MEDICARE PLAN D: IMPACT ON MEDICATION COMPLIANCE IN THE ELDERLY

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This dissertation examined the impact of Medicare Plan D on medication compliance in Medicare beneficiaries at University of Texas Health Center at Tyler, TX. Data were collected before and after the implementation of Plan D. The impacts of various types of benefits, such as private insurance, employer insurance and pharmacy assistance programs were evaluated in terms of impact on drug compliance. Medication compliance was found to increase in those respondents without Plan D. Plan D was found to be a predictor of those who spent less on basics in order to buy medications. Although compliance increased in general, these increases could not be attributed to the acquisition of a Plan D policy.
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CHAPTER 1
INTRODUCTION

Since it was signed into law in 1965 as a part of President Lyndon Johnson’s Great Society, Medicare has provided a basic program of health insurance for those Americans age 65 and older. Later, in 1972, this insurance program also included coverage for those Americans under age 65 with end stage renal disease and those who were disabled.

Although Medicare covers part of the costs of medical care for physicians, hospitals, some skilled nursing services and home health through its Parts A and B, the basic benefits of Medicare have not previously covered most outpatient prescription medications. Of course, the increasing numbers of Americans with chronic illness requiring multiple medications and the increasing expense associated with prescription medications has empowered the federal government to address the need for medication coverage as a part of Medicare.

A recent national survey of senior Medicare beneficiaries extensively examined use of prescription medication, prescription medication insurance coverage, and reasons for medication non-adherence (Safran, Neuman, Schoen, Kitchman, Wilson, Cooper et al., 2005). Overall, non-adherence due to medication cost was 26.3%. The University of Texas Health Center Internal Medicine Clinic aggressively enrolled Medicare patients without prescription medication insurance coverage into the institutionally sponsored medication program (sponsored by the pharmaceutical industry). Medicare Plan D, the federally sponsored Medicare prescription drug coverage plan began January 1, 2006. Medicare Plan D has substantially changed
prescription drug coverage options for Medicare patients, and may significantly affect prescription drug non-adherence rates for this population. Pharmaceutical industry sponsored programs for medically indigent patient (such at UT Health Center patients) have been affected by Plan D. In fact, many low-income Medicare beneficiaries who were enrolled in the drug benefit program receive no help from patient assistance programs, as many pharmaceutical companies have ended their pharmacy assistance programs.

The study examined prescription drug nonadherence for Medicare patients at University of Texas Health Center at Tyler (UTHCT) Internal Medicine Clinic. This study evaluates drug non-adherence in the studied population prior to and following the implementation of Medicare Plan D.

Significance of the Problem

It is not surprising that people with low incomes, older adults and those with chronic health problems face the biggest challenge with medication compliance. A patient’s decision to not fill prescriptions, take smaller doses than prescribed or skip doses altogether can lead to serious health complications, more hospitalizations, increased nursing home admissions and more acute visits to the emergency department. With more and more doctor’s visits resulting in prescriptions being written, medication noncompliance can be a probable occurrence in the segment of the population with no insurance coverage, those with low incomes and the elderly.

The consequences in drug noncompliance in the elderly population can be very serious. Salzman (1995) estimates noncompliance rates in the elderly to range from
40% to 75%. He found three forms of medication noncompliance in the older population: forgetting to take the medications, over or under use of medication including medication abuse, and modification of the dosages or scheduling of medications. He indicated the most common noncompliant behavior in the elderly was under use of the prescribed medication; however, discontinuing the medication can occur in 40% or more of situations.

One year before the implementation of Medicare Plan D, Soumerai, Pierre-Jacques, Zhang, Ross-Degnan, Adams, Gurwitz, Addler, & Safran, et.al. (2006) found 13% of elderly beneficiaries reported cost-related medication non-adherence. Those in fair to poor health with comorbidities and without coverage were most at risk. Sambamoorthi, Shea & Crystal (2003) found that in 1997, almost 8% of the older population or more than 2.3 million people spent more than 10% of their income on prescription medications. Despite pharmacy coverage, out-of-pocket cost burden fell most heavily on those with chronic health conditions and women.

Some describe Medicare Plan D as a real benefit for seniors, while others describe the program as a giveaway. There has been much debate on the role of the federal government in this program, particularly as it relates to applying pricing pressure on pharmaceutical companies. The new Medicare law has been labeled as a perfect plan for completely bankrupting the national health care budget by shifting those from Medicaid, which required companies to discount drugs by a minimum of 15%, to a new plan, Medicare Plan D, which prohibits discounts (Big Pharma Cashing In, 2006).

Saving (2005) states

That in terms of the financial obligation caused by Medicare Plan D and owed to the current generation, the difference between income from premiums and
expected expenses and expenditures is $6.2 trillion. He goes on to say that $10.3 trillion will be added to this debt if premiums remained unchanged and projected benefits are paid. He calculates the unfunded liability of Medicare Plan D as $16.6 trillion. (p. 4)

In testimony before the Committee on the Budget in the United States Senate, Butler (2007) representing the Heritage Foundation, stated, “Cost projections for the Medicare drug entitlement program were $822 billion through 2017. He further states that costs will be $60 billion per year by 2012 and $119 billion per year by 2017” (p. 5). According to his testimony, unfunded obligations on future generations have increased by a present value of $7.9 trillion, a figure which is larger than the entire publicly held debt in 2000.

Prescription coverage for the dual eligibles, those who were covered by both Medicaid and Medicare, shifted from Medicaid to the new Medicare prescription drug plan in 2006. States are now required to pay the federal government 90% of the cost of the prescription drug benefits of these dual eligibles. This is referred to as clawback payments. Even though states had previously paid all of the cost of these benefits for Medicaid recipients, it is unknown if this will truly result in a savings to the states. Many times states may have been able to negotiate for rebates or discounts, so this percentage may not be a true reflection of spending. Additionally, even though over time the 90% will decrease to 75% of prescription drug costs for dual eligibles, there is an inflation factor built into the clawback payment structure. It remains to be seen how the individual states will fare under this system. Initially, though, it does appear that the states may not receive as much Medicaid relief as they had expected would accompany a Medicare prescription drug benefit. With many states situations being different, it is difficult to predict the full impact on state budgets.
Medicare Plan D is projected to lower costs of medications for most elderly patients. However, seven million of these Medicare beneficiaries are projected to fall into the *doughnut hole*. This stay in the *hole* can last as long as seven months. This, of course, is based on annual drug costs. These patients are significantly more likely to try to cut their costs, an activity which can surely lead to non-adherence. Cost-cutting strategies on the part of the patient can also jeopardize other necessities, such as housing and food (Tseng, Brook, Keeler, Steers, & Mangione, 2004).

Despite some relief for some patients in prescription costs with Medicare Plan D, 3.8 million Plan D beneficiaries are expected to have annual out-of-pocket costs between $750 and $3,600, and another 3.1 million may have more than $3,600 in out-of-pocket costs for prescriptions. Of these 6.9 million, 28% have incomes less than 150% of the poverty level. Although these patients would probably qualify for low-income subsidies, it is estimated that almost 40% of beneficiaries eligible for subsidies may not enroll (Estimates of beneficiaries’ out-of-pocket, 2004). Without these subsidies, patients with low incomes and high medication costs could spend 25% of their income on prescription drugs (Stuart, Briesacher, Shea, Cooper, Baysac, Limcangca, M., 2005). Or, in many cases, patients may decide to not fill their prescriptions, skip doses or take smaller doses of their medications in order to cut their medication expenses.
CHAPTER 2
REVIEW OF THE LITERATURE

Medicare Plan D: Impact on Medication Compliance in the Elderly

Beginning in 2006, the Medicare Prescription Drug, Improvement, and Modernization Act began offering prescription drug benefits to approximately 43 million Medicare beneficiaries nationwide. The Medicare Modernization Act (MMA) represents the most substantial expansion of Medicare since the program began 40 years ago. It was projected to cost the government $720 billion in the first 10 years (Lee, 2005). This program will operate through private insurance plans (Safran et al., 2005).

Historically, Medicare has not provided coverage for outpatient prescription drugs. Because of the important role prescription drugs play in health care, particularly in older adults, and the rising costs associated with medications, Plan D was advocated as a strategy to lower cost for older adults and to improve drug-taking behavior.

The Plan

The MMA was passed by the legislature in 2003. A part of this major legislation is Medicare Plan D, which is the outpatient prescription drug benefit which became effective in January, 2006.

Prior to the passage of Medicare Plan D, there was overwhelming public support of the older population for the addition of a prescription drug benefit to Medicare. However, the Henry J. Kaiser Family Foundation (Kaiser Foundation, 2005, March/April) found that the older adults’ views of the new prescription drug benefit were mixed. Between February 2004 and December 2004, approximately 50% of older adults
expressed an unfavorable impression of the new law, compared with about 30% who said they have are in favor of the new Plan D. By April 2005, more seniors said they had an unfavorable impression (34%) than a favorable impression (21%). However, nearly half of these seniors had a neutral impression or said they did not know what to expect and had made little to no investigation as to this new plan’s impact on their own drug purchases.

