# Cost-Sharing and Non-Compliance with Prescription Drugs

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#### Abstract

Compliance with anti-diabetic medications is crucial to reducing complications such as blindness, amputations, heart disease, and stroke among diabetics. We examine compliance within 90 days after the completion of anti-diabetic drug prescriptions. About a third of the population never complies, a third always complies, and the remaining third partially complies. Using an ordered logit regression (in the order of never comply, partially comply, and always comply) we find that the drug coinsurance rate has the effect of reducing compliance (P < 0.001), after controlling for chronic conditions, number of previous refills, and demographic characteristics. In the coinsurance model, an increase in the coinsurance rate from the 25th to the 75th percentile (from 20% to 75% coinsurance) resulted in the share of those who never comply to increase by 27%, and reduced the share of fully compliant persons by 10.9%. In the copayment sample, an increase in the copayment from the 25th to the 75th percentile (from \$6 to \$10) resulted in a 13% increase in the share of non-compliant persons, and a concomitant 10.6% reduction in the share of fully compliant persons. There was a miniscule increase in the share of partially compliant individuals. This increase in copayment from \$6 to \$10 would reduce annual drug costs nationally by \$177 million, simply by the increase in non-compliance. But, this increase in non-compliance would also increase the rate of diabetic complications, resulting in an additional \$433.5 million in costs annually.

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# 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 projects 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). Driven by concerns over rising costs employers and insurers are quickly redesigning 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 (from 5/\$10 to 10/\$20) can decreasing spending on drugs by up to 30%.

In most circumstances, economists would conclude that such developments are rational responses to market imperfections in the presence of insurance increased cost sharing reduces moral hazard and excessive medical consumption, thereby improving social welfare (Pauly, 1974). However, the case of prescription drugs is more complex. Often they are associated with preventive efforts to reduce further illness and complications. In this case underutilization may be the problem, and 'too much' cost sharing may lead to a loss of welfare. 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 preventive care drugs without interruption. In particular, we will focus on the impact of cost-sharing on compliance with anti-diabetic drugs.

#### 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. Clearly, diabetes is a chronic disease that appears out-of-control in the U.S. and that would greatly benefit from preventive care measures.

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.

A person is considered compliant is he or she adheres to the anti-diabetic drug regimen prescribed by a physician. 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. 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 13%. For diabetics facing a coinsurance rate rather than a flat copayment, an increase the 25th percentile to 75 percentile in coinsurance (from 20% to 75%) increased the number of diabetics who never complied within 90 days by 27%.

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

# 2 Data

Five databases maintained by the MEDSTAT group were merged to create the analysis file. The first was the MarketScan Drug Benefit File, a large national claims database of employees and annuitants of large employers. The second was the Employer Benefit Plan Design (EBPD) database, with information on benefit design for 100+ plans drawn from 17 large employers, also found in MarketScan. The third was the MarketScan Enrollment File, which provides eight years of insurance coverage enrollment details for the employees and annuitants. The fourth and fifth were the MarketScan Hospital Inpatient File and the Outpatient Services File. Finally, the 1999 and 2000 REDBOOK (Medical Economics Company, 2001) were used to obtain additional detailed drug information.

We focus on diabetic adults with drug benefits. We consider only those continuously enrolled with drug coverage over the 18 month period from June 1, 1999, to December 31, 2000, and 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 October 1, 2000, and that ended before December 31, 2000. An anti-diabetic drug is any drug in therapeutic class 173 or 174 that is prescribed for the maintenance of a chronic (non-acute) diabetic condition. This resulted in an initial sample of 54,649 persons.

Merging the EBPD resulted in a sample of 27,026 individuals from nine large firms and enrolled in 65+ different health plans. Of these, 20,465 individuals belong to seven firms that required consumers to pay a flat copayments per prescription, while 6,561 individuals belonged to three firms that required copayment rates proportional to the prescription price. 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 firm, they were summarized as firm fixed effects in the analysis (in practice, this did not alter the effects of the copayment parameters in the regressions, as will be later discussed). 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 29 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. The 29 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, AIDS, 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.

