December 2010

Medicare Part D Program Evaluation: Analysis of the Impact of Medicare Part D on the FFS Program and Issues Related to Medication Adherence for Six Chronic Conditions—2007

Final Report

Prepared for

Benjamin Howell, PhD
U.S. Department of Health and Human Services
Centers for Medicare & Medicaid Services
Research & Evaluation Group/ORDI
Mail Stop C3-21-08
7500 Security Boulevard
Baltimore, MD 21244
410-786-6628
benjamin.howell@cms.hhs.gov

Prepared by

Melvin J. Ingber, PhD
Sara Freeman, MS
Deborah Healy, PhD
John Kautter, PhD
Sarah Siegel, PhD
RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709

RTI Project Number 0209853.009.005

MEDICARE PART D PROGRAM EVALUATION: ANALYSIS OF THE IMPACT OF MEDICARE PART D ON THE FFS PROGRAM AND ISSUES RELATED TO MEDICATION ADHERENCE FOR SIX CHRONIC CONDITIONS—2007

Authors: Melvin J. Ingber, PhD
Sara Freeman, MS
Deborah Healy, PhD
John Kautter, PhD
Sarah Siegel, PhD

Project Director: Melvin J. Ingber, PhD

Federal Project Officer: Benjamin Howell, PhD

RTI International

CMS Contract No. HSM-500-2005-0029I

December 2010

This project was funded by the Centers for Medicare & Medicaid Services under Contract No. HHSM-500-2005-0029I. The statements contained in this report are solely those of the authors and do not necessarily reflect the views or policies of the Centers for Medicare & Medicaid Services. RTI assumes responsibility for the accuracy and completeness of the information contained in this report.

The authors would like to acknowledge the following people at CMS: Dr. Steven Allen Blackwell for his insights as a pharmacist, particularly into patterns of adherence, and our project officer, Dr. Benjamin Howell, for his suggestions in improving the analysis and report. Also we would like to thank Dr. John Z. Ayanian at Harvard Medical School for his help in defining the drug classes appropriate for each disease.

CONTENTS

Executive Summary 1

Section 1 Project Introduction 11

Section 2 Descriptive Statistics Relating Part D Enrollment to Beneficiary Characteristics for Six Chronic Conditions 15
- 2.1 Introduction 15
- 2.2 Data and Methods 16
- 2.3 Cross-Disease Results 19
  - 2.3.1 Type of Coverage 19
  - 2.3.2 Beneficiary Characteristics 21
  - 2.3.3 Plan Enrollment Statistics 25
- 2.4 Disease-Specific Results 29
  - 2.4.1 Chronic Obstructive Pulmonary Disease 29
  - 2.4.2 Heart Failure 30
  - 2.4.3 Diabetes With Complications 31
  - 2.4.4 Dementia 32
  - 2.4.5 Major Depression 33
  - 2.4.6 Rheumatoid Arthritis 34
- 2.5 Discussion 35

Section 3 Adherence Measures 37
- 3.1 Introduction 37
- 3.2 Data and Methods 38
- 3.3 Medication Possession Ratios 40
  - 3.3.1 Low-Income Subsidy Status 41
- 3.4 Adherence Measures in the Gap 48
- 3.5 Discussion of Drug Adherence Measures 57

Section 4 Effect of Part D on Drug Adherence—Medicare Current Beneficiary Survey Analysis 59
- 4.1 Introduction 59
- 4.2 Methods and Data 60
  - 4.2.1 Sample Selection 60
  - 4.2.2 Analytic Variables 62
  - 4.2.3 Multivariate Statistical Methods 64
  - 4.2.4 Weighting 65
- 4.3 Descriptive Results 66
- 4.4 Multivariate Results 75
- 4.5 Discussion 78

Section 5 Impact of Part D on Medicare Spending and Utilization, 2005–2007 81
5.1 Introduction 81
5.2 Data 82
5.2.1 Definition of Disease Groups 83
5.3 Method 85
5.4 Results 88
5.5 Discussion 90

Section 6 Effect of Part D on health outcomes—Medicare Current Beneficiary Survey Analysis 93
6.1 Introduction 93
6.2 Methods and Data 94
6.2.1 Sample Selection 94
6.2.2 Analytic Variables 94
6.2.3 Multivariate Statistical Methods 96
6.2.4 Weighting 97
6.3 Descriptive Results 97
6.4 Multivariate Results 101
6.5 Discussion 103

Section 7 Analysis of the Effect of Adherence on Outcomes and Utilization 105
7.1 Introduction 105
7.2 Data 106
7.3 Methods 107
7.4 Results 109
7.5 Discussion 112

Section 8 Effect of Drug Adherence on Health Care Utilization—Medicare Current Beneficiary Survey Analysis 115
8.1 Introduction 115
8.2 Methods and Data 116
8.2.1 Sample Selection 116
8.2.2 Analytic Variables 117
8.2.3 Multivariate Statistical Methods 119
8.2.4 Weighting 119
8.3 Descriptive Results 119
8.4 Multivariate Results 123
8.5 Discussion 127

Section 9 Summary and Conclusions 129

References 131

LIST OF TABLES

Table 2.1 Chronic condition sample definitions 17
Table 2.2 Selected disease group drug plan enrollment statistics for full sample— fee-for-service and Medicare Advantage, July 2007 20
Table 2.3 Selected disease group descriptive statistics for beneficiaries enrolled in fee-for-service prescription drug plans, July 2007 23
Table 2.4 Selected disease group descriptive statistics for beneficiaries enrolled in Medicare Advantage prescription drug plans, July 2007 24
Table 2.5 Selected disease group plan enrollment statistics for beneficiaries enrolled in fee-for-service prescription drug plans, July 2007 27
Table 2.6 Selected disease group plan enrollment statistics for beneficiaries enrolled in Medicare Advantage prescription drug plans, July 2007 28
Table 3.1 Criteria for chronic conditions 39
Table 3.2 Distribution of annual medication possession ratios for beneficiaries with chronic diseases, by drug class 42
Table 3.3 Chronic obstructive pulmonary disease: 2007 mean medication possession ratios by low-income subsidy status 45
Table 3.4 Congestive heart failure: 2007 mean medication possession ratios by low-income subsidy status 45
Table 3.5 Chronic diabetes: 2007 mean medication possession ratios by low-income subsidy status 46
Table 3.6 Diabetes with acute complications: 2007 mean medication possession ratios by low-income subsidy status 46
Table 3.7 Dementia: 2007 mean medication possession ratios by low-income subsidy status 47
Table 3.8 Major depression: 2007 mean medication possession ratios by low-income subsidy status 47
Table 3.9 Rheumatoid arthritis: 2007 mean medication possession ratios by low-income subsidy status 48
Table 3.10 Frequency of beneficiaries' entering the coverage gap, by chronic condition 49
Table 3.11 Frequency of beneficiaries' entering the coverage gap, by number of chronic conditions 49
Table 3.12 Chronic obstructive pulmonary disease beneficiaries: 2007 medication possession ratios for beneficiaries who entered the coverage gap 50
Table 3.13 Congestive heart failure beneficiaries: 2007 medication possession ratios for beneficiaries who entered the coverage gap 51
Table 3.14 Chronic diabetes beneficiaries: 2007 medication possession ratios for beneficiaries who entered the coverage gap 52
Table 3.15 Diabetes with acute complications beneficiaries: 2007 medication possession ratios for beneficiaries who entered the coverage gap 53
Table 3.16 Dementia beneficiaries: 2007 Medication possession ratios for beneficiaries who entered the coverage gap 54
Table 3.17 Major depression beneficiaries: 2007 Medication possession ratios for beneficiaries who entered the coverage gap 55
Table 3.18 Rheumatoid arthritis beneficiaries: 2007 Medication possession ratios for beneficiaries who entered the coverage gap 56
Table 4.1 2006 Medicare Current Beneficiary Survey cost and use sample selection 61

Table 4.2 Descriptive statistics for the 2006 Medicare Current Beneficiary Survey analysis sample—overall and by the study's six chronic conditions....69
Table 4.3 Purchase of prescription for condition-related drug, by condition....76
Table 4.4 Self-reported failure to fill prescription received, overall sample....78
Table 5.1 Selected descriptive statistics....85
Table 5.2 Effect of 18 months of Part D on probability of an inpatient stay computed for female, age 75–79....89
Table 5.3 Effect of 18 months of Part D on probability of an emergency department visit computed for female, age 75–79....89
Table 5.4 Effect of 18 months of Part D on inpatient spending and emergency department visit counts for beneficiaries who use any of the service....90
Table 6.1 Descriptive statistics for the 2006 Medicare Current Beneficiary Survey analysis sample—overall and by the study's six chronic conditions....99
Table 6.2 Inpatient events, overall sample....102
Table 6.3 Inpatient events, selected conditions....103
Table 7.1 Selected statistics for dependent variables in regressions....108
Table 7.2 Sample size for regression for each dependent variable....109
Table 7.3 Probability of an inpatient stay computed for female, aged 75–79, with 18 months of Part D....110
Table 7.4 Effect of adherence on probability of an emergency department visit computed for female, aged 75–79, with 18 months of Part D....111
Table 7.5 Effect of adherence on inpatient spending and emergency department visit counts for beneficiaries who use the service, for 25-point change in adherence....112
Table 8.1 Descriptive statistics for the 2006 Medicare Current Beneficiary Survey analysis sample—overall and by the study's six chronic conditions....121
Table 8.2 Inpatient events as a function of adherence, overall sample....124
Table 8.3 Inpatient events as a function of adherence: Selected conditions....126

EXECUTIVE SUMMARY

This report is a follow-up to the report titled *Medicare Part D Program Evaluation: Analysis of the Impact of Medicare Part D on the Fee-For-Service Program*, which presented analyses of the effect, in 2006, of the introduction of the Part D prescription drug program on the overall Medicare program. The implementation of Part D provided an option for Medicare beneficiaries to get insurance covering prescription drugs, whether they were in fee-for-service (FFS) Medicare or in a Medicare Advantage (MA) plan. This report focuses mostly on 2007, the second year of the program, which did not have the enrollment phase-in that characterized 2006. That first year had an extended period of open enrollment. For 2007, the first year with a relatively stable enrollment, we focused on beneficiaries who had chronic conditions to address the following research questions.

1. What are Part D enrollment patterns for beneficiaries with specific chronic conditions?

2. What is the impact of Part D on patient adherence to medication therapy?

3. What is the impact of Part D on health outcomes and health care utilization and costs for beneficiaries with chronic conditions?

4. What is the relationship between differences in patient adherence and differences in health outcomes and health care utilization and cost?

To address the questions, we looked at populations with any of six chronic conditions that are considered to be sensitive to drug therapies: chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), diabetes with complications, dementia, major depression, and rheumatoid arthritis. The choice of the conditions to analyze was also driven by prevalence in the population. RTI International used data on 100 percent of the population to conduct some of these studies to keep the sample sizes high enough to estimate multivariate models as well as get reliable descriptive statistics. We also used the Medicare Current Beneficiary Survey (MCBS), which has a small sample, to approach some of the questions using information not available in the Medicare operational files. COPD was the largest group analyzed; rheumatoid arthritis was the smallest group.

The research questions investigate various aspects of the impact that access to insurance for drugs is having on the Medicare population. The underlying premise is that drugs are effective in controlling chronic diseases. The chain of logic is that the drug benefit will reduce out-of-pocket drug costs to enrollees, and this will improve adherence to drug regimens, which will in turn change health status and related utilization measures. We have examined some of the steps in this chain in conjunction with the research questions.

E.1 Descriptive Analysis of Enrollment Patterns

The descriptive analysis, in section 2, is intended to determine whether the people with chronic diseases made particular choices in enrolling in drug plans. We performed an in-depth descriptive analysis of the enrollment patterns of these populations in Part D plans and other forms of drug coverage, including Retiree Drug Subsidy plans, other forms of creditable

coverage, and no known coverage. We profiled prescription drug plans (PDPs) primarily serving FFS beneficiaries and MA drug plans (MA-PDs) integrated with the MA plans. We tabulate enrollment choices by beneficiary demographics, subsidy eligibility, medical conditions, types of plans, plan premiums, and geographic locations. A full set of the tables is included in a separate appendix of descriptive statistics.

We concentrated particularly on the enrollees who were not in low-income subsidy (LIS) status. Non-LIS beneficiaries could choose whether to enroll in Part D at all; to do so, they had to choose a specific plan. The LIS population was mostly auto-enrolled and had much lower out-of-pocket costs because of the subsidy of premiums and cost sharing. All of the beneficiaries profiled had at least one of the study diseases.

Among the notable findings in the profiles are the following:

- The non-LIS beneficiaries in the disease cohorts who are enrolled in PDPs have considerably higher than the average FFS-predicted drug expenditures according to the risk adjustment model used by CMS to pay drug plans. The predicted values for people in these disease groups are 40 to 54 percent higher.

- About 40 percent of these non-LIS enrollees chose enhanced drug plans; of those, about half chose an enhanced plan with some drug coverage in the coverage gap.

- The mean drug spending for the non-LIS enrollees in all the disease cohorts was in the coverage gap. The highest average spending was concentrated in plans that were "actuarially equivalent" or "enhanced." Actuarially equivalent plans, which like the defined standard plans have a deductible and coverage gap, had relatively high premiums and relatively low enrollment. Some enhanced plans have some coverage in the gap.

- The LIS enrollees in the diabetes with complications, major depression, and rheumatoid arthritis cohorts had mean spending in the catastrophic range.

- For those who joined MA plans with drug plans, the idiosyncrasies of MA payment for nondrug and drug services made it possible for companies to offer enhanced plans with low or no premiums. The distribution of enrollees was almost 80 percent in enhanced plans for the study populations.

From the view of the analyst, many beneficiaries are enrolled in plans that do not seem to be optimal, given the information we have. This observation reinforces concerns that beneficiaries do not fully understand the alternatives and information offered to them.

E.2 Adherence to Drug Regimens

Section 3 of the report contains measurements of adherence to drug regimens in 2007 Part D data. We were addressing the following research questions:

- Overall, what were the drug adherence rates for Medicare beneficiaries with Part D coverage?

- What was the impact of the coverage gap on drug adherence for beneficiaries with chronic conditions?

- How did the effects differ for the Medicaid and other low-income populations?

From a policy perspective these questions are interesting because, if drugs are effective in slowing health deterioration and preventing complications, then taking the drugs according to the standard regimen—maintaining a high adherence rate—would be most effective. The statistics presented here are a profile of the current status of adherence as it can be observed in the Part D data.

For each of the chronic conditions, we conducted a review of the drug classes that would usually be used to treat each condition. The drugs were grouped into classes using the American Hospital Formulary Service (AHFS) classification system. The classes for each disease cohort were chosen by reviewing literature and by consulting with physicians. In addition to COPD, CHF, diabetes with chronic complications, dementia, major depression, and rheumatoid arthritis, a subgroup of people with diabetes was added for analysis, those with acute complications as well as chronic complications.

Using the Prescription Drug Event file (PDE), each prescription filled, by each person, was assigned to a class. The measure created from the data was the medication possession ratio (MPR), the ratio of days supplied purchased to the days eligible for coverage. (Adjustments were made for days in a hospital, for taking multiple drugs in a class, and for drugs carried over from 2006 and into 2008. Nursing home residents were excluded because adherence is controlled by the facility.)

The MPR has limitations as a measure. Days supplied is not always accurate; for some drugs with frequent dosage adjustments, like insulin, it is not meaningful. It also does not capture any purchases made outside the Part D system. Some generics may be cheaper at local chain pharmacies; in the coverage gap, some brand-name drugs may be cheaper if bought over the Internet.

The statistics compiled show the following:

- Adherence varies widely between drug classes for a chronic condition and among conditions. Mean MPRs range between about 30 percent and about 74 percent. At the 75th percentile of adherence, the rate is frequently at the 90 percent level. Most MPRs fall into the 50 percent to 70 percent range, however.

- LIS and non-LIS enrollees did not consistently differ in adherence. One could argue either that the LIS group would be expected to have lower adherence because of its members' lower economic status or that higher adherence would be expected because of the low out-of-pocket costs they faced. Neither pattern was found. The effects may have been weak or may have offset each other.

- For beneficiaries who entered the coverage gap, there was a small drop in adherence for the non-LIS when the gap was reached. The pattern was not consistent across drug classes or medical conditions. This drop was not found for the LIS enrollees, although their adherence was lower in the coverage ranges before the gap.

- Having multiple chronic conditions increased the likelihood of reaching the gap, as would be expected.

Overall, the tables show adherence at levels that could be improved for many of the drug classes. We are aware that there are justifiable reasons for some portion of the populations to manifest low adherence. Patients change drugs and drug classes because of ineffectiveness or side effects. The 25th percentile adherence rates are quite low, and some of these cases could be there. Nevertheless, groups with adherence below 60 percent would be promising targets for gains. The data available in Medicare files do not enable us to sharply define the characteristics of the population that could be reached and thus to target that group. Clearly, low-income status is not a definitive marker. Ways of targeting the improvable group within Medicare would be an interesting research topic.

E.3 Effect of Part D on Adherence

In section 4 of the report, we analyze the research question of the effect of Part D on measures of adherence to drug regimens.

This is a question concerning the impact of enrollment in the program. Adherence was defined and average measures presented in the previous analysis. Is there a measurable association of a person's being in Part D and observed adherence? We attempted to use the many personal characteristics, insurance characteristics, and purchasing patterns reported in the MCBS in analyzing the impact.

The study used the latest MCBS data available, from 2006, to look for answers. The main limitation of the MCBS data is sample size. Of the approximately 12,000 people in the survey, our data had only 9,008 respondents after restrictions such as someone who resided in the community, lived through the year, and was matchable to other datasets. The maximum sample for the study diseases was 1,245 for COPD; the smallest was 205 for rheumatoid arthritis. Therefore, despite the richness of detail of the beneficiary characteristics, the power to detect effects was limited.

The following measures were used for adherence:

- Was there at least one prescription filled for a chronic condition in the survey drug events?

- The answer to the question, "During the current year, were there any prescribed medicines that you didn't get?"

The actual drug event file did not have enough detail to create measures like the MPR for all beneficiaries, so survey questions were used. The responses to the questions were the

dependent variables in a logit regression model with control variables for demographics, income status, health status, and so on. The key variables of interest were the insurance variables: Part D coverage, employer sponsored, self-purchased insurance, other insurance, and LIS status. The effects were all measured against having no insurance.

For the first question, concerning filling at least one prescription, Part D did not have a statistically significant effect in any of the separate models for the six diseases. Being an LIS enrollee was significant only for COPD and major depression.

The second question, concerning skipping a prescription, was analyzed in one large regression with markers for the six chronic conditions as well as the insurance variables. The Part D enrollment did have a small effect in the direction of reducing skipping drugs, although it was only marginally significant statistically. Employer-sponsored insurance and other insurance had similar effects with stronger statistical significance.

The limitations of MCBS related to sample size reduced the power of these rich data to get more definitive results. The answers from this analysis are only weakly indicative of the posited effect, that Part D and other insurance do improve adherence.

E.4 Effect of Part D on Parts A and B of the Medicare Program—Claims Analysis

One of the possible effects of instituting the drug program would be to improve health status and concomitantly, reduce the use of health care services associated with poorer health. In this analysis the research question was, "What is the impact of Part D on health outcomes and health care utilization and costs for beneficiaries with chronic conditions?"

In section 5 the approach is a before-and-after comparison of Medicare beneficiaries in 2005, the year before Part D was implemented, and in 2007, the second year of the program. The year 2006 analyzed in our previous report was one with an extended enrollment period and provided only a short period of coverage by the program to observe effects. The method compares, in two periods, people who would decide to enroll as well as people who would not enroll. The differences in the changes for the two groups are compared. It is a difference-in difference model approach.

The study cohorts were FFS beneficiaries in the six chronic disease groups in 2005 and the similar groups in 2007. This was not a panel study, although some of the population overlaps. LIS enrollees generally had Medicaid drug coverage in 2005 and little change in insurance status when they moved to Part D. They were excluded from the analysis.

The disease cohorts were defined using a file of 100 percent of the Medicare beneficiaries who had indicators for the diseases each beneficiary was reported to have. These indicators are the hierarchical condition category (HCC) groups, which are aggregates of clinically related diagnosis codes. Enrollment files were used to gather data for demographics and insurance status. Claims files provided spending and other data elements.

The research question was addressed by asking a set of questions for each disease cohort that would measure aspects of Part D's having an effect on the broader program:

- Did Part D affect the probability of having at least one inpatient hospital stay?
- Did Part D affect the probability of at least one emergency department (ED) visit?
- Did Part D affect the Medicare costs for inpatient stays for those who had a stay?
- Did Part D affect the number of ED visits for those who had a visit?

The particular measures used were expected to be sensitive to Part D's providing better access to drugs, conditional upon drugs being effective treatments. If disease exacerbations are reduced, we would expect hospitalizations and ED visits to be reduced. There is ambiguity in the direction of changes in some other measures. Services such as physician visits might increase if medication management requires additional visits.

The findings of the analyses were that the effects on inpatient stays were in the direction of reducing the probability of having a stay and the costs of those who did have stays. Large sample size provided statistical significance, but the effects were small.

- The probability of a stay typically decreased by only a few tenths of a percentage point.
- Inpatient spending for those who had at least one stay was decreased by about 2 percent.
- The probability of an ED visit decreased by a few tenths of a percentage point.
- The count of ED visits decreased by about 1 percent for COPD and CHF, but not for the other groups.

There are a number of reasons that the measured effects were small, even though they were measured on people with chronic diseases. The comparison group is people who have no known drug coverage. They might have been purchasing drugs throughout the period. The Part D enrollees might also have been buying their own drugs in 2005. Also some of the effect of improved access to drugs could take a few years to be manifest.

The intent of the question was not to compare people with access to drugs to people without access. It concerned the effect of implementing a program in a world in which people had access but perhaps at a higher cost than they would with Part D. The effect of an improvement in access could be marginal and could depend on the purchasing tradeoffs made by Part D enrollees before Part D started and by nonenrollees in both years.

E.5 Effect of Part D on Parts A and B of the Medicare Program—Survey Analysis

In section 6 the same basic research question was approached in a different way:

- What is the impact of Part D on health outcomes and health care utilization and costs for beneficiaries with chronic conditions?

Instead of looking for program changes before and after the implementation of Part D, a single-year cross-section of Medicare beneficiaries was used to compare service use for Part D beneficiaries and those with no or other insurance. The MCBS data were again used because of the detailed information available on those surveyed, but the sample size limitations of the survey were present.

To implement the study, we chose as our utilization variable the count of inpatient hospital stays. A regression equation was formulated to predict the number of inpatient stays using the insurance variables and many control variables accounting for demographics, health status, and income status, which would also potentially affect the tendency to use inpatient services. The insurance variables included Part D and other types of insurance as well as a marker for having no insurance. MCBS does provide information on lack or presence of insurance.

The equation used was a form of regression, Poisson, which is often used for predicting counts. But it was a variant form that also accounts for distributions of counts if there is an overabundance of observations with zero events.

The results of the analysis indicated that Part D did have a tendency to reduce stays, but the effect was not statistically significant. Another result indicated that the variable for LIS status was associated with more stays than experienced by those with no drug coverage. This high utilization is consistent with general descriptive statistics for the LIS population. These findings are present when the whole sample is modeled with markers for membership in the individual cohorts. When the six cohorts are modeled separately, the sample size is too small for statistically significant results.

E.6 Effect of Adherence on Utilization and Outcomes—Claims Analysis

The analysis now moves from the effect of the Part D program to the effect of adherence to drug regimens: What is the relationship between differences in patient adherence and differences in health outcomes and health care utilization and cost?

Having looked at measures of adherence in the program and the effects of the program, we move in section 7 to the effects of adherence for those enrolled in the program for the six chronic disease groups. We have seen that adherence is at moderate levels. If adherence is improved, would Medicare experience change in some sentinel measures that indicate changes in health status and service use?

As in the claims-based study of the effects of Part D on Parts A and B, the research question is operationalized in four parts.

- Did adherence affect the probability of having at least one inpatient hospital stay?
- Did adherence affect the probability of at least one ED visit?
- Did adherence affect the Medicare costs for inpatient stays for those who had a stay?
- Did adherence affect the number of ED visits for those who had a visit?

As adherence is measurable only for Part D enrollees, the study is based on measures in the 2007 data. The measure of adherence for each disease group was the MPR for the drug class with the greatest MPR among all the classes used to treat the condition. Multiple classes of drugs are often used to treat a condition, but not all are needed simultaneously. We considered that if there were a dominant class in terms of adherence, then the MPR for that class would be an appropriate measure. Using multiple classes would result in many classes' having an MPR of 0 simply because those classes were not prescribed. The MPR measures differ from those described earlier in that people with stays in skilled nursing facilities (SNFs) were retained in the data; eliminating people with SNF stays would distort the rate of hospitalizations, which often are followed by SNF stays. Adjustments were made for the time spent in the SNF, during which drugs are not paid for through Part D.

The equations were formulated with demographic and health status measures as explanatory variables along with the adherence variable. The samples were FFS, non-LIS enrollees in Part D in each cohort.

The results of this modeling were, as might be expected, stronger than a test of the effect of Part D overall. These beneficiaries were all taking drugs to some degree. The findings, in brief, are that adherence did have favorable effects on the target measures:

- The probability of an inpatient stay is reduced by 2 to 4 percentage points for each 25-point improvement in adherence, depending on condition. CHF has the highest probability and greatest reduction.

- Inpatient spending decreases by about 2.5 to 5 percent for a 25-point increase in adherence, varying by condition.

- The probability of an ED visit generally decreases by about 2 percentage points for each 25 points of adherence improvement. There is less variability in the probabilities of outpatient ED visits than of inpatient stays.

- Counts of ED visits for users of the service decrease by 2 to 3 percent for a 25-point change in adherence, depending on condition.

These effects are not negligible but do not indicate major changes in Medicare services. They do indicate that it is feasible to reduce the probability of an inpatient stay by as much as 10 percentage points for parts of the population with low adherence. Inpatient spending for those who have stays could be reduced by 5 percent. The effects on ED visits are somewhat smaller but also point to savings. These changes are not only cost savings. Reductions in these services usually indicate better health status with fewer complications and exacerbations of disease.

E.7 Effect of Adherence on Utilization and Outcomes—Survey Analysis

The analysis just described was a claims-based approach to the question, "What is the relationship between differences in patient adherence and differences in health outcomes and health care utilization and cost?" In section 8 we did a parallel analysis using MCBS data. This analysis differed in that the sample size was much smaller, the explanatory variable set was

richer in different types of information, and the operational variable to measure utilization and outcomes was the count of inpatient hospital stays.

Another major difference is the use of the measure of adherence. The adherence variables used as explained variables in the MCBS analysis of the effect of Part D on adherence now became explanatory variables in this model. They are as follows:

- Was there at least one prescription filled for a chronic condition in the survey drug events?

- The answer to the question, "During the current year, were there any prescribed medicines that you didn't get?"

It was not possible to construct an MPR for all people from the MCBS. However, it was possible to get these measures of adherence for all people, whether or not they had Part D. The answers to these questions were available irrespective of insurance coverage.

The sample of 9,008 observations was assembled and the regression equation formulated, as in the other MCBS models, with many control variables covering demographics, income, and health status. In addition, insurance status was used as a variable of interest along with the adherence measures. Instead of modeling each disease cohort independently, we included them all in the model with variables indicating the disease group or groups for each observation.

The results of this model again show that LIS status is associated with higher counts of inpatient stays. The insurance variables, including Part D, have no significant effects. But the second adherence variable, about skipping prescriptions, was statistically significant and strongly associated with greater numbers of stays, 54 percent greater. At the mean number of hospitalizations in this data set, the mean number of hospitalization was 0.35 per person. That would become 0.53 for those who are not adherent by this measure.

With this relatively simple measure of adherence being a stronger indicator of taking drugs for a condition than just having Part D or other insurance, the MCBS was able to detect relatively large effect with statistical significance. The finding is supportive of the findings using the claims-based models.

E.8 Conclusion

Section 9 summarizes the project, which has explored many aspects of the effects of Part D in 2007, concentrating on beneficiaries with six chronic conditions. The enrollment patterns have been described in great detail. Measures of drug adherence have been defined and measured for the program, with indications of moderate adherence levels and differences between the LIS and non-LIS populations being generally small. Modeling has been done, with multiple approaches, exploring the effect of Part D on adherence, the effect of Part D on utilization and outcomes, and the effect of adherence on utilization and outcomes. Overall, the implementation of Part D had minor effects on service use in Medicare Parts A and B. However, when focusing more closely on the degree to which drugs are taken regularly, moderate effects can be seen. With the program in operation, the analysis points to finding ways to improve adherence to reduce the medical events leading to hospitalizations. It is possible to explore

whether particular drug plans are more successful than others in the rates of adherence for enrollees. Some medication management programs may lead to better adherence. It is difficult with Medicare program data to determine relevant characteristics of enrollees to use to profile potential improvers. The Part D program does seem to offer some leverage through adherence improvement to reducing the need for other services.

SECTION 1
PROJECT INTRODUCTION

The Part D prescription drug benefit was a large addition to the Medicare program, providing insurance for a component of health care largely omitted from the program. The drugs covered by Part B of Medicare were generally those administered in physicians' offices, and the drugs covered by Part A were those administered during inpatient stays. Coverage of a wide range of outpatient drugs by the program would provide insurance for drugs for those Medicare beneficiaries who did not have coverage, or adequate coverage, from employer and retiree coverage. Such coverage, along with retiree health insurance in general, has been shrinking. The program also replaced the Medicaid drug coverage programs for those covered by Medicare as well. This expansion of the Medicare program has generated great interest in the drug benefit's effects, not only on drug purchasing, but also on the other components of Medicare.

The research questions this report addresses are as follows:

1. What are Part D enrollment patterns for beneficiaries with specific chronic conditions?

2. What is the impact of Part D on patient adherence to medication therapy?

3. What is the impact of Part D on health outcomes and health care utilization and costs for beneficiaries with chronic conditions?

4. What is the relationship between differences in patient adherence and differences in health outcomes and health care utilization and cost?

This report is a follow-up to the report titled *Medicare Part D Program Evaluation: Analysis of the Impact of Medicare Part D on the Fee-For-Service Program*, which presented analyses of the effect, in 2006, of the introduction of Part D on the Medicare program. This set of studies focuses on the program in 2007 for most analyses. It concentrates on people with chronic conditions, in particular:

- Chronic obstructive pulmonary disease

- Congestive heart failure

- Diabetes with chronic complications

- Dementia

- Major depression

- Rheumatoid arthritis

These conditions affect different body systems and range from high prevalence to moderate prevalence in the Medicare population. They also vary in the range and cost of drugs

available to treat them. By focusing on these diseases, we hoped to detect the effects of the program better than when the Medicare population as a whole was studied.

The first research question, addressed in section 1, looks at the patterns of enrollment across the many private drug plan types from which beneficiaries needing drugs must choose. Because the program is administered through private plans in which enrollees may choose to participate, the marketplace has plans that vary in such characteristics as formularies, premiums, drug costs, and cost sharing. The analysis describes the types of coverage people with the chronic conditions have, whether Part D, other creditable coverage, or no known coverage. It presents the distribution across types of plans they enroll in and levels of premiums they pay. Enrollees could choose one of the basic plan types or enhanced alternative plans, some of which cover some drugs in the program's coverage gap. It also presents distributions of beneficiary choices by health status scores, comorbidities, drug spending, geography, and other dimensions.

The choices made by beneficiaries are in the context of the structure of the benefit. The Part D benefit parameters change from year to year. This report focuses on the potential impacts of the Part D program in 2007, the program's second year. In 2007, Part D defined a standard prescription drug benefit, which included an annual $265 deductible that beneficiaries were responsible for paying. Between $265 and the initial coverage limit of $2,400, the Part D plan was responsible for 75 percent of costs, and the beneficiary paid a 25 percent coinsurance. In the coverage gap between $2,401 and $5,451.25, the enrollee paid the full drug cost. The spending threshold ending the gap and starting catastrophic coverage, with its very low beneficiary cost sharing, is computed assuming that the enrollee had no out-of-pocket costs paid by certain forms of assistance. The actual catastrophic threshold is determined by enrollees paying $3,850 in true out-of-pocket costs (TrOOP).[1] Costs in catastrophic coverage were split three ways, with the government providing reinsurance equal to 80 percent, the Part D plan covering 15 percent, and the beneficiary paying the greater of 5 percent coinsurance or copayments of $2.15 for generic drugs and $5.35 for nongeneric drugs. Enrollees receiving a low-income subsidy (LIS) paid less than the standard amounts in most cases.

In addition to the standard benefit, there were two variant plan types that were actuarially equivalent, which could vary the payment structure in the initial coverage range, the deductible, or both. There were also enhanced plans that offered some coverage in the gap or coverage for products not covered by the standard benefit. Extra coverage was not covered by payments from the Medicare program. Plans also varied, within limits, in the range of drugs offered in their formularies.

To study the effects of the program on adherence to drug regimens, or the effect of adherence on the Medicare program, it was necessary to construct measures of adherence.