Prior to the inception of Medicare Plan D, the Kaiser Foundation (2005, August) found there were gaps in older adults’ understanding of the prescription drug benefit and its impact on their particular situations. In fact, about 68% admitted they did not have a good understanding of Plan D, and, therefore, did not know how it would affect them personally. By April 2005, few older adults said they were planning to enroll in a new drug plan: less than one in ten (9%) said they would enroll, while nearly four in ten (37%) say they would not. The majority of seniors said they either had not heard enough to decide (47%) or did not know (7%) whether they would enroll (Kaiser Foundation, 2006, July 27). But, as it turned out, around 30 million had prescription drug coverage through Medicare in 2006, the first year of the new program (Medicare Part D: What’s new, 2007). About 12 million were expected to maintain their insurance coverage through their employer (Wolf, 2005). In mid-2006, more than eight in 10 seniors who were enrolled in the prescription drug plan were satisfied with their plan even though almost 20% indicated they encountered a major problem using the program (Kaiser Foundation, 2006, December 13). The Kaiser Foundation also found that nearly 90% of those reporting minor problems indicated satisfactory solutions to those problems.
In the new Medicare Plan D drug benefit, beneficiaries with high medication expenditures also face a period without drug coverage when their total drug costs exceed annual caps but are not high enough to qualify for catastrophic coverage. This, of course, can be problematic for this segment of the older population.

The MMA, which was strongly supported by drug manufacturers, is a voluntary program that is administered by private companies. This act has two specific features that have evoked considerable criticism. The first concern is that there is a very formidable gap in coverage. During 2006, participants in the plan paid the first $250, and then they had a co-pay of 25% for the next $2,250 of prescription expenditures per year. Then there is no coverage until the senior has spent $5,100. This gap, which has been referred to the *doughnut hole*, was inserted in an attempt to keep the costs of the drug coverage program less than $400 billion over a 10-year period (Altman, 2004). Once the beneficiary had spent a total of $3,600 out of pocket expenses, which included the deductible, the drug coverage would then resume. The beneficiary paid 5% of covered drug costs or a co-payment up to five dollars. There was no yearly limit.

Studies have shown that when out-of-pocket expenses for drugs increase because of increasing co-pays or loss of drug benefits, patients respond by skipping or discontinuing medications (Kaiser Foundation, 2002).

In 2007, the coverage gap, or *doughnut hole* has changed. The limit for the beneficiary’s out-of-pocket expense is $2,400. Once that limit has been reached, the beneficiary must then pay $3,850 from their own funds before the plan will resume paying for prescriptions. About one-third of the plans will offer coverage in the *doughnut hole*, with premiums averaging $40 to $50 per month. Other changes for 2007 include a
change in the yearly deductible from $250 to $265 (Medicare Prescription Plans: What’s new, 2006).

Welch (2005) expounded on some of the key features of the Medicare Plan D prescription coverage program. The coverage is not based on income. Anyone on Medicare can enroll, but the poor will be eligible for subsidies to cover out-of-pocket expenses, including premiums, co-payments and deductibles. Welch also stated that an estimated 14 million older adults, or approximately 30% of the Medicare population, would be eligible for additional aid in 2006.

Welch continued to detail how lower income older adults might qualify for increased assistance with their individual drug costs. For those who qualified, the federal government planned to pay 85% to 100% of their costs. The lower socioeconomic group of older adults would have more of their costs covered.

To qualify for this additional assistance, older adults must have incomes of less than $14,355 for individuals and $19,245 for couples, respectively, and limited assets. The assets that would be assessed included savings, investments and real estate other than the home where they live, which may not be worth more than $11,500 for individuals and $23,000 for couples.

A study by Pear (2005) showed the premiums for free-standing drug coverage would start as low as $1.87 per month, under a plan offered by Humana in a seven-state region which included Iowa, Minnesota, Montana, Nebraska, North Dakota, South Dakota and Wyoming. The monthly premiums ranged from $13.58 to $99.90 with three drug plans offered in the same region by a consortium of Blue Cross and Blue Shield Association companies. A plan through the American Association of Retired Persons
(AARP), the grassroots lobby for older Americans, is available nationally, but charges vary by state. The premium is generally $23 to $26 per month.

The average premium for Plan D coverage in 2007 is around $29 per month. There are some plans as low as $5 to $20, but the lowest premiums in most areas will be about $20 (Medicare Prescription Drug Plans: What’s new, 2006).

The number of national drug plans offering coverage in every state has risen to 17 in the second year of Medicare Plan D. The average number of drugs covered by insurers increased by 13% in 2007 to 4,390 drugs with coverage (Pear, 2007).

Those who are eligible for both Medicare and Medicaid are automatically deemed eligible for low-income subsidies. Other low-income beneficiaries of Medicare will have to meet both an income and asset test to be eligible for assistance. Asset tests are generally used for various low-income programs to focus benefits toward those truly low-income individuals and to exclude those with limited incomes but substantial assets available to them.

Rice & Desmond (2005) estimated that in 2006, when the new Medicare prescription drug benefit went into effect, 2.37 million low-income Medicare beneficiaries would not qualify for subsidized coverage because they failed the asset test. This meant these individuals would face the same doughnut hole as other beneficiaries—which means substantial out-of-pocket expenses.

This study by Rice & Desmond (2005) also looked at the types of beneficiaries and the types of assets which were involved. They found that the asset test fell most heavily on those who were widowed. Even though only 29% of Medicare beneficiaries are widowed, almost half of those were women. Additionally, widows who tend to live
alone are generally older and have more chronic illnesses necessitating prescription medications, also were found to have less family support.

As expected, they also found that most individuals who failed the asset test tended to have rather modest assets, which included small bank accounts and relatively no stocks, mutual funds or bonds. They also had little in the way of Individual Retirement Accounts (IRA) and 401(k)s, real estate (other than their home) and virtually no business equity.

Statement of the Problem

*Drug Expenditures*

The four decades since Medicare was enacted have seen a remarkable increase in the expenditures for prescription medications. Medicare beneficiaries make up about 12% of the population and account for about one-third of total United States (U.S.) drug expenditures (Steinberg, E.P., Gutierrez, B., Momani, A, et al., 2000). On average, people ages 75 to 79 spend 25% more on drugs than those 65 to 69. Nearly 20% of people on Medicare are projected to spend at least $5,000 per person in drug costs during 2006 (Novelli, 2005). This study did not include the increases in prescription medicine expenditures in the oldest old, or those individuals who were over 80 years old.

In reviewing out-of-pocket expenses and unmet health needs related to obtaining prescription drugs for the U.S. civilian population in 2002, it was found that only 16% of all families did not have an out-of-pocket expense for prescription drugs (Crimmel & Stagnitti, 2005). Families without an elderly member were more than 3 times as likely
not to have an out-of-pocket expense (19.2%) than families with an elderly member (5.4%). Slightly more than one-fifth of all families included at least one elderly person.

There are multiple factors that have caused the marked increase in expenditures for prescription drugs by the Medicare population over the last several decades. With the aging of our population as well as the increasing numbers of Baby-boomers reaching retirement age, the number of seniors with chronic conditions requiring prescription drugs is increasing and will continue to increase. Medical research has led to the development and availability of an increased number of new and effective drugs for the treatment of these chronic various conditions (Kaiser Foundation, 2004). In fact, with the first of 70 million boomers beginning to turn 60 this year, the problems of health care and prescription drug coverage are magnified (Doctors for boomers, 2005). The average number of medications per senior is increasing. From 1997 to 2001, there was a 23% increase in the number of prescriptions per senior (Kaiser Foundation, 2004).

Another major cause of the increase in drug costs in the U.S. is that the prices of brand name drugs are much higher than in the rest of the world (Kaiser Foundation, 2003). Most other industrialized countries limit drug prices by a variety of methods, such a formulary pricing, reference pricing or price controls. These techniques have been highly effective: prices of brand name drugs in other industrialized nations are 34%-59% lower than in the U.S.

Moeller, Miller & Banthin (2004) reported that the cost of prescription drugs had increased 26% greater than the rate of inflation between 1997 and 2001. Families USA (2004) reported that the average wholesale price of 30 brand-name drugs most prescribed for seniors had increased by 22% from 2001 to 2004.
Within the three months after passage of the Medicare Prescription Bill Act in December 2003, brand-name drugs increased in cost by 3.4%. This was compared to an inflation rate of 1.2% (AARP Public Policy Institute, 2004). The pharmaceutical industry espouses that these price increases are related to increased expenditures for research and development of pharmaceuticals (Families USA, 2004).

