Does Cost-Sharing Affect Compliance? Insurance and the Market for Prescription Drugs

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ABSTRACT

Insurance for prescription drugs is characterized by two regimes: flat copayments and variable coinsurance. We develop a simple model to show that patient compliance is lower under coinsurance due to uncertainty in cost-sharing. Empirically, we derive comparable models for compliance behavior in the two regimes. Using claims data from nine large firms, we focus our analysis on diabetes, a common chronic condition that leads to severe complications when inappropriately treated. In the coinsurance model, an increase in the coinsurance rate from 20% to 75% resulted in the share of persons who never comply to increase by 9.9%, and reduced the share of fully compliant persons by 24.6%. In the copayment model, an increase in the copayment from $6 to $10 resulted in a 6.2% increase in the share of never-compliers, and a concomitant 9% reduction in the share of full compliers. Similar results hold when the level of cost-sharing is held constant across regimes. While non-compliance reduces expenditures on prescription drugs it may also lead to increases in indirect medical costs due to avertable complications. Using available aggregate estimates of the cost of diabetic complications, we calculate that the $6-$10 increase in copayment would have the direct effect of reducing national drug spending for diabetes by $125 million. However, the increase in non-compliance rates is expected to increase the rate of diabetic complications resulting in an additional $360 million in treatment costs. The results suggest that both private payers and public payers may be able to reduce overall medical costs by switching from coinsurance to copayments in prescription drug plans. JEL No. I11, L11

1 Introduction

Overall drug spending in the private sector grew approximately 15-20 percent per year during the 1990s (Thomas et al, 2002), and the Centers for Medicare and Medicaid Services project similar rates of growth through the next decade. In 2002, national expenditures on prescription drugs amounted to over $160 billion, with employer-sponsored insurance covering most of the bill (Woellert, 2002). Moreover, between 2006 and 2008 the federal government's share of the national spending on drugs is expected to increase from 22% to 40% due to the introduction of the Medicare Part D prescription drug benefit for the elderly (Frank, 2004). This benefit is expected to increase drug spending by 12% to 17% (Yang et al, 2004).

Driven by concerns over rising costs, Medicare, employers, and insurers are now designing pharmaceutical benefit plans to allow greater consumer cost sharing. Early evaluations of such plans suggest that increased cost sharing is indeed helping to bring about lower consumer spending on prescription drugs, and hence, lower employer costs. For example, Joyce et al (2002) have shown that a doubling of copayments decreased total spending on drugs from 19% to 33%. However, Haiden et al (2003) find little change in spending for some drugs classes aimed at chronic conditions (statins, ACE inhibitors, and proton-pump inhibitors) after copayment increases. Goldman et al (2004) show that this is due to the fact that chronically ill patients decrease utilization of their nonessential medications more so than their chronic care drugs when copayments are increased[1].

In most circumstances, economists would conclude that such developments are rational responses to market imperfections in the presence of insurance — increased patient cost sharing reduces moral hazard and excessive medical consumption, thereby improving social welfare (Pauly, 1974). Indeed, empirical research (spurred by the Rand Health Insurance Experiment) has shown that reasonable increases in copayments lead to reduced medical

[1]Similar patterns occur with copayments for outpatient services. Liang et al, (2004), show that the use of copayments discourage the use of controversial services, such as prostate cancer screening, but have no effect on recommended services like mammography screening for breast cancer.

expenditures in a variety of situations, with little adverse impact on health (Manning et al, 1987; Newhouse 1993).

However, the case of prescription drugs is more complex. Often drugs are associated with preventive efforts to reduce further illness and complications, and the patient might not share the doctor's clinical understanding of these long run benefits of drugs. In this case underutilization may be the problem, and 'too much' cost sharing may lead to a loss of welfare. In fact, underuse of drugs with respect to clinical guidelines has long been a problem even before the additional concerns of increased cost-sharing arose. In a study of three of the ten largest health plans in California in 1999, underuse of drugs was severe: only 27.5% of antidepressant users received the recommended 6 months of continuous therapy, only 48% of asthma patients received at least one inhaled corticosteroid drug, and only 54.5% of patient with congestive heart failure received an ACE inhibitor (Gilberg et al 2003). Similar underuse of beta blockers after a heart attack are well documented nationally (National Healthcare Quality Report, 2003). In half the states, 45% of patients with an irregular heart beat did not receive follow-up blood thinning drugs (warafin) to prevent a stroke (Leatherman and McCarthy, 2002).

In this paper, we will explore the degree to which cost-sharing can act as a barrier to preventive effort as measured by 'compliance'—the adherence to refilling of prescriptions of preventive care drugs without interruption. In particular, we will focus on the impact of cost-sharing on compliance with anti-diabetic medications. It should be noted that we are not merely interested in levels of copayments. Rather, we distinguish between two main insurance regimes, namely fixed copayments and variable coinsurance (i.e., percentage copayments). While economists have begun to explore the issue of the impact of cost-sharing on utilization (but not necessarily compliance)[2], this important distinction has not

[2]The issues explored in these studies are quite different than ours. For instance, Crown et al, (2003), focus on the role of physicians in asthma prescription behavior, while Ridley (2004) focuses on the role of promotional drug advertisements on demand. They find conflicting results with regard to the impact of copayments on utilization. Ellison et al (1997) consider full price effects rather than copayments, and find some evidence of positive cross-price elasticities for drug substitutions within the same therapeutic class.

been previously considered. In fact, since drug prices increase each year, many employers are moving from flat and tiered copayments to a coinsurance rate. This forces the patient to pay 30% of any cost increase, if the coinsurance rate is 30% for example, otherwise, under a flat copayment the employer will have to pay 100% of the cost increase. However, critics argue that coinsurance is more difficult for patients to understand and leads to greater variation and uncertainty in out-of-pocket expenses, causing greater non-compliance (Bymark and Waite, 2001).