---

[1] A payment for a prescription drug constitutes an "incurred cost" and counts toward a beneficiary's TrOOP threshold only if the payment is made by or on behalf of the beneficiary. Assistance from a state pharmaceutical assistance program or from a patient assistance program sponsored by a pharmaceutical assistance program generally counts toward the TrOOP threshold. However, if the beneficiary is reimbursed for the costs by insurance, a group health plan, or other third-party arrangement, then the payments do not count toward the TrOOP threshold. Payments for drugs that are not included on the plan formulary also do not count toward the TrOOP threshold (Covington and Burling, 2005).

Section 3 of the report describes the construction of one of the measures of adherence, the medication possession ratio (MPR), and presents descriptive statistics. Conceptually the MPR is the proportion of eligible days covered by the supply of drugs purchased. The section discusses both the difficulties of construction of the measure and the limitations of the MPR as a measure of adherence.

The importance of adherence is in the context of the assumption that the drugs for the chronic diseases should be taken on an ongoing basis and that the drugs are effective in reducing disease progression, complications, exacerbations, or any combination of these. The MPR is a measure of whether beneficiaries are regularly buying prescribed drugs, which is as close as we can get in the data to whether they are taking the drugs.

In section 3 we describe how the MPR is created, not for individual products, but for classes of drugs that are related pharmacologically. The drug classes in the study were those that were deemed to be treatments for each of the disease groups. The description of adherence across the classes and the stages of the benefit structure yields information for policymakers on whether adherence is far enough from optimal levels that it is improvable and, as seen in the related studies here, whether improving the measure has effects on health and utilization.

The second research question, concerning the effects of the Part D program on drug regimen adherence, uses the Medicare Current Beneficiary Survey (MCBS) data. The analysis is in section 4. Although the data set has much information about the beneficiaries beyond the basics in claims and enrollment data, it is relatively small, with about 12,000 people in the survey each year, many of whom are excluded from the analysis for various reasons. The data do contain detailed insurance information beyond Part D, so the general effects of insurance coverage could be studied. However, it proved impossible to construct the MPR as an adherence measure for survey beneficiaries who were not in Part D because the drug event file does not contain enough detail on purchases. We used survey responses and the drug information to get two simpler measures of adherence. The sample size limitation and the nature of the adherence measures limit the conclusions that can be drawn from this particular study.

The third, somewhat large, research question—as to whether the implementation of Part D had effects on program outcomes and utilization—is first addressed in section 5 using the Medicare claims and enrollment information. Sample sizes are large for each of the study groups. Policymakers are interested in whether the program had discernible effects on the use of Part A and B services. In particular we approach this question by looking at whether there were differences in over time between the Part D enrollee population and the population that did not enroll. In this analysis, we compared the changes from 2005, pre-Part D, through 2007. The specific measures used were probability of an inpatient hospital stay, inpatient spending for people with stays, probability of an emergency department visit, and counts of visits for users of the emergency department.

It has been difficult to measure the effects because a large proportion of Part D enrollees receive the LIS, and most of this group would have had Medicaid coverage for drugs in 2005. Any changes in patterns of use for this group would be minor. We concentrate on the non-LIS population. Even in this population and concentrating on the chronic condition groups, detecting changes in program services would depend on whether the Part D enrollees were acquiring drugs

to a reasonable extent and whether similar nonenrollees also do so. All these factors reduce the effect that has to be measured. The policy question is important, but unless there was a large proportion of beneficiaries with very limited access to drugs before Part D, expectations for a large impact are not justified. The study in section 5 is able to address the issue because sample sizes are large.

We also address this research question with the MCBS, using the count of inpatient hospital stays as the utilization measure. Section 6 describes this approach and the advantages and limitations of the data.

If the program is supposed to increase access to prescription drugs, and easier access helps improve adherence, the next research question is relevant for policy: What is the relationship between adherence and measures of outcomes and utilization? This question is addressed in section 7 with claims data and in section 8 with MCBS data. The 2007 data were used for the claims analysis and 2006 data were used in the MCBS study.

As indicated in the MPR analysis in section 3, to the extent that adherence varies and is not optimal, one would want to know the magnitude of the effects on the program that result from improving adherence. The measures used are sentinel indicators of program utilization changing and of changes in the need for such services—a measure of health status. We use the same measures used in sections 5 and 6.

The regression analyses incorporate adherence measures as explanatory variables. The MPR is used in the case of the claims analysis, and the indicators of buying or skipping prescriptions are used in the MCBS analysis. As in the other analyses, many beneficiary-specific control variables potentially affecting utilization are included.

From the point of view of finding measurable effects, this analysis is much closer to finding whether taking prescribed drugs affects health status and associated utilization. Finding reasonable effects then leads to the question of what tools can be used tool improve adherence. Although that question is not addressed in this report, the study indicates that some improvement in health and utilization is possible by improving adherence.

This study has addressed four large research questions in multiple exploratory ways. The results show that we are not always measuring large effects and that each method has advantages and disadvantages. The subsequent sections describe each analysis in greater detail so that the measurement issues can be understood as well as the findings.

SECTION 2
DESCRIPTIVE STATISTICS RELATING PART D ENROLLMENT TO BENEFICIARY CHARACTERISTICS FOR SIX CHRONIC CONDITIONS

2.1 Introduction

In this part of the Part D Program Evaluation, we describe key differences in the characteristics of beneficiaries with specific chronic diseases in terms of their Part D enrollment patterns in 2007. This analysis builds on the previous report, which described enrollment data for the entire Medicare population in 2006, the first year of the Medicare Part D Program. The specific research question to be addressed in Task 5 was this:

- What are the Part D enrollment patterns for beneficiaries with specific chronic diseases?

Beneficiaries with chronic conditions may represent the population most likely to benefit from increased access to prescription drugs. These beneficiaries are more likely to need a greater number of prescription drugs and are more susceptible to suffering expensive health care complications if they do not adhere to their drug regimens. Access to affordable drugs may depend on enrollment in the most appropriate Part D plan—one that covers the specific drugs needed with cost sharing at levels that promote improved therapy adherence. Identifying and monitoring enrollment patterns by plan and benefit type for these beneficiaries may help inform policymakers on issues of access as well as cost implications for both enrollees and the Medicare program.

In this descriptive analysis, RTI studied the drug plan enrollment patterns of each chronic condition sample individually—chronic obstructive pulmonary disease (COPD), heart failure, diabetes with complications, dementia, major depression, and rheumatoid arthritis—and then looked for similarities and differences across the six disease groups. We examined fee-for-service (FFS) and Medicare Advantage (MA) populations separately. For each topic of analysis, our initial breakouts were by type of drug coverage (Part D plan, creditable coverage from another source, or no known coverage). However, our primary focus was on beneficiaries enrolled in a Part D plan. We classified enrollees by plan type into five categories: three basic plans (defined standard, actuarially equivalent, and basic alternative) and two enhanced (without gap coverage, with gap coverage). Detailed analyses were conducted that focused on beneficiary characteristics, plan structure and cost, disease profiles, and geographic characteristics.

The population of greatest interest for this study was the non-low income (non-LI) Part D enrolled population, who are more sensitive to cost and coverage than the subsidized low income (LI) population. For comparison purposes, all analyses were conducted for both populations.

Summary of Key Findings:

- Mean Part D risk scores for beneficiaries with these chronic conditions enrolled in FFS prescription drug plans (PDPs) indicated predicted drug spending 40–54 percent higher than for the baseline FFS beneficiary.

- Among non-low income beneficiaries who enrolled in PDPs, approximately 60 percent enrolled in a basic Part D plan, 20 percent enrolled in an enhanced plan without gap coverage, and 20 percent enrolled in an enhanced plan with gap coverage.

- Non-low income beneficiaries in actuarially equivalent basic plans and in enhanced plans with gap coverage had the highest drug spending.

- In all six chronic disease groups, non-low income beneficiaries enrolled in PDPs had mean drug spending indicating that they had reached the coverage gap.

- For beneficiaries receiving the low income subsidy enrolled in PDPs, those with diabetes, depression, or rheumatoid arthritis had mean spending levels in the catastrophic coverage range.

2.2 Data and Methods

The descriptive analysis for this report focused on drug plan enrollment status as of July 2007 for Medicare beneficiaries with chronic conditions. It involved multiple sources of 100 percent data files in its creation.

Six chronic conditions with significant drug costs were chosen by CMS for the study, listed here in order by population size:

- COPD
- Heart failure
- Diabetes with complications
- Dementia
- Major depression
- Rheumatoid arthritis

To identify Medicare beneficiaries with these chronic conditions, RTI used the CMS risk adjustment files containing CMS Hierarchical Condition Categories (HCCs) and Prescription Drug Hierarchical Condition Categories (RxHCCs), disease groupings used to predict medical costs and drug costs. Our assumption was that beneficiaries chose their 2007 drug plan on the basis of information they already knew in 2006 about their personal disease history. Therefore we used the 2007 risk adjustment files, which contain HCC and RxHCC flags based on 2006 diagnosis data. We excluded new enrollees (as of 2007) from our analysis because they lacked the required 2006 diagnosis profile.

As is shown in **Table 2.1**, we chose the HCC or RxHCC that best fit the chronic condition to identify beneficiaries. In most cases, such as COPD or heart failure, the selected HCC or RxHCC marker identified the chronic condition population exactly. In some cases, such as major depression, both the HCC and RxHCC classifications were broader than desired and we

chose the most restrictive definition.[2] When studying these analyses, it is important to realize that the identified population may include beneficiaries with related diagnoses but not necessarily the featured diagnosis.

Table 2.1
Chronic condition sample definitions

Chronic condition	Definition	Background
COPD	HCC108 Chronic Obstructive Pulmonary Disease	The HCC was selected over the RxHCC alternative because the RxHCC includes asthma—RxHCC 109 Asthma and COPD.
Heart failure	RxHCC91 Congestive Heart Failure	RxHCC91 is identical to the HCC alternative—HCC80 Congestive Heart Failure.
Diabetes with complications	RxHCC17 Diabetes with Complications	The RxHCC was selected over the alternative HCC set because the single RxHCC had slightly higher counts than the comparable HCCs—HCC15 Diabetes with Renal or Peripheral Circulatory Manifestation; HCC16 Diabetes with Neurologic or Other Specified Manifestation; HCC17 Diabetes with Acute Complications; and HCC 18 Diabetes with Ophthalmologic or Unspecified Complications.
Dementia	(in either RxHCC) RxHCC59 Dementia with Depression or Behavioral Disturbance RxHCC60 Dementia/Cerebral Degeneration	The RxHCCs were used because the related dementia HCC was not included in the HCC payment model.
Major depression	HCC55 Major Depressive, Bipolar, and Paranoid Disorders	Although HCC55 includes diagnoses outside of major depression (bipolar, paranoid disorders), it was selected over the RxHCC alternative, which included an even greater number of mental health diagnoses—RxHCC65 Other Major Psychiatric Disorders.
Rheumatoid arthritis	RxHCC41 Rheumatoid Arthritis and Other Inflammatory Polyarthropathy	Although RxHCC41 includes diagnoses outside of rheumatoid arthritis (inflammatory polyarthropathies), it was selected over the HCC alternative, which included an even greater number of connective tissue diagnoses—HCC38 Rheumatoid Arthritis and Inflammatory Connective Tissue Disease.

NOTE: COPD, chronic obstructive pulmonary disease; HCC, hierarchical condition category; RxHCC, prescription drug hierarchical condition category.

SOURCE: RTI International analysis of CMS risk adjustment files.

RTI used the 2006 and 2007 Part D Denominator 100 percent files as the primary source of its Part D enrollment data, with the majority of data extracted from the July 2007 file. In

[2] A newer classification of HCCs and RxHCCs was available for the FFS population. However, MA enrollees only had diagnoses submitted for them for the original version. Therefore, for the descriptive analysis, we were restricted to using the older classification. The differences are minor.

addition to Part D enrollment and beneficiary characteristics, these files contain the most reliable information on the Retiree Drug Subsidy (RDS) and other sources of creditable coverage (e.g., Federal Employees Health Benefits, TRICARE, Veterans Administration, etc.). With these enrollment data, we reduced the full 2007 chronic condition sample identified through the risk adjustment files to include only FFS and MA beneficiaries enrolled in Medicare as of July 2007.[3] Beneficiaries who died in 2007 before July were excluded from our descriptive analysis; but any beneficiaries who died after the July cutpoint were included.

We linked the Part D Denominator data to the Health Plan Management System (HPMS) files to determine drug benefit type (e.g., defined standard) and plan characteristics (e.g., level of gap coverage). RTI used the Common Medicare Environment (CME) file for demographic information. The 2006 and 2007 Prescription Drug Event (PDE) files were used to determine drug expenditures for both the FFS and MA populations. The beneficiary files (either Standard Analytic File or National Claims History) were used to profile the FFS population according to Part A and Part B characteristics of 2007, such as expenditures and hospitalizations. Because MA plans do not submit claims, we could not do the comparable Part A and Part B analysis on the MA population. Risk score files were used to profile the full population in terms of their Part A/B risk scores and Part D risk scores. The CMS risk adjustment files, described earlier as the source of our initial chronic condition designations, were also used to identify the full RxHCC profile of each beneficiary as well as end-stage renal disease (ESRD) status. County-level and Census data were used to identify geographic characteristics.

The final sample for the 2007 descriptive analysis included 11,698,968 beneficiaries classified into the six chronic conditions. The chronic conditions are not mutually exclusive. The same beneficiary may appear in more than one disease group; this occurred with 30 percent of the full sample.

Our descriptive analysis featured four main topics, with beneficiaries stratified by drug plan enrollment status:

1) Personal descriptive statistics—In these analyses, we examined the demographic composition (age, sex, race), low-income status, ESRD status, risk scores, Part D expenditures in 2006 and 2007,[4] and 2007 Part A and Part B expenditures and utilization of beneficiaries to profile each chronic condition sample.

2) Plan characteristics—Focusing only on beneficiaries enrolled in Part D plans, we analyzed plans by deductibles, cost-sharing structure, type of gap coverage, and monthly Part D premiums in terms of both mean premiums and decile distributions.

---

[3] Beneficiaries enrolled in employer-only plans were excluded from the sample, as were residents of Puerto Rico and U.S. territories. Additionally, the MA sample excluded private-fee-for-service plans, all types of cost plans, and Program of All-inclusive Care for the Elderly (PACE) plans.

[4] The 2006 and 2007 Part D expenditure analyses were done on separate panels (PDP or MA-PD) with these requirements: a) enrolled in Part D as of July 2007; b) at least one month of Part D enrollment in 2006; and c) the same type of enrollment (either all PDP or all MA-PD) for any months enrolled in Part D during both 2006 and 2007.

3) RxHCC descriptive statistics—Knowing that the majority of beneficiaries in each chronic condition sample had other diagnoses that would predict prescription drug usage, we looked at their complete RxHCC profiles to gauge how comorbidities could affect plan choice.

4) Geographic descriptive statistics—In our final subset of analyses, we investigated geographic patterns, looking at enrollment by urbanicity, Census region, and PDP or MA prescription drug plan (MA-PD) region.

The full set of 132 descriptive analysis tables for this report can be found in a separate Descriptive Analysis Appendices document available upon request. For each chronic condition by contract type (FFS or MA), there is a separate appendix with a set of tables corresponding to the four topics.

2.3 Cross-Disease Results

In this section, we pull key results from the individual chronic condition analyses to make comparisons across the six disease groups.

2.3.1 Type of Coverage

Table 2.2 presents an overview of the six chronic condition samples and their composition by contract type (FFS or MA) and type of drug coverage. For comparison purposes, full sample data from the previous 2006 analysis are included in the last column.[5] The COPD and heart failure disease groups had the largest populations, with over 4 million beneficiaries in each. The overall diabetes population is greater, but this analysis focused on the smaller diabetes with complications subset. With 827,093 beneficiaries, the rheumatoid arthritis group had the smallest population. The sample size rankings were consistent across the FFS and MA populations. The contract type breakout by disease group ranged from 78.9 to 84.5 percent for FFS and 15.5 to 21.1 percent for MA. Dementia and major depression had slightly higher concentrations in the FFS population, whereas diabetes with complications had the greatest MA concentration (21.1 percent). The latter finding could be partly due to coding intensity of diabetes with complications within MA plans. In terms of type of coverage, our 2006 analysis found that FFS beneficiaries with chronic conditions were more likely than the overall population to enroll in a drug plan. The 2007 data support that finding. The no known coverage category had nearly 19 percent of FFS beneficiaries in the 2006 sample; the 2007 data show that rate dropping to the 9- to 12-percent range by disease group. FFS beneficiaries with major depression were most likely to be enrolled in a PDP and least likely to have coverage through the Retiree Drug Subsidy or to have no known coverage. The FFS rheumatoid arthritis population had the opposite findings. In the MA population as in FFS, the major depression group had the greatest enrollment in a Part D drug plan (MA-PD). For most disease groups, about 5 to 6 percent of the MA population had RDS coverage, compared with an unusually low 1-percent rate in 2006. That could be the result of 2006 MA data quality issues.

---

5 A comparison to the full 2007 Medicare sample would have been preferable to the 2006 comparison, but that was beyond the scope of this analysis.

Table 2.2
Selected disease group drug plan enrollment statistics for full sample—fee-for-service and Medicare Advantage, July 2007

Variable	COPD	Heart failure	Diabetes with complications	Dementia	Major depression	Rheumatoid arthritis	2006—all beneficiary data
Sample size, full sample	4,419,793	4,099,995	3,086,125	2,151,450	1,500,287	827,093	39,695,184
Sample size, FFS	3,630,640	3,400,671	2,435,766	1,818,487	1,259,792	690,333	34,714,581
Sample size, MA	789,153	699,324	650,359	332,963	240,495	136,760	4,980,603
Contract type, % FFS	82.1%	82.9%	78.9%	84.5%	84.0%	83.5%	87.5%
Contract type, % MA	17.9%	17.1%	21.1%	15.5%	16.0%	16.5%	12.5%
FFS coverage, % FFS-PDP	57.7%	57.6%	58.5%	65.1%	70.3%	54.8%	45.7%
FFS coverage, % Retiree Drug Subsidy	19.8%	20.4%	20.6%	17.2%	13.3%	22.1%	19.6%
FFS coverage, % other creditable coverage	12.2%	11.5%	11.7%	8.0%	7.6%	10.7%	16.0%
FFS coverage, % no known coverage	10.3%	10.4%	9.2%	9.7%	8.9%	12.4%	18.8%
MA coverage, % MA-PD	87.9%	86.2%	88.1%	89.1%	92.7%	88.6%	93.7%
MA coverage, % Retiree Drug Subsidy	5.1%	6.2%	5.5%	5.2%	3.5%	5.0%	0.6%
MA coverage, % other creditable coverage	3.1%	3.5%	3.0%	2.1%	1.3%	2.2%	2.0%
MA coverage, % no known coverage	3.9%	4.1%	3.3%	3.7%	2.5%	4.2%	3.7%

NOTE: The full sample excludes all employer-only plans and residents of Puerto Rico and U.S. territories. Additionally, the MA sample excludes private fee-for-service plans, all types of cost plans, and Program of All-inclusive Care for the Elderly (PACE) plans. COPD, chronic obstructive pulmonary disease; FFS, fee-for-service; MA, Medicare Advantage; MA-PD, MA prescription drug plan; PDP, prescription drug plan.

Computer Output: (2007) tables_oct08.xls; (2006) partd_eval_lis_dec29_esrd_final_aug11.xls, partd_eval_lis_feb09_ma_new_final.xls.

SOURCE: RTI International analysis of CMS 100 percent enrollment data and risk adjustment files.

2.3.2 Beneficiary Characteristics

Focusing on personal descriptive statistics, **Table 2.3** and **Table 2.4** feature differences by chronic condition for beneficiaries enrolled in PDPs and MA-PDs, respectively. As would be expected, the age composition varied by disease group. Dementia was concentrated in the oldest age groups, as was heart failure to a lesser extent. Major depression was concentrated in the youngest age group (ages 64 and under, eligible for Part D primarily through disability status)—with the distribution among the PDP population (54.6 percent) greater than the MA counterpart (37.0 percent). Approximately three-fourths of the rheumatoid arthritis subgroup was female, the highest concentration by disease group. In contrast, the COPD population had the lowest female population (59.6 percent PDP; 55.4 percent MA-PD), with rates lower than 2006 comparisons of the respective full populations. Racial differences by disease groups show a higher proportion of Blacks with heart failure and diabetes with complications compared with the overall Black population. The diabetes with complications disease group also had the highest composition of "all other," a composite race category including Asians, Hispanics, and Native Americans. The percentage of the population identified as low income was greatest for disease groups at two ends of the age spectrum, major depression (youngest) and dementia (oldest).

Tables 2.3 and 2.4 also compare risk scores and mean annual Part D expenditures by disease group. The Part D risk score uses a beneficiary's diagnosis profile to predict drug spending. The Part A/B risk score predicts Medicare Part A and Part B spending. Part D risk scores for the PDP subset showed slight variability across disease groups but were significantly higher than the 2006 PDP population average. The diabetes with complications disease group had the highest mean Part D risk score, 1.54, which can be interpreted as beneficiaries' having predicted drug costs 54 percent higher than the baseline average FFS beneficiary (risk score of 1.00). The lack of variability across groups can be attributed in part to the fact that many of the beneficiaries in these disease groups are taking multiple medications, frequently for chronic conditions not featured in this study (e.g., high cholesterol or hypertension). The Part A/B risk scores showed greater variability, ranging from 1.83 (major depression) to 2.64 (heart failure). The MA-PD samples showed trends similar to those of their PDP counterparts, but with consistently lower risk scores.

The mean annual Part D expenditures, which were constructed using PDE data, represent the total drug spending by all parties (beneficiary, Part D plan, Medicare program).[6] A review of the Part D plan structure will aid in interpreting the expenditure data in Tables 2.3 and 2.4.[7]

---

6 Total spending was calculated as the sum of two PDE fields: Gross Drug Cost Below Out-of-Pocket Threshold (GDCB) + Gross Drug Cost Above Out-of-Pocket Threshold (GDCA). The mean annual Part D expenditure data reported in Tables 2.3 and 2.4 correspond to those of the Part D PDP and MA-PD panels constructed for the descriptive analysis.

As is seen in Table 2.3, PDP-enrolled, non-LI beneficiaries in all six disease groups had mean annual expenditures indicating that they had reached the coverage gap ($2,401–$5,451.25). The dementia disease group had the highest mean spending, $3,644, which corresponded to beneficiary out-of-pocket costs of $2,042.75 ($265 deductible + $533.75 initial coverage coinsurance + $1,244 gap). The PDP-enrolled, LI beneficiaries had much higher mean annual expenditures because their subsidized copayment structure continued through the gap—they were not subject to 100 percent coinsurance. Three of the disease groups had mean expenditures indicating that beneficiaries had reached the catastrophic coverage level: major depression ($6,293), rheumatoid arthritis ($5,778), and diabetes with complications ($5,602). The MA-PD-enrolled population followed a similar pattern (see Table 2.4), although spending was lower by about $700–$1,400 depending on the sample (non-LI or LI) and chronic condition. In the non-LI subset, beneficiaries in two disease groups—dementia and major depression—had mean expenditures indicating they had reached the coverage gap. None of the disease groups for the MA-PD LI subset had means within the catastrophic coverage level.

---

[7] In 2007, the Part D Defined Standard prescription drug benefit included a $265 deductible that the beneficiary was responsible for paying. Between $266 and the initial coverage limit of $2,400, the Part D plan was responsible for 75 percent of costs and the beneficiary paid a 25 percent coinsurance. There was no coverage between $2,401 and $5,451.25—the range known as the coverage gap, or "donut hole." Beneficiaries were responsible for all costs in the coverage gap up to the $5,451.25 threshold, which corresponded to $3,850 in true out-of-pocket costs. Catastrophic coverage began at that point, with costs being split among the Medicare program, providing reinsurance equal to 80 percent; the Part D plan, covering 15 percent; and the beneficiary, paying the greater of 5 percent coinsurance or copayments of $2.15 for generic drugs and $5.35 for nongeneric drugs.

Table 2.3
Selected disease group descriptive statistics for beneficiaries enrolled in fee-for-service prescription drug plans, July 2007

Variable	COPD	Heart failure	Diabetes with complications	Dementia	Major depression	Rheumatoid arthritis	2006 all FFS-PDP beneficiaries
Sample size, FFS-PDP	2,093,401	1,960,314	1,425,991	1,183,930	885,132	378,118	15,847,703
Age, % 0–64	21.8%	14.7%	22.5%	7.3%	54.6%	24.2%	23.3%
Age, % 65–74	33.7%	26.9%	35.6%	15.3%	20.2%	34.6%	37.1%
Age, % 75–84	31.2%	34.8%	31.0%	38.5%	16.7%	30.2%	27.4%
Age, % 85+	13.3%	23.6%	11.0%	39.0%	8.6%	10.9%	12.1%
Sex, % female	59.6%	63.2%	62.8%	71.6%	68.6%	78.5%	61.5%
Race, % White	83.6%	78.5%	70.8%	80.7%	83.6%	79.4%	73.7%
Race, % Black	9.8%	14.2%	18.3%	12.7%	9.9%	12.6%	11.3%
Race, % all other	6.6%	7.3%	11.0%	6.6%	6.5%	8.0%	14.9%
Low income, %	58.6%	56.6%	62.1%	66.0%	73.9%	50.6%	49.8%
Risk score, Part D	1.45	1.47	1.54	1.40	1.47	1.50	1.10
Risk score, Part A/B	2.26	2.64	2.27	2.06	1.83	1.86	1.26
2007 mean annual Part D expenditures, non-low income	$2,893	$3,058	$3,264	$3,644	$3,612	$3,031	–
2007 mean annual Part D expenditures, low income	$5,271	$5,041	$5,602	$5,095	$6,293	$5,778	–

NOTE: Risk scores for the 2006 reference population are without new enrollees to match composition of 2007 chronic disease sample. COPD, chronic obstructive pulmonary disease; FFS-PDP, fee-for-service prescription drug plan.

Computer Output: (2007) tables_oct08.xls; (2006) partd_eval_lis_dec29_esrd_final_aug11.xls, ffs_risk_scores_final.xls.

SOURCE: RTI International analysis of CMS 100 percent enrollment data, risk adjustment files, risk score files, and Prescription Drug Event files.

Table 2.4
Selected disease group descriptive statistics for beneficiaries enrolled in Medicare Advantage prescription drug plans, July 2007

Variable	COPD	Heart failure	Diabetes with complications	Dementia	Major depression	Rheumatoid arthritis	2006 all MA-PD beneficiaries
Sample size, MA-PD	693,675	602,877	573,250	296,594	223,034	121,197	4,667,132
Age, % 0–64	12.6%	9.8%	13.4%	4.3%	37.0%	18.2%	11.4%
Age, % 65–74	38.5%	30.5%	41.3%	16.7%	29.7%	39.0%	43.8%
Age, % 75–84	37.1%	39.5%	36.0%	43.4%	24.1%	33.3%	33.7%
Age, % 85+	11.8%	20.2%	9.3%	35.6%	9.2%	9.5%	11.1%
Sex, % female	55.4%	56.4%	56.2%	67.3%	70.4%	75.2%	59.0%
Race, % White	84.0%	78.1%	71.3%	80.2%	84.2%	78.7%	71.5%
Race, % Black	10.2%	15.2%	18.2%	12.4%	8.2%	13.5%	10.1%
Race, % all other	5.8%	6.7%	10.4%	7.5%	7.5%	7.8%	18.4%
Low income, %	33.2%	35.1%	35.4%	42.4%	43.0%	30.9%	22.7%
Risk score, Part D	1.35	1.41	1.44	1.35	1.42	1.42	0.99
Risk score, Part A/B	2.08	2.55	2.12	1.89	1.81	1.75	1.09
2007 mean annual Part D expenditures, non-low income	$2,084	$2,325	$2,346	$2,575	$2,457	$2,214	–
2007 mean annual Part D expenditures, low income	$4,055	$4,081	$4,248	$4,081	$5,109	$4,532	–

NOTE: Risk scores for the 2006 reference population are without new enrollees to match composition of 2007 chronic disease sample. COPD, chronic obstructive pulmonary disease; MA-PD, Medicare Advantage prescription drug plan.

Computer output: (2007) tables_oct08.xls; (2006) partd_eval_lis_feb09_ma_new_final.xls, ma_risk_scores_final.xls.

SOURCE: RTI International analysis of CMS 100 percent enrollment data, risk adjustment files, risk score files, and Prescription Drug Event files.

2.3.3 Plan Enrollment Statistics

The next set of tables summarizes plan enrollment statistics by disease group for beneficiaries enrolled in Part D prescription plans. Under the Part D program, participating organizations have the option of offering basic or enhanced benefits. In addition to the defined standard basic plan previously described, organizations may offer two actuarially equivalent variants—actuarially equivalent[8] and basic alternative.[9] Part D plans are also able to offer enhanced alternative prescription drug plans, which exceed the benefits offered in basic plans. This enhanced coverage often includes supplemental benefits including cost sharing, increased initial coverage limit or reduced deductible, provision of some coverage through the coverage gap, or any combination of these benefits. For this analysis, we stratified enhanced plans into two groups—those with gap coverage and those without. We examined the non-LI and LI populations separately because of the significant differences in cost-sharing burden (no coverage gap for LI) as well as the fact that most LI beneficiaries are auto-enrolled into basic plans.

Table 2.5 presents plan enrollment statistics for the FFS-PDP-enrolled chronic condition samples. For each disease group, the non-LI sample followed a rough breakout of 60-20-20—about 60 percent enrolled in basic plans, 20 percent in enhanced plans with gap coverage, and 20 percent in enhanced plans without gap coverage. This differs from the 2006 FFS-PDP all-beneficiaries baseline sample, which had 70 percent enrolled in basic plans and 30 percent in enhanced plans. The shift of 10 percentage points appears to be a change from defined standard plans to enhanced plans; however, because they are different samples in different years, the change cannot be definitively attributed to the chronic conditions. Among the basic plan types, beneficiaries in all disease groups preferred the basic alternative plans, which frequently offer no deductible. This plan type had the highest proportions across all disease groups, consistently in the 41- to 44-percent range. The actuarially equivalent basic plan was consistently the least popular choice, with fewer than 6 percent of the non-LI sample choosing to enroll. In terms of selecting gap coverage over none within enhanced plans, beneficiaries in the major depression and diabetes with complications disease groups had a preference for gap coverage of about 7 percentage points. The LI sample followed a completely different pattern but was strikingly consistent across disease groups because of its heavy concentration of auto-enrolled deemed beneficiaries—defined standard (19 percent), actuarially equivalent (27 percent), basic alternative (50 percent), enhanced with gap coverage (2 percent), and enhanced without gap coverage (2 percent). Because the plan type enrollment patterns across disease groups were consistent, the mean monthly premiums by disease group were also consistent. The non-LI population had a mean premium of $25 for basic plans and $44–$49 for enhanced plans, with

---

8 Actuarially equivalent plans have an overall structure similar to the defined standard benefit, but the cost sharing can differ from the 25 percent coinsurance under the standard defined benefit. These actuarially equivalent plans may have tiered copayments, for example, low dollar amounts for generic drugs and higher dollar amounts for preferred and nonpreferred brand-name drugs.

9 Under the basic alternative option, plans may have a different overall structure for the benefit, although they have to be actuarially equivalent to the standard benefit. Basic alternative benefit structures may include reductions in the deductible, changes in cost sharing, and a modification of the initial coverage limit. These benefit package alternative features provide coverage with an actuarial value equal to the defined standard coverage.

disease groups favoring gap coverage paying slightly more in premiums. (Further breakouts by disease group and plan type in the Descriptive Analysis Appendices document show monthly premium differences of about $62 for enhanced plans with gap coverage, compared with $29 for enhanced plans without gap coverage.) The LI population has slightly lower but similar monthly premiums—$23–$24 for basic plans and $41–$43 for enhanced plans.

Plan type enrollment patterns and monthly premiums were quite different within the MA-PD population because of the Medicare Advantage structure. All MA enrollees (including those in health maintenance organizations [HMOs], local and regional preferred provider organizations [PPOs], and special needs plans [SNPs]) must be offered at least basic Part D coverage as part of their total benefits package. MA-PDs can use Part C savings to subsidize premiums for enhanced Part D options as an overall incentive to attract and retain enrollees. Many MA plans take advantage of this ability, as is evident in the MA-PD plan type distribution presented in **Table 2.6**. In contrast to the FFS-PDP, non-LI 60-20-20 distribution, the non-LI population in MA-PD plans followed a rough 20-40-40 pattern—about 20 percent enrolled in basic plans, 40 percent in enhanced plans with gap coverage, and 40 percent in enhanced plans without gap coverage. There was little enrollment variation across diseases or within disease groups. Among those enrolling in a basic plan, the overwhelming choice was basic alternative. The LI MA-PD sample followed its own pattern, which was different from the non-LI MA-PD sample as well as from its LI PDP counterpart—defined standard (23 percent), actuarially equivalent (8 percent), basic alternative (23 percent), enhanced with gap coverage (16 percent), and enhanced without gap coverage (30 percent). Unlike in the PDP sample, where enhanced benefits cost more, the MA-PD monthly premium was higher for basic plans ($17–$24) than for enhanced plans ($10–$13), an artifact related to payment incentives previously described. (Further breakouts by disease group and plan type in the Descriptive Analysis Appendices document show MA-PD premiums by deciles, illustrating $0 subsidized premiums.)