Of course, as the number and cost of prescription medications has accelerated, the cost of drugs per individual has increased. In 2003, the average expenditure per Medicare beneficiary that was paid by a senior or by a third party was $2,322 per year (Oliver, Lee & Lipton, 2004). The Congressional Budget Office estimated that the average cost of drugs per beneficiary in 2006, which was the first year of Medicare’s Plan D prescription benefit program, would be $3,155 (Iglehart, 2004).

Drug costs for the older adults with multiple chronic health conditions are much greater than the averages for the total senior population (Steinberg et al., 2000). In 1995, 5% of seniors had drug costs greater than $4,000. This figure increased to 16% according to the Kaiser Foundation (2003). Fox (2003) found that in 1998 over 10% of seniors had drug expenses more than $6,000.

**Drug Compliance**

With almost two-thirds of Americans using medications, compliance has become a troublesome issue. Of those currently using medications, 49% use prescriptions drugs, while almost 30% use non-prescription medications. Twenty-two percent of Americans take less than prescribed of the medication, with 12% not filling their prescription at all. Another 12% of Americans do not take their medications even after
they have purchased them. Ten percent of all hospital admissions and 23% of all nursing home admissions are the result of patients not taking their medications correctly. The average length of stay in the hospital due to medication noncompliance is 4.2 days. Two-thirds of all Americans fail to take any or all of their prescription medications (Statistics you need to know, (n.d.)

Goldman, Joyce, Escarce, Pace, Soloman, & Laouri, et al. (2004) found that rapid changes in drug benefits have shifted a larger burden of pharmacy drug costs onto the beneficiaries. Beneficiaries have responded by reducing their use of drugs. Their study revealed that the populations most sensitive to price changes were the patients taking long-term medications who were not receiving ongoing care for a chronic condition with at least two medical visits per year associated with the chronic disease care.

Patients who are concerned about out-of-pocket medication costs often restrict their use of prescription drugs (Steinman, Sands & Covinsky, 2001). Since patients with multiple chronic illnesses often take several medications, they are particularly susceptible to the higher medication costs. Chronically ill patients who restrict their medication use because of cost often restrict essential medications such as hypoglycemics, diuretics, bronchodilators, and antipsychotics. This underuse of these medications for chronic health conditions has been associated with serious health consequences including increased emergency room visits, nursing home admissions, acute psychiatric hospitalizations, and a self-reported decline in health status (Martin & McMillan, 1996; Soumerai, Ross-Degnan, Avorn, McLaughlin & Choodnovsky, 1991).

The Kaiser Foundation (2003) conducted a survey which found that four in ten
older adults admitted that they had not taken all the drugs their doctors prescribed for
them in the past year. There were numerous reasons for their non-compliance: because
the cost of the drug(s) were too high, because they did not think the drugs were helping
them; or because they did not think they needed them.

Other findings of the survey found that of the 89% of older adults who report
taking prescription drugs in the past year, nearly half (46%) take five or more, more than
half (54%) have more than one doctor who prescribes the medicines, and about a third
(35%) use more than one pharmacy. Among older adults with a minimum of three
chronic health conditions, nearly three of four (73%) take five or more medications
regularly and more than half (53%) do not take all their drugs as prescribed (Kaiser
Foundation, 2003).

Studies have shown that when out-of-pocket expenses for drugs increase
because of increasing co-pays or loss of drug benefits, patients respond by skipping or
discontinuing medications (Kaiser Foundation, 2002). Tamblyn et al. (2001) studied the
effect of increasing out-of-pocket drug expenses on compliance with drug therapy and
its consequences. In Quebec, Canada, prior to 1996, prescriptions were free for the
older population if they were of lower socioeconomic status and, if not poor, they paid
two dollars per prescription. In 1996, the law was changed: the co-pay became $25 per
prescription. Drug use was examined before and after the new law became effective.
After the new law, 9% of the elderly discontinued essential drugs. The incidence of
adverse events (defined as first acute hospital admission or death) in those who
discontinued essential drugs doubled with the statistics showing a rise from 5.8 to 12.6
per 10,000 person-months. Further, there was a significant increase in emergency room visits by those who discontinued essential drugs.

The Kaiser Foundation (2003) also found that the average senior's out-of-pocket spending for prescription drugs increased from $644 in 2000 to $1,147 in 2004. Of course, the seniors who are most vulnerable to the increasing costs of drugs are those with multiple chronic conditions who are poor and have no drug coverage. Thirty percent of seniors have at least three chronic medical conditions that require prescription medications (Moxey, O’Connor, & Novielli, 2003).

Seniors who are poor but not on Medicaid may spend 50% of their income on health care, prescription drugs, and co-pays (Sourmerai & Ross-Degnan, 1999). As an example, middle-aged and older Americans with heart disease who have cut back on their prescribed medications because of cost were 50% more likely to suffer heart attacks, strokes, or angina than those who did not report cost-related medication underuse (NIH News, 2004). Rector and Venus (2004) studied Medicare beneficiaries in five states and found 13% did not fill or refill their prescriptions because of cost.

**Drug Coverage**

Approximately 10 million older adults, or about one in four Medicare beneficiaries, are without prescription drug coverage (Congressional Budget Office, 2003). According to a National Council on Aging report, between 3.4 million and 4.4 million Medicare beneficiaries qualify for the subsidy program under the prescription drug benefit program, however, they have not applied for the assistance. This report
also found that 2.9 million Medicare beneficiaries who are not enrolled in Medicare Plan D do not have any other coverage (National Council on Aging (NCOA), 2007).

Drug coverage has been shown to make a substantial difference in compliance issues for chronic conditions, with 37% of seniors without drug coverage reporting cost-related non-adherence, compared with 22% of seniors with drug coverage. Low-income older adults without the benefit of drug coverage generally took fewer drugs than those with drug coverage. Older adults also reported wide differences in the source of their drug coverage across states. Nationally 29% of seniors reported having employer-sponsored drug coverage, but state rates for employer-sponsored drug coverage ranged from 24% in Washington to 47% in Michigan.

The Congressional Budget Office (2003) also questioned the older adults about their prescription purchases from other countries. Overall, one in twenty seniors (5%) reported having obtained their prescription drugs from pharmacies in Canada or Mexico. Again, these rates varied across the U.S., from a high of 11% in Washington to a low of 2% in New York. Older adults without the benefit of a drug coverage program were more likely to obtain drugs from Canada or Mexico. Nationally 11% of seniors without drug coverage reported obtaining drugs from either Canada or Mexico, with state levels ranging from 19% in Colorado to 5% in Tennessee (Kaiser Foundation, 2003).

A study done by Tseng, Brook, Keeler, Steers, & Mangione (2004) found that 12 of the top 20 therapeutic classes of prescription medications most affected by decreases in use were for chronic health problems such as hypertension, hyperlipidemia, and emphysema or asthma. They contend that one of the major reasons for non-compliance with medication use was that the majority of Medicare drug
benefits in managed care have annual dollar limits or caps and many beneficiaries face temporary but potentially significant gaps in coverage after exceeding the caps before the end of the year.

The Implications

Drug Pricing Negotiations

Congress has prohibited the federal government from negotiating drug prices directly with pharmaceutical manufacturers. This has been a highly controversial decision and has added to the complexity of the program because instead of having a single, government-negotiated price schedule and formulary, each Medicare-approved prescription drug plan will negotiate its own pricing. This means that each will have their own preferred drugs, subject, of course, to federal guidelines. This will certainly affect the out-of-pocket expenses of the beneficiaries because their expenses will directly depend on whether their plan’s preferred list includes the drugs that they take. Those that they take that are not on the preferred list will pay more.

Politics has not eluded the Medicare Plan D. Most Republican Congressmen have opposed government price-setting and believe the private sector can do a better job. By prohibiting direct price negotiation, Congress also could forestall opposition from drug manufacturers that might have sunk the bill.

Many Democrats have bitterly opposed the bill that created the Medicare Plan D drug benefit. For the most part, they have favored using the government directly to administer the new coverage. They continue to argue that the benefit remains
complicated and the real reason for using the private sector to administer the benefit is to repay the drug manufacturers for their support of the Republican Party.

There is the belief that prescription drug costs may cause considerable strain on the federal government’s ability to fund the program while meeting all other obligations. The question still remains about how to keep Medicare around—and solvent—for the Baby-boomers.

**Asset Testing**

There seem to be some serious questions about the asset testing portion of the new drug benefit. Americans have always been encouraged to save for their retirement years. Those with the least potential for saving for the future will most probably have little or no income other than what they receive from Social Security. If these same people had been able to save and accumulate modest amounts of assets, they most surely would not qualify for the low-income Medicare subsidies, even though the biggest majority of them are using prescription drugs every day. Those who did save will not be able to qualify for subsidies. Those who did not will have the subsidies, but nothing else for retirement except their Social Security. The majority of those caught in this dilemma are the most vulnerable of our older population.