The variable "insurance change" in Table 2 indicates a change in coverage (which are mostly due to exogenous changes made by the employer's PBM carrier, such as a change in the number of mental health office visits covered). In no case did a patient change plans during the sample period. "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 an union. "Region" indicates the employee's geographical location. Before discussing the compliance variables, we next develop a theory of compliance.

# 3 Theory Model

Patient cost-sharing for prescription drugs 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). Both forms of cost-sharing differ in the way they offset the two following fundamental countervailing cost-benefit

incentives.

First, with a fixed copayment, the patient knows exactly what she will pay out-of-pocket for her next prescription. She will pay the fixed copayment dollar amount. However, while she knows her costs, she will not really know what economic benefit she is getting from her next prescription since the drug price is not known. That is, for a \$25 copay, will she be getting a prescription worth \$100 dollars (i.e., 25% cost-sharing) or a prescription worth \$150 dollars (i.e., 17% cost-sharing)?

In contrast, with a coinsurance rate, the patient faces the exact opposite scenario. He doesn't know what his final out-of-pocket costs will be for his next prescription (since he doesn't know the final price), but he knows the general economic benefit he is getting (i.e., the cost-sharing rate is simply his coinsurance rate). That is, he may know he is going to have 20% cost-sharing, but he doesn't know if his out-of-pocket will be \$20 on a \$100 prescription or \$30 on a \$150 prescription.

Thus, coinsurance and copayments create two fundamentally opposite countervailing incentives. We will now formally model these two incentives in terms of how they impact a patient's next purchasing decision (compliance). 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. Let Q be the number of days supplied in the prescription. Suppose that the patient believes that the random price  $\tilde{p}$  of the next prescription (for Q days) is generated by a density function with mean price p, variance  $\sigma^2$ , skewness  $\nu$ , and kurtosis  $\tau$ , where  $\nu = E[(\tilde{p} - p)^3]$  and  $\tau = E[(\tilde{p} - p)^4]$ .

Define X to be the out-of-pocket payment that the patient must make for a drug. If the patient has a fixed copayment, the copayment will be c and X = c. If the patient instead has a coinsurance rate, let the coinsurance rate be r. Then X = rp is the expected out-of-pocket under coinsurance. To simplify the exposition, assume that the patient has mean-variance utility<sup>1</sup>  $U = u_1 E(y) - u_2 Variance[y]$ , with  $u_1, u_2 > 0$ . Then, if the patient does not renew the prescription, his reservation utility will be  $u_1(y + \underline{H}) - u_2 Var[y + \underline{H}]$ , where  $\underline{H}$  is his health stock when the drug is not taken. Since this variance term is zero (since there is no random  $\tilde{p}$  term in the reservation utility), the reservation utility reduces to

$$u_1(y + \underline{H}). \tag{1}$$

### 3.1 Copayments

If the patient decides to renew the prescription while facing a fixed copayment c, his utility will be

$$U(c) = u_1 E(y - c + H(Q, \tilde{p})) - u_2 Var[y - c + H(Q, \tilde{p})],$$
(2)

<sup>&</sup>lt;sup>1</sup>While mean-variance utility is a somewhat restrictive specification, it is more general than commonly thought (Meyer 1987).

where

$$H(Q,\tilde{p}) = mQ + d + e\tilde{p} + f\tilde{p}^2 \tag{3}$$

is the expected value that the patient places on the drug, where m, e > 0, f < 0, and where d is a constant. For example, the patient places a greater value on an expensive, new high-tech drug (which has a high price), and places a lower value on an old, generic drug (which has a lower price).

Thus, under copayments, the patient will comply and buy the next prescription if this utility U(c) in (2) is larger than his reservation utility in (1):

$$U(c) = u_1 E(y - c + H(Q, \tilde{p})) - u_2 Var[y - c + H(Q, \tilde{p})] > u_1(y + \underline{H}).$$
(4)

Since H is quadratic in price, the mean and variance in (4) are complicated. However, the next Proposition expands (4) to a more usable form. Recall that X is the out-of-pocket expenditure.