Table 2.5
Selected disease group plan enrollment statistics for beneficiaries enrolled in fee-for-service prescription drug plans, July 2007

Variable	COPD	Heart failure	Diabetes with complications	Dementia	Major depression	Rheumatoid arthritis	2006 all FFS-PDP beneficiaries
Non-low income FFS-PDP sample size	866,807	850,693	540,354	402,635	230,697	186,846	7,955,494
Non-LI, plan type, % defined standard	12.7%	13.7%	12.2%	12.1%	11.0%	13.6%	25.1%
Non-LI, plan type, % actuarially equivalent	4.8%	5.1%	5.2%	4.6%	5.5%	4.6%	6.4%
Non-LI, plan type, % basic alternative	44.0%	42.8%	41.7%	42.7%	41.4%	42.2%	39.2%
Non-LI, plan type, % enhanced with gap coverage	19.5%	21.2%	23.8%	22.5%	24.2%	20.3%	—
Non-LI, plan type, % enhanced without gap coverage	19.0%	17.2%	17.1%	18.1%	17.9%	19.4%	—
Non-LI, plan type, % enhanced total	38.5%	38.4%	40.9%	40.6%	42.1%	39.6%	29.3%
Non-LI, mean monthly premium, all basic plans	$25	$25	$25	$25	$25	$25	—
Non-LI, mean monthly premium, all enhanced plans	$44	$46	$48	$49	$48	$44	—
Low-income FFS-PDP sample size	1,226,594	1,109,621	885,637	781,295	654,435	191,272	7,892,209
LI, plan type, % defined standard	18.9%	19.4%	19.5%	18.8%	19.6%	19.8%	25.7%
LI, plan type, % actuarially equivalent	27.3%	26.6%	27.1%	27.0%	27.9%	26.8%	26.4%
LI, plan type, % basic alternative	49.8%	49.8%	49.4%	50.5%	48.7%	49.0%	45.0%
LI, plan type, % enhanced with gap coverage	1.7%	1.9%	1.8%	1.7%	1.7%	2.0%	—
LI, plan type, % enhanced without gap coverage	2.3%	2.3%	2.2%	2.0%	2.0%	2.5%	—
LI, plan type, % enhanced total	4.0%	4.2%	4.0%	3.7%	3.8%	4.4%	2.0%
LI, mean monthly premium, all basic plans	$24	$24	$23	$24	$24	$23	—
LI, mean monthly premium, all enhanced plans	$41	$43	$43	$43	$43	$42	—

NOTE: The missing data cells in the 2006 comparison column occur because in the previous 2006 analysis we did not break out enhanced plans by gap coverage, nor did we examine monthly premiums. COPD, chronic obstructive pulmonary disease; FFS-PDP, fee-for-service prescription drug plan; LI, low-income.

Computer output: (2007) tables_oct08.xls; (2006) partd_eval_lis_dec29_esrd_final_aug11.xls.

SOURCE: RTI International analysis of CMS 100 percent enrollment data and risk adjustment files.

Table 2.6
Selected disease group plan enrollment statistics for beneficiaries enrolled in Medicare Advantage prescription drug plans, July 2007

Variable	COPD	Heart failure	Diabetes with complications	Dementia	Major depression	Rheumatoid arthritis	2006 all MA-PD beneficiaries
Non-low-income MA-PD sample size	463,036	391,484	370,549	170,822	127,157	83,734	3,609,269
Non-LI, plan type, % defined standard	2.0%	2.4%	2.0%	2.1%	2.0%	2.0%	2.0%
Non-LI, plan type, % actuarially equivalent	1.7%	2.0%	1.7%	2.1%	1.8%	1.9%	4.8%
Non-LI, plan type, % basic alternative	17.4%	18.6%	20.4%	19.4%	19.7%	17.3%	21.3%
Non-LI, plan type, % enhanced with gap coverage	38.1%	38.1%	38.4%	36.3%	37.2%	38.8%	—
Non-LI, plan type, % enhanced without gap coverage	40.7%	39.0%	37.4%	40.1%	39.5%	39.9%	—
Non-LI, plan type, % enhanced total	78.8%	77.1%	75.8%	76.4%	76.6%	78.7%	71.9%
Non-LI, mean monthly premium, all basic plans	$20	$21	$18	$20	$17	$20	—
Non-LI, mean monthly premium, all enhanced plans	$10	$11	$10	$11	$10	$11	—
Low-income MA-PD sample size	230,639	211,393	202,701	125,772	95,877	37,463	1,057,863
LI, plan type, % defined standard	21.2%	22.4%	23.7%	24.9%	26.4%	22.4%	27.3%
LI, plan type, % actuarially equivalent	8.6%	8.7%	8.0%	5.9%	6.2%	8.3%	4.3%
LI, plan type, % basic alternative	23.5%	24.7%	23.6%	24.2%	22.6%	21.8%	18.7%
LI, plan type, % enhanced with gap coverage	16.6%	15.5%	16.5%	13.8%	15.2%	17.2%	—
LI, plan type, % enhanced without gap coverage	30.2%	28.7%	28.1%	31.3%	29.5%	30.3%	—
LI, plan type, % enhanced total	46.7%	44.2%	44.6%	45.1%	44.8%	47.5%	49.7%
LI, mean monthly premium, all basic plans	$22	$22	$22	$24	$23	$22	—
LI, mean monthly premium, all enhanced plans	$10	$11	$10	$13	$11	$10	—

NOTE: The missing data cells in the 2006 comparison column occur because in the previous 2006 analysis we did not break out enhanced plans by gap coverage, nor did we examine monthly premiums. COPD, chronic obstructive pulmonary disease; LI, low income, MA-PD, Medicare Advantage prescription drug plan.

Computer Output: (2007) tables_oct08.xls; (2006) partd_eval_lis_feb09_ma_new_final.xls.

SOURCE: RTI International analysis of CMS 100 percent enrollment data and risk adjustment files.

2.4 Disease-Specific Results

Next we highlight key findings that are reported in tables within the Descriptive Statistics Appendices specific to each disease group. For brevity, this subsection will focus only on the FFS full sample and non-LI subgroup for each chronic condition.

2.4.1 Chronic Obstructive Pulmonary Disease

The FFS COPD descriptive analyses are presented in **Appendix A**. The COPD sample was the largest of the six chronic conditions studied (3,630,640). Its age composition was concentrated in the 65–84 years range, and it had the greatest proportion of males (45.6 percent). Compared with other disease groups, the COPD population was predominately White (83.6 percent) and its non-LI, PDP-enrolled subgroup even more so (95.2 percent). Breakouts by plan type showed that, among the non-LI COPD population, beneficiaries with the highest mean Part D risk scores and Part A/B risk scores had enrolled in enhanced plans with gap coverage. The 2007 mean annual drug spending for the enhanced with gap coverage subset was $3,892, in contrast to the defined standard basic plan subset, who had the lowest 2007 mean ($2,407).

A consistent finding in the COPD non-LI sample (and across all disease groups) revealed that, although the actuarially equivalent plan choice was the least popular, beneficiaries who enrolled in it had the second highest risk scores and extensive drug spending. For the COPD set, their 2007 mean annual drug spending of $3,704 clearly put them in the coverage gap. This could indicate that beneficiaries are having difficulty identifying the plan type that would best meet their drug needs—in this case, providing gap coverage for beneficiaries with multiple known diseases that require drugs. It could also indicate that some beneficiaries may not understand their plan structure. They could have enrolled in an actuarially equivalent basic plan, mistakenly believing that its difference from the defined standard plan was enhanced benefits. This latter error would be more likely to occur if premiums were higher for actuarially equivalent plans than for defined standard plans, as the decile distributions indicate they were.

A clear majority of the COPD population (77.3 percent) enrolled in plans with no deductible. Most of these plans (82.4 percent) had four or more cost-sharing tiers, including a specialty tier for expensive drugs. When offered, gap coverage applied primarily to generic drugs (91.1 percent). Monthly Part D premiums for all FFS-PDPs ranged from $9 to $136. Enhanced plans with gap coverage had the highest mean ($60); whereas enhanced plans without gap coverage had a mean premium equal to basic alternative plans ($28).

To gain a more complete picture of the disease profiles of COPD beneficiaries, we examined their RxHCCs, disease groups from the CMS risk adjustment models that predict drug spending. These RxHCCs were present in 40 percent or more of the non-LI COPD population:

- RxHCC 19 Disorders of Lipoid Metabolism (e.g., high cholesterol)
- RxHCC 48 Other Musculoskeletal and Connective Tissue Disorders (e.g., joint pain)
- RxHCC 92 Acute Myocardial Infarction and Unstable Angina
- RxHCC 98 Hypertensive Heart Disease or Hypertension

In our final subset of analyses, we investigated geographic characteristics**.** Among the total FFS COPD population, 73.8 percent resided in urban areas and 26.1 percent in rural. The only coverage type that differed substantively was the Retiree Drug Subsidy. RDS enrollees were more likely to reside in urban areas (80.6 percent). As was discussed previously, the non-LI COPD sample had a rough 60-20-20 percent distribution between basic plans, enhanced plans with gap coverage, and enhanced plans without gap coverage. Most Census regions followed this distribution; the Northeast was the exception, with 73 percent enrolled in basic plans and about 13 percent enrolled in each of the enhanced plan categories. There was variation in plan choice among PDP regions as well. Region 3 (New York), Region 33 (Hawaii), and Region 34 (Alaska) had the highest proportions enrolled in basic plans (over 80 percent); whereas Region 9 (North Carolina), Region 13 (Michigan), and Region 16 (Wisconsin) had the highest enrollments in enhanced plans with gap coverage (about 30 percent).

A parallel set of analyses was conducted for the MA COPD population (see **Appendix B**).

2.4.2 Heart Failure

The FFS heart failure descriptive analyses are presented in **Appendix C**. The age composition of the heart failure sample was older than that of the COPD sample, with about 60 percent age 75 years or older. This disease group had one of the higher proportions of Blacks (11.5 percent for the full FFS population; 14.2 percent for the FFS-PDP subgroup). Heart failure was one of two of the studied chronic conditions with a small but significant ESRD subpopulation—3.5 percent of the FFS population and 4.3 percent of the FFS-PDP subset. (Diabetes with complications had the highest percentage of ESRD [5.4 percent]; most chronic conditions had about 1 percent with ESRD.) The heart failure sample had the highest 2007 mean annual Part A and Part B expenditures—$16,092 for the non-LI PDP subset and $21,414 for the LI counterpart. Breakouts by plan type showed that, among the non-LI heart failure population, beneficiaries with the highest mean Rx and Part A/B risk scores had enrolled in enhanced plans with gap coverage or in actuarially equivalent basic plans. The 2007 mean annual drug spending was $3,979 for the enhanced with gap coverage subset and $3,705 for the actuarially equivalent basic plan subset, in contrast to the defined standard basic plan subset, whose 2007 mean was $2,551.

In terms of plan characteristics for the heart failure non-LI subgroup, most findings are similar to those in the other disease groups, with minimal differences due to a slightly higher percentage enrolled in defined standard basic plans. A clear majority of the population (75.4 percent) enrolled in plans with no deductible, a rate a few percentage points lower than that of the other chronic conditions. Most plans (80.8 percent) had four or more cost-sharing tiers and a specialty tier for expensive drugs (82.5 percent). Again, when offered, gap coverage applied primarily to generic drugs (90.1 percent).

The disease profiles of beneficiaries with heart failure have commonalities and differences with those of the other chronic conditions. These RxHCCs were present in 40 percent or more of the non-LI heart failure population:

- RxHCC 19 Disorders of Lipoid Metabolism
- RxHCC 21 Other Specified Endocrine/Metabolic/Nutritional Disorders (e.g., thyroid disorders)
- RxHCC 48 Other Musculoskeletal and Connective Tissue Disorders
- RxHCC 92 Acute Myocardial Infarction and Unstable Angina
- RxHCC 99 Specified Heart Arrhythmias

Additionally, if focusing on beneficiaries enrolled in enhanced plans with gap coverage, over 40 percent had diabetes—about 21 percent in RxHCC17 Diabetes With Complications and 23 percent in RxHCC18 Diabetes Without Complications. Comparing the RxHCCs listed here with those of the other chronic conditions, heart failure had the greatest number with 40 percent or more and was the only disease group with RxHCC 99 Specified Heart Arrhythmias at this high percentage rate.

The geographic enrollment patterns for FFS heart failure beneficiaries are quite similar to the COPD sample in terms of urban-rural and Census region distributions. Focusing on the non-LI subgroup, PDP Regions 3 (New York), 33 (Hawaii), and 34 (Alaska) again had the highest proportions of beneficiaries enrolled in basic plans (near or more than 80 percent), as did Region 4 (New Jersey). PDP Regions 9 (North Carolina), 13 (Michigan), and 16 (Wisconsin) again had the highest enrollments in enhanced plans with gap coverage (near or more than 30 percent), joined by Region 25, which includes Iowa, Minnesota, Montana, Nebraska, North Dakota, South Dakota, and Wyoming.

The parallel set of analyses for the MA heart failure population is in **Appendix D**.

2.4.3 Diabetes With Complications

The FFS diabetes with complications descriptive analyses are presented in **Appendix E**. Its age composition is comparable to the full 2006 PDP population, with about 65 percent concentrated in the 65–84 years age brackets. This disease group had the highest proportion of Blacks (15.8 percent for the full FFS population; 18.3 percent for the FFS-PDP subgroup) and other non-White groups (7.9 percent full FFS; 11.0 percent FFS-PDP). As would be expected, the diabetes with complications disease group had the highest ESRD subpopulation—5.4 percent of its FFS population and 6.3 percent of its FFS-PDP subset. It also had the highest Part D risk scores—1.44 for the non-LI PDP subset and 1.60 for the LI counterpart. Breakouts by plan type showed that, among the non-LI diabetes with complications population, beneficiaries with the highest mean Rx and Part A/B risk scores had enrolled in actuarially equivalent basic plans or in enhanced plans with gap coverage. The 2007 mean annual drug spending for the actuarially equivalent basic plan subset was $4,105, slightly higher than the $4,092 for the enhanced with gap coverage subset. Part A and Part B expenditures and inpatient hospital expenditures were also highest for enrollees in the actuarially equivalent basic plans.

Beneficiaries in the diabetes with complications non-LI subgroup, along with the major depression sample, enrolled in greater proportions in enhanced plans with gap coverage. Most other findings and distributions related to plan characteristics are similar to those of other disease groups.

These RxHCCs were present in 40 percent or more of the non-LI diabetes with complications population:

- RxHCC 19 Disorders of Lipoid Metabolism
- RxHCC 48 Other Musculoskeletal and Connective Tissue Disorders
- RxHCC 92 Acute Myocardial Infarction and Unstable Angina
- RxHCC 98 Hypertensive Heart Disease or Hypertension

Whereas all six chronic conditions had high percentages of beneficiaries with RxHCC 19, the diabetes with complications sample had the highest rates, and the non-LI population (73.0 percent) had even higher rates than the LI counterpart (62.7 percent).

The geographic enrollment patterns for FFS diabetes with complications beneficiaries are quite similar to those of heart failure and COPD. Differences include a slightly higher urban concentration (78 percent for the full sample) and higher rates of enrollment for the non-LI subgroup in enhanced plans with gap coverage. Two of the four PDP regions that consistently had the highest gap-coverage-plan enrollments had rates closer to 40 percent rather than 30 percent—Region 16 (Wisconsin) and Region 25 (Iowa, Minnesota, Montana, Nebraska, North Dakota, South Dakota, and Wyoming).

The parallel set of analyses for the MA diabetes with complications population is in **Appendix F**.

2.4.4 Dementia

The FFS dementia descriptive analyses are presented in **Appendix G**. Approximately 80 percent of the dementia sample were age 75 years or older, and nearly half of that set were age 85 years or older. Focusing on the PDP-enrolled subset, this disease group had a high proportion of females (71.6 percent) and a substantial LI subpopulation (66.0 percent). Furthermore, it had the highest institutionalized population (41.4 percent), identified by the zero copayment level of cost-sharing. The dementia sample had the lowest Part D risk scores—1.34 for the non-LI subset and 1.43 for their LI counterpart. However, the non-LI subset's 2007 mean annual Part D expenditures ($3,644) were highest among all six chronic diseases, whereas the LI subset's 2007 mean ($5,095) were the second lowest. The high mean for the non-LI subset could be attributed in part to the lack of generic drugs for dementia. The LI subset contains a greater number of institutionalized beneficiaries. For advanced stages of dementia, brand-name dementia drugs would have limited effect and would likely be discontinued. Additionally, comorbidities are often treated less aggressively among the oldest populations in institutions.

Most plan characteristic findings for the dementia non-LI subgroup are similar to those in the other disease groups. One minor difference is that the mean monthly premium for enhanced plans with gap coverage is slightly higher for the dementia population ($65 compared with $60–$62 for other disease groups). A greater percentage of those enhanced plans offer gap coverage for all formulary drugs (11.6 percent compared with 8.5–10.7 percent for other disease groups).

Beneficiaries with dementia had differences in their disease profiles related both to the disease itself and to their advanced ages. Among the full FFS dementia sample, 15 percent were identified by RxHCC 59 Dementia with Depression or Behavioral Disturbance, and 85 percent by RxHCC 60 Dementia/Cerebral Degeneration. These RxHCCs were present in 40 percent or more of the non-LI dementia population:

- RxHCC 19 Disorders of Lipoid Metabolism
- RxHCC 21 Other Specified Endocrine/Metabolic/Nutritional Disorders
- RxHCC 48 Other Musculoskeletal and Connective Tissue Disorders
- RxHCC 98 Hypertensive Heart Disease or Hypertension

Additionally, if focusing on beneficiaries enrolled in enhanced plans with gap coverage, we find that 40.7 percent had RxHCC 66 Other Major Psychiatric Disorders, a disease group that includes anxiety disorders. Within the LI subset, the rates for RxHCC 66 are even higher (50.5 percent for enhanced with gap coverage).

The geographic enrollment patterns for FFS dementia beneficiaries are quite comparable with those of heart failure and COPD, with a minor difference being a slightly higher urban concentration (78.5 percent for the full sample), similar to the diabetes with complications subgroup.

The parallel set of analyses for the MA dementia population is in **Appendix H**.

2.4.5 Major Depression

The FFS major depression descriptive analyses are presented in **Appendix I**. Looking at age composition, it was the youngest sample with nearly half its population under age 65 years—an age group eligible for Medicare primarily through disability. Related to this distribution, it had the highest LI population (73.9 percent of its FFS-PDP subgroup). Similar to COPD, the major depression sample had a very high proportion of Whites (86.1 percent for the full FFS population; 83.6 percent for the FFS-PDP subgroup). The 2007 mean annual drug spending was high for this sample—$3,612 for the non-LI PDP subset and $6,293 for the LI counterpart (the highest LI spending of all disease groups). Breakouts by plan type showed that, among the non-LI major depression population, beneficiaries with the highest mean Rx and Part A/B risk scores had enrolled in enhanced plans with gap coverage, whereas those with the lowest scores and mean annual spending enrolled in enhanced plans without gap coverage.

In terms of plan characteristics corresponding to the non-LI subgroup, the major depression sample had the highest proportion enrolled in enhanced plans with gap coverage (24.2 percent). Most other plan characteristics data are similar to those of other disease groups.

Only the three RxHCCs common to all six chronic condition samples were present in 40 percent or more of the non-LI major depression PDP population:

- RxHCC 19 Disorders of Lipoid Metabolism
- RxHCC 48 Other Musculoskeletal and Connective Tissue Disorders
- RxHCC 98 Hypertensive Heart Disease or Hypertension

Focusing on beneficiaries enrolled in enhanced plans with gap coverage, more than 40 percent were also identified as having RxHCC 21 Other Specified Endocrine/Metabolic/Nutritional Disorders.

The geographic enrollment patterns for FFS major depression beneficiaries indicate that this population had the highest urban concentration (80 percent) of the six chronic conditions studied. It also differed from the other disease groups in that its non-LI subset did not follow the rough 60-20-20 percent distribution between basic plans, enhanced plans with gap coverage, and enhanced plans without gap coverage. Beneficiaries with major depression were more likely to enroll in enhanced plans with gap coverage (24.2 percent). Whereas the other conditions had the same three or four PDP regions with enrollment rates near 30 percent for plans with gap coverage, there were eight such regions in the major depression sample, including Region 7 (Virginia), Region 15 (Indiana and Kentucky), Region 24 (Kansas), and Region 27 (Colorado).

The parallel set of analyses for the MA major depression population is in **Appendix J**.

2.4.6 Rheumatoid Arthritis

The FFS rheumatoid arthritis descriptive analyses are presented in **Appendix K**. The rheumatoid arthritis sample was the smallest of the six chronic conditions studied (690,333). It had the highest female concentration (74.5 percent for the full FFS sample; 78.5 percent for the FFS-PDP subgroup). The sample had the lowest percentage of LI beneficiaries, with about half of its PDP population subsidized. Similar to most other chronic condition samples, breakouts by plan type showed that, among the non-LI rheumatoid arthritis population, beneficiaries with the highest mean Rx and Part A/B risk scores had enrolled in enhanced plans with gap coverage or in actuarially equivalent basic plans. The 2007 mean annual drug spending for the enhanced with gap coverage subset was $4,185 and for the actuarially equivalent basic plan subset was $4,103, in contrast to the defined standard basic plan subset, whose 2007 mean was $2,507.

Detailed plan characteristics corresponding to the rheumatoid arthritis non-LI subgroup had findings comparable to those of the other disease groups.

Similar to major depression, the three RxHCCs common to all six chronic condition samples were present in 40 percent or more of the non-LI PDP rheumatoid arthritis population:

- RxHCC 19 Disorders of Lipoid Metabolism
- RxHCC 48 Other Musculoskeletal and Connective Tissue Disorders
- RxHCC 98 Hypertensive Heart Disease or Hypertension

However, focusing on beneficiaries enrolled in enhanced plans with gap coverage shows that more than 40 percent were also identified as having two other RxHCCs: RxHCC 21 Other Specified Endocrine/Metabolic/Nutritional Disorders and RxHCC 45 Disorders of the Vertebrae and Spinal Discs.

The geographic enrollment patterns for FFS rheumatoid arthritis beneficiaries are similar to those of the COPD population, with no unusual findings to report.

The parallel set of analyses for the MA rheumatoid arthritis population is in **Appendix L**.

2.5 Discussion

The purpose of this comprehensive descriptive analysis was to identify the Part D enrollment patterns among Medicare beneficiaries with these six chronic conditions: COPD, heart failure, diabetes with complications, dementia, major depression, and rheumatoid arthritis.

Personal descriptive statistics provided the initial framing of the disease groups. Each chronic condition had its own unique sample composition. The disease groups varied by age, sex, and race, as well as by the percentage of LI beneficiaries within each sample. Mean Part A/B risk scores varied greatly; Part D risk scores varied much less so. The tighter range of Part D risk scores, which indicate mean drug spending for the PDP population 40–54 percent higher than that of the baseline FFS beneficiary, can be explained by the finding that beneficiaries in the individual chronic condition samples are taking multiple drugs for many of the same chronic conditions, including ones not featured in this study, such as high cholesterol and hypertension.

Part D plan type analyses of the non-LI, PDP-enrolled samples had both logical and unexpected results. Beneficiaries who enrolled in enhanced plans with gap coverage had higher mean Part D risk scores (indicating more diseases predicting higher drug spending) as well as higher mean annual drug expenditures. The latter finding could be the result of a combination of factors—more diseases requiring more drug spending as well as increased adherence to drug regimens through some form of gap coverage. Whereas the actuarially equivalent basic plan was uniformly the least popular enrollment option for non-LI subsets, its Part D risk score profile and mean annual spending were consistently high for all six disease groups. Mean annual drug expenditures for this plan type ranged from $3,704 (COPD) to $4,402 (major depression)—all values clearly in the coverage gap. Beneficiaries who enrolled in actuarially equivalent plans and had high spending into the coverage gap could likely have saved money by enrolling in an enhanced plan with gap coverage. These findings add to the body of research indicating that Medicare beneficiaries are having difficulty understanding the payment structures of the various Part D plan types and choosing the “best” plan for their needs, a situation compounded by their reluctance to switch plans (Abaluck et al., 2009; Dulio et al., 2007; Kling et al., 2009; Polinski et al., 2010).

Analyses of plan characteristics illustrated each plan type's structure as well as indicating trends across disease groups. Beneficiaries clearly preferred plans with no deductibles—in basic plans or enhanced. For each disease group, the non-LI PDP samples followed a rough enrollment breakout of 60-20-20—about 60 percent enrolled in basic plans, 20 percent in enhanced plans with gap coverage, and 20 percent in enhanced plans without gap coverage.

Because of the ability of MA plans to use their Part C savings to offer subsidized drug coverage, plan structure and monthly premiums differed between PDPs and MA-PDs. About 90 percent of enhanced plans offering drug coverage in the PDP sample limited the coverage to generics. In the MA-PD sample, this figure was in the 70 percent range, with the difference being more plans offering coverage of both generic and brand drugs. MA-PDs were able to offer drug coverage with $0 monthly premiums to more than 40 percent of the MA population, resulting in enhanced plans costing less, on average, than basic plans for MA-PD enrollees.

The descriptive analysis in this section provides an extensive overview of relevant factors affecting drug plan choices for beneficiaries with chronic conditions as well as the actual enrollment patterns. However, there are limitations to this study. Looking at aggregate data, we can see in which types of plans beneficiaries with specific chronic conditions enrolled. But it is difficult to evaluate whether beneficiaries are making the "best" choices in terms of enrollment. The heterogeneity of individual drug needs within each chronic condition sample, the variety of drug plans and drugs covered within them, and the complexity of drug plan cost structures make it nearly impossible to disentangle the data for broad groups. Beneficiaries with high drug spending who do not have gap coverage are one subgroup CMS may want to target for future study, looking at multiple years of enrollment data. Another related future focus would be to study plan "switchers" and plan "stayers" to identify beneficiary or plan characteristics related to each group.

Another limitation of this analysis involved presenting mean drug expenditure data by plan type, contract type, and income status for each chronic condition to determine on average where beneficiaries fell in terms of Part D coverage. Further analyses of drug expenditures by more detailed percentile distributions could provide insight into the percentages of enrollees who are entering the coverage gap or catastrophic coverage.

SECTION 3
ADHERENCE MEASURES

3.1 Introduction

Beneficiaries with chronic diseases, such as diabetes and congestive heart failure (CHF), often need to take drugs daily. Adherence to the medication regimen is necessary for controlling the condition and avoiding a complication or adverse outcome, such as a hospitalization. However, individuals often fail to adhere to their medication regimens for a number of reasons.

The most common reason given by survey respondents for failing to fill a prescription was cost; the second most common reason given was that they did not believe that the medicine was necessary (Kennedy et al., 2008; Safran et al., 2005). Consistent with the survey findings that cost was the main reason for nonadherence, nonadherence rates are higher among vulnerable groups such as those with lower incomes and the uninsured (Kennedy et al., 2008; Safran et al., 2005). Similarly, harder economic times increase the rate of nonadherence; the rate at which patients abandoned prescriptions at the pharmacy increased consistently from 2006 to 2009 with the worsening economic conditions (Wolters Kluwer, 2009). Overall, the estimates of nonadherence in the recent literature range from very low numbers such as 4.4 percent (Kennedy, 2008) to high numbers such as 22 percent (Fischer et al., 2010).[10]

Rates are also high for those with chronic conditions and for the medications that treat those conditions, and highest for those who reported multiple chronic conditions. Chronic conditions with high nonadherence rates include diabetes, depression, CHF, chronic obstructive pulmonary disease (COPD), and rheumatoid arthritis (Fischer et al., 2010; Kennedy et al., 2008; Safran et al., 2005). Over a range of survey data, the factors that are most strongly related to nonadherence are insurance coverage, level of wealth, age, and health status (Kirking et al., 2006).

In this section, we study the drug adherence of Medicare Part D beneficiaries with chronic conditions. The chronic conditions are COPD, CHF, chronic diabetes, diabetes with acute complications, dementia, major depression, and rheumatoid arthritis. The research questions addressed in this section help answer the question of what the impact of Part D is on patients' adherence to their medication therapy. The specific research questions are as follows:

- Overall, what were the drug adherence rates for Medicare beneficiaries with Part D coverage?
- What was the impact of the coverage gap on drug adherence for beneficiaries with chronic conditions?
- How did the effects differ for the Medicaid and other low-income populations?

[10] The main reason for this disagreement is most likely differences in data sources, such as surveys compared with insurance claim data and in-person compared with telephone surveys (Kirking et al., 2006).

Underlying the questions about adherence to drug regimens is the assumption that beneficiaries with chronic conditions need to adhere to their drug regimens to control the condition and avoid complications and hospitalizations. The first question looks at whether beneficiaries with chronic conditions are adhering to their drug regimens. However, it does not answer whether the adherence rate is higher than in the absence of Part D. The second and third questions can be used to determine whether cost-sharing has an impact on drug adherence rates. Abstracting from questions about whether adherence is effective, or cost-effective, the next policy question that might be addressed is how one can change rates of adherence. This analysis is descriptive and shows the current levels of adherence. Finding the means of increasing adherence appropriate to different subpopulations would be a relevant study. This study does not point to pricing as the key tool.

As a result of this study, we found the following:

- There is a large variation in drug adherence rates among Medicare Part D beneficiaries taking drugs within a therapeutic drug class.

- There is a large variation in drug adherence rates for therapeutic drug classes used to treat the same chronic condition.

- For beneficiaries who entered the coverage gap there was a small drop in adherence for the non-low income enrollees when the gap was reached. The pattern was not consistent across drug classes or medical conditions. This drop was not found for the low income enrollees though their adherence was lower in the coverage ranges before the gap.

- Having multiple chronic conditions increased the likelihood of reaching the gap, as would be expected.

3.2 Data and Methods

The two main sources of data for the adherence measures are the Common Medicare Environment (CME) Part D enrollment files for 2006 and 2007and the 100 percent Prescription Drug Event (PDE) transaction-level claims. These two files were supplemented with information from the National Medicare Utilization Database (NMUD), long-term institutionalized (LTI) files, and Medicare Part A claims. Person-level data from the CME, denominator, and LTI files were used to construct eligibility variables. Person-level expenditure and contract/plan data from the PDE Tap files were used to construct total spending and plan liability variables. Diagnoses from the NMUD extract were used to construct person-level medical condition variables for fee-for-service (FFS) enrollees.

Our sample consisted of beneficiaries with one of seven chronic diseases: COPD, CHF, chronic diabetes, diabetes with acute complications, dementia, major depression, and rheumatoid arthritis. Unlike for section 2, we defined our chronic conditions based on newer versions of

hierarchical condition categories (HCCs) and prescription HCCs (RxHCCs).[11] We were able to use the newer classifications because we limited our sample to FFS beneficiaries. In section 2, it was necessary to use the older classifications of HCC and RxHCCs because diagnoses submitted for MA enrollees were limited to those for the older classification. **Table 3.1** shows the criteria used to define each chronic condition.

Table 3.1
Criteria for chronic conditions

Chronic condition	Beneficiary has the following:
Chronic obstructive pulmonary disease	HCC111 Chronic Obstructive Pulmonary Disease
Congestive heart failure	RxHCC87 Congestive Heart Failure
Chronic diabetes	CC18 Diabetes with Chronic Complications, but not CC17 Diabetes with Acute Complications
Diabetes with acute complications	CC18 Diabetes with Chronic Complications and CC17 Diabetes with Acute Complications
Dementia	RxHCC54 Alzheimer's Disease or RxHCC55 Dementia, Except Alzheimer's Disease
Major depression	RxHCC60 Major Depression
Rheumatoid arthritis	DXG 38.03 rheumatoid arthritis and other inflammatory polyarthropathy

NOTE: CC, condition category; DXG, diagnosis group; HCC, hierarchical condition category; RxHCC, prescription hierarchical condition category.

We further limited our analysis to beneficiaries with continuous Medicare Parts A and B coverage in 2006 and at least 1 month of Part D coverage in 2007. Finally, we excluded beneficiaries who had either a skilled nursing facility or an LTI stay.

For each of the seven chronic conditions, we evaluated beneficiary adherence in a selected set of therapeutic classes. We had three goals in selecting the therapeutic classes. First, we wanted the therapeutic classes to include drugs that an individual would take regularly as maintenance drugs for the condition itself, rather than for acute flare-ups or for side effects of the condition. Second, we wanted each therapeutic class to be sufficiently narrow so that an individual would be unlikely to take more than one drug within the class. Third, we wanted each therapeutic class to be broad enough that it would include the possible substitute drugs that an individual could switch between within a class.

[11] We used Version 21 HCCs and DXGs (diagnostic groups) and Version 03 RxHCCs, which have different classifications and numbering from the earlier risk adjustment model versions. A CC refers to a Condition Category, the disease grouping before a hierarchy has been imposed transforming it into an HCC.

To meet these goals, in consultation with a clinician, we selected a set of American Hospital Formulary Service (AHFS) eight-digit drug classes to track each chronic condition. To do this, we first constructed an exhaustive list of the drugs used to treat each of these chronic conditions. The list of drugs was derived from three primary sources: the Merck Manual;[12] reputable online sources, such as the Mayo Clinic Web site; and a physician consultant, who helped put our findings in the context of current clinical practice. We then used *AHFS Drug Information 2010* (AHFS, 2010) to categorize these drugs into drug classes, which resulted in the final list of drug classes.