**Drug Company Programs vs. Medicare Plan D**

Havrda, Omundsen, Bender & Kirkpatrick (2005) studied the impact of the MMA on lower income Medicare beneficiaries without prescription benefits who received assistance from pharmaceutical companies for medications. The findings showed that
the MMA offered the low-income Medicare population previously with minimal or no drug coverage, lower drug costs than those they would have incurred by obtaining medications without any assistance. The population they studied received help with medications through the pharmaceutical companies’ programs. This help resulted in substantial savings in total drug costs. In this group, Havrda et al. (2005) found that the Medicare drug discount program resulted in out-of-pocket costs that exceeded those associated with pharmaceutical company assistance programs. The Medicare prescription benefit offered greater savings to individuals with incomes less than 135% of the Federal Poverty Level (FPL) than to any other group. They also found that groups with incomes of 135% to 150% of FPL and greater than 150% of FPL had reduced out-of-pocket expenses with the prescription benefit compared to no assistance at all; however, an advantage over the pharmaceutical company assistance programs was not evident. Many pharmaceutical companies ended their pharmacy assistance programs after the Medicare prescription benefit began. They site concerns that the programs could violate anti-kickback laws (Appleby, 2007).

Conclusion

The need to provide adequate drug benefits for all older adults is great. As has been expected, there is still much confusion and lack of understanding on the part of those who are intended to be helped by Medicare Plan D. As with any new program, there are and will be problems and hurdles to overcome. With any government program, keeping costs down and benefits up is a difficult challenge.

There should be some areas in the future where the public and private sectors
should be able to collaborate in order to provide effective data and evidence for program modification, enhancement and new program development. There will surely be independent analyses and research based on the data on drugs, medical outcomes, chronic disease progression, costs and other data which can be extrapolated from a medication program like Medicare Plan D. It would be hoped that as a result of this research this program could then be used to provide better services, more targeted assistance, improve medication compliance and lower costs as the program evolve.

It will be interesting to see how the doughnut hole in coverage will affect older adults. Some say this gap in coverage will be of marginal benefit to older adults with multiple medical conditions. Could ways be devised to eliminate the gap without increasing expenditures? If so, who would pay? What effect will lack of negotiations by the federal government for drug pricing have on the overall program? Will drug benefits effectively reduce cost-related under use of drugs and improve clinical outcomes?

These and many other questions beg to be answered in the second year of this new drug benefit program. Research on all aspects of this program should be ongoing and hopefully will provide at least some direction, if not answers.
CHAPTER 3

METHODOLOGY

Criterion for Inclusion

Any English speaking University of Texas Health Center (UTHCT) Internal Medicine Clinic (IMC) patient who is enrolled in the Medicare program and age 65 years or older was invited to participate in this study by completing a survey. Participation in the study was completely voluntary. Completion of the survey took approximately 10 minutes and involved no foreseeable risks. Consent was considered to be obtained by the completion of the survey. All respondents’ information was completely confidential as there were no identifiers of any kind on the survey.

Protection of Human Subjects

Prior to participating in this study, participants were given verbal as well as written information, and permission was granted by the University of North Texas Institutional Review Board (See Appendix C). Completion of the survey indicated consent. Participants were assured verbally and in writing of the confidential nature of the information collected. Surveys contained no identifying information of any kind. Participation was completely voluntary. All data collected were kept in a locked file cabinet on the 5th floor of the University of Texas Health Center at Tyler.

Sample

The sample collected was a census sample. The numbers of completed surveys were expected to be 450-500; however, 789 completed surveys were collected. The
response rate was approximately 22%. These surveys were collected at two different
times. The first survey was done in October and November, 2005, prior to the
implementation of Medicare Plan D. The second survey was done in October and
November, 2006, after Medicare Plan D became effective on January 1, 2006. Only
patients of UTHCT IMC who are 65 years or older, Medicare beneficiaries and English
speaking were offered the opportunity of participating in the survey.

Survey

The survey tool developed for this study was a 36 question survey. Questions
included demographic information such as age, sex, ethnicity, education, and marital
status. Other questions queried the financial assets and monthly income of the patient,
as well as questions related to the type of medication prescription insurance currently
been utilized and questions directed toward medication compliance issues. Copies of
this survey are found in Appendix A and Appendix B. The only difference in the surveys
is question 12. The first survey conducted which was conducted in 2005 reflected the
use or non-use of Medicaid to help pay for prescriptions, while the second survey,
completed in 2006, identified those who did or did not utilize the new prescription benefit
program, Medicare Plan D.

Research Methodology

I transferred the data from the completed survey forms to a Microsoft® ACCESS
2006 database.¹ After the data were entered into the database, it was exported to

SPSS™ statistical software² for analysis. Investigations were done by looking at medication compliance issues prior to and after the implementation of Medicare Plan D. Statistics were compiled by using cross tab tables with chi-square reporting. Comparison of $t$-tests were also done. The outcome measure was always the compliance variable of - did not fill prescriptions because of expense. The outcome was evaluated in terms of the types of insurance coverage the respondent may have had, whether or not they had Medicaid and whether they utilized Medicare Plan D. Other evaluations were done exploring the effects education, gender and race may have had on nonadherence in the studied population.

² Copyright © SPSS Inc. All rights reserved.
CHAPTER 4
RESULTS

The first survey done in fall 2005 had 480 respondents, while the second one, completed in fall 2006, had 309 respondents. Both groups, however, showed many similarities in the general population characteristics. Approximately 65% of the respondents were women in both periods, while men were approximately 35% of those who responded. The average age of the surveyed population was 73.5 years in the first group and almost 75 years in the second group. Most of the respondents in both time periods were married, with 27% and 30%, respectively, indicating they were widows. Approximately 28% lived alone with over 80% in both surveys indicating they were Caucasian. The 2005 survey included 16.5% African Americans, while the 2006 survey showed 12.5% African Americans. Approximately 33% of all respondents had a high school education or more. Over 85% of all respondents indicated they took prescription medication, with 6 medications as the average taken by those surveyed. As shown in Table 1 the pre and post groups were quite similar except for decline in the number of minorities in the second sample.

Particular attention was given to drug compliance in the pre and post periods. The pre period included those respondents in fall 2006, while the post period was in fall 2006; about 10 months after Medicare Plan D became effective. Data analyzed for compliance included questions related to always filling prescriptions, never skipping doses and never taking smaller doses in order to make medications last longer. Approximately 70% of respondents in the pre group always filled their prescriptions, compared to almost 79% in the post group as depicted in Table 2.
Table 1
General Population Characteristics of Samples in Two Surveys

<table>
<thead>
<tr>
<th></th>
<th>PRE</th>
<th>POST</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Women</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>%</td>
<td>64.8</td>
<td>66.1</td>
</tr>
<tr>
<td>n</td>
<td>469</td>
<td>307</td>
</tr>
<tr>
<td><strong>Average Age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>%</td>
<td>73.48</td>
<td>74.88</td>
</tr>
<tr>
<td>n</td>
<td>478</td>
<td>308</td>
</tr>
<tr>
<td><strong>Married</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>%</td>
<td>63.3</td>
<td>62.0</td>
</tr>
<tr>
<td>n</td>
<td>477</td>
<td>308</td>
</tr>
<tr>
<td><strong>Widowed</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>%</td>
<td>26.8</td>
<td>29.9</td>
</tr>
<tr>
<td>n</td>
<td>477</td>
<td>308</td>
</tr>
<tr>
<td><strong>Lives Alone</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>%</td>
<td>28.6</td>
<td>27.6</td>
</tr>
<tr>
<td>n</td>
<td>477</td>
<td>308</td>
</tr>
<tr>
<td><strong>Caucasian</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>%</td>
<td>81.6</td>
<td>86.7</td>
</tr>
<tr>
<td>n</td>
<td>474</td>
<td>30</td>
</tr>
<tr>
<td><strong>African American</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>%</td>
<td>16.5</td>
<td>12.3</td>
</tr>
<tr>
<td>n</td>
<td>474</td>
<td>309</td>
</tr>
<tr>
<td><strong>High school &amp; more</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>%</td>
<td>33.5</td>
<td>33.6</td>
</tr>
<tr>
<td>n</td>
<td>478</td>
<td>307</td>
</tr>
<tr>
<td><strong>Total in Samples</strong></td>
<td>480</td>
<td>309</td>
</tr>
</tbody>
</table>

Table 2
Prescriptions Not Filled During a 12 Month Period Due to Expense

<table>
<thead>
<tr>
<th></th>
<th>Always Filled</th>
<th>Did not fill 1 or more times</th>
<th>Total</th>
<th>Missing Data</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pre</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>%</td>
<td>70.4</td>
<td>29.6</td>
<td>432</td>
<td>48</td>
</tr>
<tr>
<td>n</td>
<td>304</td>
<td>128</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Post</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>%</td>
<td>78.5</td>
<td>21.5</td>
<td>289</td>
<td>20</td>
</tr>
<tr>
<td>n</td>
<td>227</td>
<td>62</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The results were very similar for the other two compliance questions. In the pre group, 70% said they never skipped doses in order to make the medication last longer. In the post group, 78.95% indicated they never skipped their medication (See Table 3)