Proposition 1 Under copayments, compliance will occur if

$$BX + D_1p + D_2p^2 + MQ > K, where$$

$$\tag{5}$$

X = c;

$$\begin{split} K &= -u_1(d - \underline{H} + f\sigma^2) + u_2 e^2 \sigma^2 + u_2 f(2e\nu + f\tau - f\sigma^4); \\ B &= -u_1; \\ D_1 &= u_1 e - 4u_2 f(e\sigma^2 + f\nu); \\ D_2 &= u_1 f - 4u_2 f\sigma^2; \ and \\ M &= u_1 m. \end{split}$$

From (5) we see that there is a disutility from the out-of-pocket X, a utility from the quantity Q, and a possible utility from the price signal  $(p, p^2)$ .

### 3.2 Coinsurance

Now suppose that the patient faces a coinsurance rate r and decides to refill her prescription. Then, in contrast to the copayment utility (2), her coinsurance utility is now:

$$U(r) = u_1 E(y - r\tilde{p} + H(Q, \tilde{p})) - u_2 Var[y - r\tilde{p} + H(Q, \tilde{p})], \qquad (6)$$

where the patient's out-of-pocket is now  $r\tilde{p}$ . Thus, she will comply under coinsurance if U(r) is greater than her reservation utility in (1):

$$U(r) = u_1 E(y - r\tilde{p} + H(Q, \tilde{p})) - u_2 Var[y - r\tilde{p} + H(Q, \tilde{p})] > u_1(y + \underline{H}).$$
 (7)

This inequality (7) reduces to the following.

Proposition 2 Under coinsurance, compliance will occur if

$$BX + D_1p + D_2p^2 + G_1r + G_2r^2 + MQ > K, where$$
(8)

$$\begin{split} X &= rp; \\ K &= -u_1(d - \underline{H} + f\sigma^2) + u_2 e^2 \sigma^2 + u_2 f(2e\nu + f\tau - f\sigma^4); \\ B &= 4u_2 f\sigma^2 - u_1; \\ D_1 &= u_1 e - 4u_2 f(e\sigma^2 + f\nu); \text{ and} \\ D_2 &= u_1 f - 4u_2 f\sigma^2; \\ G_1 &= 2u_2(e\sigma^2 + f\nu); \\ G_2 &= -u_2\sigma^2; \text{ and} \\ M &= u_1 m. \end{split}$$

Thus, as in (5), in (8) we see that there is a disutility from the out-of-pocket X, a utility from the quantity Q, and a possible utility from the price signal  $(p, p^2)$ . However, there is now a possible disutility from the coinsurance rate r and  $r^2$  not related to the out-of-pocket. This appears through two countervailing factors,  $G_1$  and  $G_2$ . First, under coinsurance, the out-of-pocket is random due to the random price. Under mean-variance utility, there is a disutility from the variance of the out-of-pocket. This variance of the out-of-pocket is basically due to the variance of the price,  $\sigma^2$ . As the coinsurance rate increases, the patient is exposed to more of the variance  $\sigma^2$ , since the patient is now paying out-of-pocket a larger fraction of the price. As a result, disutility increases. This disutility from the increase in variance in the out-of-pocket arising from an increase in the coinsurance rate is captured by the factor  $G_2 = -u_2\sigma^2$  in (8).

The second countervailing factor,  $G_1$ , is a little more subtle. Note that not only is there a disutility from the variance in the out-of-pocket, but there is a disutility arising from the variance in the price signal. However, since the price signal provides positive utility and the out-of-pocket provides negative utility, they are negatively correlated. This negative correlation comes in handy: as an increase in the coinsurance rate increases the variance of the out-of-pocket, it simultaneously decreases the covariance between the out-of-pocket and the price signal. This works to lower overall variance of the utility U(c), certirus paribus. This is the countervailing effect of increasing coinsurance. It is captured by  $G_1$  in (8). Overall, either factor  $G_1$  or  $G_2$  can dominate. These countervailing incentives are quite common in finance. For example, it is well known that one may increase her overall financial utility by buying new stocks that are less correlated or negatively correlated with the old stocks in her current portfolio. While the new stocks purchased increase her exposure to variance in stock prices, it is offset by the drop in covariance between the new and old stocks. This is the same phenomenon occuring in (8). An increase in the coinsurance rate may decrease overall variance due to the offset in the covariance between the out-of-pocket and the price signal.