The adherence measure used in this section is the medication possession ratio (MPR), which is the number of days that a drug has been supplied, divided by the potential number of eligible days of supply that could have been ordered. To calculate the number of days supplied, we went back to the last quarter of 2006 because a prescription might have been filled shortly before the start of 2007 and as much as a 3 months' supply could have been in a beneficiary's possession at the beginning of the year. Similarly, we corrected for prescriptions filled in the last quarter of 2007 in cases in which the days supplied exceeded the remaining days in the year. We also controlled for the fact that people might take more than one drug within a class, by capping the days supplied of a drug in a month at the number of days in the month. To calculate the eligible days, the denominator in our ratio, we calculated the total days enrolled in Part D in 2007, and then subtracted for the days a beneficiary had a Part A stay.[13]

To answer our first research question, about the drug adherence rates for Medicare beneficiaries with Part D coverage, we analyzed annual drug adherence rates for our sample FFS beneficiaries with chronic conditions. To answer our second research question, about the impact of the coverage gap on drug adherence, we analyzed drug adherence rates separately for beneficiaries before they reached the gap, while they were in the gap, and after they exited the gap and received catastrophic coverage. Finally, we answered our third research question, about the difference in impact for low-income and Medicaid populations, in two ways. First, we compared the overall drug adherence rates for low-income and non-low-income populations. We then analyzed the MPRs separately for low-income and non-low-income populations to see whether the impact of the coverage gap differed for the low-income populations.

3.3 Medication Possession Ratios

We first analyzed the MPRs for FFS beneficiaries with one of the seven chronic conditions. **Table 3.2** shows the distribution of annual MPRs by chronic condition and drug class.

The mean MPRs in Table 3.2 vary from a low of 0.30 for amylinomimetics to treat beneficiaries with diabetes with acute complications to a high of 0.74 for beta-adrenergic blocking agents used to treat beneficiaries with CHF. For most drug classes, the 90th percentile has an MPR of 1.0, and the 75th percentile is also at or close to 1.0, suggesting that a large number of beneficiaries are adhering to their drug regimen. However, there are exceptions. For

[12] Accessed through http://www.merck.com/mmpe/index.html.

[13] In a Part A stay, the hospital or institution is required to provide the drugs.

example, incretin mimetics are used to treat beneficiaries with chronic diabetes. The MPR for the 75th percentile is only 0.69. One possibility for this is that some beneficiaries may choose to take only one injection daily rather than the recommended two injections.[14]

A second example is dipeptidyl peptidase-4 (DPP-4) inhibitors, which are also used to treat chronic diabetes. For DPP-4 inhibitors, the 90th percentile is only 0.74 and the 75th percentile is 0.50. One possible explanation is that DPP-4 inhibitors are relatively new drugs;[15] the first, Sitagliptin, was approved by the U.S. Food and Drug Administration in 2006. As such, some beneficiaries may not have begun using the DPP-4 inhibitors until later in 2007. However, we can only hypothesize about why the drug adherence rates for these two drug classes (i.e., amylinomimetics and beta-adrenergic blocking agents) and other exceptions are as low as they are.

3.3.1 Low-Income Subsidy Status

The impact of Part D may differ for LIS and non-LIS beneficiaries. One reason is that lower-income beneficiaries are often less likely to adhere to drug regimens, potentially leading to lower adherence rates. A second reason is that LIS beneficiaries often have lower copayments in the subsidized portion of Part D before the gap threshold and continue coverage in the gap. These lower copayments and continuity of coverage should theoretically lead to higher MPRs for LIS beneficiaries. Consequently, the net effects of Part D on drug adherence by LIS beneficiaries are unclear.

To study the differential impact of Part D on LIS and non-LIS beneficiaries, we analyzed MPRs by chronic diseases separately for the LIS and non-LIS populations. We defined an LIS beneficiary as a beneficiary who was either deemed or received an LIS for all 12 months of 2007. Similarly, we defined a non-LIS beneficiary as a beneficiary who was neither deemed nor received an LIS in any month in 2007. We excluded beneficiaries who were deemed or received an LIS for only part of 2007 because we wanted to tell a clear story. **Tables 3.3 through 3.9** show the MPRs separately for LIS and non-LIS beneficiaries for each of the seven chronic conditions. Tables 3.3 through 3.9 do not show a consistent pattern of either LIS or non-LIS beneficiaries having higher MPRs; therefore, we discuss each chronic disease category separately.

Table 3.3 shows the MPRs for COPD by LIS status; Table 3.4 shows the MPRs for CHF by LIS status. As can be seen in Table 3.3, LIS beneficiaries have a slightly higher MPR for two of the three drug classes. However, the difference is less than 0.02 for all three therapeutic classes, suggesting little difference in overall adherence between LIS and non-LIS beneficiaries.

---

[14] According to WebMD at http://diabetes.webmd.com/incretin-mimetics-for-type-2-diabetes.

[15] According to the Cochrane Library at http://onlinelibrary.wiley.com/o/cochrane/clsysrev/articles/CD006739/frame.html.

Table 3.2
Distribution of annual medication possession ratios for beneficiaries with chronic diseases, by drug class

Drug class	25th Percentile	Mean	75th Percentile	90th Percentile
Chronic obstructive pulmonary disease	—	—	—	—
Antimuscarinics/antispasmodics	0.08	0.38	0.66	0.95
Selective beta-2-adrenergic agonists	0.09	0.42	0.73	1.00
Respiratory smooth muscle relaxants	0.25	0.63	0.99	1.00
Congestive heart failure	—	—	—	—
Coumarin derivatives	0.41	0.65	0.94	1.00
Cardiotonic agents	0.50	0.73	1.00	1.00
Direct vasodilators	0.18	0.52	0.85	1.00
Nitrates and nitrites	0.08	0.48	0.96	1.00
Beta-adrenergic blocking agents	0.52	0.74	1.00	1.00
Angiotensin-converting enzyme inhibitors	0.42	0.69	0.99	1.00
Angiotensin II receptor antagonists	0.41	0.67	0.99	1.00
Mineralocorticoid (aldosterone) antagonists	0.25	0.60	0.96	1.00
Loop diuretics	0.33	0.63	0.96	1.00
Chronic diabetes	—	—	—	—
Alpha-glucosidase inhibitors	0.17	0.53	0.89	1.00
Biguanides	0.43	0.69	0.99	1.00
Dipeptidyl peptidase-4 (DPP-4) inhibitors	0.16	0.35	0.50	0.74
Incretin mimetics	0.14	0.42	0.69	0.92
Insulins	0.38	0.64	0.95	1.00
Meglitinides	0.19	0.52	0.85	1.00

(continued)

Table 3.2 (continued)
Distribution of annual medication possession ratios for beneficiaries with chronic diseases, by drug class

Drug class	25th Percentile	Mean	75th Percentile	90th Percentile
Sulfonylureas	0.50	0.72	1.00	1.00
Thiazolidinediones	0.33	0.62	0.94	1.00
Antidiabetic agents (miscellaneous)	0.08	0.37	0.62	0.95
Diabetes with acute complications	—	—	—	—
Alpha-glucosidase inhibitors	0.13	0.41	0.65	0.98
Amylinomimetics	0.09	0.30	0.46	0.71
Biguanides	0.26	0.58	0.92	1.00
Dipeptidyl peptidase-4 (DPP-4) inhibitors	0.09	0.35	0.50	0.75
Incretin mimetics	0.09	0.36	0.58	0.88
Insulins	0.39	0.64	0.95	1.00
Meglitinides	0.15	0.44	0.72	0.97
Sulfonylureas	0.33	0.62	0.96	1.00
Thiazolidinediones	0.25	0.53	0.85	1.00
Antidiabetic agents (miscellaneous)	0.08	0.32	0.49	0.90
Dementia	—	—	—	—
Parasympathomimetics (cholinergic agents)	0.33	0.65	0.98	1.00
Central nervous system agents (miscellaneous)	0.33	0.63	0.97	1.00
Major depression	—	—	—	—
Selective serotonin and norepinephrine reuptake inhibitors	0.23	0.57	0.95	1.00
Selective serotonin reuptake inhibitors	0.30	0.62	0.97	1.00
Serotonin modulators	0.16	0.52	0.91	1.00

(continued)

Table 3-2 (continued)
Distribution of annual medication possession ratios for beneficiaries with chronic diseases, by drug class

Drug class	25th Percentile	Mean	75th Percentile	90th Percentile
Tricyclics and other norepinephrine reuptake inhibitors	0.16	0.53	0.95	1.00
Antidepressants (miscellaneous)	0.17	0.56	0.95	1.00
Atypical antipsychotics	0.25	0.60	0.99	1.00
Rheumatoid arthritis	—	—	—	—
Antimalarials	0.18	0.56	0.93	1.00
Antineoplastic agents	0.32	0.61	0.91	1.00
Gold compounds	0.16	0.49	0.87	1.00
Disease-modifying antirheumatic agents	0.31	0.61	0.93	1.00
Immunosuppressive agents	0.19	0.55	0.91	1.00

NOTE: Excludes beneficiaries with either a skilled nursing facility or long-term institutionalized stay.

SOURCE: RTI International analysis of Medicare claims and 2006 and 2007 Prescription Drug Event data.

Table 3.3
Chronic obstructive pulmonary disease: 2007 mean medication possession ratios by low-income subsidy status

Drug class	Non-low-income subsidy	Low-income subsidy
Antimuscarinics/antispasmodics	0.38	0.39
Selective beta-2-adrenergic agonists	0.40	0.44
Respiratory smooth muscle relaxants	0.64	0.62

NOTE: Excludes beneficiaries with either a skilled nursing facility or long-term institutionalized stay.

SOURCE: RTI International analysis of Medicare claims and 2006 and 2007 Prescription Drug Event data.

Table 3.4 shows the mean MPR for beneficiaries with CHF. Table 3.4 also shows that neither LIS nor non-LIS beneficiaries consistently had higher MPRs. Among beneficiaries with CHF, LIS beneficiaries had higher MPRs for only three of the nine drug classes and lower MPRs in four of the remaining seven drug classes.

Table 3.4
Congestive heart failure: 2007 mean medication possession ratios by low-income subsidy status

Drug class	Non-low-income subsidy	Low-income subsidy
Coumarin derivatives	0.64	0.66
Cardiotonic agents	0.73	0.73
Direct vasodilators	0.54	0.50
Nitrates and nitrites	0.46	0.49
Beta-adrenergic blocking agents	0.75	0.73
Angiotensin-converting enzyme inhibitors	0.70	0.68
Angiotensin II receptor antagonists	0.66	0.69
Mineralocorticoid (aldosterone) antagonists	0.61	0.58
Loop diuretics	0.63	0.63

NOTE: Excludes beneficiaries with either a skilled nursing facility or long-term institutionalized stay.

SOURCE: RTI International analysis of Medicare claims and 2006 and 2007 Prescription Drug Event data.

Tables 3.5 and 3.6 show the MPRs by LIS status for beneficiaries with chronic diabetes and diabetes with acute complications, respectively. Tables 3.5 and 3.6 show that, irrespective of LIS status, MPRs are higher for diabetics with acute complications. In particular, the MPR for insulin is approximately 50 percent higher (0.61 to 0.90 for non-LIS and 0.65 to 0.97 for LIS) for beneficiaries with diabetes with acute complications than for those with chronic diabetes. The reason for this may be that diabetics with acute complications may need insulin more regularly than chronic diabetics, who may be able to control their diabetes with exercise and diet and do not need to take insulin as frequently. Comparing the MPR for LIS and non-LIS beneficiaries, LIS beneficiaries have higher MPRs in six of the drug classes among chronic diabetics and seven among beneficiaries with diabetes with acute complications. The drug class

where there is the most difference is incretin mimetics. Among chronic diabetics, the MPR is similar at 0.41 and 0.43 for non-LIS and LIS beneficiaries, respectively. However, for diabetics with acute complications, there is a 0.13 spread between non-LIS and LIS beneficiaries, with MPRs of 0.66 and 0.53, respectively.

Table 3.5
Chronic diabetes: 2007 mean medication possession ratios by low-income subsidy status

Drug class	Non-low-income subsidy	Low-income subsidy
Alpha-glucosidase inhibitors	0.52	0.53
Amylinomimetics	0.31	0.35
Biguanides	0.71	0.67
Dipeptidyl peptidase-4 (DPP-4) inhibitors	0.34	0.37
Incretin mimetics	0.41	0.43
Insulins	0.61	0.65
Meglitinides	0.53	0.52
Sulfonylureas	0.75	0.71
Thiazolidinediones	0.58	0.64
Antidiabetic agents (miscellaneous)	0.37	0.37

NOTE: Excludes beneficiaries with either a skilled nursing facility or long-term institutionalized stay.

SOURCE: RTI International analysis of Medicare claims and 2006 and 2007 Prescription Drug Event data.

Table 3.6
Diabetes with acute complications: 2007 mean medication possession ratios by low-income subsidy status

Drug class	Non-low-income subsidy	Low-income subsidy
Alpha-glucosidase inhibitors	0.36	0.43
Amylinomimetics	0.30	0.30
Biguanides	0.63	0.57
Dipeptidyl peptidase-4 (DPP-4) inhibitors	0.33	0.35
Incretin mimetics	0.39	0.35
Insulins	0.59	0.66
Meglitinides	0.42	0.45
Sulfonylureas	0.67	0.61
Thiazolidinediones	0.50	0.54
Antidiabetic agents (miscellaneous)	0.34	0.31

NOTE: Excludes beneficiaries with either a skilled nursing facility or long-term institutionalized stay.

SOURCE: RTI International analysis of Medicare claims and 2006 and 2007 Prescription Drug Event data.

Table 3.7 shows the MPRs by LIS status for beneficiaries with dementia. There is no difference in MPR for either of the two drug classes between LIS and non-LIS beneficiaries.

Table 3.7
Dementia: 2007 mean medication possession ratios by low-income subsidy status

Drug class	Non-low-income subsidy	Low-income subsidy
Parasympathomimetics (cholinergic agents)	0.65	0.65
Central nervous system agents (miscellaneous)	0.63	0.62

NOTE: Excludes beneficiaries with either a skilled nursing facility or long-term institutionalized stay.

SOURCE: RTI International analysis of Medicare claims and 2006 and 2007 Prescription Drug Event data.

In Table 3.8, which shows the MPRs by LIS status for beneficiaries with major depression, several therapeutic classes have substantial differences in MPRs between LIS and non-LIS beneficiaries. The largest difference is for atypical antipsychotics. The MPR for LIS beneficiaries is 0.62, 20 percent higher than for non-LIS beneficiaries at 0.51. LIS beneficiaries also have a higher MPR (0.59) for selective serotonin and norepinephrine reuptake inhibitors than do non-LIS beneficiaries (0.55). However, non-LIS beneficiaries' MPR of 0.56 for tricyclics and other norepinephrine reuptake inhibitors is also 0.04, or 7.6 percent, higher than for LIS beneficiaries.

Table 3.8
Major depression: 2007 mean medication possession ratios by low-income subsidy status

Drug class	Non-low-income subsidy	Low-income subsidy
Selective serotonin and norepinephrine reuptake inhibitors	0.55	0.59
Selective serotonin reuptake inhibitors	0.61	0.62
Serotonin modulators	0.53	0.52
Tricyclics and other norepinephrine reuptake inhibitors	0.56	0.52
Antidepressants (miscellaneous)	0.57	0.55
Atypical antipsychotics	0.51	0.62

NOTE: Excludes beneficiaries with either a skilled nursing facility or long-term institutionalized stay.

SOURCE: RTI International analysis of Medicare claims and 2006 and 2007 Prescription Drug Event data.

Table 3.9 shows the mean MPR by LIS status for beneficiaries with rheumatoid arthritis. Unlike the other chronic conditions in our analysis, with the exception of disease-modifying antirheumatic agents, non-LIS beneficiaries with rheumatoid arthritis have a substantially higher MPR than LIS beneficiaries. One possible reason that disease-modifying agents may have a higher MPR for LIS beneficiaries (0.63 to 0.59) than non-LIS beneficiaries is that several of the

disease-modifying drugs, including Humira, Enbrel, and Remicade, can cost $10,000 or more per year.[16]

Table 3.9
Rheumatoid arthritis: 2007 mean medication possession ratios by low-income subsidy status

Drug class	Non-low-income subsidy	Low-income subsidy
Antimalarials	0.61	0.50
Antineoplastic agents	0.64	0.57
Gold compounds	0.50	0.46
Disease-modifying antirheumatic agents	0.59	0.63
Immunosuppressive agents	0.58	0.52

NOTE: Excludes beneficiaries with either a skilled nursing facility or long-term institutionalized stay.

SOURCE: RTI International analysis of Medicare claims and 2006 and 2007 Prescription Drug Event data.

3.4 Adherence Measures in the Gap

Although overall possession rates may not differ substantially between LIS and non-LIS beneficiaries, the LIS status may affect MPRs for Medicare beneficiaries who enter the coverage gap. Previous literature (Fung et al., 2010; Hoadley et al., 2008) has found that adherence fell for beneficiaries in the coverage gap; if beneficiaries had coverage in the gap, then adherence should not be affected. In our next analysis, we studied the impact of entering the gap on drug adherence. Because LIS beneficiaries continue their coverage in the gap, their MPRs should not be affected. Therefore, to better isolate the impact of the gap coverage and even catastrophic coverage on beneficiaries' drug adherence, we looked separately at LIS and non-LIS beneficiaries.

For this analysis, we limited our sample to beneficiaries enrolled in Part D for all of 2007 and assumed that the individual was enrolled in the standard plan. In 2007, the coverage gap began when the total retail drug costs reached $2,400 and ended when the beneficiary's out-of-pocket costs reached $3,850 or the cumulative retail drug cost of $5,451.25. We then used total monthly drug costs to divide each beneficiary's year into up to three parts, corresponding to the months before entering the gap, the months during the gap, and the months after the gap. We then calculated the average monthly MPR separately by beneficiary and drug class for each part of the year. We excluded the transition months into and out of the gap from our analysis.

There may be a selection issue with beneficiaries who did not enter the gap if the reason was that they had lower drug adherence rates. Therefore, to better isolate the impact of the gap on drug adherence, we eliminated any beneficiaries who did not enter the coverage gap. Overall, only 23.8 percent of the beneficiaries with one of the seven chronic conditions reached the

[16] Call with John Ayanian, July 12, 2010.

coverage gap, and only 5.2 percent came out of the coverage gap. **Table 3.10** shows, however, that the percentage of beneficiaries reaching the coverage gap varied across disease categories. Similarly, **Table 3.11** shows that beneficiaries with more than one chronic condition were 60 percent more likely to enter the coverage gap than beneficiaries with only one condition.

Table 3.10
Frequency of beneficiaries' entering the coverage gap, by chronic condition

Chronic condition	Total number of beneficiaries with disease	Percentage entering the coverage gap
Chronic obstructive pulmonary disease	1,951,747	24.6
Congestive heart failure	1,628,445	21.1
Chronic diabetes	1,361,583	29.2
Diabetes with acute complications	33,414	34.3
Dementia	1,139,631	36.3
Major depression	480,712	30.3
Rheumatoid arthritis	338,756	18.5

NOTE: Includes only beneficiaries with Part D coverage for all 12 months of 2007 and excludes beneficiaries with either a skilled nursing facility or long-term institutionalized stay.

SOURCE: RTI International analysis of Medicare claims and 2006 and 2007 Prescription Drug Event data.

Table 3.11
Frequency of beneficiaries' entering the coverage gap, by number of chronic conditions

Number of chronic conditions	Total number of beneficiaries with disease	Percentage entering the coverage gap
One	3,331,336	20.0
Two or more	1,573,184	31.8
Overall	4,904,520	23.8

NOTE: Includes only beneficiaries with Part D coverage for all 12 months of 2007 and excludes beneficiaries with either a skilled nursing facility or long-term institutionalized stay.

SOURCE: RTI International analysis of Medicare claims and 2006 and 2007 Prescription Drug Event data.

Table 3.12 shows the average MPR for COPD beneficiaries who entered the coverage gap. For non-LIS beneficiaries with COPD, the mean MPR fell in the coverage gap for all therapeutic classes and increased again after beneficiaries exited the gap and began catastrophic coverage. The MPR for LIS beneficiaries with COPD, however, was not affected by the coverage gap.

Table 3.12
Chronic obstructive pulmonary disease beneficiaries: 2007 medication possession ratios for beneficiaries who entered the coverage gap

Drug class	Non-LIS mean MPR before the gap	Non-LIS mean MPR during the gap	Non-LIS mean MPR after the gap	LIS mean MPR before the gap	LIS mean MPR during the gap	LIS mean MPR after the gap
Antimuscarinics/ antispasmodics	0.65	0.62	0.66	0.55	0.57	0.58
Selective beta-2-adrenergic agonists	0.70	0.67	0.68	0.61	0.64	0.62
Respiratory smooth muscle relaxants	0.74	0.71	0.74	0.70	0.68	0.72

NOTE: Includes only beneficiaries with Part D coverage for all 12 months of 2007 and excludes beneficiaries with either a skilled nursing facility or long-term institutionalized stay. LIS, low-income subsidy; MPR, medication possession ratio.

SOURCE: RTI International analysis of Medicare claims and 2006 and 2007 Prescription Drug Event data.

Table 3.13 shows a more mixed picture: the MPR for both non-LIS and LIS beneficiaries increased for some therapeutic drug classes, but fell for others, in the coverage gap. However, for all drug classes, the mean MPR increases for non-LIS beneficiaries increased during the catastrophic phase relative to the coverage gap.

Table 3.13
Congestive heart failure beneficiaries: 2007 medication possession ratios for beneficiaries who entered the coverage gap

Drug class	Non-LIS mean MPR before the gap	Non-LIS mean MPR during the gap	Non-LIS mean MPR after the gap	LIS mean MPR before the gap	LIS mean MPR during the gap	LIS mean MPR after the gap
Coumarin derivatives	0.68	0.69	0.73	0.68	0.70	0.72
Cardiotonic agents	0.78	0.77	0.81	0.78	0.77	0.80
Direct vasodilators	0.61	0.63	0.70	0.57	0.60	0.65
Nitrates and nitrites	0.57	0.58	0.61	0.56	0.57	0.60
Beta-adrenergic blocking agents	0.82	0.81	0.85	0.79	0.80	0.82
Angiotensin-converting enzyme inhibitors	0.77	0.74	0.76	0.74	0.72	0.73
Angiotensin II receptor antagonists	0.78	0.74	0.79	0.77	0.76	0.78
Mineralocorticoid (aldosterone) antagonists	0.68	0.68	0.72	0.63	0.64	0.68
Loop diuretics	0.69	0.71	0.75	0.68	0.70	0.73

NOTE: Includes only beneficiaries with Part D coverage for all 12 months of 2007 and excludes beneficiaries with either a skilled nursing facility or long-term institutionalized stay. LIS, low-income subsidy; MPR, medication possession ratio.

SOURCE: RTI International analysis of Medicare claims and 2006 and 2007 Prescription Drug Event data.

Table 3.14 shows the mean MPRs for LIS and non-LIS beneficiaries with chronic diabetes. With the exception of DPP-4 inhibitors and insulin, the MPR for non-LIS beneficiaries fell in all drug classes in the coverage gap. For all drug classes except thiazolidinediones, the MPR for non-LIS beneficiaries with chronic diabetes then increased after beneficiaries exited the gap. Table 3.14 shows no impact of the coverage gap on the MPR for LIS beneficiaries with chronic diabetes. However, for all drug classes, the mean MPR for LIS beneficiaries with chronic diabetes either increased or remained the same during the catastrophic phase relative to the coverage gap.

Table 3.14
Chronic diabetes beneficiaries: 2007 medication possession ratios for beneficiaries who entered the coverage gap

Drug class	Non-LIS mean MPR before the gap	Non-LIS mean MPR during the gap	Non-LIS mean MPR after the gap	LIS mean MPR before the gap	LIS mean MPR during the gap	LIS mean MPR after the gap
Alpha-glucosidase inhibitors	0.63	0.58	0.67	0.60	0.60	0.62
Amylinomimetics	0.40	0.35	0.55	0.38	0.40	0.50
Biguanides	0.77	0.73	0.77	0.73	0.72	0.76
Dipeptidyl peptidase-4 (DPP-4) inhibitors	0.33	0.57	0.72	0.26	0.61	0.69
Incretin mimetics	0.56	0.50	0.65	0.48	0.52	0.58
Insulins	0.72	0.73	0.84	0.72	0.75	0.80
Meglitinides	0.67	0.62	0.70	0.60	0.60	0.64
Sulfonylureas	0.79	0.75	0.73	0.75	0.73	0.73
Thiazolidinediones	0.81	0.63	0.73	0.79	0.70	0.70
Antidiabetic agents (miscellaneous)	0.53	0.51	0.70	0.46	0.50	0.57

NOTE: Includes only beneficiaries with Part D coverage for all 12 months of 2007 and excludes beneficiaries with either a skilled nursing facility or long-term institutionalized stay. LIS, low-income subsidy; MPR, medication possession ratio.

SOURCE: RTI International analysis of Medicare claims and 2006 and 2007 Prescription Drug Event data.

The MPRs for beneficiaries with diabetes with acute complications show no correlation with entering the coverage gap for either LIS or non-LIS beneficiaries. However, with the exception of thiazolidinediones, the MPRs increased for both LIS and non-LIS upon beneficiaries' exit from the coverage gap. **Table 3.15** shows the mean MPR for LIS and non-LIS beneficiaries with diabetes with acute complications.

Table 3.15
Diabetes with acute complications beneficiaries: 2007 medication possession ratios for beneficiaries who entered the coverage gap

Drug class	Non-LIS mean MPR before the gap	Non-LIS mean MPR during the gap	Non-LIS mean MPR after the gap	LIS mean MPR before the gap	LIS mean MPR during the gap	LIS mean MPR after the gap
Alpha-glucosidase inhibitors	0.47	0.43	0.76	0.46	0.48	0.48
Amylinomimetics	0.32	0.37	0.53	0.31	0.39	0.40
Biguanides	0.67	0.61	0.67	0.61	0.60	0.63
Dipeptidyl peptidase-4 (DPP-4) inhibitors	0.34	0.53	0.59	0.23	0.56	0.63
Incretin mimetics	0.51	0.48	0.53	0.39	0.39	0.46
Insulins	0.71	0.74	0.83	0.70	0.75	0.79
Meglitinides	0.53	0.55	0.68	0.51	0.52	0.61
Sulfonylureas	0.71	0.62	0.60	0.65	0.61	0.62
Thiazolidinediones	0.76	0.55	0.64	0.70	0.58	0.57
Antidiabetic agents (miscellaneous)	0.29	0.35	0.72	0.34	0.43	0.54

NOTE: Includes only beneficiaries with Part D coverage for all 12 months of 2007 and excludes beneficiaries with either a skilled nursing facility or long-term institutionalized stay. LIS, low-income subsidy; MPR, medication possession ratio.

SOURCE: RTI International analysis of Medicare claims and 2006 and 2007 Prescription Drug Event data.

The mean MPR for non-LIS beneficiaries with dementia fell for parasympathomimetics upon beneficiaries' entering the coverage gap, but increased for central nervous system agents, suggesting that the coverage gap did not affect drug adherence rates for non-LIS beneficiaries. However, the MPRs for non-LIS beneficiaries with dementia increased substantially upon beneficiaries' exiting the coverage gap, from 0.83 to 0.90 for parasympathomimetics and from 0.80 to 0.89 for central nervous system agents. **Table 3.16** shows the mean MPRs for LIS and non-LIS beneficiaries with dementia.

Table 3.16
Dementia beneficiaries: 2007 Medication possession ratios for beneficiaries who entered the coverage gap

Drug class	Non-LIS mean MPR before the gap	Non-LIS mean MPR during the gap	Non-LIS mean MPR after the gap	LIS mean MPR before the gap	LIS mean MPR during the gap	LIS mean MPR after the gap
Parasympathomimetics (cholinergic agents)	0.85	0.83	0.90	0.79	0.83	0.87
Central nervous system agents (miscellaneous)	0.77	0.80	0.89	0.71	0.79	0.84

NOTE: Includes only beneficiaries with Part D coverage for all 12 months of 2007 and excludes beneficiaries with either a skilled nursing facility or long-term institutionalized stay. LIS, low-income supplement; MPR, medication possession ratio.

SOURCE: RTI International analysis of Medicare claims and 2006 and 2007 Prescription Drug Event data.

Table 3.17 shows the mean MPR for LIS and non-LIS beneficiaries with major depression who entered the coverage gap. For these beneficiaries, the coverage gap did not affect the MPRs for either LIS or non-LIS beneficiaries. However, as with the other disease categories, the mean MPR for both LIS and non-LIS beneficiaries increased during the catastrophic phase relative to the coverage gap.

Table 3.17
Major depression beneficiaries: 2007 Medication possession ratios for beneficiaries who entered the coverage gap

Drug class	Non-LIS mean MPR before the gap	Non-LIS mean MPR during the gap	Non-LIS mean MPR after the gap	LIS mean MPR before the gap	LIS mean MPR during the gap	LIS mean MPR after the gap
Selective serotonin and norepinephrine reuptake inhibitors	0.74	0.73	0.85	0.73	0.75	0.81
Selective serotonin reuptake inhibitors	0.72	0.70	0.78	0.74	0.72	0.77
Serotonin modulators	0.60	0.61	0.67	0.62	0.61	0.66
Tricyclics and other norepinephrine reuptake inhibitors	0.62	0.59	0.63	0.60	0.58	0.63
Antidepressants (miscellaneous)	0.69	0.70	0.79	0.68	0.68	0.75
Atypical antipsychotics	0.71	0.69	0.87	0.80	0.80	0.89

NOTE: Includes only beneficiaries with Part D coverage for all 12 months of 2007 and excludes beneficiaries with either a skilled nursing facility or long-term institutionalized stay. LIS, low-income supplement; MPR, medication possession ratio.

SOURCE: RTI International analysis of Medicare claims and 2006 and 2007 Prescription Drug Event data.

The coverage gap appeared to affect drug adherence for non-LIS beneficiaries with rheumatoid arthritis. With the exception of disease-modifying antirheumatic agents, the MPRs for non-LIS beneficiaries with rheumatoid arthritis all fell in the coverage gap. The MPR for disease-modifying antirheumatic agents actually increased 0.06 from 0.66 to 0.72 between the pre-gap and gap periods. Exiting the gap also affected drug adherence. With the exception of gold compounds, which can likely be ignored because of the small number of beneficiaries taking them, MPRs either increased or remained the same for both LIS and non-LIS beneficiaries who exited the coverage gap and began catastrophic coverage. **Table 3.18** shows the mean MPR for LIS and non-LIS beneficiaries with rheumatoid arthritis.

Table 3.18
Rheumatoid arthritis beneficiaries: 2007 Medication possession ratios for beneficiaries who entered the coverage gap

Drug class	Non-LIS mean MPR before the gap	Non-LIS mean MPR during the gap	Non-LIS mean MPR after the gap	LIS mean MPR before the gap	LIS mean MPR during the gap	LIS mean MPR after the gap
Antimalarials	0.66	0.64	0.65	0.58	0.56	0.56
Antineoplastic agents	0.69	0.67	0.68	0.63	0.61	0.60
Gold compounds	0.73	0.70	0.48	0.70	0.66	0.69
Disease-modifying antirheumatic agents	0.66	0.72	0.82	0.65	0.72	0.77
Immunosuppressive agents	0.66	0.61	0.68	0.61	0.60	0.65

NOTE: Includes only beneficiaries with Part D coverage for all 12 months of 2007 and excludes beneficiaries with either a skilled nursing facility or long-term institutionalized stay. LIS, low-income supplement; MPR, medication possession ratio.

SOURCE: RTI International analysis of Medicare claims and 2006 and 2007 Prescription Drug Event data.

Our analysis of the impact of the coverage gap on drug adherence rates showed a differential impact of the coverage gap on LIS and non-LIS beneficiaries. We found that non-LIS beneficiaries were more likely to show a decline in drug adherence as measured by the MPR when entering the coverage gap, whereas LIS beneficiaries were not affected. This suggests that the increase in out-of-pocket costs for drugs does influence whether beneficiaries continue to take their medications, even those beneficiaries with chronic conditions. Alternatively, we may just be seeing that beneficiaries who stick to their drug regimens spend more money out of pocket and are more likely to enter the coverage gap.

3.5 Discussion of Drug Adherence Measures

In the analysis of drug adherence measures, we attempted to look at drug adherence for Medicare beneficiaries with one or more of the seven chronic conditions. The specific research questions were as follows:

- Overall, what were the drug adherence rates for Medicare beneficiaries with Part D coverage?

- What was the impact of the coverage gap on drug adherence for beneficiaries with any of these chronic conditions?

- How did the effects differ for the Medicaid and other low-income populations?

Collectively, our set of descriptive tables suggests that there is a large variation in drug adherence rates among Medicare Part D beneficiaries within a therapeutic drug class and chronic condition and between drug classes. Our analyses also found little overall difference in the drug adherence rates between LIS and non-LIS beneficiaries. This is contrary to our hypothesis that low-income beneficiaries often have lower drug adherence rates than wealthier beneficiaries. One possible explanation for this finding is that the lower copayments and continued coverage in the coverage gap helped increase adherence rates sufficiently to mitigate any tendency for low-income beneficiaries to not adhere to their drug regimens.

