans. However, there is growing evidence from existing literature on the unintended effects on the process and outcomes of therapy resulting from cost sharing or cost shifting. Further research is warranted to understand the full effects on costs of increased drug copayments by examining medical spending as well as describing more completely the potential impacts on health, particularly in the chronically ill population, i.e. diabetes. These unintended consequences call to question the equity and fairness of such strategy—cost sharing or cost shifting. Therefore, the key question that employers, insurers, health policy makers and patients must address is whether the current

cost sharing practice is the optimal strategy to cut healthcare cost, or it needs to be modified to balance between reducing healthcare cost and the unintended consequences.

Appendix

Table 2.1 Classes and Actions of Medications

Class	Generic Name	Brand Name	Comments	How
Sulfonylureas	Chlorpropamide	Diabinese	Use with caution in the elderly. May cause lows	With meal
	first-generation			
	Tolazamide	Tolinase	May cause lows	With meal
	first-generation			
	Glyburide	Micronase	Take 1 to 2 times a day.	With meal
	second-	Diabeta	May cause lows	
	generation	Glynase Pres Tab		
	Glipizide	Glucotrol	Take 2 times a day or once with (XL).May cause lows	30 minutes before a meal
	second-	Glucotrol XL		
	generation			
	Glimepiride	Amaryl	Take 1 time a day. May cause lows	With meal
	third-generation			
Biguanides	Metformin	Glucophage	Not used with congestive heart, renal or liver problems. Check creatinine clearance if over 65 years of age.	With meal
Alpha-Glucosidase	Acarbose	Precose	May have side effects in the gastrointestinal	With first bite of food
	Miglitol	Glyset	tract.	
Thiazolidinediones	Rosiglitazone	Avandia	May reduce effectiveness of birth control pills.	Take at same time each day
	Pioglitazone	Actos	Check liver enzymes as directed.	
Meglitinides	Repaglinide	Prandin	Take with each meal. May cause lows	Before meals

Source: Diabetesnet.com Diabetes Medications. Available from http://www.diabetesnet.com/about-diabetes/diabetes-medications