To understand the behavioral differences between copayments and coinsurance, consider the case where there is no value or utility from the price signal (i.e., e = f = 0). In this case, in Proposition 2 we have  $G_1 = 0$  and  $G_2 < 0$ . Thus, in (8) there is a definite disutility due to the variation in price. Since  $G_2 = -u_2\sigma^2$ , the greater the variation  $\sigma^2$  of price, the greater the disutility under coinsurance, since with coinsurance the variance of the out-of-pocket is determined by the variance of the price. In contrast, under a copayment, the out-of-pocket is not random since it is simply equal to the fixed copayment. Thus, there is no disutility from the variance of price under copayments. Hence, when there is no value from a price signal, utility is higher under copayments than coinsurance (i.e., U(c) > U(r)) when the expected out-of-pocket is the same (c = rp). As a result, the patients under coinsurance will comply less often than the patients under copayments. The same result generally holds even when there are price signals of value.

## 4 Empirical Methods

Individuals in the data were sorted into three groups:

(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 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 2, 1, 0, respectively. Note that the main independent variables — copayment c, coinsurance rate r, and drug price p are averaged 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 copay and pay 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 Table 3 and Table 4, respectively.

<sup>(0) &#</sup>x27;non-compliers' — individuals who did not buy another anti-diabetic agent prescription within 90 days after the first prescription ran out;

#### **Copayment Model**

In Table 3, models 1-2 are simple linear specifications, with copayment c entered alone. Models 3-4 follow the specification given below in equation (10) derived from the theory. That is, from (5), for each patient i, we can now write the ordered logit model for copayments as

$$Pr(y_{i} = 0) = Pr(\beta X_{i} + \delta_{1}p_{i} + \delta_{2}p_{i}^{2} + \zeta Z_{i} + \mu Q_{i} + \epsilon_{i} \leq \kappa_{1}),$$
  

$$Pr(y_{i} = 1) = Pr(\kappa_{1} < \beta X_{i} + \delta_{1}p_{i} + \delta_{2}p_{i}^{2} + \zeta Z_{i} + \mu Q_{i} + \epsilon_{i} \leq \kappa_{2}),$$
  

$$Pr(y_{i} = 2) = Pr(\kappa_{2} < \beta X_{i} + \delta_{1}p_{i} + \delta_{2}p_{i}^{2} + \zeta Z_{i} + \mu Q_{i} + \epsilon_{i}),$$
(9)

where  $\kappa_1$  and  $\kappa_2$  estimate two intermediate levels of K,  $\beta$  estimates B,  $\delta_1$  estimates  $D_1$ ,  $\mu$  estimates M, and where  $\delta_2$  estimates  $D_2$  in (5), and where  $\epsilon$  is logistically distributed. Indicator  $y_i = 0$  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 cutoffs  $\kappa_1$  and  $\kappa_2$  are estimated along with the other coefficients in Table 3. Models 2 and 4 in Table 3 add firm fixed effects to the specifications.

#### **Coinsurance Model**

In Table 4, models 1-2 are simple linear specifications, with the coinsurance rate r entered alone. Models 3-4 follow the specification given below in equation (11) derived from the theory. That is, from (8), for each patient i, we can now write the ordered logit model for coinsurance as

$$Pr(y_{i} = 0) = Pr(\beta X_{i} + \delta_{1}p_{i} + \delta_{2}p_{i}^{2} + \gamma_{1}r_{i} + \gamma_{2}r_{i}^{2} + \zeta Z_{i} + \mu Q_{i} + \epsilon_{i} \leq \kappa_{1}),$$
  

$$Pr(y_{i} = 1) = Pr(\kappa_{1} < \beta X_{i} + \delta_{1}p_{i} + \delta_{2}p_{i}^{2} + \gamma_{1}r_{i} + \gamma_{2}r_{i}^{2} + \zeta Z_{i} + \mu Q_{i} + \epsilon_{i} \leq \kappa_{2}),$$
  

$$Pr(y_{i} = 2) = Pr(\kappa_{2} < \beta X_{i} + \delta_{1}p_{i} + \delta_{2}p_{i}^{2} + \gamma_{1}r_{i} + \gamma_{2}r_{i}^{2} + \zeta Z_{i} + \mu Q_{i} + \epsilon_{i}), (10)$$