Indeed, as we argue below, the incentives facing consumers under these two regimes are not identical, and therefore responses to cost-sharing should not be identical. To motivate this, we develop a simple theory; our empirical results conform with the theoretical prediction that compliance will be lower under variable coinsurance than under flat copayments. This is due to the fact that the patient does indeed face greater uncertainty in out-of-pocket drug costs under coinsurance.

Why Diabetes?

Diabetes is one of the most common chronic condition for which prescription medications exist, with 16 million Americans, or 6.2 percent of the U.S. population estimated to have this diagnosis. It is the leading cause of adult blindness, kidney failure, and amputations, and a leading cause of heart disease. 180,000 people die each year from diabetes in the U.S. The prevalence of diabetes in the U.S. increased by more than 30% over the last ten years. Moreover, the annual costs of diabetes in medical expenditures and lost productivity climbed from $98 billion in 1997 to $132 billion in 2002. As the incidence of diabetes reaches epidemic proportion, leading to spiraling costs, the need to undertake prevention measures is becoming even more pronounced.

There are two major forms of the disease. Type I diabetes occurs in about 10 percent of cases; in this manifestation of the disease, a person is unable to produce insulin, the major hormone in the body that regulates blood sugar level. Persons with type I diabetes are dependent on daily insulin injections, but few oral prescription medications are available.

In type II diabetes mellitus, persons either produce low levels of insulin or the insulin produced is deficient in regulating blood sugars. For this variant of the disease, five types of oral prescription medications are available: Sulfonylureas (SU), Non-SU (Meglitinides), Metformin, Thiazolidinediones (TZD), and alpha-Glucosidase Inhibitors (AGI). Each of these drugs targets a separate organ site in the body to control blood sugar levels, as illustrated in Table 1. These five pharmacological methods of controlling of blood sugar can substantially delay or prevent the costly medical complications arising from diabetes (see Cohen et al, 2003, for instance).

A person is considered compliant if he or she adheres to the anti-diabetic drug regimen prescribed by a physician (Hughes et al, 2001; Dezii, 2000). Since these anti-diabetic medications are intended to be taken permanently, measurement of compliance is relatively straightforward when tracking such individuals. In this paper, we will examine patient compliance with all five anti-diabetic drugs in Table 1. In particular, we focus on compliance in terms of refilling a prescription within 90 days after using all the pills supplied in the prescription. Our main concern is that increases in patient cost-sharing levels for these drugs may induce some patients to not comply with their anti-diabetic medications[3]. Indeed, we find that increases in cost-sharing from the 25th percentile to 75 percentile in copayments (from \$6 to \$10) increased the number of diabetics who never complied within 90 days by 6.2%. For diabetics facing a coinsurance rate rather than a flat copayment, an increase from the 25th percentile to 75 percentile in coinsurance (from 20% to 75%) increased the number of diabetics who never complied within 90 days by 9.9%.

The paper is organized as follows. First, section 2 sets up a theoretical model of the patient's decision to comply. Section 3 describes the data. Section 4 delineates the empirical methods. Section 5 discusses the empirical results and simulations. Section 6 concludes with a discussion.

[3]In fact, Karter et al, (2003), show that use of outpatient diabetic services decline with copayment increases.

2 Theory Model

Cost-sharing for prescription drugs by the patient-consumers can occur either in the form of a fixed copayment (e.g., $25 per prescription) or in the form of a coinsurance rate (e.g., 20% of the final price of the prescription). Patients in the two regimes face fundamentally different constraints. With a fixed copayment, the patient knows exactly what she will pay out-of-pocket for her next prescription, namely, a flat dollar amount. The opposite situation applies to a patient facing a coinsurance rate. Here, the patient does not know *a priori* what her final out-of-pocket costs will be for her next prescription (since she does not know the final price).

Thus, coinsurance and copayments create two fundamentally different sets of incentives. We will now formally model these incentives in terms of how they impact a patient's preferences, and hence, her decision to comply with the prescribed regimen by making the next purchase. Suppose a patient currently has a prescription for a chronic condition. The patient must decide whether to refill the prescription once it runs out. Let y be the patient's income. If the patient does not refill her medication, she will experience a random loss in health ϵ, and her expected reservation utility of not complying will be

$$\int U(y-\epsilon)dF(\epsilon). \tag{1}$$

Suppose that the patient believes that the random price p of the next prescription is generated by a density function with mean price $\bar{p}$. Define $X(p)$ to be the out-of-pocket payment that the patient must make for a drug:

$$X(p) = \begin{cases} c & \text{under copayments} \\ rp & \text{under coinsurance.} \end{cases} \tag{2}$$

Next, let $V(Q)$ be the value that the patient places on the drug for which she is debating whether to refill, where Q is quantity (the number of days supplied in the next prescription). We assume there is no loss of health ϵ when the patient refills the medication. Thus, if the patient decides to comply and refill her medication, her expected utility will be

$$\int U(y+V(Q)-X(p))dG(p). \tag{3}$$

Hence, the patient will comply and refill her medication only if the following holds

$$\int U(y + V(Q) - X(p))dG(p) > \int U(y - \epsilon)dF(\epsilon). \tag{4}$$

The left-hand side of (4) captures the uncertainty in the economic value of the next prescription, and the right-hand side captures the uncertainty in the relative health value (opportunity cost) of the next prescription. Our main interest in this paper lies in deriving a functional form for (4) that allows for meaningful comparisons between the two insurance regimes. Since mean-variance utility is a good approximation of concave utility functions in general, as long as the range of outcomes is not too widely spread (Levy and Markowitz (1979) and Meyer (1987)), we approximate the general utility function $U(\cdot)$ in (4) with mean-variance utility[4]: $U(\cdot) \approx u_1 E(\cdot) - u_2 Variance[\cdot]$, where $u_1, u_2 > 0$. Then, if the patient does not renew the prescription, her reservation utility in (1) will now be

$$u_1(y + \bar{\epsilon}) - u_2 Var[\epsilon], \tag{5}$$

where $\bar{\epsilon}$ is the mean of ϵ. If the patient decides to renew the prescription while facing out-of-pocket $X(p)$, her mean-variance utility version of (3) will be

$$U = u_1 E(y + V(Q) - X(p)) - u_2 Var[y + V(Q) - X(p)]. \tag{6}$$

Thus, the patient will comply and buy the next prescription if this utility U in (6) is larger than her reservation utility in (5):

$$U = u_1 E(y + V(Q) - X(p)) - u_2 Var[y + V(Q) - X(p)] > u_1(y + \bar{\epsilon}) - u_2 Var[\epsilon]. \tag{7}$$