Consistent with this overall finding in our analysis of adherence rates before, during, and after the coverage gap, we found a small drop in adherence rates for non-LIS beneficiaries in the coverage gap; although the pattern was not consistent across drug classes or chronic conditions. This drop was not found for the LIS enrollees though their adherence was lower in the coverage ranges before the gap. This finding suggests that the increase in out-of-pocket costs for drugs may affect whether beneficiaries continue to take their medications, even those beneficiaries with chronic conditions. We also found in our analysis of the coverage gap that all beneficiaries, both LIS and non-LIS, had higher adherence rates after exiting the coverage gap and beginning the catastrophic coverage. There are several possible explanations for this. One explanation is that beneficiaries who adhere to their drug regimens spend more out of pocket and are more likely to enter and exit the coverage gap. A second explanation is that the beneficiary's share of the price of drugs during the catastrophic phase is the lowest amount in the coverage year. Beneficiaries may simply be responding to these low prices with increased demand.

However, there are two limitations to these conclusions. First, we have data only on prescriptions filled under Part D and not on days of the drug taken. This is a problem for two reasons. First, as we saw with insulin, the days supplied in the PDE data may not have a one-to-one correspondence with days taken of the drug. Second, beneficiaries may fill prescriptions outside of Part D at large chain discount pharmacies if the costs are lower. This may be more likely in the coverage gap when beneficiaries bear significantly higher out-of-pocket costs for drugs. This could lead to a negative bias in the adherence rates in the gap. The second limitation is that, in our analysis of the coverage gap, we did not have data on whether a beneficiary actually was in the coverage gap or whether the beneficiary's plan had any coverage in the gap.

SECTION 4
EFFECT OF PART D ON DRUG ADHERENCE—MEDICARE CURRENT BENEFICIARY SURVEY ANALYSIS

4.1 Introduction

In this section, the 2006 Medicare Current Beneficiary Survey (MCBS) was used to address the following research question: What is the impact of Part D on patient adherence to medication therapy? This analysis focused, primarily although not exclusively, on beneficiaries with the six selected chronic conditions (i.e., chronic obstructive pulmonary disease [COPD], heart failure, diabetes with complications, dementia, major depression, and rheumatoid arthritis). Treatment of chronic disease generally entails prescription medication, but a substantial percentage of Medicare beneficiaries on medications for chronic illnesses do not fully take their prescription regimens as prescribed. This results in billions of dollars per year in avoidable medical spending, as well as increased risks of hospitalization and mortality (Hubbard and Daimyo, 2010). Thus investigation of this research question is of importance to CMS and policymakers in that it analyzes the impacts that access to insurance for drugs is having on drug adherence.

The MCBS is particularly useful to investigate this research question because it provides a well-defined comparison group for beneficiaries with Part D drug coverage. The MCBS is a continuous, multipurpose, rotating panel survey of a representative national sample of the Medicare population. The MCBS contains survey information on prescription drug health insurance coverage, including coverage categories for Part D employer-sponsored, self-purchased, other public or private, and no drug coverage. The MCBS also includes survey information on prescription drug events (PDEs) and drug adherence, which was used to create two simple measures of drug adherence that were used in the analysis: whether a patient filled at least one prescription for one of the six chronic conditions and whether a patient failed to fill at least one prescription (regardless of whether the prescription was for a chronic condition). Finally, the MCBS also includes a wealth of other survey information useful for the analysis (e.g., health status and functioning, socioeconomic data, etc.).

Prior studies have used the MCBS to examine drug adherence in the Medicare population. Madden and colleagues (2008) used data from the 2004-2006 waves of the MCBS to estimate the impact of the Part D program on cost-related nonadherence (CRN). The researchers concluded that there was evidence of a small, but significant, overall decrease in CRN and in foregoing of basic needs after Part D implementation. However, no net decrease in CRN after Part D was observed among the sickest beneficiaries, who continued to experience higher rates of CRN. Kennedy and colleagues (2008) used the 2004 MCBS to determine the rates of self-reported failure to fill at least one prescription prescribed to them during the year for any condition. The researchers found that most Medicare beneficiaries filled their prescriptions, but adherence was somewhat better for beneficiaries with employer-sponsored drug coverage. Stuart and colleagues (2009) used the 1997–2004 MCBS to estimate the effects of persistence in medication fills on health outcomes for patients with diabetes. The researchers found that, for users of older oral antidiabetes agents, each additional prescription filled was associated with significantly lower risk of hospitalization, fewer hospital days, and lower Medicare spending.

To the best of our knowledge, no studies that examine the impact of drug coverage on medication adherence have a research design that incorporates each of the following: (1) a nationally representative sample of the Medicare population, (2) a time period after Part D implementation, and (3) survey data on prescription drug events and on drug insurance coverage. Thus we believe the analysis in this section is a contribution to the drug adherence literature.

The key findings in this section are as follows:

- The vast majority of beneficiaries with heart failure, diabetes, and major depression filled at least one prescription for a drug to treat their chronic conditions during 2006.
- Beneficiaries with Part D drug coverage were no more likely to fill at least one prescription for a given condition than beneficiaries with no drug coverage. The same result held for beneficiaries with non-Part D drug coverage.
- However, Part D low-income subsidy (LIS) beneficiaries were more likely to fill at least one prescription for a given condition if they had COPD or major depression and less likely if they had rheumatoid arthritis.
- The strongest predictor of filling at least one prescription for a given condition was the RxHCC risk score, with higher risk scores (worse health) predicting higher drug adherence.

4.2 Methods and Data

4.2.1 Sample Selection

Our analysis of the effect of Part D on drug adherence was conducted on the 2006 MCBS Cost and Use File, which has a total of 11,984 observations. The sample selection criteria were as follows:

- Community-residing in 2006
- 12 months of Parts A and B enrollment during 2006
- Alive at the end of 2006
- United States resident in 2006
- Able to merge data to 2006 Medicare RxHCC Risk Score file
- Able to merge data to 2006 MCBS Access to Care file

The reasons for these criteria are varied. Importantly, the sample excluded beneficiaries residing in nursing homes because, presumably, nursing home patients are generally prescribed necessary medications and are assisted in taking their medications as required. The measure used for community-residing was that respondents were in their homes during the third round of

interviews in 2006, when many of the relevant questions were asked. In addition, the sample excluded new Medicare enrollees and decedents, who would have had a partial year of experience in the Medicare program. Beneficiaries who resided in U.S. territories during 2006 were excluded because there were some questions on the comparability of the data for these beneficiaries. Also important for our analyses were variables from the 2006 Medicare RxHCC Risk Score File and the 2006 MCBS Access to Care file, so beneficiaries who could not be merged to those data sources were excluded. This restriction is almost equivalent to excluding all observations from the MCBS supplemental sample—those who were added to the sample after the initial selection was made based on the Medicare population in January 2005. Because the supplemental sample was not included in most of the 2006 survey, we do not have high-quality data for this sample, which is another reason to exclude them.

Table 4.1 summarizes the sample selection and the number of observations by each restriction. After all the sample criteria were applied, the sample size was $N = 9{,}008$.[17] Finally, out of the 9,008 beneficiaries meeting the above sample criteria, we identified beneficiaries with each of the selected chronic diseases: COPD (1,245), heart failure (1,126), diabetes with complications (822), dementia (423), major depression (355), and rheumatoid arthritis (205).[18]

Table 4.1
2006 Medicare Current Beneficiary Survey cost and use sample selection

Sample criteria	*N*
2006 Medicare Current Beneficiary Survey cost and use sample	11,984
Community-residing	11,048
12 months Parts A and B	10,492
Nondecedents	11,375
United States residents	11,757
Merged to RxHCC Risk Score file	11,282
Merged to Access to Care file	9,850
2006 Medicare Current Beneficiary Survey cost and use sample—after exclusions	9,008
Chronic obstructive pulmonary disease	1,245
Heart failure	1,126
Diabetes with complications	822
Dementia	423
Major depression	355
Rheumatoid arthritis	205

SOURCE: RTI International analysis of 2006 Medicare Current Beneficiary Survey.

[17] Technically, the number of observations after applying these sample criteria was 9,205, but because of item nonresponses across our analytic variables, the final count was lowered to 9,008.

[18] Our methodology for identifying patients with the selected chronic conditions is presented in section 2.

4.2.2 Analytic Variables

Drug Adherence. The variable of interest is prescription drug adherence. The analysis in this section focuses on two simple measures of drug adherence. We first describe these measures, and then provide some justification for them.[19]

1. At least one prescription filled to treat a chronic condition. A binary indicator for whether patients had at least one prescription filled to treat their chronic conditions.[20] PDEs are identified in the MCBS Record Identification Code Prescription Medicine Event (RIC PME) file. MCBS interviewers verified the data collected for this file by asking respondents to provide prescription bottles when possible. This file includes a variable that identifies whether the event is survey-only, PDE-only, or survey matched to PDE. To create this measure of drug adherence, we excluded the PDE-only events. Otherwise, there would be a bias for Part D enrollees compared with non-Part D enrollees.

2. All prescriptions filled/at least one prescription skipped. A binary indicator for whether patients filled all of their prescriptions. The respondent was asked, "During the current year, were there any prescribed medicines that you didn't get?" This information is located in the MCBS Access to Care file (RIC Access to Care). Note that prescriptions were not restricted to those used to treat the patients' chronic conditions. Also this question was relevant only to those who received a prescription for at least one medication. However, because 95 percent of the analysis sample (and over 99 percent of each of the chronic condition subgroups) filled at least one prescription during the year, this is a small limitation. Also, this measure was based on simple self-reporting, without any external verification.

These are similar to adherence measures used in other studies of prescription adherence using the MCBS. Madden and colleagues (2008), studying CRN, used the survey question on which our second definition is based, combined with follow-up questions about whether the prescription was not filled because of cost and other questions related to taking smaller doses or skipping doses. Kennedy and colleagues (2008) used only the question that forms the basis of our second measure along with the direct follow-up questions identifying the specific medications and the reasons for not filling the prescription. Stuart and colleagues (2009), studying the effects of medication use by beneficiaries with diabetes, used the number of prescriptions filled in a given drug class during the year. All of these are similar to, although slightly more complex than, the measures used in this section.

Drug Coverage. We examined the effects of drug coverage on drug adherence. We created indicator variables for drug coverage, including Part D, employer-sponsored, self-purchased, other public or private, and no drug coverage. These are derived from the MCBS health insurance file (RIC 4), which uses a combination of survey-reported and administrative

---

[19] Limitations of these measures and plans for future improvement are discussed in section 4.5.

[20] We also created an indicator for whether beneficiaries had at least two prescriptions filled to treat their chronic conditions, but it was highly correlated with whether they had at least one prescription filled.

information to identify drug coverage. We followed the hierarchy of drug coverage assignment used by Kaiser Family Foundation (2008) as follows:

> Part D > employer-sponsored > self-purchased > other public or private > no drug coverage

Beneficiaries with multiple sources of drug coverage were assigned to the drug coverage appearing highest in the hierarchy, based on having at least 1 month of this type of coverage during 2006. Thus each beneficiary was assigned to one, and only one, drug coverage category.

Control Variables. The analysis examined the impact of drug coverage on drug adherence, controlling for a large number of beneficiary characteristics as follows:

- Demographics and socioeconomics
  - Age (0–64, 65–74, 75–84, and 85+)
  - Sex (female/male)
  - Race (Black, White, other)
  - Census region (Northeast, South, Midwest, West)
  - Urbanicity (metropolitan/nonmetropolitan)
  - Income ($0–$15,000; $15,001–$30,000; $30,001–$50,000; $50,001+)
  - Part D LIS (yes/no)[21]
  - Education—high school graduate (yes/no)
  - Household composition—lives alone (yes/no)
  - Access to help with medications (yes/no)[22]
- Health status and functioning
  - RxHCC risk score quintiles (0–20 percent, 20–40 percent, 40–60 percent, 60–80 percent, and 80–100 percent)
  - Memory loss (yes/no)

---

[21] Beneficiaries having a Part D LIS were primarily a subset of beneficiaries with Part D coverage. There were very few beneficiaries with a Part D LIS who did not have Part D coverage.

[22] For community-residing beneficiaries, the survey question on access to help with medications was applicable only to a few hundred beneficiaries who resided in housing that offered help with services. However, given that the focus of our study was drug adherence, we believed that it was appropriate to include these data.

- Difficulty reading prescription instructions or labels (yes/no)
- End-stage renal disease (ESRD) (yes/no)
- Self-rated general health status compared with other beneficiaries of the same age (excellent, very good, good, fair, poor)
- Difficulties with activities of daily living (ADLs; 0, 1 or 2, 3 or 4, 5 or 6)
- Difficulties with instrumental ADLs (IADLs; 0, 1 or 2, 3 or 4, 5 or 6)

- Other control variable
  - Proxy responder for MCBS interview (yes/no)

Demographic and socioeconomic control variables were derived from the MCBS. Age, sex, race, census region, urbanicity, and LIS are each derived from the Administrative Identification file (RIC A). Income and education were derived from the Survey Identification file (RIC 1). Household composition and access to help with medications are derived from the Household Composition file (RIC 5).

The RxHCC risk score, a measure of health status, is the most important control variable for our analysis. It was derived from the 2006 Medicare RxHCC Risk Score file, which is based on the Risk Adjustment Model used for Part D capitation payments (CMS, 2005). In the RxHCC model, demographics and diagnoses are used to predict Part D expenditures, similar to the method used to risk-adjust Part C capitation payments (Pope et al., 2004). Specifically, 84 disease groups, or RxHCCs, from 2005 are used to predict Part D expenditures in 2006. The RxHCC risk score is an expenditure-weighted index of a beneficiary's diagnoses that predicts the relative risk of future Medicare Part D expenditures. The risk score measures used in our analysis were indicators of what quintile a beneficiary's risk score was in the first quintile, scores of 0–20 (lowest); the second quintile, scores of 21–40; and so on up to the fifth quintile, which was those with scores of 81-100 (highest). These quintiles were defined on the full analysis sample.

4.2.3 Multivariate Statistical Methods

Recall that our measures of drug adherence were binary indicator variables: (1) at least one prescription filled to treat a chronic condition, and (2) at least one unfilled prescription. Given that our dependent variables were binary variables, we used a logistic regression model as shown in Equation 1:

$$Log\ [P/(1-P)] = a_0 + a_1X + a_2D + e \qquad \text{(Eq. 1)}$$

In Equation 1, P is the probability of a Medicare beneficiary either (1) filling at least one prescription or (2) failing to fill at least one prescription. The beneficiary's characteristics, represented by X, include the demographic, socioeconomic, health status and functioning, and

other control variables described in section 4.2.2.[23] The model also includes indicator variables for drug coverage, represented by D, including indicators for Part D coverage, employer-sponsored coverage, self-purchased coverage, and other public or private coverage. The omitted drug coverage category was for no drug coverage.

We estimated the logistic regression models on each of the following samples of beneficiaries on the basis of the study's selected chronic conditions:

- COPD
- Heart failure
- Diabetes with complications
- Dementia
- Major depression
- Rheumatoid arthritis

To increase sample size, we also estimated the models for beneficiaries having one or more of the six chronic conditions. When the analysis was conducted on this overall sample, indicators were included for having each of the six conditions. Because some beneficiaries had more than one of these conditions, these categories were not mutually exclusive, so each condition could be included in the regression.

We reported the marginal effects, which provided the change in the probability of drug adherence attributed to each factor in the model, holding the other factors constant. For example, if the marginal effect for Part D drug coverage was 0.01, then having Part D drug coverage would increase the probability of drug adherence by 1 percentage point. For each marginal effect, we reported t-statistics and identified statistical significance at the 1-percent and 5-percent levels.

4.2.4 Weighting

Similar to virtually all surveys, the MCBS is subject to several forms of nonresponse. These include unit nonresponse, in which beneficiaries are not interviewed, and item nonresponse, in which interviewed beneficiaries do not answer certain questions. In addition, in longitudinal surveys such as the MCBS, there is the potential for beneficiaries to drop out of the survey entirely (attrition). Consequences of nonresponse include the following: (1) biases in point estimators, (2) inflation of the variances of point estimators, and (3) biases in customary estimators of precision (Dillman, et al., 2002). We thus weight our descriptive and multivariate

[23] Note that certain 2006 MCBS health status and functioning variables were measured in the same year as our dependent variables. We excluded these variables because we believed that they were endogenous to the model. However, for our follow-up analysis of the 2007 MCBS, these variables could be used as control variables because they would have been measured in the previous year.

statistics by the MCBS cross-sectional sample weights, which adjust for nonresponse and account for differential probabilities of selection (beneficiaries eligible for Medicare by disability, and the oldest beneficiaries eligible by age, are oversampled in the MCBS).

In addition, the MCBS employs a complex sample design. As discussed by Berglund (2002), complex samples differ from simple random samples (SRS) in that SRS designs assume independence of observations, whereas complex samples do not. Statistical procedures assuming SRS result in underestimation of variances when analyzing data from complex samples. Therefore, we accounted for the complex sample design of the MCBS when estimating standard errors. The Taylor Series Linearization method was used, which derives a linear approximation of variance estimates that are in turn used to develop standard errors.

4.3 Descriptive Results

Table 4.2 presents descriptive results for the MCBS analysis sample overall and by each of the study's six selected chronic condition samples. The sample size for the overall sample was 9,008, with 34.4 percent of the observations having at least one of the six chronic conditions. The sample consisted of 14.1 percent COPD, 12.2 percent heart failure, 9.6 percent diabetes with complications, 4.3 percent dementia, 3.7 percent major depression, and 2.2 percent rheumatoid arthritis. Typically beneficiaries identified with one of the six chronic conditions have comorbidities. For example, for beneficiaries identified with COPD, approximately one-third have heart failure, which is more than double the rate for the overall sample.

Our variable of interest for this section was drug adherence. The first drug adherence measure was at least one prescription filled to treat a chronic condition. Note that this measure was not applicable for the overall sample. The results for the six chronic condition samples varied substantially. Heart failure, diabetes with complications, and major depression each had high percentages, with heart failure at 93.3 percent, diabetes with complications at 86.4 percent, and major depression at 85.7 percent. The other three chronic conditions had substantially lower rates, with COPD at 57.4 percent, rheumatoid arthritis at 51.1 percent, and dementia at 46.2 percent. These results seem to indicate that drug therapy was especially important for heart failure, diabetes with complications, and major depression.

Among the overall sample, 96.5 percent of beneficiaries self-reported that they filled all of the prescriptions that received from their health care providers. For the beneficiaries identified by the chronic conditions, the percentage of those filling all prescriptions was broadly similar to the overall sample. The one exception was beneficiaries with major depression, who had a lower fill rate by 4 percentage points (92.5 percent). This result might be explained by noting the adverse effects of antidepressants, along with the nature of the disease itself. As discussed in section 3, 96.5 percent is a very high rate of adherence. Kirking and colleagues (2006) discuss several reasons for this figure. First, in-home surveys such as MCBS generally resulted in higher values than telephone surveys. Second, this question references "this year," which, based on the design of the MCBS, refers to 9–11 months, so adherence would be higher than that found over 1 full year. Lastly, surveys that focused specifically on medications found lower adherence rates than more general surveys such as MCBS.

The study agenda included examining the impacts of drug coverage on drug adherence and health outcomes. In the overall sample, more than half of the beneficiaries had Part D drug coverage (55.7 percent). For the remaining beneficiaries, approximately 30 percent had employer-sponsored coverage, and approximately 10 percent had no coverage. The remaining two drug coverage categories were self-purchased coverage and other public or private coverage (3.1 percent and 1.9 percent, respectively). Relative to the overall sample, beneficiaries with chronic conditions had a higher rate of Part D drug coverage and a higher rate of drug coverage in general. The rates of Part D coverage ranged from 58.1 percent for rheumatoid arthritis to 66.7 percent for major depression. In addition, the rates of no drug coverage ranged from 4.7 percent for diabetes with complications to 7.0 percent for dementia. Possible reasons for the higher rate of Part D drug coverage (and drug coverage in general) among the beneficiaries with chronic conditions included the higher demand for prescription drugs and the higher probability of receiving a Part D LIS.

In addition to drug adherence and drug coverage, Table 4.2 provides results for various beneficiary characteristics, including demographic, socioeconomic, and health status and functioning categories. For each beneficiary characteristic, we compared the distributions for the chronic condition samples with the distribution for the overall sample. The fraction of beneficiaries eligible for Medicare by disability (age 0–64) was 14.1 percent for the overall sample, but the percentages were relatively low for dementia (5.1 percent) and relatively high for major depression (53.1 percent). These results make sense, given that the onset and progression of dementia increases as beneficiaries age and that persons with disabilities have a high proportion of psychiatric diseases such as major depression. Female beneficiaries comprise 56.5 percent of the overall sample, but their percentage for rheumatoid arthritis was substantially higher, at more than 80 percent. It is well established that females have a predisposition for rheumatoid arthritis (Mayo Clinic, 2010). For the overall sample, 9.4 percent are Black, but the percentage of Blacks with diabetes with complications was almost double that (15.1 percent). Blacks with diabetes are more likely than Whites to have uncontrolled blood sugar, which increases the chance of complications (Kirk et al., 2006). The distributions for geographic location (e.g., census region, urbanicity) were broadly similar between the overall sample and the chronic condition samples.

For the overall sample, 30.9 percent had incomes of $0–$15,000, and 20.7 percent had the Part D LIS. The beneficiaries in the chronic condition samples were substantially poorer than those in the overall sample. For incomes of $0–$15,001, the range was 30.9 percent (rheumatoid arthritis) to 45.3 percent (major depression); for Part D LIS, the range was 22.3 percent to 43.7 percent. Clearly, the beneficiaries in our chronic condition samples were poorer than the average Medicare beneficiary. In addition to being poorer, the beneficiaries in our chronic condition samples were generally less educated than the average Medicare beneficiary. For the overall sample, 73.2 percent were high school graduates, but the high school graduation rates were noticeably lower for the chronic condition samples, with the exception of rheumatoid arthritis. The percentage of beneficiaries living alone (31.2 percent) in the overall sample was broadly similar to the chronic condition samples. It is important to note that the chronic condition samples varied in the percentage of beneficiaries living alone, ranging from 29.3 percent for major depression to 35.8 percent for heart failure.

The RxHCC risk score quintiles are defined on the full analysis sample. This means that 20 percent of the overall sample was contained in each of the quintiles. The percentage of beneficiaries in the highest RxHCC risk score quintile was approximately twice this amount for the chronic condition samples, ranging from 36.8 percent for dementia to 51.1 percent for diabetes with complications. This means that more than one-third of those with dementia and more than half of those with diabetes with complications were in the unhealthiest 20 percent of the overall analysis sample. These results were mirrored by the self-reported health status and functioning measures. Beneficiaries rating their general health status as poor ranged from 13.4 percent for dementia to 19.2 percent for major depression, compared with only 7.3 percent for the overall sample. The results for difficulties with ADLs and IADLs follow a similar pattern. Thus, not surprisingly, beneficiaries in the chronic condition samples had worse health status and functioning than the average Medicare beneficiary.

The remaining patient characteristics included in Table 4.2 can affect our variables of interest (patient adherence, health outcomes). Compared with the overall sample, the chronic condition samples have substantially higher percentages of beneficiaries with memory loss, difficulty reading prescription instructions or labels, and proxy respondent for the MCBS interview.

Table 4.2
Descriptive statistics for the 2006 Medicare Current Beneficiary Survey analysis sample—overall and by the study's six chronic conditions

Variable	Analysis sample	Chronic obstructive pulmonary disease	Heart failure	Diabetes with complications	Dementia	Major depression	Rheumatoid arthritis
Number of observations	9,008	1,245	1,126	822	423	355	205
Study's six chronic conditions	—	—	—	—	—	—	—
At least 1	34.4	100	100	100	100	100	100
Chronic obstructive pulmonary disease	14.1	100	33.7	20.8	14.9	22.7	18.5
Heart failure	12.2	29.2	100	29.5	24.1	13.8	11.9
Diabetes with complications	9.6	14.2	23.2	100	11.4	11.9	7.0
Dementia	4.3	4.5	8.4	5.1	100	8.0	4.4
Major depression	3.7	5.9	4.1	4.5	6.9	100	4.1
Rheumatoid arthritis	2.2	2.9	2.2	1.6	2.3	2.5	100
None	65.6	0	0	0	0	0	0
At least 1 prescription filled to treat a chronic condition	—	—	—	—	—	—	—
Yes	N/A	57.4	93.3	86.4	46.2	85.7	51.1
No	N/A	42.6	6.7	13.6	53.8	14.3	48.9
All prescriptions filled	—	—	—	—	—	—	—
Yes	96.5	96.5	96.9	96.8	96.3	92.5	97.1
No	3.5	3.5	3.1	3.2	3.7	7.5	2.9

(continued)

Table 4.2 (continued)
Descriptive statistics for the 2006 Medicare Current Beneficiary Survey analysis sample—overall and by the study's six chronic conditions

Variable	Analysis sample	Chronic obstructive pulmonary disease	Heart failure	Diabetes with complications	Dementia	Major depression	Rheumatoid arthritis
Drug coverage	—	—	—	—	—	—	—
Part D	55.7	61.6	60.4	64.1	60.4	66.7	58.1
Employer-sponsored	29.6	26.4	28.7	27.8	26.8	20.0	33.4
Self-purchased	3.1	2.4	2.8	2.2	2.9	2.1	0.8
Other public or private	1.9	1.5	1.6	1.2	2.8	5.1	1.8
No drug coverage	9.8	8.1	6.5	4.7	7.0	6.1	5.9
Age	—	—	—	—	—	—	—
0–64	14.1	14.4	10.1	16.7	5.1	53.1	15.0
65–74	43.0	39.3	32.3	42.2	18.8	22.4	42.3
75–84	33.6	38.0	40.9	35.0	48.1	20.4	35.1
85+	9.3	8.3	16.6	6.1	28.0	4.1	7.6
Sex	—	—	—	—	—	—	—
Female	56.5	52.6	53.7	57.3	64.5	66.9	80.5
Male	43.5	47.4	46.3	42.7	35.5	33.1	19.5
Race	—	—	—	—	—	—	—
White	86.3	89.3	83.8	79.6	87.8	85.2	80.1
Black	9.4	7.8	12.6	15.1	8.8	7.8	13.9
Other	4.3	2.9	3.6	5.3	3.4	7.0	6.0

(continued)

Table 4.2 (continued)
Descriptive statistics for the 2006 Medicare Current Beneficiary Survey analysis sample—overall and by the study's six chronic conditions

Variable	Analysis sample	Chronic obstructive pulmonary disease	Heart failure	Diabetes with complications	Dementia	Major depression	Rheumatoid arthritis
Census region	—	—	—	—	—	—	—
Northeast	19.0	18.4	21.4	22.7	18.3	18.9	17.7
South	37.8	41.9	37.7	37.4	36.0	38.5	43.0
Midwest	23.3	21.2	24.2	19.6	26.8	23.5	21.4
West	19.9	18.4	16.7	20.3	18.9	19.1	17.9
Urbanicity	—	—	—	—	—	—	—
Metropolitan	74.9	71.6	74.8	76.1	76.4	79.8	79.4
Nonmetropolitan	25.1	28.4	25.2	23.9	23.6	20.2	20.6
Income	—	—	—	—	—	—	—
$0–$15,000	30.9	36.5	37.1	39.0	40.0	45.3	30.9
$15,001–$30,000	33.0	36.2	35.2	34.1	32.8	28.7	37.9
$30,001–$50,000	21.7	18.2	18.9	15.5	15.0	13.8	20.1
$50,001+	14.3	9.1	8.8	11.4	12.2	12.2	11.1
Part D low-income subsidy	—	—	—	—	—	—	—
Yes	20.7	28.0	26.5	30.1	22.7	43.7	22.3
No	79.3	72.0	73.5	69.9	77.3	56.3	77.7
Education	—	—	—	—	—	—	—
High school graduate	73.2	64.2	66.1	66.0	64.1	72.8	76.3
Not high school graduate	26.8	35.8	33.9	34.0	35.9	27.2	23.7

(continued)

Table 4.2 (continued)
Descriptive statistics for the 2006 Medicare Current Beneficiary Survey analysis sample—overall and by the study's six chronic conditions

Variable	Analysis sample	Chronic obstructive pulmonary disease	Heart failure	Diabetes with complications	Dementia	Major depression	Rheumatoid arthritis
Household composition	—	—	—	—	—	—	—
Lives alone	31.2	35.1	35.8	29.7	32.8	29.3	35.9
Does not live alone	68.8	64.9	64.2	70.3	67.2	70.7	64.1
Access to help with medications	—	—	—	—	—	—	—
Yes	0.9	0.4	1.8	0.9	2.8	2.0	1.3
No	99.1	99.6	98.2	99.1	97.2	98.0	98.7
RxHCC risk score	—	—	—	—	—	—	—
0–20% (lowest)	20.6	8.7	5.4	3.8	8.4	4.8	4.9
20–40%	19.7	12.4	9.7	6.4	14.0	9.1	11.6
40–60%	20.4	16.3	15.8	11.6	20.2	17.1	17.2
60–80%	19.9	24.6	26.1	27.1	20.6	21.5	26.0
80–100% (highest)	19.4	37.9	43.0	51.1	36.8	47.5	40.3
Memory loss	—	—	—	—	—	—	—
Yes	10.9	12.6	14.2	13.9	53.7	30.1	9.9
No	89.1	87.4	85.8	86.1	46.3	69.9	90.1
Difficulty reading prescriptions	—	—	—	—	—	—	—
Yes	13.5	18.0	18.5	21.4	22.8	17.2	14.6
No	86.5	82.0	81.5	78.6	77.2	82.8	85.4

(continued)

Table 4.2 (continued)
Descriptive statistics for the 2006 Medicare Current Beneficiary Survey analysis sample—overall and by the study's six chronic conditions

Variable	Analysis sample	Chronic obstructive pulmonary disease	Heart failure	Diabetes with complications	Dementia	Major depression	Rheumatoid arthritis
End-stage renal disease	—	—	—	—	—	—	—
Yes	0.7	1.2	2.7	3.9	1.0	0.5	0.0
No	99.3	98.8	97.3	96.1	99.0	99.5	100.0
General health status	—	—	—	—	—	—	—
Excellent	14.8	5.6	4.9	5.0	7.7	4.5	5.2
Very good	28.1	17.8	18.9	18.0	22.2	14.8	18.1
Good	32.7	34.1	35.7	35.3	28.6	34.1	37.0
Fair	17.2	26.4	25.5	27.3	28.1	27.5	22.1
Poor	7.3	16.1	15.0	14.4	13.4	19.2	17.6
Difficulty with activities of daily living	—	—	—	—	—	—	—
0	71.5	59.1	53.5	55.1	46.2	60.6	56.6
1 or 2	19.9	26.9	28.1	31.5	24.3	24.1	27.7
3 or 4	5.8	8.9	12.7	9.1	15.1	9.7	10.7
5 or 6	2.9	5.0	5.8	4.3	14.4	5.6	5.0
Difficulty with instrumental activities of daily living	—	—	—	—	—	—	—
0	54.2	38.7	34.7	39.1	25.1	38.2	33.7
1 or 2	29.8	37.0	36.2	36.2	24.6	35.6	37.0
3 or 4	10.2	15.3	15.7	15.0	18.9	18.2	22.5
5 or 6	5.7	9.1	13.3	9.6	31.5	7.9	6.9

(continued)

Table 4.2 (continued)
Descriptive statistics for the 2006 Medicare Current Beneficiary Survey analysis sample—overall and by the study's six chronic conditions

Variable	Analysis sample	Chronic obstructive pulmonary disease	Heart failure	Diabetes with complications	Dementia	Major depression	Rheumatoid arthritis
Proxy for the Medicare Current Beneficiary Survey interview	—	—	—	—	—	—	—
Yes	10.4	10.9	13.7	11.3	36.1	12.9	7.2
No	89.6	89.1	86.3	88.7	63.9	87.1	92.8

NOTE: Values are descriptive statistics weighted by MCBS sampling weights.

SOURCE: RTI International analysis of the 2006 the Medicare Current Beneficiary Survey.

4.4 Multivariate Results

Table 4.3 shows the relationship between participation in Part D and whether a beneficiary with a given condition filled a prescription for a drug used to treat that condition in 2006. Note that the logistic regression in Table 4.3 includes the control variables described in section 4.2, but they are not presented in the table; the full logistic regression, including the control variables, is presented in **Table A4.1** in Section 4 Technical Appendix.

These are the results of the logistic regressions of the variable, at least one prescription filled to treat a chronic condition, on enrollment in Part D and controls, including other measures of drug coverage and measures of health status, demographics, and socioeconomic status. Just over a quarter (28 percent) of the MCBS analysis sample filled a prescription for a drug used to treat one of the six chronic conditions of interest. Table 4.3 has six columns of results, one for each chronic condition of interest, each giving the results on only the sample with that particular condition. The coefficients shown in the table are marginal effects at the mean values of the independent variables, and t-statistics are shown in parentheses.

Part D is not statistically significantly related to filling at least one prescription for any of these conditions; in fact, none of the health insurance variables were significant or even borderline significant. The most important variables in these regressions seemed to be the risk scores, with sicker beneficiaries having higher drug adherence. It is possible that sicker beneficiaries had more of an incentive for medication adherence.[24] The other variables, which focused on other aspects of participants' health, demographic, and socioeconomic characteristics and the area of the country in which they lived, were significant in some cases, but did not show a consistent pattern across conditions.