where  $\kappa_1$  and  $\kappa_2$  estimate two intermediate levels of K,  $\beta$  estimates B,  $\delta_1$  estimates  $D_1$ ,  $\delta_2$  estimates  $D_2$ ,  $\mu$  estimates M,  $\gamma_1$  estimates  $G_1$ , and where  $\gamma_2$  estimates  $G_2$  in (8), and where  $\epsilon$  is logistically distributed. The cutoffs  $\kappa_1$  and  $\kappa_2$  are estimated along with the other coefficients in Table 4. Models 2 and 4 in Table 4 add firm fixed effects to the specifications.

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 the hypothesis that non-compliance is higher under the coinsurance regime.

## 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 reduces the size and significance of this effect in the linear specifications, but has little effect on the alternative specification. The quadratic price effect is positive and significant overall. This is consistent with our theory, which treats price as a signal of the value a patient places on a drug (quality). To account for a small percentage of prescriptions in the data that had more or less than the typical 30 day period, we adjusted for average days supplied (per prescription). This ensures that the price signal captures quality and not quantity.

Other variables are of lesser interest, and were included as controls to allow us to obtain adjusted price or cost-sharing effects. Nevertheless, a number of results are worth noting: The greater the number of past refills the greater the overall likelihood of compliance (the omitted category is 'zero refills', i.e., a new prescription); 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. The variables hospitalization and insurance change (the latter is mostly due to exogenous benefit changes made by the employer's PBM carrier) represent interruptions in daily drug regimen, and, thus, not surprisingly, both reduce compliance significantly.

#### **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) has the expected negative effect on compliance. The sign reverses in the theory-based model (specifications 3 an 4), but this should be interpreted with caution, as the full effect in this model also depends on the coefficient of copayment, here the average of r \* p. The simulation in Table 5 demonstrates that the full effect 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. In the copayment sample we allow for an increase from the 25th to the 75th percentile, which is equivalent to an increase from \$6 to \$10. This resulted in a 13% increase in the share of non-compliant persons, and a concomitant 10.6% reduction in the share of fully compliant persons. There was a miniscule 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 a more dramatic increase in the share of those who never comply, up by 27%, while the reduction in fully compliant persons was about equal to same as in the copay model, 10.9%.

These results suggest that increasing cost sharing leads to greater noncompliance, and to lower compliance in both regimes. Although the 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=39%). The comparison in Table 6 suggests that non-compliance is much higher in the coinsurance case, as predicted by the theoretical model.

### 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 mitigated adverse health effects and minimize future treatment costs. We found that increased costsharing results in lower rates of compliance and higher rates of non-compliance in both the copayment and coinsurance regimes. The adverse effects of cost sharing, in terms of higher non-compliance, are larger in the coinsurance regime than in the copay regime. The theory suggests that this is due to greater uncertainty created under coinsurance.

The implications of these results are broad, for both employers and government programs. In 2002, 19% of employers switched from copayments to coinsurance (Encinosa, 2002). This will force the employee to pay (1-r)% of any drug price increases, where r is the coinsurance rate. As we have shown, this added uncertainty over the burden of drug price increases will induce a higher non-compliance rate than under flat copayments. For state Medicaid programs, the recent budget deficits have forced some states to raise drug copays. For low income people, the non-compliance effect could be much larger than we estimate here. Since Medicare does not currently offer a drug benefit, Congress is currently debating a Medicare prescription drug benefit plan for the elderly that will cost at most about \$300 billion over 10 years. The general plan discussed is a 'donut' type plan, where the beneficiary has a 20% coinsurance rate up to some level of spending, a 100% coinsurance rate thereafter up to a second limit, at which point the copay is then zero again. The high copays under such a plan in the middle range of spending may be detrimental to expensive preventive care drugs such as anti-diabetic drugs.

It is possible to design benefits which accomplish higher compliance in a budget-neutral way, by opting for a flat copay regime, rather than a coinsurance regime. Future research should examine the design of optimal flat copay levels. Moreover, future research should estimate the averted treatment costs from improved prevention/compliance (cost-benefit analysis). In our paper we can only do the following rough cost-benefit analysis of compliance.