Next, using a linear specification for the value of the drug, $V(Q) = d + mQ$, where $d > 0$ and $m > 0$, Proposition 1 presents (7) in a more usable form. We assume the patient knows that the random price p is generated by a density with mean $\bar{p}$ (perhaps from experience with previous prescriptions).

[4]Mean-variance utility has been used in various health economic applications. See Chapter 10 of the textbook by Breyer, Zweifel, and Kifmann (2003). The coefficient u_2 can be thought of as the degree of risk aversion, with $u_2 = 0$ being risk neutral. We assume all patients have the same level of risk aversion.

Proposition 1 *Under copayments, compliance will occur if*

$$D + Bc + MQ > K, \ \ and \tag{8}$$

Under coinsurance compliance will occur if

$$D + Br\bar{p} + Gr^2 + MQ > K, \ \ where \tag{9}$$

$D = u_1 d > 0$*;*

$B = -u_1 < 0$*;*

$G = -u_2\sigma^2 < 0$*;*

$M = u_1 m > 0$*; and*

$K = u_1\bar{\epsilon} - u_2 var[\epsilon] > 0.$

From (8) and (9) we see that there is a disutility from the expected out-of-pocket c or $r\bar{p}$, a utility from the quantity Q, and a possible additional disutility from the squared coinsurance rate r^2, which is due to the interaction between price p and coinsurance rate r in the out-of-pocket rp. Under coinsurance, the out-of-pocket is random due to the random price. Incorporating this into the mean-variance utility function, there is a disutility from the variance of the out-of-pocket which is basically due to the variance of the price, σ^2. To see this note that when $X(p) = rp$, the first variance term in (7) reduces to $-u_2 Var[y + d + mQ - rp] = -u_2 r^2\sigma^2$. As the coinsurance rate increases, the patient is exposed to more of the variance σ^2, since the patient is now paying a larger fraction of the price out-of-pocket. As a result, disutility increases overall. This is captured by the factor $G = -u_2\sigma^2$ in (9).

Since G is negative, we can easily see from comparing (8) and (9) that compliance occurs less often under coinsurance in (9) than under flat copayments in (8) when the expected out-of-pocket is equal across the two regimes.

Corollary 1 *When faced with the same expected level of out-of-pocket costs ($c = r\bar{p}$), compliance occurs more often with copayments than with coinsurance.*

Finally, note that if prices are known *a priori* with certainty, so that there is no variance in prices, then both the copayment model and the coinsurance model are identical and provide the same utility (since G=0 in (9) in this case). However, empirically, drug prices do vary on a monthly basis, with some drugs increasing in price by up to 30% over the year. Thus, with such price uncertainty, Corollary 1 shows that patients are less likely to comply under coinsurance since coinsurance exposes their out-of-pocket to the same uncertainty underlying the drug prices.

3 Data

In this analysis we use one of the largest available databases of privately insured individuals in the U.S., which is the MarketScan database maintained by the Medstat group. This database encompasses up to 3.5 million individuals who are covered by employer-sponsored health insurance offered by about forty large firms. These include both regular employees and annuitants (retirees). The complete database contains various files with detailed information on medical conditions, insurance coverage, and payments for persons with any insurance claims for inpatient, outpatient, and prescription drug services. For purposes of this study five different files belonging to MarketScan 1999-2000 were linked to create a single analysis file. The first file was the MarketScan Drug Benefit File, which contains the insurance drug claims for all individuals who purchased prescription drugs. The second was the Employer Benefit Plan Design (EBPD) database, with information on benefit design and drug copayment structure from some of the larger employers in MarketScan, offering a total of 50+ insurance plans with prescription drug benefits. The third was the MarketScan Enrollment File, which linked individuals to their health plan enrollment history. The fourth and fifth files, respectively, were the MarketScan Hospital Inpatient File

and the Outpatient Services File containing information on patients' medical conditions and certain demographic characteristics. Finally, the 1999 and 2000 Redbooks (Medical Economics Company, 2001) were used to obtain additional explanations about the particular prescription drugs for diabetes as they appear in the data.

We focus on adults over the age of eighteen with chronic type II diabetes who require oral anti-diabetic medications on an ongoing basis as previously described (Table 1). Access to detailed patient information allows us to track patient compliance, as measured by the sequence of prescription refills within a defined time interval. We observe an 18 month period from June 1, 1999, to December 31, 2000, and consider individuals who are continuously enrolled with drug coverage over this entire period. To allow for a uniform 90 day tracking interval for all observations, we only track individuals with at least one purchase of an anti-diabetic drug prescription with a 30-35 day drug supply that started between June 1, 1999 and September 1, 2000, and that ended no later than October 1. This resulted in an initial sample of 54,649 persons.

Merging the EBPD resulted in a sample of 27,057 individuals belonging to nine large firms for which we had drug copayment information. Of these, 20,494 individuals belong to seven firms with insurance plans that required consumers to pay a flat copayments per prescription, while 6,563 individuals belonged to three firms with plans that required copayment rates proportional to the prescription price (only one firm offered plans in both types of copayment regimes). In the rest of the paper we will refer to these as the 'copayment' and the 'coinsurance' regimes, respectively. There were many other payment features such as payment caps, formulary restrictions, and copayments tiers. Since these were different in every single plan, they were summarized as either firm fixed effects or drug benefit fixed effects in the analysis. In the copayment regime there were 26 different drug benefit plans, while in the coinsurance regime there were 4 drug benefits. A fuller discussion of the benefit features in these data is available in Encinosa (2002).