Table 3
*Doses Skipped During the Last 12 Months to Make Prescription Last Longer*

<table>
<thead>
<tr>
<th></th>
<th>No / Never</th>
<th>Yes, Sometimes or Often</th>
<th>Total</th>
<th>Missing Data</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pre</strong></td>
<td>% 70.0</td>
<td>30.0</td>
<td>423</td>
<td>57</td>
</tr>
<tr>
<td>n</td>
<td>296</td>
<td>127</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Post</strong></td>
<td>% 78.9</td>
<td>21.1</td>
<td>285</td>
<td>24</td>
</tr>
<tr>
<td>n</td>
<td>225</td>
<td>60</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

In terms of taking smaller doses in order to make their medication last longer, 71% of those in the pre group indicated they had never done so while 79.6% in the post group indicated they had never taken smaller doses. (See Table 4)

Table 4
*Smaller Doses Taken During the Last 12 Months to Make Prescription Last Longer*

<table>
<thead>
<tr>
<th></th>
<th>No / Never</th>
<th>Yes, Sometimes or Often</th>
<th>Total</th>
<th>Missing Data</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pre</strong></td>
<td>% 70.7</td>
<td>29.3</td>
<td>427</td>
<td>53</td>
</tr>
<tr>
<td>n</td>
<td>302</td>
<td>125</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Post</strong></td>
<td>% 85.4</td>
<td>14.6</td>
<td>288</td>
<td>21</td>
</tr>
<tr>
<td>n</td>
<td>246</td>
<td>42</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Overall, about 70% were compliant in these three areas before Medicare Plan D, and approximately 79% were compliant after Medicare Plan D. These increases might possibly be related to the acquisition of Plan D by some who may have had no other coverage previously.
From Time 1 to Time 2 there were some interesting shifts in coverage. The most significant was in benefits for prescriptions. When asked whether they had insurance or benefits to help pay for prescriptions, 52% of the respondents in the pre period said they had some type of benefits to help them. However, that figure increased to almost 80% in the post period. This increase might be due to an increase in those respondents who now had coverage under Plan D. Those with coverage through their job or employer remained fairly stable between the two periods. However, those with insurance they bought for themselves (private insurance) increased from 19.6% in the pre period to 30.7% in the post period. This increase in those who said they had private insurance after Medicare Plan D became effective might be because those who now had Plan D coverage may have considered that to be a form of private insurance. Some people may have had both private insurance and Medicare Plan D. (See Table 5)

Table 5

<table>
<thead>
<tr>
<th>Benefits and Types of Coverage</th>
<th>Pre</th>
<th>Post</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>Have Benefits for Prescriptions</td>
<td>51.7</td>
<td>441</td>
</tr>
<tr>
<td>Company Drug Insurance</td>
<td>28.4</td>
<td>447</td>
</tr>
<tr>
<td>Private Drug Insurance</td>
<td>19.6</td>
<td>443</td>
</tr>
<tr>
<td>VA Drug Insurance</td>
<td>11.9</td>
<td>438</td>
</tr>
<tr>
<td>Pharmacy Discount Card</td>
<td>20.3</td>
<td>444</td>
</tr>
<tr>
<td>UT Pharmacy Assistance Program</td>
<td>24.7</td>
<td>438</td>
</tr>
<tr>
<td>Another Pharmacy Program</td>
<td>6.2</td>
<td>433</td>
</tr>
<tr>
<td>Part D</td>
<td>(n/a)</td>
<td></td>
</tr>
<tr>
<td>Medicaid</td>
<td>11.9</td>
<td>441</td>
</tr>
</tbody>
</table>

*Note: n/a = not applicable.*
Those respondents indicating they had either a pharmacy discount card or utilized the University of Texas Pharmacy Assistance Program (UTPAP) sharply declined in the post period. This would be an expected finding, as many Pharmacy Assistance Programs (PAPs) were not available to help Medicare beneficiaries pay for medications after Plan D became effective. However, interestingly, when respondents were asked about utilizing another pharmacy program, 15.6% of those in post group responded that they did utilize such a program, while only 6.2% indicated such usage in the pre group. The analysis of those with either an outside pharmacy assistance program or Medicare Plan D showed 17.4% of respondents with both as shown in Table 5. This might be explained by the thought that many respondents may see Medicare Plan D as another pharmacy program that they now used to help with their prescriptions.

Over 50% of the population indicated having Plan D coverage, while previously only a small percentage indicated they had Medicaid coverage. It is possible to say there was a big boost with Plan D and that might explain the increase in benefits in prescription coverage. However, although it is true that the categories of private insurance and other PAPs did show increases, these increases are not of significant magnitude to explain this boost in coverage.

We have now returned to the central question: Did Medicare Plan D enhance compliance? Table 6 shows a comparison between Year 1 (pre Plan D) and Year 2 (Plan D) across compliance questions. Year 2 is further considered in terms of those who did and did not have Plan D coverage. Compliance increased substantially in Time 2 compared with Time 1. However, those increases in compliance were greater in those who did not have Plan D. Although overall compliance was increased between the two
time periods, the major concern remains as to whether this increase can be attributed to coverage. Increased compliance is not explained by having Plan D coverage.

At Time 2, after the changes to Medicare coverage, having Medicare Plan D was cross tabulated by failure to fill a prescription due to cost and the two variables were related, ($X^2 = 14.4, p = .013$). For those who indicated having Plan D coverage, 71.5% indicated never having failed to fill a prescription, while for those without Plan D coverage, 86.5% indicated never failing to fill a prescription. Thus, those patients covered by Plan D were less likely to be fully compliant in filling prescriptions than those without Plan D as Table 6 reflects.

Of those with Medicare Plan D, 73.6% indicated that they never skipped doses of a medicine in order to make the prescription last longer. Among those without Plan D coverage, 85.6% indicated they never skipped their medicines in order to make them last longer as shown in Table 6. These variables were found to be significantly related to each other ($X^2 = 6.0, p = .049$).

The comparison of those who did or did not have Medicare Plan D in terms of taking smaller doses of medicines in order to make them last longer found the two variables to be unrelated ($X^2 = 4.316, p = .116$). Plan D coverage did not significantly predict the taking of smaller doses. (See Table 6)

Thus, overall, Plan D coverage significantly predicts greater noncompliance in sometimes failing to fill prescriptions or in skipping doses to make them last longer. Obviously, having Medicare Plan D could not explain the increased compliance on two of these measures.
Table 6
Comparison between Year 1 (Pre Plan D) and Year 2 (Plan D) across Compliance Questions

<table>
<thead>
<tr>
<th></th>
<th>Year 1 (Pre)</th>
<th>Year 2 (Post)</th>
<th>Year 2 (Post)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Part D</td>
<td>Not</td>
</tr>
<tr>
<td>Always Filled</td>
<td>%</td>
<td>70.4</td>
<td>71.5</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>304</td>
<td>140</td>
</tr>
<tr>
<td>Never Skipped Doses</td>
<td>%</td>
<td>70.0</td>
<td>73.6</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>296</td>
<td>148</td>
</tr>
<tr>
<td>Never Took Smaller Doses</td>
<td>%</td>
<td>70.7</td>
<td>82.7</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>302</td>
<td>150</td>
</tr>
</tbody>
</table>

Thus, overall, Plan D coverage significantly predicts greater noncompliance in sometimes failing to fill prescriptions or in skipping doses to make them last longer. Obviously, having Medicare Plan D could not explain the increased compliance on two of these measures.

Next, the compliance questions were evaluated in terms of those who indicated they had some type of assistance to help pay for prescriptions other than Plan D. Survey results found that 81.6% of those in the pre period who indicated they had some type of benefit or insurance to help with medications always filled their prescriptions. A similar number of 81.5% was reported in the post period. However, 58.2% of those in the pre period who indicated they did not have any benefit or insurance to help with their medication needs reported always filling their prescriptions compared to 72.2% in the post period. (See Table 7) Therefore, although an increase in compliance was found among those without coverage those with coverage tended to have greater compliance.
Table 7

Those Who Indicated They Had Benefits or Insurance to Help Pay for Prescriptions in Terms of Filling or Not Filling Their Prescriptions

<table>
<thead>
<tr>
<th>Benefit</th>
<th>Always Filled</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Pre</td>
<td>Post</td>
</tr>
<tr>
<td>Yes</td>
<td>%</td>
<td>81.6</td>
<td>81.5</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>178 / 218</td>
<td>181 / 222</td>
</tr>
<tr>
<td>No</td>
<td>%</td>
<td>58.2</td>
<td>72.2</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>116 / 199</td>
<td>39 / 54</td>
</tr>
</tbody>
</table>

As displayed in Table 8, in terms of those who did or did not have benefits for prescriptions, 73.3% of those in the pre period indicated they never skipped doses because of expense. This is similar to 79.5% who had benefits and did not skip in the post period. However, 79.2% of those in post period who said they had no benefits or insurance for prescriptions indicated they never skipped doses compared to 57.5% in the pre period.