First, suppose we are in a world that offers only copayments. From Table 2, we see that the average drug price was \$39.24 dollars for about a 30 days supply in the copayment 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). So, let's assume a partial complier buys drugs for half of the 90 days, at cost \$59. Now suppose we increase copayments from \$6 to \$10. From Table 5, we can see the change in distribution of compliers and non-compliers under this increase in copayment. Under a \$6 copay, the national costs of compliance are N[0+0.319(59)+0.376(118)]=\$631.89 million, where N=10 million diagnosed diabetics in the U.S. Similarly, under a \$10 copay, the national costs of compliance are N[0+0.324(59)+0.336(118)]=\$587.64 million. Thus, the net cost-savings of increasing the copay are \$631.89-\$587.64=\$44.25 million per 90 days.

the annual net cost-savings are \$177 million.

However, the incidence and costs of diabetic complications (such as blindness, amputations, etc.) may increase as compliance declines. Let's assume the annual national costs of diabetic complications are C if no one took medication. The anti-diabetic drugs of Table 1 have been shown to reduce complications by 25% (Inzucchi, 2002). Let's assume partial compliers reduce complications by 12%, since they comply half as much. Then, using the distributions of compliers in Table 5, at a \$6 copay the costs of complications are [(0.306)1+(0.319)(1-0.12)+(0.376)(1-0.25)]\*C=.869C. At a \$10 copay, the costs of complications are [(0.346)1+(0.342)(1-0.12)+(0.336)(1-0.25)]\*C=.899C. Thus, there is a \$0.03C increase in costs. That is, the costs of complications increases by 3.5%.

What is a reasonable estimate for C? Total costs of diabetic complications in 2002 were \$24.6 billion in the U.S. In year 2000 dollars, that would be \$23.12 billion. Since about 10 million out of 16 million diabetics take drugs, we assume C=\$14.45 billion. Actually, \$14.45 billion would be a lower bound for C, since C is the costs if no one complied. So, a lower bound on the increase in the costs of complications under an increase in copays would be 0.03\*(14.45 billion)=\$433.5 million. Unfortunately, this increased costs of complications outweighs the drug cost-savings of \$177 million arising from increased non-compliance. This is only a rough estimate of the benefits and costs of increasing the copay from \$6 to \$10. We have not included the costs of lost productivity. Future research should examine the costs and benefits of copay increases in finer detail.

### References

Elixhauser, A., C. Steiner, D. Harris, and R. Coffey (1988). Comorbidity measures for use with administrative data. *Medical Care* 36:1, 8-27.

Encinosa, W, 2002, Pharmacy Benefit Design Options Available to Employers. *Expert Review of Pharmacoeconomics and Outcomes Research* 2(4):389-396, 2002.

Inzucchi, S. 2002. Oral Antihyperglycemic therapy for type 2 diabetes. *Journal of the American Medical Association* 287:3, 360-372.

Joyce, GF, JJ Escarce, MD Solomon, DP Goldman, 2002, Employer Drug Benefit Plans and Spending On Prescription Drugs. *Journal of the American Medical Association* 288:4, 1733-1739.

McDonald K, Romano P, Geppert J, et al. Measures of Patient Safety Based on Hospital Administrative Data-The Patient Safety Indicators (2002). *Technical Review 5*. AHRQ Publication No. 02-0038. Rockville, MD: Agency for Healthcare Research and Quality.

Meyer, J. Two-moment decision models with expected utility maximization, American Economic Review June 1987, vol 77 421-450.

Pauly, M V, 1974. Overinsurance and the public provision of insurance: the role of moral hazard and adverse selection. Q.J.E 88:1, 44-62.

Thomas CP, SS Wallack, S. Lee, and GA Ritter (2002), Impact of Health Plan Design and Management on Retirees' Prescription Drug Use and Spending. *Health Affairs*, Dec 2002 v21: w408-w409.

Woellert, L. 2002. Soon We Will All Be Paying More for Prescription Drugs. *Business Week*, May 6.

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	$\alpha$ -Glucosidase Inhibitors (AGI)	

<sup>a</sup>Source: Inzucchi (2002).