[24] However, one might think that drug nonadherence could cause beneficiaries to become sicker. However, as discussed in section 4.2, our risk scores were based on diagnoses measured in the year before the sample year.

Table 4.3
Purchase of prescription for condition-related drug, by condition

Variable	Chronic obstructive pulmonary disease	Heart failure	Diabetes with complications	Dementia	Major depression	Rheumatoid arthritis
Part D	0.018 (0.33)	0.044 (1.04)	0.074 (0.99)	0.047 (0.54)	−0.192 (1.73)	0.021 (0.13)
Drug coverage	—	—	—	—	—	—
Employer-sponsored	0.060 (1.06)	0.050 (1.54)	0.030 (0.44)	−0.019 (0.19)	−0.225 (1.48)	−0.098 (0.63)
Self-purchased	−0.191 (1.80)	0.034 (0.77)	0.028 (0.28)	0.069 (0.41)	−0.518 (1.67)	−0.233 (1.10)
Other public or private	0.037 (0.23)	—†	—†	0.066 (0.39)	—†	−0.126 (0.46)
Part D low-income subsidy	0.131** (2.97)	0.051 (1.84)	0.039 (0.93)	0.103 (1.50)	0.134* (2.19)	−0.208* (2.07)

* $p<0.05$; ** $p<0.01$

† Variable was excluded due to multicollinearity. Because of small sample sizes and the close correlations among some variables, in some samples, some variables were linear combinations of other variables and were automatically removed during analysis.

NOTES: Marginal effects are reported, which provide the change in the probability of drug adherence attributed to each factor in the model, holding the other factors constant. For each marginal effect, t-statistics and identified statistical significance at the 1-percent and 5-percent levels are reported. Coefficients are weighted by Medicare Current Beneficiary Survey sampling weights, and standard errors are adjusted for Medicare Current Beneficiary Survey complex sampling design. The full model results, including the control variables, can be found in Table A4.1 in Section 4 Technical Appendix.

SOURCE: RTI International analysis of the 2006 Medicare Current Beneficiary Survey data.

Table 4.4 shows alternative logistic regressions of drug adherence on Part D enrollment and other factors, with the drug adherence measure being whether the beneficiary failed to fill at least one prescription received from a health care provider in 2006. Note that the logistic regression in Table 4.4 includes the control variables described in section 4.2, but they are not presented in the table; the full logistic regression, including the control variables, is presented in **Table A4.2** in Section 4 Technical Appendix. Although enrollment in Part D was not significantly related to this adherence measure, when analysis was conducted on the full MCBS analysis sample (the first column of results), it appeared to be related, at just a small amount under conventional levels of significance. The relationship is in the expected direction, with those enrolled in Part D being less likely to report that they did not fill a prescription.

Other measures of drug insurance were also important in the expected direction, with beneficiaries with private employer-sponsored drug coverage and other public or private drug insurance each being just over 2 percentage points less likely to say that they failed to fill a prescription. Because only 3.5 percent of the overall sample reported failing to fill a prescription, 2 percentage points is, in fact, quite a large effect. Among the control variables, age seems to be a particularly important factor in explaining this measure of adherence, with older age groups having higher adherence.

Table 4.4
Self-reported failure to fill prescription received, overall sample

Variable	Full analysis sample	At least one condition
Part D	−0.011	−0.010
	(1.84)	(0.82)
Drug coverage	—	—
Employer-sponsored	−0.022**	−0.024*
	(4.81)	(2.35)
Self-purchased	−0.003	−0.016
	(0.44)	(1.35)
Other public or private	−0.023**	—†
	(6.47)	
Part D low-income subsidy	0.001	0.002
	(0.23)	(0.22)
Six conditions	—	—
Chronic obstructive pulmonary disease	−0.002	0.000
	(0.36)	(0.02)
Heart failure	−0.001	0.002
	(0.14)	(0.25)
Diabetes	−0.007	−0.006
	(1.20)	(0.73)
Dementia	0.007	0.010
	(0.89)	(1.01)
Depression	0.004	0.001
	(0.63)	(0.15)
Rheumatoid arthritis	−0.008	−0.005
	(0.78)	(0.42)

* $p<0.05$; ** $p<0.01$

† Variable was excluded due to multicollinearity. Because of small sample sizes and the close correlations among some variables, in some samples, some variables were linear combinations of other variables and were automatically removed during analysis.

NOTES: Marginal effects are reported, which provide the change in the probability of drug adherence attributed to each factor in the model, holding the other factors constant. For each marginal effect, t-statistics and identified statistical significance at the 1-percent and 5-percent levels are reported. Coefficients are weighted by Medicare Current Beneficiary Survey sampling weights, and standard errors are adjusted for Medicare Current Beneficiary Survey complex sampling design. The full model results, including the control variables, can be found in Table A4.2 in Section 4 Technical Appendix.

SOURCE: RTI International analysis of the 2006 Medicare Current Beneficiary Survey data.

4.5 Discussion

This analysis was conducted on an overall sample of 9,008 MCBS respondents, 34 percent of whom had at least one of the six chronic conditions of interest. The first drug adherence measure was whether the patients filled at least one prescription for their chronic conditions. Our descriptive results show that the vast majority of beneficiaries with heart failure,

diabetes, and major depression filled at least one prescription for a drug to treat their conditions during 2006. The second drug adherence measure was whether the patients failed to fill at least one of their prescriptions (regardless of whether the prescriptions were for their chronic conditions). Only 3.5 percent reported that they had failed to fill at least one prescription, although this number was much higher for those with major depression, at 7.5 percent. Well over half of those with these conditions had Part D coverage, and they were lower income and in worse health than the Medicare population as a whole.

Logistic regressions show no relationship between Part D enrollment and the probability of filling at least one prescription for a given condition. These regressions also show no relationship between this probability and other drug coverage, with the exception that those receiving the Part D LIS are slightly more likely to fill a prescription if they have COPD or major depression, and less likely if they have rheumatoid arthritis. The strongest predictors in these regressions are the risk scores, with higher risk scores predicting higher drug adherence.

The results are different when the adherence measure is failure to fill at least one prescription that beneficiaries were given in the past year, and they suggest an impact of Part D enrollment. In that regression, the strongest predictors are having employer-sponsored insurance, which lowers the probability of skipping a prescription, and being in the youngest age group, which raises it. In addition, although Part D enrollment is not a significant predictor at the 5-percent level used here, it is significant at the 10-percent level. According to this result, beneficiaries who were enrolled in Part D were 1.1 percentage points less likely to fail to fill a prescription. Because the overall rate was only 3.5 percent, this is a 31 percent reduction in the chances of skipping a prescription, quite a large effect.

A number of characteristics of these data, combined with the fact that drug adherence by its nature is difficult to measure, have resulted in some limitations in our research. One important limitation was the small sample size of the MCBS, which limited the analysis that could be conducted with the less common chronic conditions. Possibly the greatest limitation, however, was that two very important pieces of information were not provided in the MCBS for non-Part D enrollees: a PDE's "days supplied" and a "service date" or other indication of when the prescription was filled. Without this information, it was not possible to create a medication possession ratio (MPR), defined as the ratio of days supplied of prescription drugs divided by total days in the time period. MPR is the preferred measure of adherence and was used in the sections of this report that do not rely on the MCBS. We therefore used simple measures of drug adherence, which were not ideal. Our first adherence measure was whether the beneficiary had at least one prescription filled during the year to treat the chronic condition (identified by survey-reported PDE data). This measures only whether the MPR is greater than zero, which is clearly not an ideal measure of adherence. Our second measure of adherence is a self-reported measure of whether beneficiaries failed to fill at least one prescription prescribed to them during the year (for any condition). One problem with this measure is that not all beneficiaries receive a prescription during the year, and to the extent that some beneficiaries receive no prescriptions, this measure will be biased. In addition, given that the vast majority of beneficiaries report filling all their prescriptions, this measure of adherence might lack face validity.

These limitations are one possible reason that the multivariate analysis did not show a consistent relationship between Part D enrollment and adherence. We hope to mitigate some of

these limitations in future research in two ways. First, we plan to create a measure that takes into account more of the variation in drug adherence, rather than the current simple indicator variables. Second, we will incorporate the 2007 MCBS survey data into our analytic database, thereby increasing our statistical power and ability to identify the effects of Part D drug coverage on medication adherence. Also, the results of this analysis of 2006 data could be affected by the fact that 2006 was the first year of the Part D program. We thus expect analysis using the 2007 data to be more robust and generalizable to future program years.

SECTION 5
IMPACT OF PART D ON MEDICARE SPENDING AND UTILIZATION, 2005–2007

5.1 Introduction

The question addressed in this analysis is this: What is the impact of Part D on health outcomes and health care utilization and costs for beneficiaries with chronic conditions? The approach compares the utilization of services in 2007, the second program year, to the base year, 2005, before the program started. The measures to be examined for effects were inpatient hospital spending and use of the hospital emergency department (ED). By controlling for many factors that affect utilization, the effect of Part D is estimated for five of the six disease classes that are the subject of this report.

In the earlier work reported, we had studied Medicare beneficiaries irrespective of health status. The sample was based on a 5 percent sample of beneficiaries. With a wide range of health statuses in the study, the effects of Part D were not expected to be easy to detect, and mixed results were found. The late enrollment of a portion of the population in 2006 also would tend to reduce any observable effects in that year. Because the benefits of drug therapies often take time to manifest themselves, we are now looking further out from the implementation year.

In this study, limited to people with chronic diseases that have chronic drug treatments, the probability of detecting a Part D effect was enhanced. The conditions studied were chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), diabetes with complications, major depression, and rheumatoid arthritis. We compare changes that occurred over time for Part D enrollees with changes for nonenrollees in a population, excluding low-income subsidized enrollees, most of whom had drug coverage through Medicaid in 2005.

The effect of Part D is addressed with the following specific questions for each disease cohort:

- Did Part D affect the probability of having at least one inpatient stay?
- Did Part D affect the probability of at least one ED visit?
- Did Part D affect the Medicare costs for inpatient stays for those who had a stay?
- Did Part D affect the number of ED visits for those who had a visit?

The findings in brief are as follows:

- Although statistically significant, the change in the probability of having at least one inpatient stay was reduced by only a few tenths of a percentage point.
- The effects for the probability of at least one ED visit were of the same magnitude.

- For those who used inpatient services, the effect of Part D was to reduce spending by about 2 percent.

- For those who used the ED, the number of visits decreased less than 1 percent for the COPD and CHF and not by any statistically significant amount for the other three disease cohorts.

The effects estimated are small. The mean inpatient spending in 2007 for those who used inpatient services was about $17,000 per year. A reduction of 2 percent is about $340 per person. Because the effects of drugs on reduction of complications are cumulative over the years, the ultimate effect may be considerably larger.

It is important to note that the effect measured is that of enrollment in the Part D program, not the effect of drugs. Access to drugs may be improved by enrollment in the program, but the extent of the purchase of drugs in 2005, before Part D, is not known. The comparison group is one of no known drug coverage, not necessarily persons with no drug coverage. The degree to which the comparison group is self-funding drug purchases is also not known. All the people in the study, enrollees and nonenrollees, were matched on their diagnosis group.

5.2 Data

This analysis incorporated data on Medicare fee-for-service (FFS) beneficiaries who were not low income by the definitions used by the program. Most of the low-income beneficiaries were auto-enrolled into the Part D program in 2006 and 2007, and the enrollment was confounded with the time effect. The low-income beneficiaries who were in the Part D category of "Deemed," based on State data for people receiving Medicaid or assistance with paying for Medicare, are the vast majority of the low-income population who receive a subsidy. The pharmacy benefit under Medicaid continued under Part D, so there was no significant coverage change for this group. Their utilization of Part A and B services was also quite different from those who are not officially low income, making any use of this group as a contrast to determine the Part D effect a dubious effort.

To have sufficient sample size for the subpopulations in the study, we used Medicare 100 percent eligibility and claims data for each year. Subsets and exclusions were made from this point. The basic criteria used in defining the analytic populations for prediction years 2005 and 2007 are listed below. The term "base year" refers to the year before the prediction year.

- Both Part A and B coverage for 12 months in the base and prediction years.

- No Medicare Advantage (MA) plan enrollment in the base and prediction years.

- No Medicare Secondary Payer status in either year.

- No Deemed, other low-income subsidy status, or Medicaid buy-in months.

- No beneficiaries with a status of end-stage renal disease.

- United States resident for all years.

- No decedents.

These criteria were intended to ensure that we have complete information on each beneficiary with respect to characteristics, such as diagnoses and spending. The end-stage renal disease population was omitted because this condition can have utilization effects that overwhelm the effects of each of the study conditions. Elimination of decedents makes the two years in each study more homogeneous; it also eliminates beneficiaries whose disease may have been too advanced for the access to drugs to make a significant difference.

The data used for the dependent variables were the Inpatient claims files for inpatient spending and the Outpatient claims files for hospital outpatient claims, with ED usage determined by the presence of revenue codes for ED use. To be able to study the subpopulation with the study diseases, it was necessary to start with 100 percent of the population and claims and then subset to the study groups. The independent control variables were demographic information from the Medicare Enrollment Data Base (EDB) and Denominator files, Part D enrollment and other drug coverage in the Common Medicare Environment (CME) files, and disease markers in risk adjustment files originally created for payment of MA plans. Because the disease markers for dementia were not in the risk adjustment files for 2005, that cohort was not studied in this analysis.

5.2.1 Definition of Disease Groups

Because data were needed from 2004 through 2007, uniform definitions of medical conditions were needed. The use of the most recent and refined version of the conditions could not easily be used, particularly for 2004. By allowing some broadening of some of the conditions to the level of the Version 12 hierarchical condition categories (HCCs), the same clusters were available in all years. The definitions of the study groups are as follows:

- COPD—HCC108. This includes COPD and some pulmonary hypertension cases. Use of this definition excludes the few people with cystic fibrosis from this group.

- CHF—HCC80. This is congestive heart failure.

- Diabetes with Complications—this includes diabetes diagnosis codes that indicate renal, vascular, neurological, ophthalmologic, and acute complications (HCCs 15–18). The beneficiaries coded with uncomplicated diabetes are excluded.

- Dementia—this group was excluded from the HCC model used and was not included in these analyses.

- Major Depression—HCC55. This group includes major depression, bipolar, and paranoid disorders. The large majority are coded with major depression. Limiting to this group excluded people with mental disorders such as schizophrenia.

- Rheumatoid Arthritis—HCC38. This group does include people with similarly treated inflammatory conditions and some rare conditions such as Behçet's.

Although these definitions are a bit broader than those used in section 3, for this kind of analysis the effects are minor. A few more codes from the *International Classification of Diseases, 9th edition, Clinical Modification* (ICD-9-CM) are admitted to the grouping definitions. These are much narrower groups than the population as a whole and are all chronic conditions treated with drugs. They are suited as indicators for the effects of Part D on such subgroups.

Table 5.1 presents selected utilization statistics on the five disease populations for the 2 years. More comprehensive descriptive statistics for the cross-section samples are in Technical Appendix Section 5. Even though these are two similar cross-sections of Medicare beneficiaries, the population averaged a few months older in 2007. The advent of Part D resulted in a move from traditional FFS to MA plans because drug premiums were subsidized in MA prescription drug plans by rebates from the MA nondrug part of the program. Typically, older beneficiaries are more reluctant to move from FFS than younger beneficiaries. The following are selected observations concerning the populations.

- CHF is the highest inpatient expenditure group. The order in 2005 was CHF ($5,128), diabetes with complications ($4,228), and COPD ($3,992). The increase in ED visits is modest, typically 3 to 4 percent. Major depression remains the highest visit group, with users at a mean of 1.80 visits in 2005 and 1.84 in 2007.

- Major depression is clearly skewed to the younger, under-age-65 population compared with the other conditions. Females outnumber males by more than 2 to 1 in this population. The rheumatoid arthritis group is even more skewed toward females, at more than 2 to 1. The age distribution is older and more like CHF, a relatively high proportion in the 80–84 age range.

- The proportion of the population enrolled in Part D does not vary widely. The diabetes group has the lowest penetration of Part D at about 37.7 percent; depression and rheumatoid arthritis are a bit over 40 percent. The mean months in Part D reflect this variation as the means include those with 0 months of Part D.

Table 5.1
Selected descriptive statistics

Chronic condition	Mean inpatient spending, 2005	Mean inpatient spending, 2007	Mean ED visits, 2005	Mean ED visits, 2007	Mean ED visits, users, 2005	Mean ED visits, users, 2007
Chronic obstructive pulmonary disease	$3,992	$4,779	0.413	0.458	1.60	1.66
Congestive heart failure	5,128	5,811	0.447	0.497	1.60	1.66
Diabetes with complications	4,228	4,801	0.405	0.439	1.57	1.61
Major depression	3,624	4,220	0.527	0.570	1.80	1.84
Rheumatoid arthritis	3,385	3,929	0.374	0.410	1.54	1.59

NOTE: ED is hospital emergency department.

SOURCE: RTI International analysis of Medicare claims data, 2005 and 2007

5.3 Method

A simple comparison of 2 years cannot reveal effects of the "treatment" of implementing Part D; there are many confounding changes over the years in addition to the implementation of Part D. There are differences from year to year in payment policies, payment levels, and the FFS population profile, as well as a difference between enrollees and nonenrollees. The difference between the year-to-year differences is the effect that is to be measured. This analysis was done on cross-sections of beneficiaries who were indicated to have the study diseases. The results will be described after the formulation of the model is discussed.

The data contain 2 years of observations (2005, 2007). For each year, a set of variables were used as predictors of spending for that year. The dependent variables in this work are probability of having an inpatient stay, inpatient expenditures for those with at least one stay, probability of an ED visit, and counts of ED visits for those with a visit. This approach can indicate separately the relative effect of the program on any use and quantity. The predictor variables include a broad range of beneficiary characteristics that are known to affect spending and the variables indicating drug coverage.

The variables chosen for analysis are those that should have a clear direction of change if Part D is enhancing access to drugs. Inpatient spending captures both numbers of stays and the severity of the nature of the stay as reflected in the diagnosis-related group (DRG) weights that determine payment. ED visits would also reflect exacerbations of conditions. The hypothesis is that both of these would decrease if Part D enrollment is having the desired effect. The approach

was to use a two-part model. In the first stage, the probability of any use of the service is estimated. In the second stage, the amount of inpatient spending or counts of ED visits are estimated for beneficiaries who use the service.

For each prediction year, 2005 and 2007, the main predictor variables conceptually are as follows:

- Demographic variables

    a. 24 age/sex classes such as female 60–64, female 65–69, female 70–74, etc. Each sex category has 12 age groups. The under-65 age categories also capture that a beneficiary is eligible by disability in the sample year.

    b. Originally disabled. This is a marker for a beneficiary who is at least age 65 but who once had eligibility as a disabled beneficiary.

These variables are used to capture spending not captured by the more clinical variables, which encompass many, but not all, medical conditions.

- Diagnosis/condition categories. These are the HCCs developed for CMS to predict costs for payment of MA plans. The HCCs used here capture the most important conditions for predicting spending in the Medicare population. These groupings are clusters of ICD-9-CM diagnosis codes that have been grouped by both clinical homogeneity and predicted cost implications. Separate sets of these are used to predict Part A and B costs and Part D costs. Because we are predicting nondrug costs, the former set was used.

  For this modeling, the beneficiaries' diagnoses from the year before each prediction year were used. This decision is not related to the fact that the HCCs are being used this way in the payment system for MA plans; it is because the prevalence of diseases in the prediction years could be affected by the presence of the drug plan. This endogeneity of a variable that should be predicting as though Part D was not present is removed by using prior year diagnoses, 2004 to predict 2005 and 2006 to predict 2007.

  To use these variables effectively, we restricted the study population to those beneficiaries who had been in FFS Part A and B for 12 months of each diagnosis year. This provides full information on the whole sample.

- Long-term institutionalized (LTI). This is a marker for a person considered a nursing home resident. Prior research has indicated that models for the community dwelling tend to overpredict spending when applied to the LTI population. These people are costly to Medicare on average, but they use less Medicare-covered care than people with similar disease constellations in the community. The operational definition is that used for the MA program. It draws on the nursing home minimum data set (MDS) 90-day patient assessments to start an LTI period and a discharge lasting at least 30 days to end the period. In this model, it is the fraction of a year in LTI status.

- Year_2007 is a marker differentiating 2007 from 2005. The average effect of policy and payment changes is captured here.

- Part_D_enrollee is a control variable. More explicit predictors do not capture all the differences in service use between the type of beneficiaries who decide to enroll, and those who do not. This variable aims to capture those differences. For people who are enrollees, it is set to 1 in both years.

- Part_D_months_2007 is the count of months of Part D enrollment since the program started. Time is a factor because the effect of taking drugs for a chronic condition may not be apparent until differences in accumulated negative events can be detected. When the effects in 2006 were evaluated, it was important to account for when a beneficiary enrolled over the extended enrollment period. By 2007, enrollment periods had normalized and the time in the program would be more important. The count can vary from 1 to 24 for enrollees.

- Other drug coverage. The model has months of coverage by Retiree Drug Subsidy plans and other creditable coverage from TRICARE, Federal employee health benefits, the Veterans Administration, State pharmacy assistance plans, and employer group coverage plans that make Medicare a secondary payer for medical services.

  The model in skeleton form is as follows:

$$\begin{aligned}\text{Service use} = {} & (a_1 \times \text{demographic}_1 + a_2 \times \text{demographic}_2 + \ldots.) \text{ for Year\_2005} \\ & + (b_1 \times \text{demographic}_1 + b_2 \times \text{demographic}_2 + \ldots) \text{ for Year\_2007} \\ & + (c_1 \times \text{HCC1} + c_2 \times \text{HCC}_2 + \ldots) \text{ for Year\_2005} \\ & + (d_1 \times \text{HCC1} + d_2 \times \text{HCC}_2 + \ldots) \text{ for Year\_2007} \\ & + (\text{lti}_1 \times \text{long-term institutionalized}) \text{ for Year\_2005} \\ & + (\text{lti}_2 \times \text{long-term institutionalized}) \text{ for Year\_2007} \\ & + t_1 \times \text{Year\_2007} \\ & + e_1 \times \text{Part\_D\_enrollee, marked for 2005 and 2007} \\ & \mathbf{+ f_1 \times Part\_D\_months\ \_Year\_2007, \text{ the treatment effect sought}} \\ & + g_1 \times \text{Other drug coverage variables}\end{aligned}$$

The coefficients for the control variables are estimated separately for each year in this method. Because they vary across the years, they pick up much of the effect that would simply be captured by the year variable. This approach differs from the more usual simple additive term for the "treatment" year. It allows groups of predictor variables to vary in their 2007 effects compared with their 2005 effects as well as allows a treatment year additive effect.

Conceptually, in a difference-in-difference regression analysis, if the equation pertaining to 2005 is subtracted from the equation for 2007, the difference is an equation in which terms that are identical in both years, like Part_D_enrollee, vanish. Terms that are similar, but different in magnitude, like the demographics or clinical terms, become the 2007−2005 differences for those terms. Terms that appear as nonzero in only one year remain in the difference equation (for example, the year term and Part D months in 2007).

The difference equation above that applies to nonenrollees is subtracted from the difference equation for the enrollees. Some terms in this equation have the same coefficients for the Part D and non-Part D beneficiaries. These terms vanish from this difference. Such terms are those related to the demographic and clinical variable sets. In addition, the Year_2007 term applies equally to both groups and is differenced away. The only term that remains of the difference-in-difference process is $f_1 \times$ Part_D_months_Year_2007, in which f_1 is the effect of enrollment in Part D in an implementation year. The magnitude of this term is the Part D effect per month of enrollment in this formulation, the treatment effect.

The technical aspects of the modeling require different model structures for each equation type. The probability-of-use models for both inpatient and ED are logit models. The log of the use variable is the dependent variable and the error term distribution is binomial. The inpatient spending model again uses a log of spending as the dependent variable, with a gamma distribution for the error term. The ED visits are a count variable and are used in log form with a Poisson error term. These issues are noted because they affect the way the results are reported.

5.4 Results

The coefficients for Part D months were statistically significant in most of the models. The results of the regressions are best presented as transformations of the estimated coefficients of interest. Logit coefficients are measures of the log of odds ratios and are best understood when transformed to probabilities. Odds ratios do not convey the magnitudes of the probabilities of events. The spending and counts have coefficients that indicate changes in the log of the spending and counts; these coefficients are best transformed into percentage effects.

Table 5.2 shows the probability of an admission for a female age 75–79 who has the disease for the cohort modeled. The effect of adding 18 months of Part D is computed. In a logit model, the effect of a change in a variable is dependent on the values of the other variables in the model. All the HCC disease comorbidity variables are set to 0, as are the originally disabled variable and LTI variable. The probability of a stay or ED visit is affected by these values, but the magnitude of the effect of the Part D variable does not change drastically. The effect of changing from 0 months of enrollment to 18 months was measured by computing the probabilities with Part D set to 0 and 18 to get the best measure for the change. The Part D enrollee variable was also set to allow an estimation of the Part D effect for a person who was of the type to enroll in Part D. The significance of the change column is the incremental effect of implementing Part D with an enrollment of 18 months over what would have been expected over the time period. The changes are at the level of only tenths of a percentage point, with CHF having the largest change and rheumatoid arthritis the smallest.

Table 5.2
Effect of 18 months of Part D on probability of an inpatient stay computed for female, age 75–79

Chronic condition	Probability of stay with 18 Part D months	Probability of stay with 0 Part D months	Percentage-point change for enrollment increase from 0 to 18 months
Chronic obstructive pulmonary disease	5.86	6.03	−0.17
Congestive heart failure	6.71	6.96	−0.25
Diabetes with complications	4.79	4.93	−0.14
Major depression	5.20	5.34	−0.14
Rheumatoid arthritis	4.38	4.45	−0.07

SOURCE: RTI International analysis of Medicare claims data, 2005 and 2007

Table 5.3 is a similar table for the probability of an ED visit. The computation is for the beneficiary with the same characteristics as in the inpatient table. The effect on ED visits is smaller than the effect on inpatient stays.

Major depression is affected the most and has the highest probability of an ED visit. Changes in the hundredths' place are of marginal statistical significance. The coefficients for the cases of diabetes and rheumatoid arthritis are significant only at the 6 and 8 percent level.

Table 5.3
Effect of 18 months of Part D on probability of an emergency department visit computed for female, age 75–79

Chronic condition	Probability of visit with 18 Part D months	Probability of visit with 0 Part D months	Percentage-point change for enrollment increase from 0 to 18 months
Chronic obstructive pulmonary disease	6.47	6.57	−0.10
Congestive heart failure	6.67	6.72	−0.04
Diabetes with complications	6.33	6.47	−0.14
Major depression	8.45	8.66	−0.21
Rheumatoid arthritis	5.56	5.62	−0.06

SOURCE: RTI International analysis of Medicare data

In the second stage of analysis, the effect of Part D enrollment on inpatient spending and numbers of ED visits was estimated for those who used such services. This is a separate measure of the effect to determine whether those who use any of the services use them at a lower intensity.

In these regressions, the log of spending or counts was the dependent variable and the coefficients were changes in the log of the dependent variable. The coefficient was converted from a change of the log of service use to into a percent change by exponentiation (computing the value of the constant "e" to the power of the coefficient). This value represents the percentage change in the spending or count variable for a unit change in the Part D months variable. The effect in the table is expressed as change from 0 to 18 months. **Table 5.4** displays the percent changes in inpatient spending and ED visits for users of the services. Unlike with the logit models, these computations are not specific to a person with particular characteristics.

Table 5.4
Effect of 18 months of Part D on inpatient spending and emergency department visit counts for beneficiaries who use any of the service

Chronic condition	Percent change in inpatient spending	Percent change in emergency department visits
Chronic obstructive pulmonary disease	−1.96	−0.90
Congestive heart failure	−2.31	−0.72
Diabetes with complications	−2.31	0.00*
Major depression	−2.14	0.00*
Rheumatoid arthritis	−2.14	0.00*

NOTES: *These coefficients had poor significance levels of 16 percent or greater. ED is hospital emergency department.

SOURCE: RTI International analysis of Medicare claims data, 2005 and 2007

Inpatient spending for people who have inpatient admissions is reduced about 2 percent compared with what would have been expected for each of the conditions. ED visits are reduced only slightly, with the percentages statistically insignificant for three of the conditions. COPD and CHF do show some reductions, although less than 1 percent.

5.5 Discussion

The difference-in-difference analysis of the effect of implementing Part D—comparing 2005, pre-Part D, with 2007, the second year of Part D—has shown only small effects at the program level. The effects are largest in reducing the spending on inpatient care for those who use it. This could be related to fewer stays or lower-cost stays related to lower-weight DRGs or

reduced outlier payment stays. Each of the cohorts studied does have a chronic condition treatable by drugs. The effect of the Part D enrollment, on average, for the 75-year-old female does not include any measure of the degree to which drugs were purchased. In a sensitivity analysis, the mean of each of the demographic and comorbidity variables, instead of the age 75 female, was tested for the major depression population using the regression for the probability of an inpatient stay. In the result in Table 5.2, the effect of 18 months of Part D was −0.14 percentage points. Using the mean values for each model variable, which are the proportions of people with the comorbidities and in each of the demographic groups, resulted in a change of −0.27 percentage points. This is double the value found for the 75-year-old female but is still not a very substantive amount. Doing the same test in the probability of an ED visit resulted in the −0.21 point change above becoming −0.33 points. These tests affect only the probability-of-use models. Both show that a sicker population would have a larger reduction in the likelihood of using these services, but not a large reduction.

Another limitation in interpreting this analysis is that the nonenrollees in Part D, with whom enrollees are compared, have no *known* drug insurance. This is not to say that they have no drug insurance. In addition, the Part D enrollees, as well as nonenrollees, will have been acquiring drugs to an unknown degree in 2005, before Part D. Both these circumstances will result in the observed program effect being weaker than it might have been in a world in which access to drugs was solely related to Part D. Therefore, finding small effects in the expected direction is not surprising.

This analysis looks at the effects of the program overall. In section 7 of this report, the question addressed is the effect of the regularity of buying (and probably taking) drugs. The analysis moves from the loose link between Part D enrollment and Part A and B spending, to a question closer to the effectiveness of drugs in changing Part A and B service use.

SECTION 6
EFFECT OF PART D ON HEALTH OUTCOMES—MEDICARE CURRENT BENEFICIARY SURVEY ANALYSIS

6.1 Introduction

In this section, the 2006 Medicare Current Beneficiary Survey (MCBS) was used to address the following research question: What is the impact of Part D on health outcomes and health care utilization and costs for beneficiaries with chronic conditions? This analysis focused primarily, although not exclusively, on beneficiaries with the six selected chronic conditions (i.e., chronic obstructive pulmonary disease [COPD], heart failure, diabetes with complications, dementia, major depression, and rheumatoid arthritis). The outcome measure used is the number of inpatient events (hospitalizations) experienced by a beneficiary during 2006. Inpatient hospital services account for over one-quarter of Medicare benefit payments (27 percent) (Kaiser Family Foundation, 2010). Because of these large costs, one of the goals of the introduction of Medicare Part D was to lower costs through lowering hospitalizations (Stuart et al., 2007). Thus investigation of this research question is of importance to CMS and policymakers in that it analyzes the impacts that access to insurance for drugs is having on hospitalizations.

A number of researchers have looked at the relationship between drug coverage and hospitalizations. Stuart and colleagues (2007), Khan and colleagues (2008), and Briesacher and colleagues (2005) all used MCBS data and found no relationship between drug coverage and Medicare spending for hospital services (in the case of Stuart et al. and Briesacher et al.) or hospitalization rates (in the case of Khan et al.). Chandra, Gruber, and McKnight (2007), on the other hand, found that an increase in patient cost-sharing for physician visits and prescription drugs did result in an increased number of hospitalizations. The relationship between drug coverage and hospitalizations is thus an important and open question, and this project adds to the body of knowledge by being one of the first, if not the first, to use the 2006 MCBS data to analyze this question. The 2006 MCBS are the first data that (1) form a nationally representative sample of the Medicare population, (2) cover a time period after Part D implementation, and (3) contain survey data on prescription drug events and on drug insurance coverage.

The 2006 MCBS is a continuous, multipurpose, rotating panel survey of a representative national sample of the Medicare population. For this report, our analysis in this section focused only on inpatient events. The MCBS contains a number of other measures of health outcomes, health care utilization, and costs; future research plans include analysis using these additional measures. It also contains a rich array of background information about respondents, used to create a full set of control variables. For this section, we analyzed the relationship between Part D enrollment and inpatient hospital stays using zero-inflated Poisson (ZIP) regression, a method that is uniquely appropriate for these types of "event data."

Key results of the analysis include the following:

- Part D enrollment is not a statistically significant predictor of the number of inpatient stays.
- Part D low-income subsidy (LIS) recipients have more inpatient events than beneficiaries who have no drug coverage, controlling for other factors.