Table 3.4 Elixhauser Comorbidity Measures

Definitions of Comorbidities	ICD9 CM Diagnosis Codes	V28 DRGs
1. Congestive Heart Failure	398.91, 402.01, 402.11, 402.91, 404.01, 404.03, 404.11, 404.13, 404.91, 404.93, 428.0-428.9	Cardiac: 001-002, 215-238, 242-251, 253-254, 258-262, 265, 280-293, 296-298, 302-303, 306-313
2. Valvular disease	093.20-093.24, 394.0-397.1, 397.9, 424.0-424.99, 746.3-746.6, V42.2, V43.4	Cardiac: 001-002, 215-238, 242-251, 253-254, 258-262, 265, 280-293, 296-298, 302-303, 306-313
3. Pulmonary Circulation disorders	415.11-415.19, 416.0-416.9, 417.9	Cardiac: 001-002, 215-238, 242-251, 253-254, 258-262, 265, 280-293, 296-298, 302-303, 306-313 or COPD asthma 190-192, 202-203
4. Peripheral vascular disease	440-440.9, 441.00-441.9, 442.0-442.9, 443.1-443.9, 444.21-444.22, 447.1,449, 557.1, 557.9, V43.5	Peripheral vascular: 299-301
5. Hypertension (combine uncomplicated and complicated)	Hypertension, uncomplicated: 401.1, 401.9, 642.00-642.04	Hypertension: 077-079, 304-305
	Hypertension, complicated: 401.0, 402.00-405.99, 437.2, 642.10-642.24, 642.70-642.94	Cardiac: 001-002, 215-238, 242-251, 253-254, 258-262, 280-293, 296-298, 302-303, 306-313 or Renal: 652, 656-661, 673-675, 682-700 or Hypertension: 077-079, 304-305
6. Paralysis	342.0-344.9, 438.20-438.53, 780.72	Cerebrovascular: 020-022, 034-038, 064-072
7. Other neurological disorders	330.1-331.9, 332.0, 333.5, 333.5, 333.71-333.79, 333.85, 333.94, 334.0-335.9, 338.0, 340, 341.1-341.9, 345.00-345.11, 345.2-345.3, 345.40-345.91, 347.00-347.01, 347.10-347.11, 649.40-649.44, 768.7, 768.70, 768.71, 768.72, 768.73, 780.3, 780.31, 780.32, 780.39, 780.97, 784.3	Nervous system: 020-042, 052-103
Changes from 3.5 to 3.6	***Added 780.33***	
8. Chronic pulmonary disease	490-492.8, 493.00-493.92, 494-494.1, 495.0-505, 506.4,	COPD asthma: 190-192, 202-203
9. Diabetes without chronic complications	249.00-249.31 250.00-250.33, 648.00-648.04	Diabetes: 637-639
10. Diabetes with chronic complications	249.40-249.91 250.40-250.93, 775.1	
11. Hypothyroidism	243-244.2, 244.8, 244.9	Thyroid endocrine: 625-627, 643-645
12. Renal failure	403.01, 403.11, 403.91, 404.02, 404.03, 404.12, 404.13, 404.92, 404.93, 585.3, 585.4, 585.5, 585.6, 585.9, 586, V42.0, V45.1, V45.11, V45.12, V56.0-V56.32, V56.8	Kidney transplant, Renal failure/dialysis: 652, 682-685
13. Liver disease	070.22, 070.23, 070.33, 070.44, 070.54, 456.0, 456.1, 456.20, 456.21, 571.0, 571.2, 571.3, 571.40-571.49, 571.5, 571.6, 571.8, 571.9, 572.3, 572.8, V42.7	Liver: 420-425, 432-434, 441-446
14. Chronic Peptic ulcer disease (includes bleeding only if obstruction is also present)	531.41, 531.51, 531.61, 531.70, 531.71, 531.91, 532.41, 532.51, 532.61, 532.70, 532.71, 532.91, 533.51, 533.51, 533.61, 533.70, 533.71, 533.91, 534.41, 534.51, 534.61, 534.70, 534.71, 534.91	GI Hemorrhage or ulcer: 377-384
15. HIV and AIDS (Acquired immune deficiency syndrome)	042-044.9	HIV: 969-970, 974-977
16. Lymphoma	200.00-202.38, 202.50-203.01, 203.02-203.82, 203.8-203.81, 238.6, 273.4	Leukemia/lymphoma: 820-830, 834-849
17. Metastatic cancer	196.0-199.1, 789.51, 209.70, 209.71, 209.72, 209.73, 209.74, 209.75, 209.79, 789.51	Cancer, Lymphoma: 054, 055, 146-148, 180-182, 374-376, 435-437, 542-544, 582-583, 597-599, 656-658, 686-688, 715-716, 722-724, 736-741, 754-756, 826-830, 843-849
18. Solid tumor without metastasis	140.0-172.9, 174.0-175.9, 179-195.8, 209.00-209.24, 209.25-209.3, 209.31,	Cancer, Lymphoma: 054, 055, 146-148, 180-182, 374-376, 435-

Definitions of Comorbidities	ICD9 CM Diagnosis Codes	V28 DRGs
	209.32, 209.33, 209.34, 209.35, 209.36, 258.01-258.03	437, 542-544, 582-583, 597-599, 656-658, 686-688, 715-716, 722-724, 736-741, 754-756, 826-830, 843-849
19. Rheumatoid arthritis/collagen vascular diseases	701.0, 710.0-710.9, 714.0-714.9, 720.0-720.9, 725	Connective tissue: 545-547
20. Coagulation deficiency	286.0-286.9, 287.1, 287.3-287.5, 289.84, 649.30-649.34	Coagulation disorders: 813
21. Obesity	278.0, 278.00, 278.01, 649.10-649.14, 793.91, V85.30-V85.4, V85.54	
Changes from 3.5 to 3.6	***Added 278.03, V85.41-V85.45***	
22. Weight loss	260-263.9, 783.21, 783.22	Nutrition/metabolic: 640-641
23. Fluid and electrolyte disorders	276.0-276.9	Nutrition/metabolic: 640-641
24. Blood loss anemia	280.0, 648.20-648.24	Anemia: 808-812
25. Deficiency anemias	280.1-280.9, 285.21-285.29, 285.9	Anemia: 808-812
26. Alcohol abuse	291.0-291.3, 291.5, 291.8, 291.81, 281.82, 291.89, 291.9, 303.00-303.93, 305.00-305.03	Alcohol or drug: 894-897
27. Drug abuse	292.0, 292.82-292.89, 292.9, 304.00-304.93, 305.20-305.93, 648.30-648.34	Alcohol or drug: 894-897
28. Psychoses	295.00-298.9, 299.10, 299.11	Psychoses: 885
29. Depression	300.4, 301.12, 309.00, 309.1, 311	Depressive neurosis: 881
Comments: The following DRGs had been deleted prior to 2007 and renumbered to a different DRG; they did not have a corresponding V25 MSDRG value, but the renumbered DRGs were included in the 2007 update and has been represented by the equivalent v25 MSDRGs: 004-005, 020, 024-025, 107, 109, 112, 115,-116, 298, 363, 400, 414, 434-437, 514, 516-517, 522, 526-527		