To further control for patient heterogeneity (case mix), we use indicators for 28 chronic conditions developed by Elixhauser et al (1998) in the AHRQ Comorbidity Software

(www.ahrq.gov/data/hcup/comorbid.htm), and updated by McDonald et al, (2002). These comorbidities were obtained from the MarketScan Hospital Inpatient File and the Outpatient Services File. Summary statistics are reported in Table 2; to conserve space, we do not report coefficients of chronic indicators in subsequent tables, and only highlight the four most important conditions in Table 2[5].

The 0/1 variable "Hospitalization" indicates whether the patient was hospitalized during the prescription or during the 90 days following the prescription. Such a hospitalization might give the patient less of an opportunity to refill the prescription. "Union" indicates whether the employee is in a union. "Hourly" indicates if the patient had a job with an hourly wage rather than a salary. If the patient was not the primary insurance policy holder, but a dependent, this is recorded in the variable "Dependent." The four regions indicate the employee's geographical location.

4 Empirical Methods

Individuals in the data were sorted into three groups:

(0) 'non-compliers' — individuals who did not buy another anti-diabetic agent prescription within 90 days after the first prescription ran out;
(1) 'partially compliant' individuals — individuals that buy one or more prescriptions within 90 days, but those prescriptions do not cover the full 90 days (allowing a 5 days grace period after each prescription); and
(2) 'fully compliant' individuals — individuals that buy one or more prescriptions within

[5]The 28 conditions are congestive heart failure, arrhythmias, valvular disease, pulmonary circulation disease, peripheral vascular disease, hypertension, paralysis, other neurological disorders, chronic pulmonary disease, diabetes with chronic complications, hypothyroidism, renal failure, liver disease, peptic ulcer disease with bleeding, lymphoma, metastatic cancer, solid tumor without metastasis, rheumatoid arthritis coolagen, coagulopthy, obesity, weight loss, fluid and electrolyte disorders, chronic blood loss anemia, deficiency anemias, alcohol abuse, drug abuse, psychoses, and depression. In the coinsurance sample no one has an obesity diagnosis.

90 days that cover all 90 days.

We estimate compliance among these three groups as an ordered logit model, with outcomes ranked, as above, as 0, 1, 2, respectively. Note that the main independent variables — copayment c, coinsurance rate r, and expected drug price $\bar{p}$ — are averaged for each patient over the period of the duration of the first prescription plus 90 days after that. Since we subset to prescriptions with 30-35 days supplied, the copayments and prices are averaged over a period of approximately 120-125 days. Following the theoretical model, estimation was carried out separately for the copayment sample and coinsurance sample in Tables 3 and 4, respectively.

Copayment Model

In Table 3, models 1-3 follow the specification given below in equation (10) derived from the theory. That is, from (8), for each patient i, we can now write the ordered logit model for copayments as

$$\begin{aligned} Pr(y_i = 0) &= Pr(\delta + \beta c_i + Z_i\zeta + \mu Q_i + \omega_i \ \leq \ \kappa_1), \\ Pr(y_i = 1) &= Pr(\kappa_1 \ < \ \delta + \beta c_i + Z_i\zeta + \mu Q_i + \omega_i \ \leq \ \kappa_2), \\ Pr(y_i = 2) &= Pr(\kappa_2 \ < \ \delta + \beta c_i + Z_i\zeta + \mu Q_i + \omega_i), \end{aligned} \tag{10}$$

where κ_1 and κ_2 estimate two intermediate levels of K, δ estimates D, β estimates B, μ estimates M in (8), and where the error term ω is logistically distributed. Note that $y_i = 0$ if the patient never complied within 90 days of finishing her last prescription; $y_i = 1$ if the patient sometimes complied, but not always; and $y_i = 2$ if the patient always complied for the 90 days. Vector Z_i is a vector of patient risk adjustors. The term δ is actually a vector of drug fixed effects for each of the different antidiabetic drug compounds. The cutoffs κ_1 and κ_2 are estimated along with the other coefficients in Table 3. Model 1 has no drug fixed effects. Model 2 includes firm fixed effects and drug fixed effects (7 firms and 19 drug

classes). Model 3 includes 19 drug fixed effects and 26 drug benefit fixed effects.

Coinsurance Model

In Table 4, models 1-3 are simple linear specifications with the coinsurance rate r entered alone. Models 4-6 follow the specification given below in equation (11) derived from the theory in (9), where r^2 and copayment $r\bar{p}$ are used instead of r. That is, from (9), for each patient i, we can now write the ordered logit model for coinsurance as

$$\begin{aligned} Pr(y_i = 0) &= Pr(\delta + \beta r\bar{p}_i + \gamma r_i^2 + Z_i\zeta + \mu Q_i + \omega_i \;\; \leq \;\; \kappa_1), \\ Pr(y_i = 1) &= Pr(\kappa_1 \;\; < \;\; \delta + \beta r\bar{p}_i + + \gamma r_i^2 + Z_i\zeta + \mu Q_i + \omega_i \;\; \leq \;\; \kappa_2), \\ Pr(y_i = 2) &= Pr(\kappa_2 \;\; < \;\; \delta + \beta r\bar{p}_i + \gamma r_i^2 + Z_i\zeta + \mu Q_i + \omega_i), \end{aligned} \tag{11}$$

where κ_1 and κ_2 estimate two intermediate levels of K, δ estimates D, β estimates B, μ estimates M, γ estimates G in (9), and where the error term ω is logistically distributed. The cutoffs κ_1 and κ_2 are estimated along with the other coefficients in Table 4. Models 1 and 4 do not have drug fixed effects. Models 2 and 4 in Table 4 add 3 firm fixed effects and 18 drug fixed effects to the specifications. Models 3 and 6 includes 18 drug fixed effects and 4 drug benefit fixed effects.