6.2 Methods and Data

6.2.1 Sample Selection

Our analysis of the effect of Part D on drug adherence was conducted on the 2006 MCBS Cost and Use File, which has a total of 11,984 observations. The sample selection criteria were the same as those used in section 4:

- Community-residing in 2006
- 12 months of Parts A and B enrollment during 2006
- Alive at the end of 2006
- United States resident in 2006
- Able to merge data to 2006 Medicare RxHCC risk score file
- Able to merge data to 2006 MCBS Access to Care file

The reasons for these criteria are varied, and they are described in detail in section 4. They were chosen to balance the opposing goals of having consistent, high-quality data for analysis and having sufficient observations, a significant challenge with MCBS data. Table 4.1 summarizes the sample selection and the number of observations by each restriction. After all the sample criteria were applied, the sample size was $N = 9{,}008$. Out of these 9,008 beneficiaries, we identified beneficiaries with each of the selected chronic diseases: COPD (1,245), heart failure (1,126), diabetes with complications (822), dementia (423), major depression (355), and rheumatoid arthritis (205).[25]

6.2.2 Analytic Variables

Hospitalizations. The variable of interest is the number of hospitalizations, which is based on survey information on individual hospital stays for the MCBS sample, including both fee-for-service and Medicare Advantage enrollees.

Drug Coverage. We examined the effects of drug coverage on hospitalizations. We created indicator variables for drug coverage, including Part D, employer-sponsored, self-

[25] Our methodology for identifying patients with the selected chronic conditions is presented in section 2.

purchased, other public or private, and no drug coverage. These are derived from the MCBS health insurance file (RIC 4), which is based on both administrative and survey-reported data. We followed the hierarchy of drug coverage assignment used by the Kaiser Family Foundation (2008) as follows:

Part D > employer-sponsored > self-purchased > other public or private > no drug coverage

Beneficiaries with multiple sources of drug coverage were assigned to the drug coverage appearing highest in the hierarchy, on the basis of having had at least 1 month of this type of coverage during 2006. Thus each beneficiary was assigned to one, and only one, drug coverage category.

Control Variables. The analysis examined the impact of drug coverage on drug adherence, controlling for a large number of beneficiary characteristics as follows:

- Demographics and socioeconomics
  - Age (0–64, 65–74, 75–84, and 85+)
  - Sex (female/male)
  - Race (Black, White, other)
  - Census region (Northeast, South, Midwest, West)
  - Urbanicity (metropolitan/nonmetropolitan)
  - Income ($0–$15,000; $15,001–$30,000; $30,001–$50,000; $50,001+)
  - Part D LIS (yes/no)[26]
  - Education—high school graduate (yes/no)
  - Household composition—lives alone (yes/no)
  - Access to help with medications (yes/no)[27]
- Health status and functioning
  - RxHCC risk score quintiles (0–20 percent, 20–40 percent, 40–60 percent, 60–80 percent, and 80–100 percent)

---

[26] Beneficiaries having a Part D LIS were primarily a subset of beneficiaries with Part D coverage. There were very few beneficiaries with a Part D LIS who did not have Part D coverage.

[27] For community-residing beneficiaries, the survey question on access to help with medications was applicable only to a few hundred beneficiaries who resided in housing that offered help with services. However, given that the focus of our study was drug adherence, we believed that it was appropriate to include these data.

- Memory loss (yes/no)
- Difficulty reading prescription instructions or labels (yes/no)
- End-stage renal disease (yes/no)
- Self-rated general health status compared with beneficiaries own age (excellent, very good, good, fair, poor)
- Difficulties with activities of daily living (0, 1 or 2, 3 or 4, 5 or 6)
- Difficulties with instrumental activities of daily living (0, 1 or 2, 3 or 4, 5 or 6)

• Other control variable

- Proxy responder for MCBS interview (yes/no)

Demographic, socioeconomic, and health status and functioning control variables were derived directly from the MCBS. Further details on the RxHCC risk score, an important casemix adjuster used in our study, are provided in section 4.2.2.

6.2.3 Multivariate Statistical Methods

To estimate the impact of Part D on hospital stays, we use a ZIP regression model, which takes into account the structure of "count data." Count data refer to data that consist of the number of times an event happens. This can be anything from the number of fish caught on a trip to a park to the number of times a student was absent from class to, in this case, the number of inpatient events a Medicare beneficiary had during the course of a year. These data are always thus made up of nonnegative integers—0, 1, 2, 3,…, *n*. Poisson regression takes this unique structure of the data into account. ZIP regression also takes into account that in many cases there are essentially two parts to the process: one that determines whether there will be any events at all, and one that determines how many events there will be if there is at least one. Statistical tests conducted with the regressions concluded that ZIP is a more appropriate model than the standard Poisson.

Note that the zero-inflated negative binomial (ZINB) regression model is a popular and more generalized alternative to Poisson. However, both approaches use maximum likelihood estimation, a process that, in some cases, does not "converge"—the computer program is unable to produce an estimate. Because this was a very serious problem with the ZINB model when applied to the MCBS data and less of a problem with the ZIP, we chose to use the ZIP for this application. Even with the ZIP, we are not able to present results of every model for each of the six conditions, because the models on some of the smaller samples do not converge.

Another alternative to ZIP is a two-step model, where logit regression is used to estimate the probabilities of having at least one event, and zero-truncated Poisson or negative binomial is used to estimate the number of events, given a beneficiary experiences at least one event. This is the method used to model emergency department visits in section 5. One challenge of this approach, however, is that the second stage—the Poisson regression in the case of section 5—

uses only the observations on the beneficiaries with at least one event. As shown in **Table 6.1**, because only 18 percent of the sample had at least one hospitalization, this cuts down drastically on an already small sample. The two-stage "hurdle" model, while more easily interpretable than the ZIP model, is thus not practical for use with the MCBS data analyzed in this section.

The results of the analyses are shown as two columns. The first column presents incidence-rate ratios (IRRs). These are ratios that, in our case, show the ratio of the expected number of inpatient events when a given variable is equal to 1, to the expected number when the variable is equal to 0. The second column shows the zero-inflated section of the results. These are more difficult to interpret, but if the coefficient on the Part D indicator is *above 1*, that means those with Part D are *more likely to have zero inpatient events* than those who are not on Part D. A value below 1 means that persons with Part D are less likely to have zero inpatient events. Another way to think about the second column is that it can be thought of as a prediction of the number of "excess zeros" beyond what would be expected by the standard Poisson model. More detailed information on the interpretation of these results will be given as the results are described in the following section.

6.2.4 Weighting

We weight our descriptive and multivariate statistics by the MCBS cross-sectional sample weights, which adjust for nonresponse and also account for differential probabilities of selection. In addition, we account for the complex sample design of the MCBS when estimating standard errors, using appropriate survey commands for our data analysis. Our weighting methods and the reasons for their use are described in detail in section 4.

6.3 Descriptive Results

Table 6.1 presents key descriptive results for the MCBS analysis sample overall and by each of the study's six selected chronic condition samples. The sample size for the overall sample was 9,008, with 34.4 percent of the observations having at least one of the six chronic conditions. The percentages with each condition are 14.1 percent for the sample with COPD, 12.2 for heart failure, 9.6 for diabetes with complications, 4.3 for dementia, 3.7 for major depression, and 2.2 with rheumatoid arthritis. Typically beneficiaries identified with one of the six chronic conditions have comorbidities. For example, for beneficiaries identified with COPD, approximately one-third have heart failure, which is more than double the rate for the overall sample.

Our variable of interest for this section was the number of inpatient events. Approximately one-fifth of beneficiaries had at least one hospital inpatient admission, which is typical for the Medicare population. However, as expected, the hospitalization rate is much higher for the beneficiaries with chronic conditions. The hospitalization rates are more than double for COPD (40.0 percent), heart failure (48.6 percent), and diabetes with complications (42.7 percent). The hospitalization rates for the other three chronic conditions range from 25.3 to 33.0 percent.

The study agenda included examining the impacts of drug coverage on health care utilization. For the overall sample, more than half of the beneficiaries had Part D drug coverage (55.7 percent). For the remaining beneficiaries, approximately 30 percent had employer-

sponsored coverage, and approximately 10 percent had no coverage. The remaining two drug coverage categories were self-purchased coverage and other public or private coverage (3.1 percent and 1.9 percent, respectively). Relative to the overall sample, beneficiaries with chronic conditions had a higher rate of Part D drug coverage and a higher rate of drug coverage in general. The rates of Part D coverage ranged from 58.1 percent for rheumatoid arthritis to 66.7 percent for major depression. In addition, the rates of no drug coverage ranged from 4.7 percent for diabetes with complications to 7.0 percent for dementia. Possible reasons for the higher rate of Part D drug coverage (and drug coverage in general) among the beneficiaries with chronic conditions included the higher demand for prescription drugs and the higher probability of receiving a Part D LIS.

In addition to hospitalizations and drug coverage, descriptive analysis of various beneficiary characteristics, including demographic, socioeconomic, and health status and functioning, are presented in section 4. For each beneficiary characteristic, we compared the distributions for the chronic condition samples with the distribution for the overall sample.

Table 6.1
Descriptive statistics for the 2006 Medicare Current Beneficiary Survey analysis sample—overall and by the study's six chronic conditions

Variable	Analysis sample	Chronic obstructive pulmonary disease	Heart failure	Diabetes with complications	Dementia	Major depression	Rheumatoid arthritis
Number of observations	9,008	1,245	1,126	822	423	355	205
Study's six chronic conditions	—	—	—	—	—	—	—
At least 1	34.4	100	100	100	100	100	100
Chronic obstructive pulmonary disease	14.1	100	33.7	20.8	14.9	22.7	18.5
Heart failure	12.2	29.2	100	29.5	24.1	13.8	11.9
Diabetes with complications	9.6	14.2	23.2	100	11.4	11.9	7.0
Dementia	4.3	4.5	8.4	5.1	100	8.0	4.4
Major depression	3.7	5.9	4.1	4.5	6.9	100	4.1
Rheumatoid arthritis	2.2	2.9	2.2	1.6	2.3	2.5	100
None	65.6	0	0	0	0	0	0
Hospitalized	—	—	—	—	—	—	—
Yes	18.1	40.0	48.6	30.8	42.7	33.0	24.3
No	81.9	60.0	51.4	69.2	57.3	67.0	75.7

(continued)

Table 6.1 (continued)
Descriptive statistics for the 2006 Medicare Current Beneficiary Survey analysis sample—overall and by the study's six chronic conditions

Variable	Analysis sample	Chronic obstructive pulmonary disease	Heart failure	Diabetes with complications	Dementia	Major depression	Rheumatoid arthritis
Drug coverage	—	—	—	—	—	—	—
Part D	55.7	61.6	60.4	64.1	60.4	66.7	58.1
Employer-sponsored	29.6	26.4	28.7	27.8	26.8	20.0	33.4
Self-purchased	3.1	2.4	2.8	2.2	2.9	2.1	0.8
Other public or private	1.9	1.5	1.6	1.2	2.8	5.1	1.8
No drug coverage	9.8	8.1	6.5	4.7	7.0	6.1	5.9

NOTE: Descriptive statistics were weighted by Medicare Current Beneficiary Survey sampling weights.

SOURCE: RTI International analysis of the 2006 the Medicare Current Beneficiary Survey.

6.4 Multivariate Results

Table 6.2 shows the results of the ZIP analysis of the number of inpatient events among the analysis sample. The coefficient on Part D in this regression was not significant in either the first or the second columns, although the point estimate, because it is less than 1 (0.847), indicates that Part D enrollees may have fewer inpatient events. In fact, the only drug coverage-related variable that was significant is the Part D LIS. The coefficient of 1.4 in the first column means that beneficiaries with Part D LIS had 1.4 times as many inpatient events as those with no drug coverage. Four conditions—COPD, heart failure, dementia, and major depression—had significant coefficients in both columns with values above 1 in the first column and below 1 in the second, meaning people with these four conditions were more likely to have an inpatient event, and to have more events, than other beneficiaries. The values in the first column mean that those with COPD had 1.4 times as many events, those with heart failure had 1.5 times as many, those with dementia had 1.3 times as many, and those with major depression had 1.4 times as many. Other controls that had significant relationships with the number of events are primarily measures of health status, such as RxHCC risk scores and end-stage renal disease, as well as some demographic variables. Full results are shown in the section 6 technical appendix in Table A6.1.

Table 6.2
Inpatient events, overall sample

Variable	Number of events	Zeros
Part D	0.847	0.701
	(0.94)	(1.30)
Drug coverage	—	—
Employer-sponsored	0.976	0.762
	(0.15)	(1.08)
Self-purchased	0.931	1.206
	(0.15)	(0.28)
Other public or private	1.091	0.571
	(0.24)	(0.98)
Part D low-income subsidy	1.434**	1.378
	(2.88)	(1.55)
Six conditions	—	—
Chronic obstructive pulmonary disease	1.376**	0.362**
	(3.89)	(6.13)
Heart failure	1.514**	0.257**
	(5.01)	(7.52)
Diabetes	0.925	0.615
	(0.64)	(1.74)
Dementia	1.258*	0.306**
	(2.17)	(3.66)
Depression	1.449*	0.828
	(2.31)	(0.63)
Rheumatoid arthritis	0.911	0.569
	(0.44)	(1.10)

* $p<0.05$; ** $p<0.01$

NOTES: "Number of events" are incidence rate ratios (IRRs). "Zeros" are the prediction of excess zeros. See section 6.2.3 for details. T-ratios in parentheses. Coefficients weighted by MCBS survey sampling weights, and standard errors adjusted for Medicare Current Beneficiary Survey complex sampling design.

SOURCE: RTI International analysis of the 2006 the Medicare Current Beneficiary Survey.

Table 6.3 shows this same regression for two specific subgroups: beneficiaries with COPD and with heart failure.[28] Once again, the coefficients on Part D are far from significant in these regressions, and here the ones on Part D LIS are as well, although the point estimates are fairly similar to those found in Table 6.2. The loss of significance for Part D LIS can thus

[28] It was not possible to estimate these regressions for the subgroups with the other conditions—the computer algorithm was not able to calculate an estimate for these specifications.

largely be explained by the fact that the sample sizes for these subgroups are far smaller. In fact, none of the drug coverage variables predict the number of events, and only one is related to the number of excess zeros.[29] Thus, when outliers are excluded, the relationship between drug coverage and inpatient events is not strong enough to identify in the small samples available when analyzing condition subgroups using MCBS. Control variables are also overwhelmingly not statistically significant, with the exception of two of the categorical age variables. Full results are shown in the section 6 technical appendix in Table A6.2.

Table 6.3
Inpatient events, selected conditions

Variable	COPD—number of events	COPD—zeros	Heart failure—number of events	Heart failure—zeros
Part D	0.934	0.907	0.907	3.136
	(0.25)	(0.15)	(0.39)	(0.73)
Drug coverage	—	—	—	—
Employer-sponsored	1.235	1.003	0.916	1.086
	(0.68)	(0.01)	(0.20)	(0.03)
Self-purchased	0.518	3.286	1.323	27.207
	(0.71)	(0.75)	(0.55)	(1.90)
Other public or private	0.497	0.000**	0.843	1.819
	(1.41)	(8.45)	(0.25)	(0.26)
Part D low-income subsidy	1.219	1.119	1.408	1.114
	(0.62)	(0.13)	(1.36)	(0.18)

* $p<0.05$; ** $p<0.01$

NOTES: "Number of events" are incidence rate ratios (IRRs). "Zeros" are the prediction of excess zeros. See section 6.2.3 for details. T-ratios in parentheses. Coefficients are weighted by Medicare Current Beneficiary Survey sampling weights, and standard errors are adjusted for MCBS complex sampling design. COPD, chronic obstructive pulmonary disease.

SOURCE: RTI International analysis of the 2006 the Medicare Current Beneficiary Survey.

6.5 Discussion

In this section, we analyzed the relationship between Part D enrollment and inpatient hospital stays in the MCBS using ZIP regression, a method that is uniquely appropriate for these type of "event data." The results are suggestive that beneficiaries who are enrolled in Part D may have fewer inpatient stays, but our very limited sample size in the MCBS means that the coefficients on Part D were not significant in any specification. The one important, statistically significant result is that Part D LIS recipients, according to analysis using the full analysis sample, have more inpatient events than do Medicare beneficiaries with no drug coverage. One

[29] The significant predictor of excess zeros is other public or private coverage. This was a very small fraction of the sample; as shown in section 4, only 1.9 percent of the sample had this form of coverage. The coefficient of 0.00 here means that those with this type of drug coverage were very, very unlikely to be an "excess zero"—they had a nearly zero probability of falling into the category of beneficiaries who will never be admitted to a hospital.

possible reason for this result is that Part D LIS beneficiaries, who for the most part are Medicare/Medicaid dually eligible, have more preventable hospital admissions. For dually eligible beneficiaries, lack of access to care, poor quality of care, and inadequate management of health conditions could lead to hospital admissions that are potentially preventable (Jiang et al. 2010). This result is not found when subsamples of beneficiaries with the six conditions of interest are studied because of the resulting very small sample sizes.

This analysis has a number of limitations. The most important one may be the small sample size of the MCBS, which limited the analysis that could be conducted, especially with the less common chronic conditions. This limitation will be mitigated substantially in the next phase of this project, when we will incorporate the 2007 MCBS survey data into our analytic database, thereby greatly increasing our statistical power and ability to identify the effects of Part D drug coverage on health outcomes and health care utilization and costs. These limitations are one possible reason the multivariate analysis did not show a consistent relationship between Part D enrollment and adherence. Another limitation is that this analysis has focused solely on one outcome variable, hospitalizations. Although this is a very important outcome, the MCBS contains numerous additional measures of health outcomes and health care utilization and costs that could be explored. Potential additional outcomes include self-reported health status, other measures of health such as difficulties with activities of daily living, and nondrug medical costs. Finally, the results of this analysis of 2006 data could be affected by the fact that 2006 was the first year of the Part D program; we thus expect analysis using the 2007 data to be more robust and generalizable to future program years.

SECTION 7
ANALYSIS OF THE EFFECT OF ADHERENCE ON OUTCOMES AND UTILIZATION

7.1 Introduction

This section of the report focuses on the general research question: What is the relationship between differences in patient adherence and differences in health outcomes and health care utilization and cost? In other sections we have examined the effect of Part D on such measures. If Part D improves access, and access improves adherence, the next link to examine is the connection between adherence to a drug regimen and measures of outcomes and service use.

Adherence is measured here as a form of the medication possession ratio (MPR), the ratio of days supplied to days eligible in the program. Adjustments were made for time spent in hospitals or skilled nursing facilities. We can measure this variable only for the Part D enrollees. The focus is the non-low income subsidy population with the six disease cohorts, chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), diabetes with complications, dementia, major depression, and rheumatoid arthritis.

As a matter of policy interest, it would be relevant whether adherence, at least as measured by purchases, did affect the outcome and utilization measures. Efforts to improve adherence would be more likely to be undertaken if effects could be measured.

To operationalize the general research question, we ask the following more specific questions:

- What is the effect of adherence on the probability of having an inpatient hospital stay?
- For those who have stays, what is the effect of adherence on inpatient spending?
- What is the effect of adherence on the probability of having an emergency department (ED) visit?
- For those who have visits, what is the effect on the number of visits?

Medicare fee-for-service claims data were used to create the service use variables and the variables used to control for health status. The diagnoses from these claims were used to identify people in the disease cohorts. The Prescription Drug Event file (PDE) was used to identify people who were users of the drugs and create the MPRs. We tracked not the use of individual drugs but the use of drugs by class. For this analysis we recognized that beneficiaries do not take all the classes of drugs that could be used to treat their condition. We would consider beneficiaries adherent if they were adherent to one of the relevant classes. Thus the maximum MPR across the multiple classes used for a condition was used as a measure.

The effect of the quantity of drug therapy used, rather than just enrollment in Part D, was expected to be stronger than the effect of simply enrolling in Part D, even for a population with

chronic diseases. Indeed, significant and substantive effects were measured, with some variation across the conditions.

The findings, in brief, are that adherence did have favorable effects on the target measures:

- The probability of an inpatient stay is reduced by 2 to 4 percentage points for each 25-point improvement in adherence, depending on condition. CHF has the highest probability and greatest reduction.

- Inpatient spending decreases by about 2.5 to 5 percent for a 25-point increase in adherence, varying by condition.

- The probability of an ED visit generally decreases by about 2 percentage points for each 25 points of adherence improvement. There is less variability in the probabilities of outpatient ED visits than inpatient stays.

- Counts of ED visits for users of the service decrease by 2 to 3 percent for a 25-point change in adherence, depending on condition.

These findings indicate that there is an effect of adherence improvement. Because the disease cohorts have people who may have other medical conditions as well, and because adherence was measured for the drugs used to treat the diseases defining the cohort, it is possible that the changes measured are less than what is achievable. If adherence to drugs for their comorbidities is correlated with the cohort-specific adherence, the numbers may be about right. If adherence to drugs for the comorbidities can also be improved, the overall effects of adherence may be higher.

7.2 Data

The sample used for the study is a subset of the 2007 non-low-income subsidy enrollees in Part D who were indicated to have at least one of the study conditions: COPD, CHF, diabetes with chronic complications, dementia, major depression, or rheumatoid arthritis.[30] They also had to have at least one record of a filled prescription for one of the study drug classes in the PDE records for 2007. These restrictions produced smaller sample sizes than were used in the study of the effect of Part D in section 5.

The adherence measures are a variation on those described in section 3. The MPR, the number of days supplied of a drug divided by the potential eligible days of supply that could have been ordered, is adjusted for carryover from 2006 and for carryover into 2008. We also adjusted for days in an inpatient hospital or skilled nursing facility (SNF). Beneficiaries who were in an SNF were included in the analysis, as many hospital inpatients are discharged to SNFs; excluding these beneficiaries would result in a distortion of the data on inpatient stays. Beneficiaries in nursing facilities in nonskilled stays were excluded. Because there are enrollees

[30] More specific definitions of the conditions are found in Table 2.1 of this report.

who seem to purchase drugs despite being covered for drugs during the inpatient stays, and other causes of noise in the data, the MPR values that exceed 1 are capped at a maximum value of 1.

Each person in the sample for each disease may have multiple conditions and multiple drug classes used for each condition. When analyzing a cohort with a particular condition, we included an adherence measure relevant to the drug classes for that condition as an explanatory variable along with control variables for demographics and comorbidities. For the latter, the hierarchical condition categories (HCCs) for diseases reported in the prior year, 2006, were used.

The data elements necessary were derived from the Medicare 100 percent claims and enrollment data as well as the PDE data for prescriptions filled. The classes of drugs for each condition were arrived at through the literature and in discussions with physicians, as described in section 3. The drug classes assigned were those in the American Hospital Formulary Service schema, mapped to specific drugs by First DataBank.

7.3 Methods

A two-part method of analysis was used. In the first stage, a regression was run to predict any use of a service. In the second stage, only users of the service were included to determine the quantity of the service. For prediction of probability of inpatient use, a logit analysis was used. Then, for those who had at least one inpatient hospital stay, the inpatient spending was modeled using the log of spending and a gamma distribution for the error term. This two-part approach is often called the "hurdle" method. For this analysis, it enables us to look at both parts of the causes of spending—having a hospitalization and then the costs of hospitalizations conditional on having at least one.

In the case of use of ED services, the same method was used for the first stage, a logit regression to predict use of the ED. The second stage, which models a count of ED visits for users of the service, applied a Poisson regression. The log of the visit count is the dependent variable, and the error term is modeled with a Poisson distribution, appropriate for counts of discrete events.

The equations have the following form:

Log dependent variable =

$$a_1 \times \text{demographic}_1 + a_2 \times \text{demographic}_2 + \ldots$$
$$+ b_1 \times \text{HCC1} + b_2 \times \text{HCC}_2 + \ldots$$
$$+ c \times \text{fraction of year long-term institutionalized}$$
$$+ d \times \text{originally eligible due to disability}$$
$$+ e \times \text{Part\_D\_months enrolled}$$
$$+ f \times \text{adherence measure}$$

A number of possibilities were considered for the adherence measure: the MPR for each drug class, a set of variables marking ranges for the MPR (e.g., 0–20 percent, 20–40 percent …) or the variable chosen, and the maximum MPR for the classes used for the condition. This last variable has some advantages. It is not necessary to take all the classes that treat a disease to be

treating the disease. A number of MPRs would be equal to 0 because some other class was being used. It would not be appropriate to consider this zero score to be nonadherence. The interpretation of the coefficients becomes difficult. A measure indicating that some drug related to the condition was regularly taken (or at least purchased) was deemed a good indicator of adherence. Thus, in these equations the maximum value of the MPRs for the condition-related drug classes was the variable included. It could range from just greater than 0 to 1.

To facilitate the interpretation of the results, **Table 7.1** presents some of the statistics for the inpatient spending and ED counts for each of the condition cohorts.

Table 7.1
Selected statistics for dependent variables in regressions

Chronic condition	Proportion with inpatient stay	Mean spending for those with an inpatient stay ($)	Proportion with emergency department visit	Mean number of visits for those with a visit
Chronic obstructive pulmonary disease	0.41	16,211	0.32	1.74
Congestive heart failure	0.50	17,768	0.36	1.72
Diabetes with complications	0.33	17,342	0.29	1.65
Dementia	0.39	12,847	0.38	1.68
Major depression	0.37	17,752	0.35	1.85
Rheumatoid arthritis	0.27	14,529	0.25	1.53

The rheumatoid arthritis cohort had the lowest proportion of people with inpatient stays and with ED use. The CHF cohort had the highest proportion with inpatient stays, but this group was second to dementia in the proportion using the ED. For ED users, people with major depression had the greatest number of visits. Overall in Medicare, the proportion of beneficiaries with hospital stays is approximately 0.2; these populations were clearly high users.

The mean inpatient spending for users was more than $17,000 for three groups, with CHF a bit more costly than major depression and diabetes with complications. Dementia inpatients had the lowest average, under $13,000. Inpatient use was certainly higher for these selected groups of chronically ill beneficiaries than for Medicare as a whole. To the extent that drugs are effective, these costs can be reduced.

Table 7.2 presents the counts of people used in each regression. The logit regressions, estimating probability of use, have users and nonusers of services. The regressions for users have smaller samples, reflecting the proportions of users in each cohort shown in Table 7.1.

Table 7.2
Sample size for regression for each dependent variable

Chronic condition	Sample size: Proportion with inpatient stay	Sample size: Mean spending for those with an inpatient stay	Sample size: Proportion with an emergency department visit	Sample size: Mean number of visits for those with a visit
Chronic obstructive pulmonary disease	470,193	194,990	470,193	152,078
Congestive heart failure	705,989	351,939	705,989	250,802
Diabetes with complications	466,127	155,155	466,127	134,799
Dementia	242,388	95,406	242,388	92,142
Major depression	136,587	50,347	136,587	47,793
Rheumatoid arthritis	92,802	24,942	92,802	23,241

7.4 Results

The coefficients for adherence were statistically significant in all the models. The results of the regressions are best presented as transformations of the estimated coefficients of interest. Logit coefficients are measures of the log of odds ratios and are best understood when transformed to probabilities. Odds ratios do not convey the magnitudes of the probabilities of events. The spending and counts have coefficients that indicate changes in the log of the spending and counts and are best transformed into percentages.

Table 7.3 shows the probability of an admission for a female age 75–79 who has the disease for the cohort modeled and has 18 months of Part D. In a logit model, the effect of a change in a variable is dependent on the other variable values in the model. All the HCC disease comorbidity variables are set to 0, as are the originally disabled variable and the long-term institutionalized variable. The probabilities vary as the values of the characteristics vary, but the differences do not vary dramatically as variables are changed. The effect of changing by 25 percentage points of adherence is measured by computing the probabilities with adherence set to these values rather than using the formula for marginal probability to get the best measure for the change.

Table 7.3
Probability of an inpatient stay
computed for female, aged 75–79, with 18 months of Part D

Chronic condition	Adherence 100% (%)	Adherence 75% (%)	Adherence 50% (%)	Adherence 25% (%)
Chronic obstructive pulmonary disease	25.1	27.4	29.9	32.6
Congestive heart failure	40.5	44.3	48.2	52.1
Diabetes with complications	18.9	21.2	23.7	26.4
Dementia	24.9	27.5	30.2	33.0
Major depression	25.3	27.9	30.6	33.4
Rheumatoid arthritis	17.0	18.9	21.0	23.2

Changes in response to adherence are largest for the conditions with the highest probabilities of an inpatient stay. CHF probabilities change by about 4 percent for each 25 points of adherence change. Rheumatoid arthritis had the lowest admission probability and a correspondingly smaller drop of 2 percentage points for each 25-point increase in adherence. The two mental conditions of dementia and major depression were very similar. The drops in rates were roughly proportional to the initial rates. These effects are strong indicators that adherence does matter for the Medicare program.

Table 7.4 is a similar table for the probability of an ED visit. The computation is for the beneficiary with the same characteristics as in the inpatient table. Clearly, for some conditions, CHF in particular, the probability of an inpatient stay is greater than that of an outpatient ED visit. The probability of an ED visit varied less across conditions than the probability of an inpatient stay. The effect of adherence on ED visits was smaller than the effect on inpatient stays. The range of probability changes is from 1.4 to 2.3 percentage points for a change of 25 percentage points in adherence. Outpatient ED visits are less expensive than inpatient stays but are also less responsive to adherence in this analysis.

Table 7.4
Effect of adherence on probability of an emergency department visit computed for female, aged 75–79, with 18 months of Part D

Chronic Condition	Adherence 100% (%)	Adherence 75% (%)	Adherence 50% (%)	Adherence 25% (%)
Chronic obstructive pulmonary disease	22.0	23.7	25.5	27.3
Congestive heart failure	27.9	29.6	31.3	33.0
Diabetes with complications	20.3	22.3	24.4	26.6
Dementia	30.1	31.5	33.0	34.4
Major depression	26.5	28.6	30.7	32.9
Rheumatoid arthritis	17.3	19.2	21.3	23.6

In the second stage of analysis, the effect of adherence on inpatient spending and numbers of ED visits was estimated for those who used such services. This is a separate measure of the effect of adherence to determine if those who use any of the service use it at a lower intensity.

In these regressions, the log of spending or counts was the dependent variable, and the coefficients are changes in the log of the dependent variable. The number calculated by the exponentiation of the coefficients represents the percentage change in the spending or count variable for a unit change in the adherence variable, expressed as a proportion (from 0 to 1). **Table 7.5** displays the percent changes in inpatient spending and ED visits for users of the services. The percent changes were computed for a change in the proportion from 0.25 to 0.50 to determine the effect of a 25-point change in adherence. The numbers differ slightly when other 25-point intervals are used.

The values in this table are substantive, with the largest effects on inpatient spending for complicated diabetes and dementia, −4.3 and −3.9 percent for a 25-point adherence improvement. For ED visit counts, the effects were largest for rheumatoid arthritis and major depression, 3.9 and 3.7 percent.

Table 7.5
Effect of adherence on inpatient spending and emergency department visit counts for beneficiaries who use the service, for 25-point change in adherence

Chronic condition	Percent change in inpatient spending	Percent change in emergency department visits
Chronic obstructive pulmonary disease	−3.6	−1.9
Congestive heart failure	−2.5	−2.5
Diabetes with complications	−4.3	−3.0
Dementia	−5.0	−2.5
Major depression	−2.8	−3.7
Rheumatoid arthritis	−3.9	−3.9

NOTE: Percent changes were computed at the 50 percent adherence level. They differ slightly at other levels.

7.5 Discussion

In this analysis, the use of inpatient stays and ED visits are regarded both as utilization measures for the Medicare program and as outcome measures as markers of undesirable medical events. Models were estimated that decomposed the measures into probability of use and intensity of use for users. The explanatory variable of greatest interest was adherence to a drug regimen, measured by the highest MPR among the drug classes used to treat the condition defining the sample under study. Because there are multiple classes for each condition, and not all are used by each person, adherence to any one of the treatment classes indicates treating the condition.

For all six disease groups (COPD, CHF, diabetes with chronic complications, dementia, major depression, and rheumatoid arthritis), greater adherence had favorable results. Both the probability of hospital use and the extent of use were decreased. This is also true, to a lesser extent, for the ED visits. These two components of the adherence effects can be seen separately. This has favorable implications for Part A and B program costs as well as for patient health.

A limitation of this analysis is that the defined disease cohorts include members who may have a variety of comorbidities. The presence of the comorbidities is largely accounted for by the HCC control variables, but the adherence to drugs for those conditions is not. The adherence effects described here are specific to the diseases under study. Adherences to drug regimens for any other diseases that may be present are not explicitly accounted for separately. In addition, nonadherence in the form of not filling any prescription for a condition could not measured; we required at least one fill to be included.

Net savings, including the cost of Part D drugs, were not part of this study. However, with inpatient hospital costs for users in these groups averaging $17,000 per year, savings of 10

percent are not insignificant to the program, and reducing the likelihood of a person's having even one stay by 3 or 4 percent adds to the potential savings. The mechanisms for raising adherence are not a topic for study in this work, but they are clearly of interest. The private sector has been experimenting with methods, but a controlled study comparing approaches, especially with the Medicare population, would seem indicated.