Table 8

Those Who Indicated They Had Benefits or Insurance to Help Pay for Prescriptions in Terms of Those Who Never Skipped Doses

<table>
<thead>
<tr>
<th>Benefit</th>
<th>Never Skipped Doses</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Pre</td>
<td>Post</td>
</tr>
<tr>
<td>Yes</td>
<td>%</td>
<td>73.3</td>
<td>79.5</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>175 / 210</td>
<td>175 / 220</td>
</tr>
<tr>
<td>No</td>
<td>%</td>
<td>57.5</td>
<td>79.2</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>114 / 198</td>
<td>42 / 53</td>
</tr>
</tbody>
</table>

In terms of those who responded that they never took smaller doses in order to make the medication last longer, 79.8% in the pre period indicated they had benefits and were compliant compared to 85.6% in the post period. Of those who said they had
no benefits or insurance for medications, 62.8% in the pre period indicated always
taking a full dose, however, this figure increased to 83.3% in the post period as
exhibited in Table 9.

Table 9
_Those Who Indicated They Had Benefits or Insurance to Help Pay for Prescriptions In Terms of Taking Smaller Doses to make the Medication Last Longer_

<table>
<thead>
<tr>
<th>Benefit</th>
<th>Never Took Smaller Doses</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre</td>
</tr>
<tr>
<td>Yes</td>
<td>%</td>
</tr>
<tr>
<td></td>
<td>79.8</td>
</tr>
<tr>
<td>n</td>
<td>170 / 213</td>
</tr>
<tr>
<td>No</td>
<td>%</td>
</tr>
<tr>
<td></td>
<td>62.8</td>
</tr>
<tr>
<td>n</td>
<td>125 / 199</td>
</tr>
</tbody>
</table>

Across the compliance questions in terms of having or not having benefits to help
pay for prescriptions those without benefits showed positive change in population
compliance in the post period. There were no significant changes over time in
compliance in patients with drug coverage.

Effects

An item evaluating those who never spent less on food or basics in order to buy
medications can be taken to represent a possible outcome of drug coverage. On this
item, 70.4% of those in the pre period never spent less to buy their prescriptions, while
77.5% in the post period said they never spent less on basics in order to purchase
medicines. (See Table 10) This may be hypothesized to the acquisition of a Plan D
policy to assist in purchasing medications.
The food item, those who never, sometimes or often spent less on food to buy medications, was cross tabulated in the post period with Medicare Plan D coverage. These variables were found to be strongly related ($X^2 = 23.41$, $p < .001$). Of those respondents with Plan D, 66.4% never spent less on basic needs in order to buy their prescriptions, while 24.2% sometimes did so and 9.4% often did so. In the group who did not have Plan D coverage, 90.6% never spent less on food and other basic needs in order to buy their prescriptions, while 5.5% sometimes did so and 3.9% often did so. (See Table 11)

Table 11

<table>
<thead>
<tr>
<th>Medicare Plan D</th>
<th>Yes, Often</th>
<th>Yes, Sometimes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>9.4</td>
<td>24.2</td>
<td>66.4</td>
</tr>
<tr>
<td>No</td>
<td>3.9</td>
<td>5.5</td>
<td>90.6</td>
</tr>
</tbody>
</table>
In summary, those with Medicare Plan D were more likely than those without Plan D to sacrifice food, in order to fill prescriptions. This could reflect the greater economic need of those who have Plan D. Also, many of those who do not have Plan D coverage may have had coverage by an employer or job which might be better coverage than Plan D. Nevertheless, having Plan D coverage significantly predicted sometimes spending less on other necessities in order to afford prescribed medications, undermining any expectation that Plan D helped in this regard.

Table 12 shows a comparison of the amount spent per month on all prescription pills in both the pre and post periods. There was an increase in the post period in the numbers of expenditures in the $0 to $50 range, but a decrease in expenditures in the $51 and over category. The increase in those prescriptions in the lower cost category may reflect an increased compliance in filling prescriptions after the acquisition of a Plan D policy.

**Table 12**

*A Comparison of the Amount Spent per Month on all Prescription Pills in the Pre and Post Periods*

<table>
<thead>
<tr>
<th></th>
<th>$0-$50 (%)</th>
<th>$51 and over (%)</th>
<th>Total (N)</th>
<th>Missing Data (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre</td>
<td>35.7</td>
<td>64.3</td>
<td>401</td>
<td>260</td>
</tr>
<tr>
<td>Post</td>
<td>47.1</td>
<td>52.9</td>
<td>79</td>
<td>49</td>
</tr>
</tbody>
</table>
CHAPTER 5

CONCLUSIONS

The Medicare Plan D prescription drug benefit, introduced in January 2006, aimed to relieve the burden of out-of-pocket drug costs for Americans over age 65. Results have varied. The hope that Plan D would provide financial relief for many seniors may have been a false assumption.

The focus of this research has been on the compliance side of medication-taking in Medicare beneficiaries before and after the implementation of Medicare Plan D. Medication compliance in terms of always filling prescriptions, never taking smaller doses and skipping doses in order to make the medication last longer was evaluated. We hoped to find out whether having Medicare Plan D improved compliance in seniors.

In addition, several influencing factors were evaluated in terms of their possible effects on compliance issues in the studied population. The effects of employer insurance, private insurance, VA coverage, and several pharmacy assistance programs were explored. When asked if they had benefits for prescriptions, those in the period after Medicare Plan D was implemented were more likely to indicate they had some type of coverage. This could, however, have been related to the acquisition of a Plan D policy.

No significant changes were found in the compliance issues in those with insurance through their employer or job. In today’s changing economic times, this might need to be revisited, as more and more companies are modifying or discontinuing their health insurance coverage of retirees.

Those indicating they had private insurance increased in the post period. This
might mean that some of the respondents felt acquiring a Plan D policy was a type of private insurance, particularly those Medicare beneficiaries who had to purchase a policy of their own.

Pharmacy assistance programs, including the one at University of Texas Health Center, were found to be declining after the introduction of Plan D. One exception was an increase in using an outside pharmacy assistance program (PAP). The increase in this utilization in the post period might be attributed to the fact that they may have looked at the PAP as another a benefit or insurance form to help with prescriptions.

In attempting to answer the question as to whether medication compliance improved or not after Plan D was implemented, surprising results were found. Medication compliance was increased in those respondents who did not have Medicare Plan D. Although increased compliance is not explained by having Plan D coverage, those without Plan D coverage may have had better coverage through an employer or the VA or felt that a purchase of a policy was unwarranted as their medication usage was minimal. At the time of this research, the four dollar plans offered by some chain stores were just becoming available. Quite possibly, depending on the individual situation, the Medicare beneficiary may have been able to avoid a monthly policy fee and just pay cash for medications. This would, of course, depend on the medications the patient used and whether they were available at the four dollar co-payment. With the wide variety of generics available, and the cooperation of those who prescribe, to ensure they write prescriptions that will be covered under such plans, it is possible for this scheme to be of benefit to some.

I also suggest that in terms of having Plan D coverage, patients with Plan D were
more noncompliant in filling their prescriptions or skipping doses because of expense.

In terms of evaluating those with or without benefits to help with prescription cost, those who said they did not have benefits or insurance exhibited more compliant behaviors in the post period. This, again, could be because of the particular health situation of the individual, the number of medications they were taking, or their particular financial situation.

Plan D coverage was found to be a significant predictor of spending less on food or basics in order to buy medications. But, it is possible that those who enrolled in Plan D had a greater need than some who did not enroll.

Although there were some differences in the amount spent per month on medications in the pre and post period, these differences were not significant.

The research in this dissertation suggests that although overall compliance may have increased in those areas, these increases cannot be attributed to the acquisition of a Medicare Plan D policy. It is not clear to this researcher the reasons for increased compliance. This is an area where more research with more focused data collection might be of benefit.

Limitations

The data from this study was collected in two different time periods and in two different patient populations. Although the patient pool is very similar for each time period and is representative of the patient population at University of Texas Health Center at Tyler, changes cannot be attributed directly to changes in persons or changes in the population. No multivariate analyses were performed so there was no control for
other factors, such as age, gender, living situations and others. Because this is an exploratory research study, attribution of effects is tentative.

The 2003 drug bill was a huge, and, many say, unaffordable new entitlement. Medicare faces many challenges; but two major ones loom large in the future. First, an aging population with multiple medical problems requiring health care options is particularly problematic in a population with a declining number of workers to finance health care expenditures. Second, keeping Medicare and Social Security solvent is an even bigger problem.