TABLE 2: DESCRIPTIVE STATISTICS <sup><math>a</math></sup>			
	Copayment	Coinsurance	
Variables:	Sample	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 Price	39.235	38.725	
	(34.699)	(31.268)	
Average Days Supplied	31.890	30.691	
	(6.490)	(3.983)	
Previous Fills	1.874	1.933	
	(2.281)	(2.418)	
Hospitalization	.070	.060	
	(.254)	(.238)	
Age	67.300	64.306	
-	(12.518)	(12.718)	
Female	.498	.545	
	(.500)	(.498)	
Union	.242	0.0	
	(.428)	-	
Insurance Change	.187	.308	
	(.390)	(.462)	
HMO	.135	1.0	
	(.342)	-	
North East	.283	.003	
North Central	.362	.079	
	(.481)	(.270)	
South	.312	.913	
	(.463)	(.282)	
West	.043	.005	
	(.203)	(.070)	
Diabetic complications	.061	.036	
	(.239)	(.186)	
Peripheral vascular disease	.035	.023	
	(.184)	(.151)	
Hypertension	.251	.085	
	(.433)	(.279)	
Chronic pulmonary disease	.055	.035	
~	(.227)	(.184)	
Congestive heart failure	.053	.035	
	(.224)	(.183)	
Number of Observations	20,465	6,561	
Number of Firms	7	3	

<sup>a</sup>Standard deviations are in parentheses.

TABLE 3: ORDERED LOGIT ESTIMATES OF COMPLIANCE				
U	NDER COP	AYMENTS <sup>a</sup>		
Independent Variables:	(1)	(2)	(3)	(4)
Auono no Concorrect	019*	0.05	044*	0.25*
Average Copayment	(005)	(.005)	(.005)	035
Average Dave Supplied	(.003)	(.003)	(.005)	(.000)
Average Days Supplied	(003)	(043)	(003)	(003)
Average Price	(.005)	(.005)	013*	012*
Inverage i nee			(001)	(001)
$(Average Price)^2$	_	_	- 00006*	- 00005*
(riverage rince)			(000008)	(000008)
One Previous Fill	599*	581*	(.000000) 594*	(.000000)
	(.052)	(.052)	(.052)	(.052)
Two Previous Fills	.724*	.712*	.728*	.715*
	(.057)	(.058)	(.058)	(.058)
3+ Previous Fills	1.414*	1.393*	1.412*	1.381*
	(.042)	(.042)	(.042)	(.043)
Hospitalization	493*	487*	501*	495*
-	(.057)	(.057)	(.057)	(.057)
Age 65-73	2.661*	2.526*	2.628*	2.509*
-	(.062)	(.063)	(.062)	(.063)
Age 74+	$2.646^{*}$	$2.511^{*}$	$2.653^{*}$	2.529*
	(.063)	(.064)	(.063)	(.064)
Female	.029	.047	.032	.049
	(.032)	(.032)	(.032)	(.032)
Union	.223*	011	.219*	016
	(.040)	(.056)	(.04)	(.056)
Insurance Change	567*	603*	569*	6*
	(.045)	(.045)	(.045)	(.046)
HMO	-6.338*	-6.475*	-6.34*	-6.481*
	(.709)	(.710)	(.709)	(.710)
North Central	.343*	.098	.240*	.094
	(.042)	(.063)	(.042)	(.063)
South	.066	.036	.035	.031
	(.044)	(.058)	(.044)	(.058)
West	.336*	.142	.267*	.125
	(.09)	(.094)	(.09)	(.09)
$\kappa_1$	2.380	4.656	2.393	4.858
	(.113)	(.489)	(.117)	(.487)
$\kappa_2$	4.936	(.225	4.966	(.442
20 abrania arr litirur	(.120) Vec	(.491) Vaa	(.123) Vac	(.488) Vaa
29 chronic conditions	res	Yes	res	Yes
FITH FIXED Effects	INO	res	110	res
Number of Observations	20.465	20.465	20 465	20.465

Number of Observations20,46520,46520,46520,465aRobust standard errors are in parentheses.Dependent variable isordered as: 3 if Always Comply, 2 if Partially Comply, and 1 if Never Comply. \* Significant at 1%.