The original table appeared in the paper by Elixhauser et al (1998). This table has been updated to reflect the ICD-9-CM and DRG/MS-DRG updates in the software.

Source: Healthcare Cost and Utilization Project (HCUP).
http://www.hcup-us.ahrq.gov/toolssoftware/comorbidity/comorbidity.jsp

Table 3.6 Annual total Expenditures on Pharmaceutical, Outpatient Services and Inpatient Services, By Selected Characteristics of Patients with Diabetes

	Intervention Group		Comparison Group	
	N=2,447		N=810	
Personal Characteristics	**Pre-Change**	**Post-Change**	**Pre-Change**	**Post-Change**
Expenditure (Mean (SD)) $				
Total Healthcare	4456.34 (6345.07)	4827.03 (6451.19)	4220.47 (4011.81)	6573.15 (11039.91)
Total Rx	2937.34 (2943.91)	3234.34 (3090.43)	3187.62 (3101.99)	3694.41 (3584.14)
Total Inpatient	655.34 (4512.11)	771.90 (4740.55)	172.38 (91344.60)	1559.45 (9108.52)
Total Outpatient	864.78 (2143.31)	821.91 (1683.41)	860.47 (1551.70)	1319.29 (2024.89)
Total Out-of-Pocket	201.80 (241.11)	227.05 (243.57)	106.51 (139.96)	114.97 (139.97)
Age (No. (%))				
18-34	244 (9.97)		115 (14.20)	
35-44	495 (20.23)		124 (15.31)	
45-54	871 (35.59)		392 (4840)	
55-62	837 (34.21)		179 (22.10)	
Sex				
Male	1387 (56.68)		477 (58.89)	
Female	1060 (43.32)		333 (41.11)	

Plan Type				
Comprehensive	133 (5.44)	126 (5.14)	810 (100.00)	810 (100.00)
HMO	121 (4.94)	121 (494)		
PPO	290 (11.85)	290 (11.84)		
POS	515 (21.05)	515 (21.02)		
POS Capitated	1388 (56.72)	1398 (57.06)		
Comorbidity Score (Mean (SD))	1.56 (4.27)	1.21 (3.38)	0.07 (0.52)	0.15 (0.68)
Region				
Northeast	637 (26.03)		1 (0.12)	
North Central	639 (26.11)		805 (99.38)	
South	960 (39.23)		3 (0.37)	
West	211 (8.62)		1 (0.12)	
Residence				
Urban	2412 (98.57)		786 (97.04)	
Rural	35 (1.43)		24 (2.96)	
Income (Mean(SD))	30872.22 (7507.22)		29223.99 (7950.03)	

Abbreviations: HMO, health maintenance organization; POS, point of service; PPO, preferred provider organization. *The sample consists of 3257 patients with diabetes (based on pharmaceutical claims) enrolled in drug plans. Data are from the 2000 and 2001 Market Scan Research Database (MEDSTAT, Ann Arbor, MI).