The coefficients in the ordered logit are not marginal effects. However our main interest is in assessing the impact of the change in cost-sharing policy on compliance. In Table 5 we present simulations that demonstrate the effect of an increase in copayments or coinsurance rates, over a reasonable range, on the distribution of compliance. Note that marginal effects for each alternative can be calculated for continuous variables. To conserve space we do not report effects for all alternatives separately, but these are available from the authors upon request. Coefficients in Tables 3-4 can be interpreted as indicators of the effect of covariates on the relative propensity to comply. In Table 6 we present another simulation, where the copayment and coinsurance rate are set so that the expected out-of-pocket is at the same

$15 level in both the copayment sample and the coinsurance sample. This allowed us to test Corollary 1's assertion that non-compliance is higher under the coinsurance regime. All standard errors in Tables 5 and 6 were computed using the delta method.

5 Results

Copayment Model

In Figure 1, we see that in the first week of the 90 days following the prescription, about 54% of the copayment sample fully complied. By week 4, more than 60% were fully complying. This tapers off to about 58% by the end of the 90 days. Figure 2 provides the hazard rate of compliance. For the copayment sample, about 46% of the people had not complied by the end of the first week. By the end of the 90 days, about 31% still had never complied. This corroborates the general claim of drug manufacturers that about 30% of people do not take their medication appropriately. From Figure 2, we also see that about 69% had complied for at least one week by the end of 90 days. Thus, about 15% of the initial non-compliers became partial compliers during the 90 days.

In Table 3, copayment always has the expected negative sign, indicating that cost sharing reduces compliance. Including firm fixed effects and drug fixed effects increased the size of this effect. The drug fixed effects allow there to be different reservation utilities in (1) for each type of drug. This allows us to tease out the effect of copays on compliance more accurately. There was not much difference between using drug benefit fixed effects compared to firm fixed effects. To account for a small percentage of refill prescriptions in the data that had more or less than the typical 30 day period, we adjusted for average days supplied (per prescription). Compliance increased with average days supplied, as predicted by M in the theory equation (8).

Other variables are of lesser interest, and were included as controls to allow us to obtain adjusted cost-sharing effects. Nevertheless, a number of results are worth noting. First,

the variable hospitalization represents interruptions in daily drug regimen, and, thus, not surprisingly, reduces compliance significantly. Compliance is significantly higher for union workers, but not for hourly wage workers. Also, dependents are more likely to comply compared to primary policy holders. Finally, compliance is significantly higher for those over age 65. A possible explanation is that this is a time-price effect — retired individuals have more free time to reach a pharmacy or follow their regimen, compared with working age adults.

Coinsurance Model

In Figure 1, we see that people under coinsurance generally have the same behavioral pattern as the people under copayments, except that compliance is systematically about 10% lower under coinsurance. In the first week following the end of the prescription, about 44% of the coinsurance sample people fully complied. By week 4, about 50% were fully complying. This tapers off to about 48% by the end of the 90 days. Figure 2 provides the hazard rate of compliance. For the coinsurance sample, about 56% of the people had not complied by the end of the first week. By the end of the 90 days, about 42% still had never complied. We also see that about 58% had complied for at least one week by the end of 90 days. Thus, about 14% of the initial non-compliers became partial compliers during the 90 days.

In Table 4, the simpler specification average coinsurance (r) in columns (1) – (3) has the expected negative effect on compliance. The sign on r^2 in the theory-based model (specifications (4)–(6)) is negative and significant, as expected by the negative G term in the theory equation (9). Note that the copayment term $r\bar{p}$ is not significant. But, this should be interpreted with caution, as the full effect of coinsurance in this model depends on the coefficients of both copayment $r\bar{p}$ and r^2. The coefficients on both these terms have a joint Wald test of significance $P < 0.001$ in each specification (4)–(6). Moreover, the simulation in Table 5 demonstrates that the full effect of coinsurance is negative as in all previous cases. Other effects are qualitatively similar to those in the copayments model.

Sensitivity Analysis

Table 5 shows the effects of a simulated response to increased cost sharing on the distribution of compliance probabilities[6]. In the copayment sample, we simulate an increase from the 25th to the 75th percentile, which is equivalent to an increase from \$6 to \$10. This resulted in a 6.2% increase in the share of non-compliant persons, and a concomitant 9% reduction in the share of fully compliant persons. There was a statistically insignificant increase in the share of partially compliant individuals.

In the coinsurance model, the increase from the 25th to the 75th percentile corresponded to an increase from 20% to 75% in the coinsurance rate. This resulted in an increase in the share of those who never comply, up by 9.9%, while the reduction in fully compliant persons was much higher than in the copayment model, 24.6%.

These results suggest that increasing cost sharing leads to greater non-compliance, and to lower compliance in both regimes. Even though the marginal effects seem to be more dramatic in the coinsurance case, the cost sharing parameters pertain to different scales, thus making comparisons difficult. To address this, we perform another simulation in Table 6, where the copayment and coinsurance rate are constructed so that the expected out-of-pocket is equal for the two regimes, at \$15. That is, the copayment is set $c = 15$ in the copayment sample, and, to generate an equivalent case in the coinsurance sample, we took the coinsurance rate r to be $r = 15/E(p)$, the rate that would yield a \$15 out-of-pocket, on average (i.e., r=70%). The comparison in Table 6 suggests that non-compliance is much higher in the coinsurance case (45.3% versus 35.1%), as predicted by the theoretical model in Corollary 1.