Baby-boomers and seniors continue to hope for a health care plan that is workable, uncomplicated, and affordable and that will maximize their health care options. I am not sure Medicare Plan D is that plan. It was intended to be assistance to seniors in a time of skyrocketing medication costs, but it may prove to have been an ill-advised program. If the costs of the program do not lead to major benefits for Medicare population, policy makers and politicians will need to redesign the program for the sake of the aged and the needy.
APPENDIX A

PRESCRIPTION MEDICATION SURVEY FOR MEDICARE PATIENTS
Prescription Medication Survey For Medicare Patients

PLEASE COMPLETE THIS SURVEY if you are age 65 years or older, in the Medicare program, and you have not already completed this survey. This research project has been reviewed and approved by the UNT IRB @ (940) 565-3940.

The results of this research may help us understand if our Medicare patients are having trouble affording the cost of prescription medications. You do not have to complete this survey if you do not want to. The purpose of this research study is to examine medication use in UTHCT Internal Medicine Clinic Patients before and after Medicare Plan D is implemented in January 2006. This research will examine the impact of Plan D on prescription drug compliance rates for the population studied. You are being asked to complete a survey that will take about 10 minutes. Completion of the survey involves no foreseeable risks. Participation is voluntary and you may stop at any time. You give consent by completing the survey. No individual responses will be reported to anyone because data will be reported on a group basis. If you have any questions regarding this study, please contact me, Billie Huff at (903) 877-7911 or Dr. Stan Ingman, UNT Dept. of Gerontology at (940) 565-2298. Your answers are completely confidential. Thank you for responding.

Please answer the questions below. When you are finished, place the survey in the wooden box at the check-out desk before leaving.

<table>
<thead>
<tr>
<th>BACKGROUND INFORMATION</th>
<th>5. What is the highest grade you completed in school?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How old are you?</td>
<td>□ 1 Grade School</td>
</tr>
<tr>
<td></td>
<td>□ 2</td>
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<tr>
<td></td>
<td>□ 3</td>
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<td>□ 4</td>
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<td>□ 7</td>
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<td></td>
<td>□ 9 High School</td>
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<td>□ 10</td>
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<td>□ 11</td>
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<td>□ 12</td>
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<td>□ 13 College</td>
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<td>□ 14</td>
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<td>□ 15</td>
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<td>□ 16</td>
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<td></td>
<td>□ 17 + Post Grad</td>
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<tr>
<td>2. Are you male or female?</td>
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<tr>
<td>□ Male</td>
<td></td>
</tr>
<tr>
<td>□ Female</td>
<td></td>
</tr>
<tr>
<td>3. Are you Spanish, Hispanic, or Latino?</td>
<td></td>
</tr>
<tr>
<td>□ Yes</td>
<td>□ 9 High School</td>
</tr>
<tr>
<td>□ No</td>
<td>□ 10</td>
</tr>
<tr>
<td>4. Which of the following best describes your race?</td>
<td></td>
</tr>
<tr>
<td>□ White or Caucasian</td>
<td>□ 11</td>
</tr>
<tr>
<td>□ Black or African-American</td>
<td>□ 12</td>
</tr>
<tr>
<td>□ Asian</td>
<td>□ 13 College</td>
</tr>
<tr>
<td>□ Native Hawaiian or other Pacific Islander</td>
<td></td>
</tr>
<tr>
<td>□ American Indian or Alaskan native</td>
<td></td>
</tr>
<tr>
<td>□ Other (please describe)</td>
<td>□ 14</td>
</tr>
<tr>
<td></td>
<td>□ 15</td>
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<td></td>
<td>□ 16</td>
</tr>
<tr>
<td></td>
<td>□ 17 + Post Grad</td>
</tr>
<tr>
<td>6. What is your current marital status?</td>
<td></td>
</tr>
<tr>
<td>□ Married</td>
<td></td>
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<tr>
<td>□ Separated</td>
<td></td>
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<tr>
<td>□ Divorced</td>
<td></td>
</tr>
<tr>
<td>□ Widowed</td>
<td></td>
</tr>
</tbody>
</table>
7. Do you currently live alone?
   □ Yes
   □ No

8. What language do you use most in your daily life?
   □ English
   □ Spanish
   □ Other __________________________
   (please describe)

9. What is your total MONTHLY income including income from a job, pension Social Security, SSI or any other source? (Include your spouse’s income, if you are married.)
   $ __________ per month

10. How much total financial assets do you (and your spouse, if married) have?
    Include savings, checking, real estate, stocks, and other financial assets.
    Do not include the value of the home you live in or your cars.
    □ $ 0 - $10,000
    □ $10,001 - $20,000
    □ more than $20,000

   NOTE
   For answering the next questions, you may want to have your insurance card handy - or any other cards that you use when you pay for your prescription medicines.

   YOUR PRESCRIPTION MEDICINES

   A prescription medicine is one that you can ONLY get if you have a prescription from a doctor.

   □ Never been married (single)

   11. Do you have any benefits or insurance that help pay for your prescription medicines?
       □ No
       □ Yes → ________________________
       (please name the insurance program)

   12. Does the Medicaid program currently help pay for your prescription medicines? (Medicaid is a state program offered to people who have either very low income or very high medical bills.)
       □ Yes
       □ No

   13. Do you currently have health insurance from an employer, job or union that helps pay for your prescription medicines?
       □ Yes
       □ No

   14. Do you currently have health insurance that you bought for yourself that helps pay for your prescription medicine (for example: a Medigap plan, Blue Cross Blue Shield or AARP)?
       □ Yes
       □ No

   15. Does the Veteran's Administration or Defense Department currently help pay for your prescription medicines?
       □ Yes
       □ No

   16. Do you have any discount pharmacy cards (for example, from a drug store or pharmaceutical company) that help you get a lower price on prescription medicines?
       □ No
       □ Yes → ________________________
17. Are you currently enrolled in the pharmacy assistance program run by U.T. Health Center?
   □ No
   □ Yes

18. Are you currently enrolled in a pharmacy assistance program run by another organization?
   □ No
   □ Yes → (please name the organization or program)

19. During the last 12 months, was there one month or more that you had no insurance or benefits to help pay for your prescriptions?
   □ No
   □ Yes

20. Do you currently take any prescription medicines?
   □ Yes → Go to question # 21
   □ No → Go to question # 32

21. Do you take any prescription medicines that are **pills**?
   □ Yes
   □ No

22. How many different types of prescription **pills** do you currently take?
   □ [ ] [ ] [ ] (fill in a number)

23. Each month, how much do you spend for all your prescription **pills**?
   □ Nothing
   □ 50 cents - $20
   □ $21 - $50
   □ $51 - $75
   □ $76 - $100
   □ $101 - $300
   □ more than $300

24. Do you take any prescription medicines that are **inhalers**?
   □ Yes
   □ No

25. Each month, how much do you spend for all your prescription **inhalers**?
   □ Nothing
   □ 50 cents - $20
   □ $21 - $50
   □ $51 - $75
   □ $76 - $100
   □ $101 - $300
   □ more than $300

26. Do you take any prescription medicines that are **eye drops**?
   □ Yes
   □ No

27. Each month, how much do you spend for all your prescription **eye drops**?
   □ Nothing
   □ 50 cents - $20
   □ $21 - $50
   □ $51 - $75
   □ $76 - $100
   □ $101 - $300
   □ more than $300

28. Do you take any prescription medicines that are **skin creams** or **skin patches**?
   □ Yes
   □ No
29. **Each month**, how much do you spend for all your prescription skin creams and skin patches?

- [ ] Nothing
- [ ] 50 cents - $20
- [ ] $21 - $50
- [ ] $51 - $75
- [ ] $76 - $100
- [ ] $101 - $300
- [ ] more than $300

30. Do you take any prescription medicines that are injections?

- [ ] Yes
- [ ] No

31. **Each month**, how much do you spend for all your prescription injections?

- [ ] Nothing
- [ ] 50 cents - $20
- [ ] $21 - $50
- [ ] $51 - $75
- [ ] $76 - $100
- [ ] $101 - $300
- [ ] more than $300

32. During the last 12 months, **how many times** did you decide not to fill a prescription because it was too expensive?

- [ ] None
- [ ] 1 time
- [ ] 2 times
- [ ] 3 - 4 times
- [ ] 5 - 9 times
- [ ] 10 or more times

33. Did you **let your doctor know** that you decided not to fill a prescription because it was too expensive?

- [ ] Yes, I let my doctor know
- [ ] No, I did not let my doctor know
- [ ] Does not apply -- I filled all my prescriptions

34. During the last 12 months, have you skipped doses of a medicine to make the prescription last longer?

- [ ] Yes, often
- [ ] Yes, sometimes
- [ ] No, never

35. During the last 12 months, have you taken a **smaller dose** of medicine so that the prescription would last longer (for example, by cutting pills in half)?

- [ ] Yes, often
- [ ] Yes, sometimes
- [ ] No, never

36. During the last 12 months, have you spent less on food, heat or other basic needs so that you would have enough money for your medicines?