TABLE 4: ORDERED LOGIT ESTIMATES OF COMPLIANCE				
under Coinsurance <sup>a</sup>				
Independent Variables:	(1)	(2)	(3)	(4)
Average Copayment	-	-	033* (.004)	$033^{*}$
Average Days Supplied	.054*	$.054^{*}$	.052*	.053*
Average Price	-	-	.017*	.017*
$(Average Price)^2$	-	-	(.003) 00005* (.000)	(.004) 00005* (.000)
Average Coinsurance Rate	-1.321*	-1.327*	(.000) $7.121^{*}$ (.563)	(.000) $7.179^{*}$ (.568)
(Average Coinsurance Rate) <sup>2</sup>	-	-	$-6.655^{*}$	$-6.705^{*}$
One Previous Fill	.51*	.507* (104)	(.450) .454* (.106)	(.454) $.455^{*}$ (.107)
Two Previous Fills	(.104) $.673^{*}$ (.142)	(.104) $.664^{*}$ (.142)	(.100) $.519^{*}$ (.142)	(.107) $.503^{*}$ (.142)
3+ Previous Fills	(.142) $1.778^{*}$	(.143) $1.767^{*}$	(.142) $1.555^{*}$	(.143) $1.535^{*}$ (.007)
Hospitalization	(.097) 526* (.105)	(.099) 527*	(.090) 530*	(.097) $535^{*}$
Age 65-73	(.125) $4.098^{*}$	(.126) $4.102^{*}$	(.132) $3.847^{*}$	(.132) $3.837^{*}$
Age 74+	(.132) 4.159*	(.133) 4.161*	(.134) 3.877*	(.136) 3.864*
Female	(.134) 118** (.061)	(.135) $118^{**}$ (.061)	(.137) $122^{**}$ (.063)	(.139) $126^{**}$ (.063)
Union	-	-	-	-
Insurance Change	$834^{*}$	844*	759* (080)	775* (082)
НМО	-	-	-	-
North Central	346	264	163	199 (66)
South	221 (.640)	312	(.025) .104 (.617)	(.00) 198 (.648)
West	(.040) 940 (.763)	(.039) 895 (.757)	(.017) 802 (.752)	(.048) 807 (.765)
$\kappa_1$	2.951	2.943	4.744	5.044
$\kappa_2$	(.697) (.699)	(.675) (.677)	(.703) (.769) (.708)	8.070 (.700)
29 chronic conditions	Yes	Yes	Yes	Yes
Firm Fixed Effects	No	Yes	No	Yes
Number of Observations	6,561	6,561	6,561	6,561

<sup>a</sup>Robust standard errors are in parentheses. Dependent variable is ordered as: 3 if Always Comply, 2 if Partially Comply, and 1 if Never Comply. \* Significant at 1%. \*\* Significant at 5%.

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: <sup><math>b</math></sup>	\$6	\$10	
Never Comply	0.306	0.346	$13.1\%^{*}$
Partially Comply	0.319	0.324	1.4%*
Always Comply	0.376	0.336	(0.001) -10.6%* (0.0003)
Coinsurance Sample:			
Coinsurance Rate: $^{c}$	20%	75%	
Never Comply	0.409	0.519	27.0%* (.011)
Partially Comply	0.307	0.309	0.6%
Always Comply	0.284	0.253	(.004) -10.9%* (.004)

 $^{a}$ 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 Tables 3 and 4. Standard errors are in parentheses.

\* Significant at 1%.

 $\overset{\scriptstyle O}{}{}^{\rm M}{}$  Moving from 25th to 75th copayment percentiles.

<sup>c</sup>Moving from 25th to 75th coinsurance percentiles.

TABLE 6: SIMULATED COMPARISON OF COPAYMENTS VS. COINSURANCE <sup><math>a</math></sup>			
	Copayment Model Distribution	Coinsurance Model Distribution	
Never Comply	$0.335^{*}$ (0.003)	$0.379^{*}$ (0.005)	
Partially Comply	(0.341*) (0.001)	0.291* (0.002)	
Always Comply	$0.324^{*}$ (0.002)	0.330* (0.004)	
Observations:	20,465	6,561	

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