While we can only perform a rough cost-benefit analysis at this stage, the following may be instructive. First, suppose we are in a world that offers only copayments. From Table

[6]The Table 5 simulations were based on the drug fixed effects and drug benefit fixed effects regressions in column (3) of Table 3 and column (6) of Table 4. The simulations for the drug fixed effects and drug benefit fixed effects in the simple specification of column (3) in Table 4 were almost identical to those in theory specification of column (6), and so are not reported.

2, we see that the average drug price was $39.24 dollars for about a 30 days supply in the corresponding sample. Thus, for 90 days, the costs of always complying is $118. From Figure 2, we see from the hazard rate that most partial compliers complied by week 7 out of 13 weeks (13 weeks is 91 days); therefore, we assume a partial complier buys drugs for half of the 90 days, at a cost of $59. Now suppose we increase copayments from $6 to $10. Using the distribution of compliers and non-compliers from Table 5, under a $6 copayment, the national costs of compliance are N[0+0.313(59)+0.380(118)]=$632.7 million, where N=10 million diagnosed diabetics in the U.S. Similarly, under a $10 copayment, the national costs of compliance are N[0+0.328(59)+0.346(118)]=$601.5 million. Thus, the net cost-savings associated with increasing the copayment are $632.7-$601.5=$31.2 million per 90 days. On an annualized basis, this amounts to a reduction of $124.8 million or 4.9% in national expenditures on anti-diabetic medications.

So far, we have ignored the averted treatment costs that are associated with better compliance. In particular, the incidence and costs of diabetic complications (such as blindness, amputations, etc.) may increase as compliance declines. Noting that lack of adherence to anti-diabetic medications results in poor glycemic control in patient, we can address this using available aggregate estimates: Wagner et al (2001) have shown that diabetics with poor glycemic controls spent $685 more in 1997 ($748 in 2000 dollars) on medical care per year than diabetics with good glycemic control, adjusting for health status. Taking medical costs of compliers as a baseline ($472 per year for diabetics medication), and adding the incremental cost due to poor glycemic control yields the estimate of the full cost for non-compliers at $1,220. For partial compliers we assume that they incur half the incremental cost of noncompliers since they comply about half as much, on average. This implies a full cost of $846 for this group ($= \$472 + \frac{1}{2} * \$748$). Then, using the distributions of compliers in Table 5, the extra medical cost of noncompliance under a $6 copayment is N[(.307)(1,220)+(.313)(846)]=$6.39 billion per year. Under a $10 copayment, the extra costs of noncompliance are
N[(.326)(1,220)+(.328)(846)]=$6.75 billion per year. Thus, the extra medical costs per year

due to the increased copayments are $360 million. This is a 6.4% increase in medical costs for this population. Unfortunately, this increased medical cost of poor glycemic control outweighs the savings in drug costs of $124.8 million arising from increased non-compliance. This estimate of the net cost of increasing the copayment from $6 to $10, though rough and preliminary, is probably conservative as we have not included costs of lost productivity.

6 Discussion

We examined compliance and non-compliance with drug prescription regimens in a sample of non-insulin diabetics. Diabetes represents a case in which prescription medication must be taken permanently to mitigate adverse health effects and consequently minimize future treatment costs. We found that increased cost-sharing results in lower rates of compliance and higher rates of non-compliance regardless of the cost-sharing mechanism in place. However, the negative effects of cost-sharing on non-compliance are larger in the coinsurance regime than in the copayment regime. The theory suggests that this is due to greater uncertainty in out-of-pocket costs created under coinsurance.

The implications of these results are broad, for both private employers and for government programs. First, payers may wish to reexamine benefit policies that have imposed higher levels of cost-sharing for prescription drugs, often ignoring the function of prescription drugs in prevention of complications from chronic conditions such diabetes, arterial diseases, hypertension and the like. For instance, the recent run-up in state budget deficits have forced some state-managed Medicaid programs to raise drug copayments. For low income people who are the beneficiaries of Medicaid coverage, the non-compliance effect could be larger than we estimate here. Medicare will begin implementing a prescription drug benefit plan for the elderly starting in 2006 that is estimated to cost more than $500 billion over 10 years, but will involve high copayments at certain ranges: in a so-called 'donut' type plan, beneficiaries will face a 25% coinsurance rate up to some level of spend-

ing, a 5% coinsurance rate above a certain upper limit, but a full 100% coinsurance rate in the middle range. The findings of this study suggest that compliance in this range will be particularly low.

Second, in our empirical analysis we demonstrated that non-compliance is higher under coinsurance compared with fixed copays, holding the *level* constant; this suggests that cost-savings can be attained in a budget neutral way by switching from variable coinsurance rates to flat copayment rates in various benefit plans. This applies not only to Medicare, but also to prescription drug plans offered in the private sector. Apparently, many employers are moving in the wrong direction: In 2002, 19% of employers who offer prescription drug benefits to their employees switched from copayments to coinsurance at the expiration of their contracts (Encinosa, 2002).

Interestingly, anecdotal evidence suggests that other employers are beginning to recognize the compliance issue, and are revising their benefit structure accordingly. For example, Pitney Bowes, a firm with 35,000 employees, recently dropped its coinsurance rate for diabetic drugs from 50% to 10%. According to the firm, this reduced the overall costs of care for the median diabetic by 12% (Fuhrmans, 2004). There is surprisingly little literature, however, that can shed light on the optimal level of cost sharing in such plans. Chernew, Encinosa, and Hirth (2000) show that it is sometimes optimal to have negative copayments, i.e., actually offer rebates, for patients with severe chronic conditions or for individuals likely to opt for low quality treatment at the margins[7]. There is a need for further theoretical and empirical research on this issue. Future research should also examine the costs and benefits of patient cost-sharing increases in finer detail. Specifically, there is a need to develop estimates of averted treatment costs from improved compliance and prevention.

[7](Zweifel, 1995) has also examined such rebates in the German health care system.