Table 5.1 This is the **Full Regression Model**:
Total Healthcare and Total Out-of-Pocket (OOP) Expenditure

Explanatory Variables	Log Total Healthcare Expenditure (DV)	ME ($) Total Healthcare Expenditure	Log Total OOP Expenditure (DV)	ME ($) Total OOP Expenditure
Plan	0.02	99.71	0.62***	96.67***
	(0.07)	(303.50)	(0.06)	(8.05)
Year	0.43***	2022.91***	0.07	12.63
	(0.05)	(242.81)	(0.04)	(7.61)
Plan*Year	-0.34***	-1532.32***	0.06	11.69
	(0.05)	(245.18)	(0.05)	(8.82)
Female	0.13***	627.00***	0.04	7.36
	(0.04)	(184.88)	(0.03)	(6.10)
Age (35-44)	0.36***	1865.53***	-0.08	-13.84
	(0.08)	(466.57)	(0.06)	(10.30)
Age (45-54)	0.35***	1713.66***	-0.18**	-31.06***
	(0.06)	(307.51)	(0.05)	(9.35)
Age (55-62)	0.49***	2547.07***	-0.21***	-36.91***
	(0.06)	(353.32)	(0.05)	(9.11)
Income	0.00	0.00	0.00*	0.00*
	(0.00)	(0.01)	(0.00)	(0.00)
Urban	0.13	559.07	0.07	11.61
	(0.09)	(354.83)	(0.16)	(26.52)
Comorbidity	0.04***	177.75***	0.03***	4.93***
	(0.00)	(19.81)	(0.00)	(0.75)
North Central	0.04	200.57	0.09	16.62
	(0.07)	(324.93)	(0.05)	(9.00)
South	-0.12*	-556.36*	0.03	4.85
	(0.05)	(243.43)	(0.05)	(8.33)
West	-0.00	-8.70	0.36***	74.81***
	(0.09)	(436.63)	(0.08)	(20.78)
_cons	7.76***		4.45***	
	(0.15)		(0.19)	

N=3257

Note: Dependent variable (DV); marginal effects (ME); Standard errors (SE) in parentheses; age category reference (18-34); region category reference (northeast). * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Table 5.2 This is the **Model for Individual Service Expenditure**:
Pharmaceutical Services and Inpatient Services

Explanatory Variable	Log Pharmaceutical Services (DV)	ME ($) Pharmaceutical Services	Log Inpatient Services (DV)	ME ($) Inpatient Services
Plan	-0.10	-311.24	1.41***	545.24***
	(0.05)	(175.64)	(0.35)	(117.69)
Year	0.15***	475.78***	2.24***	1396.56***
	(0.02)	(56.61)	(0.30)	(270.54)
Plan*Year	-0.05*	-160.46*	-2.07***	-969.64***
	(0.02)	(63.86)	(0.34)	(184.35)
Female	0.12***	374.47***	0.18	93.02
	(0.03)	(102.32)	(0.17)	(86.71)
Age (35-44)	0.47***	1672.16***	0.42	243.42
	(0.06)	(263.78)	(0.30)	(201.21)
Age (45-54)	0.63***	2135.61***	-0.01	-6.90
	(0.05)	(190.43)	(0.25)	(128.65)
Age (55-62)	0.76***	2773.08***	0.46	259.31
	(0.05)	(226.29)	(0.27)	(167.73)
Income	-0.00	-0.00	0.00	0.01
	(0.00)	(0.01)	(0.00)	(0.01)
Urban	-0.00	-3.89	1.13	352.00**
	(0.09)	(268.25)	(0.64)	(114.14)
Comorbidity	0.01***	22.15***	0.21***	107.74***
	(0.00)	(6.37)	(0.01)	(9.79)
North Central	-0.02	-50.63	0.26	134.03
	(0.06)	(173.76)	(0.28)	(150.16)
South	-0.08	-238.29	-0.55*	-251.71*
	(0.04)	(130.41)	(0.25)	(108.15)
West	-0.09	-252.79	0.26	151.16
	(0.07)	(191.66)	(0.39)	(252.54)
_cons	7.48***		2.80***	
	(0.14)		(0.82)	

N=3257

Note: Dependent variable (DV); marginal effects (ME); Standard errors (SE) in parentheses; age category reference (18-34); region category reference (northeast). * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Table 5.3 This is the **Model for Individual Service Expenditure**:
Outpatient Services