- [ ] Yes, often
- [ ] Yes, sometimes
- [ ] No, never

THANK YOU FOR COMPLETING THIS SURVEY
APPENDIX B

PRESCRIPTION MEDICATION SURVEY FOR MEDICARE PATIENTS
Prescription Medication Survey For Medicare Patients

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Please answer the questions below. When you are finished, place the survey in the wooden box at the check-out desk before leaving.

**BACKGROUND INFORMATION**

1. How old are you?
   - ___________ years old

2. Are you male or female?
   - [ ] Male
   - [ ] Female

3. Are you Spanish, Hispanic, or Latino?
   - [ ] Yes
   - [ ] No

4. Which of the following best describes your race?
   - [ ] White or Caucasian
   - [ ] Black or African-American
   - [ ] Asian
   - [ ] Native Hawaiian or other Pacific Islander
   - [ ] American Indian or Alaskan native
   - [ ] Other __________________________ (please describe)

5. What is the highest grade you completed in school?
   - [ ] 1 Grade School
   - [ ] 2
   - [ ] 3
   - [ ] 4
   - [ ] 5
   - [ ] 6
   - [ ] 7
   - [ ] 8
   - [ ] 9 High School
   - [ ] 10
   - [ ] 11
   - [ ] 12
   - [ ] 13 College
   - [ ] 14
   - [ ] 15
   - [ ] 16
   - [ ] 17 + Post Grad

6. What is your current marital status?
   - [ ] Married
   - [ ] Separated
   - [ ] Divorced
   - [ ] Widowed
7. Do you currently live alone?
   □ Yes
   □ No

8. What language do you use most in your daily life?
   □ English
   □ Spanish
   □ Other
   (please describe)

9. What is your total MONTHLY income including income from a job, pension, Social Security, SSI or any other source? (Include your spouse's income, if you are married.)
   $       per month

10. How much total financial assets do you (and your spouse, if married) have? Include savings, checking, real estate, stocks, and other financial assets. Do not include the value of the home you live in or your cars.
    □ $ 0 - $10,000
    □ $10,001 - $20,000
    □ more than $20,000

NOTE
For answering the next questions, you may want to have your insurance card handy - or any other cards that you use when you pay for your prescription medicines.

YOUR PRESCRIPTION MEDICINES

A prescription medicine is one that you can ONLY get if you have a prescription from a doctor.

11. Do you have any benefits or insurance that help pay for your prescription medicines?
    □ No
    □ Yes → (please name the insurance program)

12. Does the Medicare program currently help pay for your prescription medicines? (Medicare Part D is the new federal program that helps pay for prescription medicines.)
    □ Yes
    □ No

13. Do you currently have health insurance from an employer, job or union that helps pay for your prescription medicines?
    □ Yes
    □ No

14. Do you currently have health insurance that you bought for yourself that helps pay for your prescription medicine (for example: a Medigap plan, Blue Cross Blue Shield or AARP)?
    □ Yes
    □ No

15. Does the Veteran's Administration or Defense Department currently help pay for your prescription medicines?
    □ Yes
    □ No

16. Do you have any discount pharmacy cards (for example, from a drug store or pharmaceutical company) that help you get a lower price on prescription medicines?
    □ No
    □ Yes →
17. Are you currently enrolled in the pharmacy assistance program run by U.T. Health Center?
☐ No
☐ Yes

18. Are you currently enrolled in a pharmacy assistance program run by another organization?
☐ No
☐ Yes → (please name the organization or program)

19. During the last 12 months, was there one month or more that you had no insurance or benefits to help pay for your prescriptions?
☐ No
☐ Yes

20. Do you currently take any prescription medicines?
☐ Yes → Go to question # 21
☐ No → Go to question # 32

21. Do you take any prescription medicines that are pills?
☐ Yes
☐ No

22. How many different types of prescription pills do you currently take?
☐☐☐ (fill in a number)

23. Each month, how much do you spend for all your prescription pills?
☐ Nothing
☐ 50 cents - $20
☐ $21 - $50
☐ $51 - $75
☐ $76 - $100
☐ $101 - $300
☐ more than $300

24. Do you take any prescription medicines that are inhalers?
☐ Yes
☐ No

25. Each month, how much do you spend for all your prescription inhalers?
☐ Nothing
☐ 50 cents - $20
☐ $21 - $50
☐ $51 - $75
☐ $76 - $100
☐ $101 - $300
☐ more than $300

26. Do you take any prescription medicines that are eye drops?
☐ Yes
☐ No

27. Each month, how much do you spend for all your prescription eye drops?
☐ Nothing
☐ 50 cents - $20
☐ $21 - $50
☐ $51 - $75
☐ $76 - $100
☐ $101 - $300
☐ more than $300

28. Do you take any prescription medicines that are skin creams or skin patches?
☐ Yes
☐ No
29. **Each month, how much do you spend for all your prescription skin creams and skin patches?**

<table>
<thead>
<tr>
<th>Option</th>
<th>Number</th>
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<tbody>
<tr>
<td>Nothing</td>
<td></td>
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<tr>
<td>50 cents - $20</td>
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<tr>
<td>$21 - $50</td>
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<td>$51 - $75</td>
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<td></td>
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<tr>
<td>$101 - $300</td>
<td></td>
</tr>
<tr>
<td>more than $300</td>
<td></td>
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</tbody>
</table>

30. **Do you take any prescription medicines that are injections?**

<table>
<thead>
<tr>
<th>Option</th>
<th>Number</th>
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</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

31. **Each month, how much do you spend for all your prescription injections?**

<table>
<thead>
<tr>
<th>Option</th>
<th>Number</th>
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</thead>
<tbody>
<tr>
<td>Nothing</td>
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<td></td>
</tr>
<tr>
<td>more than $300</td>
<td></td>
</tr>
</tbody>
</table>

32. **During the last 12 months, how many times did you decide not to fill a prescription because it was too expensive?**

<table>
<thead>
<tr>
<th>Option</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td></td>
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<tr>
<td>1 time</td>
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<tr>
<td>2 times</td>
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<td>3 - 4 times</td>
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<td>5 - 9 times</td>
<td></td>
</tr>
<tr>
<td>10 or more times</td>
<td></td>
</tr>
</tbody>
</table>

33. **Did you let your doctor know that you decided not to fill a prescription because it was too expensive?**

<table>
<thead>
<tr>
<th>Option</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes, I let my doctor know</td>
<td></td>
</tr>
<tr>
<td>No, I did not let my doctor know</td>
<td></td>
</tr>
<tr>
<td>Does not apply -- I filled all my prescriptions</td>
<td></td>
</tr>
</tbody>
</table>

34. **During the last 12 months, have you skipped doses of a medicine to make the prescription last longer?**

<table>
<thead>
<tr>
<th>Option</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes, often</td>
<td></td>
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<tr>
<td>Yes, sometimes</td>
<td></td>
</tr>
<tr>
<td>No, never</td>
<td></td>
</tr>
</tbody>
</table>

35. **During the last 12 months, have you taken a smaller dose of medicine so that the prescription would last longer (for example, by cutting pills in half)?**

<table>
<thead>
<tr>
<th>Option</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes, often</td>
<td></td>
</tr>
<tr>
<td>Yes, sometimes</td>
<td></td>
</tr>
<tr>
<td>No, never</td>
<td></td>
</tr>
</tbody>
</table>

36. **During the last 12 months, have you spent less on food, heat or other basic needs so that you would have enough money for your medicines?**

<table>
<thead>
<tr>
<th>Option</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes, often</td>
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<td>Yes, sometimes</td>
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<td>No, never</td>
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</table>

**THANK YOU FOR COMPLETING THIS SURVEY**
APPENDIX C

INSTITUTIONAL REVIEW BOARD PERMISSION LETTER
October 10, 2005

Billie Huff  
Department of Gerontology  
University of North Texas

Re: Human Subjects Application No. 05-263

Dear Ms. Huff:

As permitted by federal law and regulations governing the use of human subjects in research projects (45 CFR 46), the UNT Institutional Review Board has reviewed your proposed project titled “Medication Compliance Before and After Medicare Plan D.” The risks inherent in this research are minimal, and the potential benefits to the subject outweigh those risks. The submitted protocol and consent form are hereby approved for the use of human subjects in this study. Federal Policy 45 CFR 46.109(e) stipulates that IRB approval is for one year only.

Enclosed is the consent document with stamped IRB approval. Please copy and use this form only for your study subjects.

It is your responsibility according to U.S. Department of Health and Human Services regulations to submit annual and terminal progress reports to the IRB for this project. Please mark your calendar accordingly. The IRB must also review this project prior to any modifications.

Please contact Shelia Bourns, Research Compliance Administrator, or Boyd Herndon, Director of Research Compliance, at extension 3940, if you wish to make changes or need additional information.

Sincerely,

Scott Simpkins, Ph.D.  
Chair  
Institutional Review Board

SS: sb
REFERENCES


Steinberg, E. P., Gutierrez, B. Momani, A. et al. (2000). Beyond survey data: A claims-based analysis of drug use and spending by the elderly. *Health Affairs,* 19, 198-211.