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Table 1: Pharmacological Treatment of Type 2 Diabetes Mellitus[a]

Major Metabolic Defect	Drug Therapy
Defective Insulin Secretion	*Secretagogue Therapy*
Pancreatic Beta Cells (decreased insulin secretion)	Sulfonylureas (SU) Non-SU Secretagogues (Meglitinides)
Insulin Resistance	*Insulin Sensitizer Therapy*
Skeletal Muscle (decreased glucose uptake)	Thiazolidinediones (TZD)
Liver (increased glucose production)	Biguanides (Metformin) TZD
Adipose Tissue (increased lipolysis)	TZD
Carbohydrate Absorption	**Drug Therapy**
Small Intestines	α-Glucosidase Inhibitors (AGI)

[a]Source: Inzucchi (2002).

Table 2: Descriptive Statistics[a]

Variables:	Copayment Sample	Coinsurance Sample
Never Comply	30.92	42.23
Partially Comply	32.15	28.91
Always Comply	36.93	28.85
Average Copayment	8.953	15.833
	(3.7)	(17.416)
Average Coinsurance Rate	.404	.47
	(.275)	(.333)
Average Days Supplied	31.890	30.691
	(6.490)	(3.983)
Hospitalization	.070	.060
Age	67.300	64.306
	(12.518)	(12.718)
Female	.498	.545
Union	.242	0.0
Hourly	.324	.008
Dependent	.268	.284
North East	.283	.003
North Central	.362	.079
South	.312	.913
West	.043	.005
Diabetic complications	.061	.036
Peripheral vascular disease	.035	.023
Hypertension	.251	.085
Chronic pulmonary disease	.055	.035
Congestive heart failure	.053	.035
Number of Observations	20,494	6,563
Number of Firms	7	3

[a]Standard deviations are in parentheses.

Table 3: Ordered Logit Estimates of Compliance under Copayments[a]

Independent Variables:	(1)	(2)	(3)
Average Copayment	-0.025**	-0.055**	-0.050**
	(0.005)	(0.008)	(0.008)
Average Days Supplied	0.035**	0.038**	0.037**
	(0.003)	(0.003)	(0.003)
Hospitalization	-0.529**	-0.517**	-0.533**
	(0.055)	(0.056)	(0.055)
Age 65-73	3.831**	3.715**	3.547**
	(0.060)	(0.061)	(0.062)
Age 74+	3.825**	3.729**	3.553**
	(0.061)	(0.063)	(0.064)
Female	0.041	0.047	0.031
	(0.029)	(0.030)	(0.030)
Union	0.810**	0.650**	0.666**
	(0.067)	(0.072)	(0.070)
Hourly Wage	-0.456**	-0.458**	-0.434**
	(0.060)	(0.074)	(0.074)
Dependent	0.261**	0.263**	0.292**
	(0.035)	(0.036)	(0.036)
North Central	0.146**	0.079	0.055
	(0.038)	(0.057)	(0.057)
South	0.081*	0.010	-0.019
	(0.040)	(0.053)	(0.052)
West	0.203**	0.135	0.102
	(0.078)	(0.084)	(0.083)
28 chronic conditions	Yes	Yes	Yes
κ_1	2.607**	5.540**	5.284**
	(0.104)	(0.586)	(0.603)
κ_2	4.934**	7.893**	7.653**
	(0.110)	(0.587)	(0.604)
19 Drug Fixed Effects	No	Yes	Yes
7 Firm Fixed Effects	No	Yes	No
26 Drug Benefit Fixed Effects	No	No	Yes
Wald $\chi^2(df)$	7,340 (40)	7,639 (64)	593,862 (83)
Psuedo R^2	0.29	0.30	0.30
Number of Observations	20,494	20,494	20,494

[a]Robust standard errors are in parentheses. Dependent variable is ordered as: 2 if Always Comply, 1 if Partially Comply, and 0 if Never Comply.
** Significant at 1%.
* Significant at 5%.
† Significant at 10%.

Table 4: Ordered Logit Estimates of Compliance under Coinsurance[a]

Independent Variables:	(1)	(2)	(3)	(4)	(5)	(6)
Average Copayment				-0.002	0.002	0.001
				(0.002)	(0.003)	(0.003)
Average Days Supplied	0.045**	0.046**	0.046**	0.045**	0.045**	0.045**
	(0.007)	(0.007)	(0.007)	(0.007)	(0.007)	(0.007)
Average Coinsurance Rate	-0.678**	-0.793**	-0.794**			
	(0.101)	(0.105)	(0.106)			
(Average Coinsurance Rate)^2				-0.960**	-1.138**	-1.140**
				(0.103)	(0.117)	(0.117)
Hospitalization	-0.513**	-0.510**	-0.511**	-0.534**	-0.530**	-0.531**
	(0.111)	(0.112)	(0.112)	(0.111)	(0.113)	(0.113)
Age 65-73	5.009**	4.965**	4.965**	5.007**	4.941**	4.939**
	(0.117)	(0.120)	(0.120)	(0.117)	(0.121)	(0.121)
Age 74+	5.022**	4.973**	4.972**	5.025**	4.952**	4.946**
	(0.120)	(0.125)	(0.127)	(0.120)	(0.125)	(0.127)
Female	-0.096	-0.090	-0.090	-0.106†	-0.100†	-0.102†
	(0.059)	(0.059)	(0.060)	(0.059)	(0.060)	(0.060)
Union	–	–	–	–	–	–
Hourly Wage	-1.365**	-2.169**	-2.169**	-1.365**	-2.190**	-2.190**
	(0.497)	(0.541)	(0.541)	(0.496)	(0.542)	(0.542)
Dependent	-0.027	-0.008	-0.008	-0.026	-0.007	-0.006
	(0.067)	(0.067)	(0.067)	(0.067)	(0.067)	(0.068)
North Central	-1.072	-0.623	-0.623	-1.100	-0.607	-0.611
	(0.946)	(0.787)	(0.788)	(0.966)	(0.809)	(0.809)
South	-0.296	-0.542	-0.543	-0.239	-0.526	-0.530
	(0.943)	(0.786)	(0.786)	(0.963)	(0.810)	(0.810)
West	-1.454	-1.171	-1.171	-1.482	-1.171	-1.173
	(1.018)	(0.852)	(0.852)	(1.036)	(0.871)	(0.870)
27 chronic conditions	Yes	Yes	Yes	Yes	Yes	Yes
κ_1	3.058**	2.907**	3.968**	3.073**	2.975**	4.074**
	(0.988)	(0.798)	(0.852)	(1.010)	(0.817)	(0.874)
κ_2	5.640**	5.504**	6.566**	5.683**	5.602**	6.702**
	(0.990)	(0.799)	(0.855)	(1.011)	(0.818)	(0.877)
18 Drug Fixed Effects	No	Yes	Yes	No	Yes	Yes
3 Firm Fixed Effects	No	Yes	No	No	Yes	No
4 Drug Benefit Fixed Effects	No	No	Yes	No	No	Yes
Wald $\chi^2(df)$	2,153 (38)	2,341 (58)	2341 (59)	2,153 (39)	2,401 (59)	2,402 (60)
Psuedo R^2	0.40	0.40	0.41	0.40	0.40	0.41
Number of Observations	6,563	6,563	6,563	6,563	6,563	6,563