SECTION 8
EFFECT OF DRUG ADHERENCE ON HEALTH CARE UTILIZATION—MEDICARE CURRENT BENEFICIARY SURVEY ANALYSIS

8.1 Introduction

In this section, the 2006 Medicare Current Beneficiary Survey (MCBS) was used to address the following research question: What is the impact of drug adherence and drug coverage on health outcomes and health care utilization and cost? This analysis focused primarily, although not exclusively, on beneficiaries with the six selected chronic conditions (i.e., chronic obstructive pulmonary disease [COPD], heart failure, diabetes with complications, dementia, major depression, and rheumatoid arthritis). The outcome measure used is the number of inpatient events (hospitalizations) experienced by a beneficiary during 2006. Inpatient hospital services account for over one-quarter of Medicare benefit payments (27 percent) (Kaiser Family Foundation, 2010). Because of these large costs, one of the goals of the introduction of Medicare Part D was to lower costs through lowering hospitalizations by increasing beneficiaries' use of prescription drugs (Stuart et al., 2007). Thus investigation of this research question is of importance to CMS and policymakers in that it analyzes the impacts that access to insurance for drugs and the resulting increasing use of drugs may be having on hospitalizations.

A number of researchers have looked at the relationship between drug adherence and hospitalizations. Stuart and colleagues (2009) used the MCBS to look at the effects of medication adherence by Medicare beneficiaries with diabetes and found that, "for users of older oral antidiabetes agents, ACE inhibitors, ARBs, and statins, each additional prescription fill was associated with significantly lower risk of hospitalization, fewer hospital days, and lower Medicare spending" (p. 647). Murray and colleagues (2009) and Tu and colleagues (2005) both studied patients with heart failure participating in randomized trials, and both found that better adherence to certain medications was associated with fewer hospital admissions. These studies all focus on small and specific subgroups of people with a particular condition; the more general relationship between drug adherence and hospitalizations is thus an important and open question, and this project adds to the body of knowledge by being one of the first, if not the first, to use the 2006 MCBS data to analyze this question. The 2006 MCBS are the first data that (1) form a nationally representative sample of the Medicare population, (2) cover a time period after Part D implementation, and (3) contain survey data on prescription drug events and on drug insurance coverage.

The 2006 MCBS is a continuous, multipurpose, rotating panel survey of a representative national sample of the Medicare population. For this report, our analysis in this section focused only on inpatient events. The MCBS contains a number of other measures of health outcomes, health care utilization, and costs; our future research plans include analyses using these additional measures. The MCBS also contains a rich array of background information about respondents, used to create a full set of control variables. For this section, we analyzed the relationship between Part D enrollment, drug adherence, and inpatient hospital stays using zero-inflated Poisson (ZIP) regression, a method that is uniquely appropriate for this type of event data. This analysis is identical to that conducted in section 6, with the exception that our two measures of adherence are included in the regressions.

The first drug adherence measure was whether the patient filled at least one prescription for their chronic conditions; the second was whether the patients failed to fill at least one of their prescriptions (regardless of whether the prescriptions were for their chronic conditions). Overall, our results are very similar to those found in section 6, with one addition:

- Part D enrollment was not a statistically significant predictor of the number of inpatient stays.
- Part D low-income subsidy (LIS) recipients had more inpatient events than beneficiaries who had no drug coverage, controlling for other factors.
- Those who failed to fill a prescription had 1.54 times as many hospitalizations as those who said they never failed to fill one. At the mean number of hospitalizations, 1.54 times as many translates into approximately 0.53 rather than 0.35 events during the year.

8.2 Methods and Data

8.2.1 Sample Selection

Our analysis of the effect of Part D on drug adherence was conducted on the 2006 MCBS Cost and Use File, which has a total of 11,984 observations. The sample selection criteria were the same as those used in section 4, as follows:

- Community-residing in 2006
- 12 months of Parts A and B enrollment during 2006
- Alive at the end of 2006
- United States resident in 2006
- Able to merge data to 2006 Medicare RxHCC risk score file
- Able to merge data to 2006 MCBS Access to Care file

The reasons for these criteria are varied, and they are described in detail in section 4. They were chosen to balance the opposing goals of having consistent, high-quality data for analysis and having a sufficient number of observations, a significant challenge with MCBS data. Table 4.1 summarizes the sample selection and the number of observations by each restriction. After all the sample criteria were applied, the sample size was $N = 9{,}008$. Out of these 9,008 beneficiaries, we identified beneficiaries with each of the selected chronic diseases: COPD (1,245), heart failure (1,126), diabetes with complications (822), dementia (423), major depression (355), and rheumatoid arthritis (205).

8.2.2 Analytic Variables

Hospitalizations. The variable of interest is the number of hospitalizations, derived from survey information on individual hospital stays for the MCBS sample, including both fee-for-service and Medicare Advantage enrollees.

Drug Adherence. This section examines the impact of drug adherence and drug coverage on inpatient stays. The analysis focuses on two simple measures of drug adherence, described below.

1. At least one prescription filled to treat a chronic condition. A binary indicator for whether patients had at least one prescription filled to treat their chronic conditions.[31] MCBS interviewers collected these data by asking respondents to identify all prescriptions they had filled during 2006 and to provide prescription bottles when possible.

2. All prescriptions filled/at least one prescription skipped: A binary indicator for whether a patient filled all of his or her prescriptions. The respondent was asked, "During the current year, were there any prescribed medicines that you didn't get?" Note that prescriptions were not restricted to those used to treat the patients' chronic conditions, and this was relevant only to those who received a prescription for at least one medication.

More details about the creation of these variables, why they were chosen, and their limitations is provided in section 4.

Drug Coverage. We created indicator variables for drug coverage, including Part D, employer-sponsored, self-purchased, other public or private, and no drug coverage. These variables are derived from the MCBS health insurance file (RIC 4), which utilizes both administrative data and survey data. We followed the hierarchy of drug coverage assignment used by Kaiser Family Foundation (2008) as follows:

Part D > employer-sponsored > self-purchased > other public or private > no drug coverage

Beneficiaries with multiple sources of drug coverage were assigned to the drug coverage appearing highest in the hierarchy if they had at least 1 month of this type of coverage during 2006. Thus each beneficiary was assigned to one, and only one, drug coverage category.

Control Variables. The analysis examined the impact of drug coverage on drug adherence, controlling for a large number of beneficiary characteristics as follows:

- Demographics and socioeconomics
  - Age (0–64, 65–74, 75–84, and 85+)

[31] We also created an indicator for whether beneficiaries had at least two prescriptions filled to treat their chronic conditions, but it was highly correlated with whether they had at least one prescription filled.

  - Sex (female/male)
  - Race (Black, White, other)
  - Census region (Northeast, South, Midwest, West)
  - Urbanicity (metropolitan/nonmetropolitan)
  - Income ($0–$15,000; $15,001–$30,000; $30,001–$50,000; $50,001+)
  - Part D LIS (yes/no)[32]
  - Education—high school graduate (yes/no)
  - Household composition—lives alone (yes/no)
  - Access to help with medications (yes/no)[33]
- Health status and functioning
  - RxHCC risk score quintiles (0–20 percent, 20–40 percent, 40–60 percent, 60–80 percent, and 80–100 percent)
  - Memory loss (yes/no)
  - Difficulty reading prescription instructions or labels (yes/no)
  - End-stage renal disease (yes/no)
  - Self-rated general health status compared with beneficiaries of one's own age (excellent, very good, good, fair, poor)
  - Difficulties with activities of daily living (ADLs) (0, 1 or 2, 3 or 4, 5 or 6)
  - Difficulties with instrumental ADLs (IADLs) (0, 1 or 2, 3 or 4, 5 or 6)
- Other control variable
  - Proxy responder for MCBS interview (yes/no)

---

[32] Beneficiaries having a Part D LIS were primarily a subset of beneficiaries with Part D coverage. There were very few beneficiaries with a Part D LIS who did not have Part D coverage.

[33] For community-residing beneficiaries, the survey question on access to help with medications was only applicable to a few hundred beneficiaries who resided in housing that offered help with services. However, given that the focus of our study was drug adherence, we believed that it was appropriate to include these data.

Demographic, socioeconomic, and health status and functioning control variables were derived directly from the MCBS. Details on the prescription hierarchical condition code (RxHCC) risk score, a key casemix control variable, are provided in section 4.2.2.

8.2.3 Multivariate Statistical Methods

To estimate the impact of Part D on hospital stays, we use a ZIP regression model, which takes into account the structure of "count data." Count data refer to data that consist of the number of times an event happens. The results of the analyses are shown as two columns. The first column presents incidence rate ratios (IRRs). These are ratios that in our case show the ratio of the expected number of inpatient events when a given variable is equal to one, to the expected number when the variable is equal to zero. The second column shows the "zero-inflated" section of the results. More detail on the ZIP method, the reasons for its use, and explanation of the interpretation, are provided in section 6.2.3.

8.2.4 Weighting

We weight our descriptive and multivariate statistics by the MCBS cross-sectional sample weights, which adjust for nonresponse and also account for differential probabilities of selection. In addition, we account for the complex sample design of the MCBS when estimating standard errors, using appropriate survey commands for our data analysis. Our weighting methods and the reasons for their use are described in detail in section 4.

8.3 Descriptive Results

Table 8.1 presents descriptive results for the MCBS analysis sample overall and by each of the study's six selected chronic condition samples. The sample size for the overall sample was 9,008, with 34.4 percent of the observations having at least one of the six chronic conditions. The percentages with each condition range from 14.1 percent for the sample with COPD, 12.2 for heart failure, 9.6 for diabetes with complications, 4.3 for dementia, 3.7 for major depression, to 2.2 with rheumatoid arthritis. Typically beneficiaries identified with one of the six chronic conditions have comorbidities. For example, for beneficiaries identified with COPD, approximately one-third have heart failure, which is more than double the rate for the overall sample.

Our variable of interest for this section was hospitalizations. Approximately one-fifth of beneficiaries had at least one hospital inpatient admission, which is typical for the Medicare population. However, as expected, the hospitalization rate was much higher for the beneficiaries with chronic conditions. The hospitalization rates were more than double for COPD (40.0 percent), heart failure (48.6 percent), and diabetes with complications (42.7 percent). The hospitalization rates for the other three chronic conditions ranged from 25.3 to 33.0 percent.

This section examines the impact of drug adherence and drug coverage on hospitalizations. The first drug adherence measure, at least one prescription filled to treat a chronic condition, was not applicable for the overall sample. The results for the six chronic condition samples varied substantially. Heart failure, diabetes with complications, and major depression each had high percentages, with heart failure at 93.3 percent, diabetes with complications at 86.4 percent, and major depression at 85.7 percent. The other three chronic

conditions had substantially lower rates, with COPD at 57.4 percent, rheumatoid arthritis at 51.1 percent, and dementia at 46.2 percent. These results seem to indicate that drug therapy was especially important for heart failure, diabetes with complications, and major depression.

Among the overall sample, 96.5 percent of beneficiaries self-reported that they filled all of the prescriptions that they received from their health care providers. For the beneficiaries identified by the chronic conditions, the percentage of those filling all prescriptions was broadly similar to the overall sample. The one exception was beneficiaries with major depression, who had a lower fill rate by 4 percentage points (92.5 percent). This result might be explained by noting the adverse effects of antidepressants, along with the nature of the disease itself. As discussed in section 4, 96.5 percent is a very high rate of adherence. Kirking and colleagues (2006) discuss several reasons for this very high rate. First, in-home surveys such as MCBS generally resulted in higher values than telephone surveys. Second, this question references "this year," which, based on the design of the MCBS, refers to 9–11 months, so adherence would be higher than that found over 1 full year. Lastly, surveys that focused specifically on medications found lower adherence rates than more general surveys such as MCBS.

For the overall sample, more than half of the beneficiaries had Part D drug coverage (55.7 percent). For the remaining beneficiaries, approximately 30 percent had employer-sponsored coverage, and approximately 10 percent had no coverage. The remaining two drug coverage categories were self-purchased coverage and other public or private coverage (3.1 percent and 1.9 percent, respectively). Relative to the overall sample, beneficiaries with chronic conditions had a higher rate of Part D drug coverage and a higher rate of drug coverage in general. The rates of Part D coverage ranged from 58.1 percent for rheumatoid arthritis to 66.7 percent for major depression. In addition, the rates of no drug coverage ranged from 4.7 percent for diabetes with complications to 7.0 percent for dementia. Possible reasons for the higher rate of Part D drug coverage (and drug coverage in general) among the beneficiaries with chronic conditions included the higher demand for prescription drugs and the higher probability of receiving a Part D LIS.

In addition to health care utilization, drug adherence, and drug coverage, descriptive analysis of various beneficiary characteristics, including demographic, socioeconomic, and health status and functioning, are presented in section 4. For each beneficiary characteristic, we compared the distributions for the chronic condition samples with the distribution for the overall sample.

Table 8.1
Descriptive statistics for the 2006 Medicare Current Beneficiary Survey analysis sample—overall and by the study's six chronic conditions

Variable	Analysis sample	Chronic obstructive pulmonary disease	Heart failure	Diabetes with complications	Dementia	Major depression	Rheumatoid arthritis
Number of observations	9,008	1,245	1,126	822	423	355	205
Study's six chronic conditions	—	—	—	—	—	—	—
At least 1	34.4	100	100	100	100	100	100
Chronic obstructive pulmonary disease	14.1	100	33.7	20.8	14.9	22.7	18.5
Heart failure	12.2	29.2	100	29.5	24.1	13.8	11.9
Diabetes with complications	9.6	14.2	23.2	100	11.4	11.9	7.0
Dementia	4.3	4.5	8.4	5.1	100	8.0	4.4
Major depression	3.7	5.9	4.1	4.5	6.9	100	4.1
Rheumatoid arthritis	2.2	2.9	2.2	1.6	2.3	2.5	100
None	65.6	0	0	0	0	0	0
At least 1 prescription filled to treat a chronic condition	—	—	—	—	—	—	—
Yes	N/A	57.4	93.3	86.4	46.2	85.7	51.1
No	N/A	42.6	6.7	13.6	53.8	14.3	48.9
All prescriptions filled	—	—	—	—	—	—	—
Yes	96.5	96.5	96.9	96.8	96.3	92.5	97.1
No	3.5	3.5	3.1	3.2	3.7	7.5	2.9
Hospitalized	—	—	—	—	—	—	—
Yes	18.1	40.0	48.6	30.8	42.7	33.0	24.3
No	81.9	60.0	51.4	69.2	57.3	67.0	75.7

(continued)

Table 8.1 (continued)
Descriptive statistics for the 2006 Medicare Current Beneficiary Survey analysis sample—overall and by the study's six chronic conditions

Variable	Analysis sample	Chronic obstructive pulmonary disease	Heart failure	Diabetes with complications	Dementia	Major depression	Rheumatoid arthritis
Drug coverage	—	—	—	—	—	—	—
Part D	55.7	61.6	60.4	64.1	60.4	66.7	58.1
Employer-sponsored	29.6	26.4	28.7	27.8	26.8	20.0	33.4
Self-purchased	3.1	2.4	2.8	2.2	2.9	2.1	0.8
Other public and/or private	1.9	1.5	1.6	1.2	2.8	5.1	1.8
No drug coverage	9.8	8.1	6.5	4.7	7.0	6.1	5.9

NOTE: Values are descriptive statistics weighted by Medicare Current Beneficiary Survey sampling weights.

SOURCE: RTI International analysis of the 2006 Medicare Current Beneficiary Survey.

8.4 Multivariate Results

Table 8.2 shows the results of the ZIP analysis of the number of inpatient events on both Part D enrollment and adherence among the analysis sample. This is the same analysis as in Table 6.2, with one difference: our two measures of adherence have been added to the dependent variables list. The second measure of adherence—self-reported failure to fill at least one prescription—is a very strong and statistically significant predictor of the number of inpatient events. In fact, those who failed to fill a prescription have 1.54 times as many events. Although this is quite a large effect, it is not as large as it appears because, although the number of events varies from 0 to 11,[34] the mean number is 0.35. Thus, at the mean, 1.54 times as many translates into approximately 0.53 rather than 0.35 events. Likewise, as in Table 6.2, we find that Part D LIS recipients have 1.4 times as many hospitalizations.

The pattern of significance and values for the other variables included is virtually identical to that in Table 6.2. The coefficient on Part D was not significant in either the first or the second columns, although the point estimate, because it is less than 1 (0.839), indicates that Part D enrollees may have had fewer inpatient events. Four conditions—COPD, heart failure, dementia, and major depression—have significant coefficients in the first column, with values above 1.0; three of these four also have significant coefficients in the second column with values below 1.0. This means that a person with one of these four conditions was more likely to have an inpatient event, and have more events, than other beneficiaries. The values in the first column mean that those with COPD had 1.4 times as many events, those with heart failure had 1.5 times as many, those with dementia had 1.2 times as many, and those with major depression had 1.4 times as many. Other controls that had significant relationships with the number of events are primarily measures of health status, such as RxHCC risk scores and end-stage renal disease, as well as some demographic variables. Full results are shown in Technical Appendix Section 8 in Table A8.1.

[34] 11 is the maximum only once outliers are discarded—the raw maximum is 27.

Table 8.2
Inpatient events as a function of adherence, overall sample

Variable	Number of Events	Zeros
Part D	0.839	0.694
	(0.95)	(1.29)
Drug coverage	—	—
Employer-sponsored	0.977	0.759
	(0.14)	(1.07)
Self-purchased	0.965	1.241
	(0.08)	(0.34)
Other public or private	1.074	0.556
	(0.18)	(0.92)
Part D low-income subsidy	1.423**	1.376
	(2.74)	(1.55)
Adherence	—	—
Filled at least one prescription for chronic condition	1.037	0.745
	(0.27)	(1.14)
Failed to fill a prescription	1.544*	1.185
	(2.04)	(0.56)
Six conditions	—	—
Chronic obstructive pulmonary disease	1.370**	0.411**
	(3.77)	(5.13)
Heart failure	1.483**	0.312**
	(3.35)	(4.54)
Diabetes	0.947	0.777
	(0.41)	(0.78)
Dementia	1.229*	0.319**
	(2.00)	(3.31)
Depression	1.409*	0.961
	(2.18)	(0.14)
Rheumatoid arthritis	0.917	0.649
	(0.42)	(0.87)

* $p<0.05$; ** $p<0.01$

NOTES: Values in the "Number of events" column are incidence rate ratios. "Zeros" are the prediction of excess zeros; see section 6.2.3 for details. T-ratios in parentheses. Coefficients are weighted by Medicare Current Beneficiary Survey sampling weights, and standard errors are adjusted for Medicare Current Beneficiary Survey complex sampling design.

SOURCE: RTI International analysis of the 2006 the Medicare Current Beneficiary Survey.

Table 8.3 shows this same regression, but with three subgroups: beneficiaries with COPD, with heart failure, and with diabetes.[35] This is again very similar to Table 6.3, with the one difference being that our two measures of adherence have been added to the dependent variables list. The first adherence measure is different for each condition, because it is whether they filled at least one prescription to treat the given condition of interest. Only the one appropriate for the given condition is used in each regression—in the table, this is listed as filled COPD prescription for those with COPD, and so on. The second measure is the self-reported failure to fill at least one prescription that they received. Neither adherence measure is significant in any of these subsamples. Again, as in Table 6.3, the point estimates remain similar to the full sample estimates, so the loss of significance for Part D LIS can thus largely be explained by the fact that the sample sizes for these subgroups are far smaller. In fact, none of the drug coverage variables predict the number of events, and only one is related to the number of excess zeros.[36] Thus, when outliers are excluded, the relationship between drug coverage, adherence, and inpatient events is not strong enough to identify in the small samples available when analyzing condition subgroups using MCBS. Control variables are also overwhelmingly not statistically significant, with scattered exceptions. Full results are shown in Technical Appendix Section 8 in Table A8.2.

[35] It was not possible to estimate these regressions for the subgroups with the other conditions—the computer algorithm was not able to calculate an estimate for these specifications.

[36] The significant predictor of excess zeros is other public or private coverage. This was a very small fraction of the sample; as shown in section 4, only 1.9 percent of the sample had this form of coverage. The coefficient of 0.00 here means that those with this type of drug coverage were very, very unlikely to be an "excess zero"—they had a nearly zero probability of falling into the category of beneficiaries who will never be admitted to a hospital.

Table 8.3
Inpatient events as a function of adherence: Selected conditions

Variable	COPD—number of events	COPD—zeros	Heart failure—number of events	Heart failure—zeros	Diabetes—number of events	Diabetes—zeros
Part D	0.940	0.933	0.875	2.306	0.780	0.805
	(0.22)	(0.10)	(0.48)	(0.69)	(0.33)	(0.13)
Drug coverage	—	—	—	—	—	—
Employer-sponsored	1.273	1.086	0.901	0.801	0.800	0.482
	(0.86)	(0.13)	(0.35)	(0.12)	(0.42)	(0.61)
Self-purchased	0.420	2.150	1.283	20.528*	3.079*	3.876
	(1.03)	(0.53)	(0.48)	(2.58)	(2.21)	(1.20)
Other public or private	0.520	0.000**	0.917	2.028	3.384	0.968
	(1.30)	(14.37)	(0.12)	(0.32)	(1.95)	(0.02)
Part D low-income subsidy	1.110	0.898	1.406	1.245	1.592	0.880
	(0.44)	(0.14)	(1.10)	(0.26)	(1.45)	(0.20)
Adherence	—	—	—	—	—	—
Filled a COPD prescription	1.040	0.825	—	—	—	—
	(0.24)	(0.44)				
Filled a heart failure prescription	—	—	0.829	0.389	—	—
			(1.05)	(1.91)		
Filled a diabetes prescription	—	—	—	—	1.097	0.521
					(0.27)	(0.72)
Failed to fill a prescription	1.487	1.825	1.814	1.158	2.643	4.248
	(0.73)	(0.39)	(1.65)	(0.13)	(1.47)	(1.14)

* $p<0.05$; ** $p<0.01$

NOTES: Values in the "Number of events" columns are incidence rate ratios. "Zeros" are the prediction of excess zeros; see section 6.2.3 for details. T-ratios in parentheses. Coefficients are weighted by Medicare Current Beneficiary Survey sampling weights, and standard errors are adjusted for Medicare Current Beneficiary Survey complex sampling design.

SOURCE: RTI International analysis of the 2006 the Medicare Current Beneficiary Survey.

8.5 Discussion

In this section, we analyze the impact of drug adherence and Part D enrollment on inpatient hospital stays in the MCBS using a method that is uniquely appropriate for this type of "event data" called ZIP regression. This analysis is identical to that conducted in section 6, with the exception that our two measures of adherence are included in the regressions. Overall, our results are very similar to those found in section 6. The results suggest that beneficiaries who are enrolled in Part D may have fewer inpatient stays, but our very limited sample size in the MCBS means that the coefficients on Part D were not significant in any specification. The one important, statistically significant result from section 6 remains true here—Part D low-income subsidy recipients, according to analysis using the full analysis sample, have substantially more inpatient events than those with no drug coverage. The additional result in this section is that those who failed to fill a prescription have 1.54 times as many hospitalizations as those who say they never failed to fill a prescription. At the mean number of hospitalizations, 1.54 times as many translates into approximately 0.53 rather than 0.35 events. This result agrees with other research (Murray et al., 2009; Stuart et al., 2009; Tu et al., 2005) that has found a strong association between low medication adherence and hospitalization rates in certain populations.

SECTION 9
SUMMARY AND CONCLUSIONS

This report explored the following research questions in different ways:

1. What are Part D enrollment patterns for beneficiaries with specific chronic conditions?

2. What is the impact of Part D on patient adherence to medication therapy?

3. What is the impact of Part D on health outcomes and health care utilization and costs for beneficiaries with chronic conditions?

4. What is the relationship between differences in patient adherence and differences in health outcomes and health care utilization and cost?

We considered these questions for Medicare beneficiaries with chronic conditions that are treated with outpatient prescription drugs: chronic obstructive pulmonary disease, congestive heart failure, diabetes with complications, dementia, major depression, and rheumatoid arthritis. Many results, using a number of methodological approaches, have been presented, along with descriptions of the analytical challenges that explain the nature of the findings to a degree.

In the big picture, the questions are about the choices made by enrollees with chronic diseases in selecting drug plans, characteristics of adherence to drugs by these groups, and the direct or indirect effects on other services covered by the Medicare program.

The issue of enrollment patterns addresses whether plan choices seem reasonable for a population with a regular need for drugs. If their choices do not seem reasonable, one might question whether improvements are needed to the information received by potential enrollees and whether the plan finder Web site needs to be modified. It has been observed that Part D enrollees have a tendency to stay in the plan they have been enrolled in. Renewing the search for an optimal plan each year seems to be difficult for many. A major challenge to enrollees in 2007 was that in many parts of the country the number of plans to choose from was quite large. The finding that many beneficiaries with high drug spending were enrolled in basic plans that were as expensive as some enhanced plans may be indicative of the problem. Since 2007, Medicare has made an effort to get insurers to reduce the number of plan offerings that were hardly distinguishable from each other. The marketing methods of private plans have also often been an issue for the program. For these reasons, monitoring these enrollment patterns over time as CMS changes its rules would seem advisable.

The descriptive presentation of adherence to drug regimens provides a window on the degree to which an insurance program alone is not sufficient to ensure that patients take drugs according to the patterns found to be effective. Although there are reasons for some people to take some of these drugs episodically, to change drugs, and to drop drugs that are not working, there seems to be room to improve adherence on average. This work begins to analyze the effect of price on adherence by looking at adherence in the coverage gap. Our analysis of the Medicare Current Beneficiary Survey was a start in examining factors affecting adherence. More

multivariate analysis can be done in this area. The gap itself will be phased out over time under the Reconciliation Act associated with the Affordable Care Act. The effects of the phaseout should be monitored as well. There is evidence in some of our other analyses that higher adherence has favorable consequences for beneficiaries and the Medicare program.

Whether the implementation of the Part D program changes trends in Medicare utilization is important for those who are looking for cost savings to offset the cost of the Part D program. It is also of interest to those who are interested in the changes in health status that are related to changes in utilization patterns. To some extent, the program changed the financing for many enrollees rather than access to drugs. Beneficiaries dually eligible for both Medicare and Medicaid were formerly covered by State drug benefits and now are covered by the Federal benefit and receive the low-income subsidy. The population that did not receive the low-income subsidy was studied here to look for the "bend in the curve" so sought after by those reducing costs.

Because even in that population beneficiaries were likely acquiring drugs before and after the program implementation, the changes in access would be ones of degree. Our large sample analyses did show small effects in inpatient hospital use and emergency department use. The measures were chosen because they were expected to be sensitive indicators.

Another factor determining effect sizes is that drugs often take time to have measurable effects and thus to reduce the frequency of expensive events such as hospitalizations, the full effect of the program may yet to be measured. Longer time series will be needed in future analysis.

In looking at the effects of adherence itself on utilization and health status, we examined a more direct link between purchasing, if not consumption, of drugs and the service use measures. Adherence is a measure of how well beneficiaries are using the access provided by insurance, and the analyses measure whether that makes a difference. If one wanted to make the drug program more effective in reducing costs and improving health, investing in methods to improve adherence could be worthwhile. These analyses are promising in showing reductions in service use as adherence rates increase. In future work, with longer time series, one could test for larger effects than were measured in our single-year studies. Experiments in methods to encourage adherence have been reported; the finding of at least moderately favorable short-term effects of higher levels of adherence could encourage more such trials.

Our exploratory work has profiled aspects of the program and points toward the need for future analyses to understand a dynamic program. Not only do effects of such a program likely take time to be fully felt, but also the government is changing important aspects of the program, reducing the number of look-alike plans, improving monitoring of marketing, and phasing out the coverage gap that was faced by many of those in the chronic disease cohorts we studied. All of these factors will affect the issues that we studied.

REFERENCES

Abaluck, J.T., and Gruber, J.: Choice Inconsistencies Among the Elderly: Evidence from Plan Choice in the Medicare Part D Program. Working Paper No. 14759. Cambridge, Mass. National Bureau of Economic Research, Feb. 2009.

American Hospital Formulary Service: AHFS Drug Information 2010. Bethesda, Md. American Society of Health-System Pharmacists, 2010.

Berglund, P.: Analysis of complex sample survey data using the SURVEYMEANS and SURVEYREG procedures and macro coding. Paper presented at the SAS SUGI Proceedings. Orlando, Fla., April 14-17, 2002.

Briesacher, B., Stuart, B., Doshi, J.et al.: Medicare beneficiaries and the impact of gaining prescription drug coverage on inpatient and physician spending. Health Serv. Res. 40(5, Part 1):1279-1296, Oct. 2005.

Centers for Medicare and Medicaid Services: 2006 Final Notice. Baltimore, Md. April 4, 2005.

Chandra, A., Gruber, J., and McKnight, R.: Patient Cost-Sharing, Hospitalization Offsets, and the Design of Optimal Health Insurance for the Elderly. Working Paper 12972. Cambridge, Mass. National Bureau of Economic Research, March 2007.

Dillman, D.A., Eltinge, J.L., Groves, R.M., et al.: Survey nonresponse in design, data collection, and analysis. In Survey Nonresponse, edited by R.M. Groves, D.A. Dilman, J.L. Eltinge, and R.J.A. Little. New York. John Wiley & Sons, Inc., 2002.

Dulio, A., Perry, M., and Cubanski, J.: Voices of Beneficiaries: Attitudes Toward Medicare Part D Open Enrollment for 2008. Washington, D.C. Kaiser Family Foundation, Dec. 2007.

Fischer, M.A., Stedman, M.R., Lii, J., et al.: Primary medication non-adherence: Analysis of 195,930 electronic prescriptions. J. Gen. Intern. Med. 25(4):284-290, 2010.

Hubbard, T., and Daimyo, S.: Medication Adherence and Care Teams: A Call for Demonstration Projects. Cambridge, Mass. New England Healthcare Institute, Sept. 2010.

Jiang, H.J., Wier, L.M., Potter, D.E.B., et al: Potentially Preventable Hospitalizations Among Medicare-Medicaid Dual Eligibles, 2008. Statistical Brief No. 96. Rockville, Md. Healthcare Cost and Utilization Project (HCUP), Agency for Healthcare Research and Quality, Sept. 2010.

Kaiser Family Foundation: Examining Sources of Coverage Among Medicare Beneficiaries: Supplemental Insurance, Medicare Advantage, and Prescription Drug Coverage Findings From the Medicare Current Beneficiary Survey, 2006. Menlo Park, CA. August 2008.

Kaiser Family Foundation: Medicare: A Primer, 2010. Report No.7615-03. Menlo Park, Ca. Kaiser Family Foundation, April 2010. Retrieved from http://www.kff.org/medicare/upload/7615-03.pdf Dec 6, 2010.

Kennedy, J., Tuleu, I., and Mackay, K.: Unfilled prescriptions of Medicare beneficiaries: Prevalence, reasons, and types of medicines prescribed. J. Manag. Care Pharm. 14(6):553-560, July/Aug. 2008.

Khan, N., Kaestner, R., and Lin, S.: Insurance coverage and healthcare: Effect of prescription drug coverage on health of the elderly. Health Serv. Res. 43(5, Part I):1576-1597, Oct. 2008.

Kirk, J.K., D'Agostino, R.B., Jr., Bell, R.A., et al.: Disparities in HbA1c levels between African-American and Non-Hispanic White adults with diabetes. Diabetes Care 29(9):2130-2136, Sept. 2006.

Kirking, D.M., Lee, J.A., Ellis, J.J., et al.: Patient-reported underuse of prescription medications: A comparison of nine surveys. Med. Care Res. Rev. 63(4):427-446, 2006.

Kling, J.R., Mullainathan, S., Shafir, E., et al.: Misperception in Choosing Medicare Drug Plans. Unpublished paper. October 2009.

Madden, J.M.: Cost-related medication nonadherence and spending on basic needs following implementation of Medicare Part D. JAMA 299(16):1922-1928, Apr. 2008.

Mayo Clinic: Rheumatoid Arthritis. Retrieved from http://www.mayoclinic.com/health/rheumatoid-arthritis/DS00020, November 3, 2009.

Murray, M.D., Tu, W., Wu, J., et al.: Factors associated with exacerbation of heart failure include treatment adherence and health literacy skills. Clin. Pharmacol. Ther. 85(6):651-658, June 2009.

Polinski, J.M., Bhandari, A., Saya, U.Y., et al.: Medicare beneficiaries' knowledge of and choices regarding Part D, 2005 to the present. J. Am. Geriatr. Soc. 58(5):950-966, May 2010.

Pope, G.C., Kautter, J., Ellis, R.P., et al.: Risk adjustment of Medicare capitation payments using the CMS-HCC Model. Health Care Financing Rev. 25(4):119-141, Summer 2004.

Safran, D.G., Neuman, P., Schoen, C., et al.: Prescription drug coverage and seniors: Findings from a 2003 national survey [Web exclusive]. Health Aff. W5-152 through W5-166, April 19, 2005.

Stuart, B.C., Briesacher, B.A., Doshi, J.A., et al.: Will Part D produce savings in Part A and Part B? The impact of prescription drug coverage on Medicare program expenditures. Inquiry 44:146-156, summer 2007.

Stuart, B.C., Simoni-Wastila, L., Zhao, L., et al.: Increased persistency in medication use by U.S. Medicare beneficiaries with diabetes is associated with lower hospitalization rates and cost savings. Diabetes Care 32(4):647-649, Apr. 2009.

Tu, W., Morris, A.B., Li, J., et al.: Association between adherence measurements of metoprolol and health care utilization in older patients with heart failure. Clin. Pharmacol. Ther. 77(3):189-201, Mar. 2005.

Wolters Kluwer Pharma Solutions: Pharma Insight 2009: Patients Take More Power Over Prescription Decisions. Retrieved from http://www.wolterskluwerpharma.com/sites/default/files/Pharma-Insight-2009.pdf.