Explanatory Variable	Log Outpatient Services (DV)	ME ($) Outpatient Services
Plan	-0.00	-2.74
	(0.10)	(86.08)
Year	0.43***	373.69***
	(0.06)	(57.39)
Plan*Year	-0.45***	-364.41***
	(0.08)	(64.99)
Female	0.09	74.88
	(0.06)	(52.11)
Age (35-44)	-0.07	-62.59
	(0.09)	(74.22)
Age (45-54)	-0.30**	-249.77***
	(0.09)	(72.41)
Age (55-62)	-0.30***	-243.92***
	(0.09)	(68.91)
Income	-0.00	-0.00
	(0.00)	(0.00)
Urban	0.08	63.66
	(0.20)	(158.46)
Comorbidity	0.05***	46.28***
	(0.01)	(8.27)
North Central	0.18	156.82
	(0.09)	(82.90)
South	0.08	73.98
	(0.10)	(86.23)
West	-0.01	-10.31
	(0.14)	(114.57)
_cons	6.73***	
	(0.26)	

N=3257

Note: Dependent variable (DV); marginal effects (ME); Standard errors (SE) in parentheses; age category reference (18-34); region category reference (northeast). * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Table 5.4 This is the **Model for Out-of-Pocket (OOP) Expenditure**s:
Pharmaceutical Services and Inpatient Services

Explanatory Variable	Log OOP Pharmaceutical Services (DV)	ME ($) OOP Pharmaceutical Services	Log OOP Inpatient Services (DV)	ME ($) OOP Inpatient Services
Plan	1.36***	79.36***	1.95***	11.23***
	(0.04)	(2.07)	(0.27)	(1.99)
Year	0.05*	3.47*	0.18	1.45
	(0.02)	(1.46)	(0.17)	(1.38)
Plan*Year	0.20***	15.64***	0.23	1.89
	(0.02)	(1.84)	(0.28)	(2.33)
Female	-0.06**	-4.67**	0.05	0.42
	(0.02)	(1.78)	(0.19)	(1.57)
Age (35-44)	-0.07	-5.40	0.01	0.04
	(0.04)	(3.20)	(0.38)	(3.05)
Age (45-54)	-0.09*	-7.00*	0.13	1.07
	(0.04)	(2.90)	(0.35)	(2.88)
Age (55-62)	-0.19***	-14.19***	0.23	1.98
	(0.04)	(2.82)	(0.36)	(3.18)
Income	0.00***	0.00***	0.00	0.00
	(0.00)	(0.00)	(0.00)	(0.00)
Urban	0.18*	12.67*	-0.04	-0.32
	(0.08)	(5.25)	(0.56)	(4.68)
Comorbidity	-0.00	-0.15	0.24***	1.90***
	(0.00)	(0.21)	(0.01)	(0.19)
North Central	0.04	3.39	0.30	2.44
	(0.04)	(2.83)	(0.34)	(2.92)
South	0.07*	5.78*	0.41	3.64
	(0.03)	(2.60)	(0.34)	(3.30)
West	0.14**	10.98**	1.76***	34.52*
	(0.05)	(4.18)	(0.44)	(17.52)
_cons	2.97***		-1.09	
	(0.10)		(0.88)	

N=3257

Note: Dependent variable (DV); marginal effects (ME); Standard errors (SE) in parentheses; age category reference (18-34); region category reference (northeast). * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Table 5.5 This is the **Model for Out-of-Pocket (OOP) Expenditures***:*
Outpatient Services

Explanatory Variable	Log OOP Outpatient Services (DV)	ME ($) OOP Outpatient Services
Plan	0.10	8.15
	(0.09)	(6.70)
Year	0.08	6.33
	(0.05)	(4.46)
Plan*Year	-0.14*	-11.48*
	(0.06)	(5.07)
Female	0.12*	9.77*
	(0.05)	(4.06)
Age (35-44)	-0.10	-7.83
	(0.10)	(7.38)
Age (45-54)	-0.26**	-21.03**
	(0.08)	(6.55)
Age (55-62)	-0.28**	-21.65***
	(0.09)	(6.41)
Income	-0.00	-0.00
	(0.00)	(0.00)
Urban	0.03	2.40
	(0.20)	(15.60)
Comorbidity	0.04***	3.17***
	(0.00)	(0.35)
North Central	0.09	7.54
	(0.08)	(6.62)
South	-0.10	-8.38
	(0.07)	(5.63)
West	0.17	15.47
	(0.11)	(10.48)
_cons	4.44***	
	(0.24)	