[a]Robust standard errors are in parentheses. Dependent variable is ordered as: 2 if Always Comply, 1 if Partially Comply, and 0 if Never Comply.

** Significant at 1%.

* Significant at 5%.

† Significant at 10%.

Table 5: Simulated Percent Change in Compliance Associated with an Increase in Cost-Sharing[a]

	Initial Compliance Distribution	Final Compliance Distribution	Change in Compliance Distribution	
Copayment Sample:				
Copayment:[b]	\$6	\$10		
Never Comply	0.307**	0.326**	0.019**	[+6.2%]
	(0.011)	(0.011)	(0.0001)	
Partially Comply	0.313**	0.328*	0.015	[+4.8%]
	(0.129)	(0.162)	(0.066)	
Always Comply	0.380**	0.346**	-0.034**	[-9.0%]
	(0.018)	(0.019)	(0.0006)	
Coinsurance Sample:				
Coinsurance Rate:[c]	20%	75%		
Never Comply	0.414**	0.455**	0.041**	[+9.9%]
	(0.013)	(0.015)	(0.0006)	
Partially Comply	0.265*	0.303*	0.038	[+14.3%]
	(0.138)	(0.156)	(0.022)	
Always Comply	0.321**	0.242**	-0.079**	[-24.6%]
	(0.024)	(0.024)	(0.001)	

[a]Columns 1 and 2 give the probability of being in each of the three compliance categories. Results are simulated from regressions in column (3) of Table 3 and column (6) of Table 4. Standard errors are in parentheses.

** Significant at 1%. * Significant at 5%.

[b]Moving from 25th to 75th copayment percentiles.

[c]Moving from 25th to 75th coinsurance percentiles.

Table 6: Simulated Comparison of Copayments vs. Coinsurance[a]

	Copayment Model Distribution	Coinsurance Model Distribution
Never Comply	0.351**	0.453**
	(0.013)	(0.015)
Partially Comply	0.345**	0.301*
	(0.142)	(0.155)
Always Comply	0.304**	0.246**
	(0.020)	(0.025)
Observations:	20,494	6,563

[a]Columns 1 and 2 give the probability of being in each of the three compliance categories when the copayment and the coinsurance rate are set so that the expected out-of-pocket is $15. Results are simulated from regressions in column (3) of Table 3 and column (6) of Table 4. Standard errors are in parentheses. ** Significant at 1%. * Significant at 5%.

Figure 1: Rate of Weekly Compliance

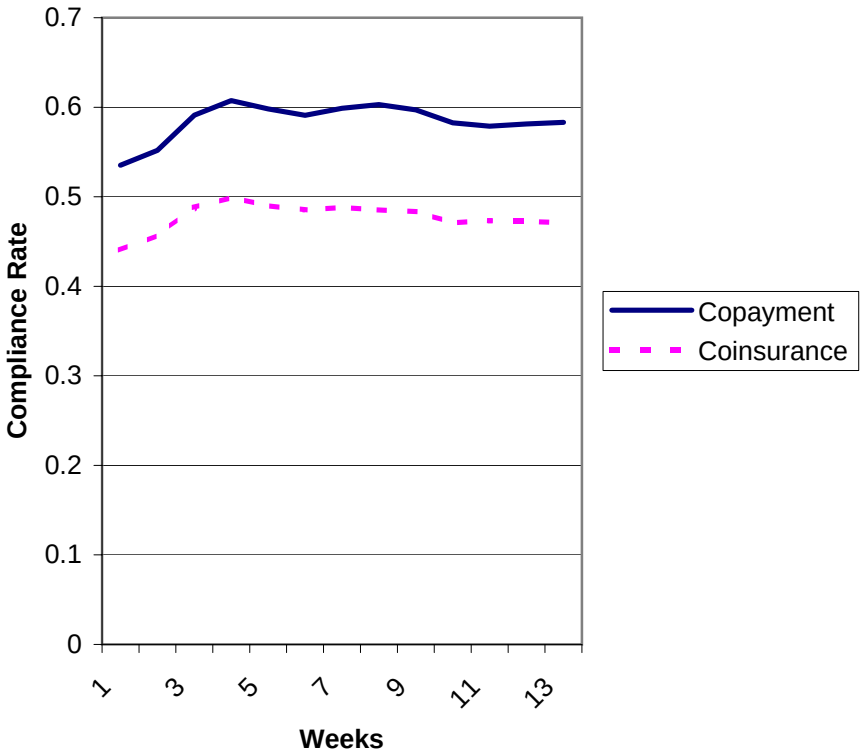


Figure 2: Compliance Hazard Rate