N=3257

Note: Dependent variable (DV); marginal effects (ME); Standard errors (SE) in parentheses; age category reference (18-34); region category reference (northeast). * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Table 5.6 Variable Summary

Variable Name	Variable Definition
Response Variable	
Total Healthcare Expenditure	Sum of employer and patient's payment for drug, inpatient and outpatient services
Total Out-of-pocket Expenditure	Sum of patient's copay and deductible for drug, inpatient and outpatient services
Pharmaceutical Service Expenditure	Sum of employer & patient's payment for pharmaceutical services
Inpatient Service Expenditure	Sum of employer & patient's payment for inpatient services
Outpatient Service Expenditure	Sum of employer & patient's payment for outpatient services
Out-of-pocket Pharmaceutical Expenditure	Patient's copay and deductible for pharmaceutical services
Out-of-pocket Inpatient Expenditure	Patient's copay and deductible for inpatient services
Out-of-pocket Outpatient Expenditure	Patient's copay and deductible for outpatient services
Explanatory Variables	
Plan	Indicator for change in drug benefit plan (1=intervention group; 0=comparison group)
Gender	Male* = 0 Female = 1
Age0*	18-34
Age1	35-44
Age2	45-55
Age3	55-64
Income	Indicator for income (continuous variable)

Urban	Rural* = 0 Urban = 1
Region0*	Northeast Region
Region1	North Central Region
Region2	South Region
Region3	West Region
Comorbidity Score	Elixhauser comorbidity score used in the regression model to control for comorbid effect

* indicates that it was used as the reference group in the regression model.

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ABSTRACT

THE EFFECT OF CHANGES IN DRUG BENEFIT DESIGN AMONG INDIVIDUALS WITH DIABETES IN LARGE EMPLOYER-SPONSORED INSURANCE PLANS

by

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With spending for prescription drugs rising so rapidly, employers and insurers are seeking different cost-cutting strategies to stem this tide. Given that prescription drugs have become an indispensable means to treat and manage chronic illnesses, the issues of affordability and trade-offs between medications and other health care services are important for chronically ill patients, particularly for patients with diabetes who typically have more than one comorbidity that require drug therapy, and their health insurance plans. In this dissertation, I analyze the effect of prescription drug cost-shifting via changes in drug benefit design on healthcare expenditure among individuals with diabetes; I take into account the comorbid effect of diabetes for the age population ranging from 18 to 62.

Study design, data and organization of the report:

This study uses a retrospective research design with observational historical data from the MarketScan Research Database from 2000 to 2001. The subjects are individuals enrolled in large employer-sponsored health insurance plans aged 18 to 62 who were diagnosed with diabetes from 2000 to 2001. The analysis of this study relies on the assumption that changes in spending are caused by changes in the drug benefit plan resulting from the action of employers

as they seek different ways to cut cost. Regression using GEE estimation technique was used for the analysis.

Major findings and conclusions:

The overall effect on total healthcare expenditure was a decrease of $1,532.32 on average in the intervention group relative to the comparison group. The average follow-up year incremental out-of-pocket spending for drug following the changes in drug benefit design for an individual in the intervention group was $15.64. Changes in benefit plan design continue to be a significant predictor for drug spending only. Specifically, relative to the comparison group's drug spending, the intervention group is more likely to decrease spending on average by $160.45 for drug services. To a certain extent, geographic region appears to be a significant predictor for inpatient (i.e. south) but not for drug spending and outpatient services spending. The comorbidity score is a significant predictor for increased spending in all three services and total healthcare expenditure and total out-of-pocket expenditure below 1% level. In the models for out-of-pocket expenditure for each service, the plan change conditional on time has a significant effect on only drug and outpatient services out-of-pocket spending, not on inpatient services.

The findings suggest that the decrease in total health care expenditure borne mostly by the employers and insurers is explained by changes in drug benefit plan design during the study period from 2000 to 2001. Thus, higher levels of cost sharing transfer a large financial burden to the patient. All things considered, if all changes in healthcare spending are broadly defined as changes in drug benefit design imposed by the employers, then such changes are effective in managing the demand side of healthcare cost even in a chronically ill population who depends on regular drug therapy.

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